cancer trials ireland

Together, we're finding answers to cancer.

DSSG Digest

Spring 2017—Vol. 11 ISSUE 1

CONTENT

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

It is published by Cancer Trials Ireland three times a year.

Cancer Trials Ireland is supported by

Irish Cancer Society

HRB Health Research Board

We should let patients decide if they would like to be referred to another hospital

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

I would like to firstly welcome Dr Linda Coate and wish her every success in her role as Vice Clinical Lead with Cancer Trials Ireland.

Linda has been very actively involved in many cancer studies and trials and brings to the leadership of the organisation enormous expertise and experience.

Linda is based in the University Hospital Limerick and has played a pivotal role in the development of the local research unit.

While this location will place additional demands on her time when attending to the business of the organisation, I am very pleased that the west coast is represented at national level. Linda will bring her leadership and knowledge to expanding our lung cancer portfolio nationally.

I would also like to take this opportunity to thank outgoing Vice Clinical Lead, Prof Ray McDermott. The contribution Ray has made to the development of the organisation over the years as Clinical Lead and latterly as Vice Clinical Lead has been immense.

Ray has brought to the challenges that we have faced not only a huge amount of hard work, but deep insights and support to the Board, the management team, DSSG meetings, colleagues and cancer trials research units across the country.

2016 was a good year

During 2016 we opened a number of exciting trials. These include Flipper, LOXO 101, CheckMate 401, PEARLS, INTENSE, Nala, POSITIVE, PALLAS, NeoTRIP, PantHER and CyBord-DARA.

Results have been published in top line publications such as The New England Journal of Medicine and we have had abstracts and posters presented at prestigious international conferences such as ASCO and ASH.

For 2017 we will continue to open more studies and trials. These will include PEARL, Add-Aspirin, CLL-13, Inecalcitol and Lithium.

Cross hospital referral

In an ideal world we would make all trials available in all 14 research units across the country, making it as easy and convenient as possible for eligible patients to participate. For many reasons this is not possible.

It is essential therefore that we do what we can to make sure that eligible patients do not miss out on taking part in a trial because of where they live and the unavailability of a trial in their local hospital.

We can do this through cross hospital referral. I have experienced this with my own PantHER study where patients attending hospitals where the trial is not open have been referred by their consultant to my team at Beaumont Hospital. These patients met the eligibility criteria and are currently taking part in the trial at Beaumont Hospital.

Clinicians sometimes have reservations with the idea of referring patients to hospitals in other parts of the country, not least because of the inconvenience of extended travel for patients.

However, from my experience, for some patients this may not be as big an issue as we might think.

When I worked in the M.D. Anderson Cancer Center in Texas it was not unusual for patients to travel from the other side of the USA, and indeed from another country to take part in a cancer trial.

Naturally for some patients travelling a long distance can be problematic. However, on balance, I think that we should offer patients the opportunity to be screened for a trial that may suit them even if it is not in the hospital they are attending. Patients should have the opportunity to decide.

As we start into the New Year I would greatly appreciate if you would review the 77 studies and trials listed in this DSSG Digest and see do you have any patients that may be eligible to take part in a trial and discuss with them the possibility of putting their name forward.

And if the trial is not available within your hospital, pick up the phone and talk to the Principal Investigator about referring the patient to the hospital where it is available.

Getting the balance right

Eibhlin Mulroe, CEO.

It's that time of the year when we are busy making applications to our main funders, the Health Research Board and the Irish Cancer Society.

It's an exercise that brings our funding into sharp focus.

We receive income from three main sources; our funders above, international collaborative groups for whom we are running trials in Ireland and other parts of Europe and pharmaceutical companies. We also receive philanthropic donations.

For the pharmaceutical companies we provide a range of cancer trials services. This can range from adopting a trial as part of our portfolio and giving it a Cancer Trials Ireland number to providing a full range of trial services.

All adopted trials are listed on our website, in this regular Digest and, importantly, are part of the scientific discussions at each DSSG meeting. At these closed meetings each trial is discussed and suggestions are made to the Chairs of the respective DSSG Groups in relation to recruitment and any issues that may be emerging. It also provides access to our highly experienced research team at head office.

Having trials adopted adds to the overall endeavour of finding answers to cancer by sharing ideas and knowledge among the leaders in cancer trials in Ireland.

In addition to adopting trials like this, we also provide a range of income generating services to pharmaceutical companies. These can range from feasibility assessment, protocol, ethics applications, accrual, monitoring and reporting. We are working on the development of an integrated trials data management system which will enable us to streamline further the delivery of these services.

In-house / investigator led trials are sometimes supported by pharmaceutical companies. This is an important aspect of our work. These trials enable us to pursue avenues of enquiry that may lead to new standards of care which do not necessarily involve a new drug or combination of drugs. It could for example involve how existing standards of care in surgery, chemotherapy and radiotherapy are delivered.

As these types of trials do not necessarily involve testing a new drug or combination of drugs, they do not always fit into the mandate of pharmaceutical companies. As such, this support is very welcome. Pharmaceutical companies also support our work by supporting attendance by key research staff at select international conferences, which are critical for developing ties with collaborative groups.

While we really appreciate the support we receive from our colleagues in the pharmaceutical industry we are also very mindful that Cancer Trials Ireland was established as a non-profit driven research organisation committed to pursuing answers to question that may not necessarily provide a commercial return but will have a significant impact on improving how cancer is detected and treated.

The challenge for us all at Cancer Trials Ireland is to get the right balance in our portfolio between international collaborative group trials, in-house/investigator-led trials and commercial trials funded by pharmaceutical companies.

In determining this balance it is essential that we reflect on the need to support and develop the 14 cancer research units around the country which benefit from funding from the pharmaceutical companies. While the Health Research Board provides significant support to the research units, unfortunately in some units this funding represent just 30% of their overall funding.

As our vision is to open high quality and relevant cancer trials that seek better ways to extend and enhance lives, it is vital that we have a well resourced and vibrant network of research units.

This is an area that we will be looking at very carefully over the next few months and developing a funding model that is both equitable and sustainable.

This may involve recalibrating how the various research units are funded. It may also involve investigating whether research units can also pursue funding from local philanthropic sources which may be consistent with our pursuit of cures for cancer.

Just as we must balance the variety of different services we provide to different stakeholders, its is essential that we strike the right balance between the funding available and the funding provided to research units around the country.

International trial with Irish involvement confirms treatment to slow cancer growth

An international cancer trial, in which Cancer Trials Ireland has had a lead role, has confirmed a treatment that can significantly reduce the risk of the cancer progressing in women with advanced breast cancer

The Paloma-2 trial confirmed that the new drug palbociclib taken with the standard hormone therapy letrozole slows the progress of cancer among postmenopausal women with advanced (ER-positive, HER2-negative) breast cancer.

The results of the trial have been published in the New England Journal of Medicine.

Dr Janice Walshe, Consultant Medical Oncologist at St. Vincent's University Hospital and Tallaght Hospital, is the Principal Investigator of the Irish arm of the trial and is one of the article's authors.

Dr Walshe said the findings were highly significant for women with breast cancer which has spread to other parts of their bodies.

"These are very exciting breakthrough findings and have set a new standard for the treatment of this kind of breast cancer.

Dr Janice Walshe talks about the findings of the Paloma-2 trial.

"Our trial found that this combination of palbociclib and letrozole slowed the rate of cancer cell growth", Dr Walshe said.

"For patients on the combination, cancer cells stopped growing for just over two years (median 24.8 months). This compared with 14.5 months for patients taking the standard of care drug letrozole alone. That's a 42% increase in the amount of time without cancer growth."

"This finding means that the need for women with this type of cancer to start chemotherapy could be delayed.

"This is unprecedented for this patient population and is a material step forward. Breaking this 2 year barrier is highly significant," Dr Walshe said.

Palbociclib belongs to a class of drugs known as a CDK (cyclin-dependent kinase) inhibitor. It works by blocking the proteins called CDK 4 and 6 in cancer cells. Blocking these proteins interferes with the ability of the cancer cell to grow, divide, repair and/or communicate with other cells.

Paloma-2 is a randomised double-blind Phase 3 trial and involved a total of 666 women who had no prior treatment for advanced disease from 186 global centres in 17 countries. 22 patients in Ireland were enrolled on the trial and 17 are still receiving treatment on the trial. The trial was funded by Pfizer. It will continue up to 2018 to determine if this combination has an effect on the overall survival of patients.

Breast cancer is the most common invasive cancer among women in Europe, with more than 464,200 new cases and 131,260 deaths per year.

Up to 30 percent of women diagnosed with and treated for early breast cancer will go on to develop advanced breast cancer.

Dr Linda Coate takes up post as Vice Clinical Lead

Dr Linda Coate, Consultant Medical Oncologist, University Hospital Limerick, has taken up the post of Vice Clinical Lead of Cancer Trials Ireland starting on 1st January 2017.

Dr Coate graduated from University College Dublin in 2000. She completed an MD thesis focusing on translational thoracic oncology research in 2006.

In 2008 she took up a clinical research fellowship in the Princess Margaret Hospital in Toronto under the mentorship of Prof Frances Shepherd.

Dr Coate received a Merit Award from ASCO for an elderly Non Small Cell Lung Cancer study in 2010.

She was appointed as a Consultant Medical Oncologist at University Hospital Limerick in 2011, and took over as Principal Investigator of the Cancer Clinical Trials Unit. Linda continues to play an active role in education and clinical research.

Dr Coate sits on the Clinical Executive of Cancer Trials Ireland and chairs its lung DSSG (disease specific subgroup) which is responsible for the development and conduct of the Irish Thoracic Oncology Clinical trial portfolio.

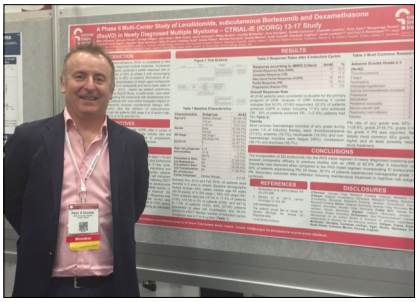
Dr Linda Coate

In that capacity Dr Coate has been, and continues to be, the National Principal Investigator for numerous thoracic oncology studies, and sits on a number of steering committees and advisory boards.

I am sure that you will join us in extending our heartiest congratulations to Dr Coate and wish her every success.

Blood cancer trial results presented at ASH Conference

The results of two Cancer Trials Ireland trials were presented at the recent 58th Annual conference of the American Society of Hematology (ASH) held in San Diego.



Prof Peter O'Gorman

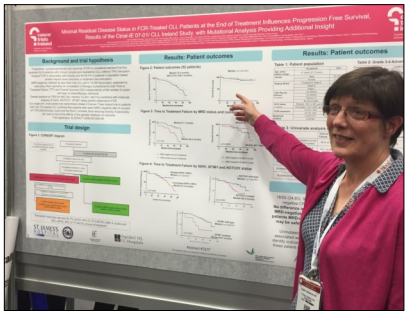
Prof Peter O'Gorman, (left) Consultant Haematologist at the Mater Hospital presented preliminary results of the RsqVD trial.

The trial started in 2014 and was co-ordinated by Cancer Trials Ireland. It was a multi-center, open-label single arm phase II trial involving 42 patients with newly diagnosed multiple myeloma.

The trial investigated the subcutaneous (SQ) administration of bortezomib with lenalidomide and dexamethasone.

The administration of the combination subcutaneously improved tolerability when compared with the same drugs given intravenously; it reduced the side effects of peripheral neuropathy which causes numbness and pain in hands and feet.

During the trial 92.5% of patients experienced a positive response. Of these, 45% of patients experienced a very good partial response (VGPR) and 17.5% experienced a complete response and went into remission.



Prof Elisabeth Vandenberghe,

Also at the ASH conference Prof Elisabeth Vandenberghe, (right) Consultant Haematologist at St James's Hospital, presented the results of the CLL Ireland Study. This trial investigated if Minimal Residual Disease (MRD) Status in FCR-Treated CLL Patients at the End of Treatment Influences Progression Free Survival

The trial was a single arm, multi-centre non-randomised phase II trial in patients with non 17p-deleted CLL. It confirmed that patients who were MRD-negative after 4 courses of FCR chemotherapy could omit the final 2 courses, thus reducing toxicity. A secondary aim was to look at the effects of the genetic analysis on outcome.

POSITIVE to investigate pregnancy after breast cancer

An international cancer study has opened in Ireland to investigate the risks for young women who had breast cancer and want to attempt to become pregnant.

Young women who have cancer can require ongoing hormone treatment for 5-10 years. This treatment prevents conception. The study will examine the risk of breast cancer returning among young women who interrupt their treatment for up to 2 years to attempt pregnancy.

Internationally over 500 patients who had breast cancer will take part in the study. It will involve 30 patients from Dublin, Cork, Limerick, Waterford and Galway.

Dr Cathy Kelly, Consultant Medical Oncologist at the Mater Hospital, and Chair of the Breast DSSG is leading the study in Ireland. She said that it was a highly significant study as it involved a consortium of 50 dedicated investigators from 19 countries around the world and was investigating an area of increasing concern for young women.

"Over the past few decades women have tended to delay having children for a variety of personal reason. As a result, for an increasing number of young women, they can get breast cancer before they have completed their plans for a family.

"The best available evidence, based on reviewing records retrospectively, suggests that in certain instances pregnancy after breast cancer does not negatively impact disease outcome and is safe for the baby.

"But we really need to have real time scientific evidence to confirm this. This study will give us that evidence. Hopefully it will be invaluable for future generations of women in this situation," she said.

Dr Cathy Kelly

Participants in the study have to be 42 years old or younger, have had early stage breast cancer, completed 18-30 months of hormone treatment and want to have a baby. Participants will interrupt their treatment for a maximum of 2 years during which time they will attempt to get pregnant. Participants will be followed for at least 10 years after enrolling in the study.

Hospitals participating in the study include the Mater University Hospital, Mater Private Hospital, St Vincent's University Hospital, St James's Hospital, University Hospital Galway, University Hospital Limerick, University Hospital Waterford and Cork University Hospital.

To find out more about this study contact Dr Cathy Kelly at the Mater Hospital, Dublin; catherine.kelly@ucd.ie or Kathleen Scott, Clinical Program Lead Kathleen.Scott@cancertrials.ie

PALLAS to test new treatment for early stage breast cancer

The Irish arm of a global cancer trial which will involve 4,600 patients in 500 hospitals around the world has been opened in Ireland by Cancer Trials Ireland.

The trial will investigate whether the new drug palbociclib will decrease the chance of cancer recurring in women and men with early stage HR positive /HER2 negative breast cancer when given in combination with the current standard anti-hormone therapy.

Known as the PALLAS trial, it is hoped that at least 50 patients will take part in Ireland in 6 hospitals; Cork University Hospital, University Hospital Waterford, and in Dublin, Mater University Hospital, Beaumont Hospital, St James's Hospital and St Vincent's University Hospital.

Dr Patrick Morris, Consultant Medical Oncologist at Beaumont Hospital, Dublin, and Co-Chair of the Breast Group of Cancer Trials Ireland, is the trial's Principal Investigator for Ireland. Dr Morris said:

"No new drugs have been developed for early stage breast cancer for a number of years. In the last decade our research has focussed on different durations and combinations of available hormone therapy.

"This trial could materially change how early stage breast cancer is treated in the future."

"Given the impressive benefits we have seen with palbociclib for advanced breast cancer, which is when cancer has spread from the original tumour, we are tremendously excited about investigating its potential in early stage breast cancer.

"This new drug is not yet available to patients with early stage breast cancer outside a trial setting so we are delighted that Irish participants will have access to the trial.

"As this is the most common form of breast cancer, up to 30% of patients develop disease recurrence despite the standard adjuvant treatment, there may be many women and men in Ireland in the decades ahead who could potentially benefit from the findings of this trial.

"This trial could materially change how early stage breast cancer is treated in the future," he said.

"There are a large number of participants in this trial from around the world and Ireland's participation reflects the global and co-operative nature of cancer research," Dr Morris said.

"Having a well-developed cancer trials network means we can take part in these types of trials," he said.

Dr Morris added: "While many patients with early stage breast cancer respond very well to standard anti-hormone therapy and are cured, there remains a risk of recurrence, particularly for those patients with involved lymph nodes. So we need to improve the effectiveness of current treatments for these patients and find ways to stop or delay recurrence of their cancer. Research has shown that HR positive /HER2 negative breast cancer is relatively insensitive to chemotherapy."

Dr Patrick Morris

"Palbociclib has shown promising results in the treatment of metastatic HR positive /HER2 negative breast cancer. One of the most exciting aspects of this therapy is that side-effects, which include the risk of low white blood cell counts, seem to be manageable.

"We look forward to investigating its effectiveness for early stage breast cancer," he said.

Background

The PALLAS trial is being led by the Austrian Breast & Colorectal Cancer Study Group (ABCSG) in participating countries outside of the US and in the US by Alliance Foundation Trials LLC (AFT). Cancer Trials Ireland is managing the Irish part of the trial. It is being conducted in conjunction with the Breast International Group (BIG) as well as other collaborating Study Groups in Europe and the US.

Pfizer Inc., the pharmaceutical company that manufactures and markets the trial drug, is supporting the trial by providing the drug palbociclib and funding this trial.

Palbociclib is an approved treatment for HR positive /HER2 negative advanced or metastatic breast cancer when taken in combination with an aromatase inhibitor or with fulvestrant in women who have received prior endocrine therapy. (See article on Paloma-2 trial on page 4)

The PALLAS trial will test whether the new drug palbociclib used in combination with the standard post-operative anti-hormone therapy will produce better results than the current standard anti-hormone therapy alone.

Palbociclib works by blocking the activity of two closely related enzymes (proteins that help chemical reactions occur in the body), called Cyclin Dependent Kinases 4 and 6 (CDK 4/6) which are among the primary promoters of breast cancer cell growth.

As patients with early stage breast cancer can remain on hormone therapy for up to 10 years to prevent recurrence, the trial is planned to take 10 years to complete.

To find out more about this trial contact Dr Patrick Morris at Beaumont Hospital patrickmorris@beaumont.ie or Kathleen Scott, Clinical Program Lead Kathleen.Scott@cancertrials.ie

Continuing our series on the work of our head office team, Gráinne O'Dowd gives us an insight into her work as a Clinical Research Associate II

Cancer trials is a diverse industry involving a wide variety of stages, tasks, personnel and responsibilities.

A CRA's role can be defined loosely as being the first point of contact for a trial or study. We are also responsible for ongoing monitoring of patient safety and assuring data integrity, protocol adherence, Good Clinical Practice (GCP) and regulatory guideline adherence at participating research units.

While it often feels like there is no such thing as a typical day, here I've tried to capture a flavour of life as a CRA. I hope it sheds some light on our elusive profession!

Monday

Because our work can be very fast-paced and unpredictable, continually prioritising and organising tasks is an important part of the job. With this in mind I tend to be office based during the early part of the week. I evaluate where I'm at on all my ongoing projects and organise myself to ensure I have a productive week.

As we are the primary contact for studies and trials, it's not uncommon for me to receive about 50 emails a day, with each involving a new query, request, or task. These can range from protocol-related questions, to case report form (CRF) issues and administrative requests. They can be from anyone such as colleagues, collaborative groups, investigators, pharmacists, data managers or research nurses.

Many requests are often time sensitive, for example in the case of queries relating to patient eligibility or study schedules, so I always prioritise urgent emails and tasks, which requires good time management. Being responsive and adaptable to priorities is an extremely important skill for CRAs.

Tuesday

A lot of my work involves visiting research units where the trials I am managing are being run. The purpose is to make sure that all of the requirements of the trial are being met, trouble shoot and assist with any unanticipated issues which may arise. I usually schedule these visits for Wednesdays and Thursdays, so a lot of Tuesday is spent preparing.

In addition to planning and carrying out field work, I have regular meetings with colleagues to discuss progress, current workload and challenges. This can involve a teleconference between research units and collaborative groups across many participating countries to discuss broader study issues or updates, such as accrual or the outcomes of an interim review.

Preparation for the monitoring visits involves reviewing outstanding queries from the last visit, the status of patients, safety issues and serious adverse events (SAEs) and so on. This helps to make sure all issues are covered and I am not placing too many demands on colleagues in the research units.

Because we can be involved with many different industry and collaborative group trials, our own in-house trials and studies and many other interesting projects at any one time, I will also have a lot of other administration and management work on my plate.

Gráinne O'Dowd, CRAII.

Wednesday: Monitoring Visit Day 1

My travel to a research unit can take between 20 minutes to over 3 hours so can involve some days with 6am starts and 8pm finishes. When I arrive at a research unit I first meet with a member of the study team; research nurse/data manager/co-ordinator to discuss any important study updates or recent developments with patients. It's also good to catch up on a personal level. Being a nomad goes with the territory of being a CRA, as does conducting a lot of your communication with colleagues via emails, so it's nice to be made feel welcome and have the opportunity to interact face to face during the visit.

Generally the first thing I do is review high priority items such as any new SAEs, new patient registrations (including eligibility and consent) and patient withdrawals since the last visit. I also review whether any new staff have started working on the study and ensure this has been appropriately documented and they have been trained. Once high priority items are completed I review patient visits/forms and begin Source Data Verification (SDV) of data in the CRFs. Monitoring and SDV generally takes up the majority of the visit time.

As CRAs don't have any direct contact with patients, when we're monitoring we get to appreciate the patient's experiences and their progression on the trial. For me, this reinforces my sense of involvement in this important work.

As a CRA we approach the data from a different perspective to other members of the study team; attention to detail, looking for consistency, and considering the 'bigger picture' of compliance with the protocol, GCP and regulatory guidelines are all very important, and are what sometimes lead us to identify issues that a colleague might not be aware of. This can be very satisfying and validating as identifying even minor issues can have important ramifications for the validity of the data or the trial itself.

Thursday: Monitoring Visit Day 2

I usually arrange to visit colleagues in the pharmacy first thing in the morning on day 2 of a visit.

Continued on page 8.

Sporting heroes support cancer trials at Limerick opening

The recent opening of the newly renovated Cancer Clinical Trials Unit at University Hospital Limerick (UHL) got a welcome boost with support from All-Ireland winning hurlers Noel McGrath (Tipperary) and Richie Bennis (Limerick), both of whom have had cancer treatment at UHL. Legendary Clare hurling manager Ger Loughnane, a fellow cancer survivor, also supported the opening.

Grand Slam and European Cup winning rugby hero Marcus Horan also lent his support. Marcus was representing his close friend and former Shannon, Munster and Ireland team-mate, the late Anthony Foley. Anthony's parents, Brendan and Sheila, also attended the opening.

Pictured at the opening of the new Cancer Clinical Trials Unit at University Hospital Limerick were (l to r) All-Ireland winners Noel McGrath and Richie Bennis; Dr Linda Coate; Consultant Medical Oncologist, UL Hospitals Group and Vice Clinical Lead for Cancer Trials Ireland; Prof Rajnish Gupta, Regional Director of Cancer Services for the Mid-West; Eibhlin Mulroe, CEO, Cancer Trials Ireland and Marcus Horan.

Anthony was a member of the board of the Mid-Western Cancer Foundation. He was at the Limerick unit last May to celebrate International Clinical Trials Day.

Marcus Horan said Anthony Foley had been a great supporter of cancer services in the Mid-West

"When the nurses got on to me to see if I could step in for Axel, I just jumped at it. His involvement here was something he was very proud of and he would have loved to have been able to see through to the opening. It is a great honour to be here today, especially with his parents Brendan and Sheila," said Marcus.

Noel McGrath, who was named Tipperary Person of the Year 2016 by the Tipperary Association Dublin for his cancer awareness work, stressed the importance of patients taking part in trials. Noel rebounded from being treated for cancer last year to winning a second All-Ireland medal in September.

"I was very well looked after here; had treatment and a positive outcome at the end. For people that have not had as good an outcome as me, it is about trying to prevent as many of those cases as possible and to help as many people as we can. Initiatives like this, especially here in Limerick where the oncology unit is very good, any steps we can take to make it even better is a very positive thing," said Noel.

Richie Bennis, was treated for cancer in UHL in 2009.

"Trials are very important," said Richie. "I am delighted to support. Trials save lives and if something saves lives, everybody should do it."

The new unit at UHL has been renovated with the help of charitable donations. Two new research nurse positions and a number of administrative posts have also been approved by UL Hospitals Group to support the Clinical Trials Unit and make more trials available to patients in the Mid-West.

Continued from page 7

Gráinne O'Dowd gives us an insight into her work as a Clinical Research Associate II

This primarily involves reviewing the study investigational product (IP) accountability including; checking supplies, shipments, receipts, dispensing records and logs, return logs, storage temperature logs.

In the afternoon I finish the patient data monitoring and start on other outstanding tasks, for example reviewing the investigator site file to ensure all the required essential documents are present and collecting copies of any new documents for the in-house sponsor files.

Before I leave for the day, I meet with the main research nurse/data manager/coordinator for the study again to discuss any findings, actions or issues required.

Ideally I also meet with the Principal Investigator for a brief discussion, this is particularly important if there have been any significant findings. These meetings allow for quick resolution of any issues and make a big difference to the smooth conduct of the trial.

Friday

I would normally spend most of Friday following-up on items from the monitoring visit, other ongoing tasks and responding to communications that came in while I was out of the office.

Actions from the monitoring visit can include things like updating the issues and actions log, looking into queries raised by the site research team, discussing issues found with my project manager if necessary, sending documents to the research unit, and ultimately completing the monitoring visit report and follow-up letter.

Although I will, time allowing, usually begin this work the day after the visit, it can take a few days to complete, as there are always other ongoing and time sensitive tasks to attend to at any given time.

There's no 'typical' week for a CRA. No two days, let alone weeks, are the same. However, I hope this article shows you how we fit into the clinical research ecosystem, and why, if you are based in one of the cancer trials research units we always seem to be on the go with coffee in hand!

A very big thanks!

Cancer Trials Ireland has received a very generous donation of €7,760 towards its work on finding answers to cancer from family and friends of Ronnie Cox who sadly passed away in June 2016.

Before he died Ronnie organised a fundraiser with the Lough Conn Anglers for a charity to be selected by his oncologists Prof Ray McDermott. Prof McDermott, who was Vice Clinical Lead with Cancer Trials Ireland during 2016, recommended Cancer Trials Ireland.

We greatly appreciate the generosity of Ronnie's family and friends and all who contributed to the fundraising effort, and particularly Ronnie himself.

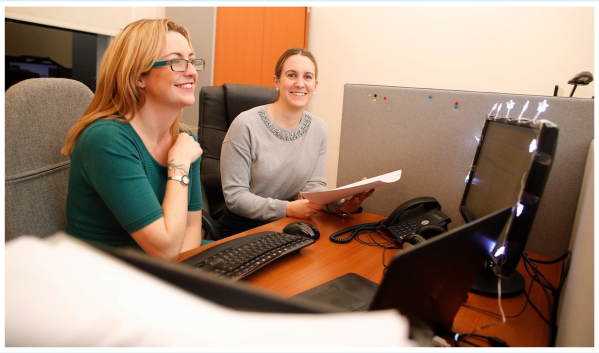
Ar dheis Dé go raibh a anam.

Pictured at the presentation were (l to r) Gavin Cox, Rebecca Cox, Carmel Cox, Verena Murphy (Clinical Program Lead), Eibhlin Mulroe (CEO), Prof Ray McDermott, Consultant Oncologist, along with Michael Monaghan and Eamon Ross representing the Lough Conn Anglers.

Caught on camera — Say hello to some of our hardworking team at head office

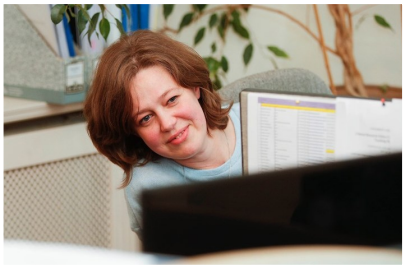
Jillian Burns (Left), Clinical Research Associate with Paulina Lawner, Clinical Project Manager.

Laura Maher, Clinical Project Manager.



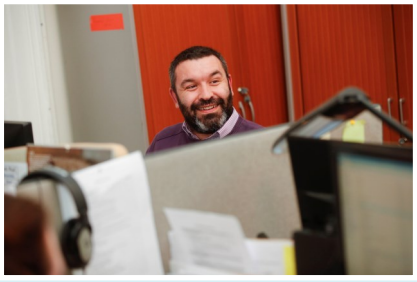
Lisa Tucker (Left), Clinical Project Manager and Aoibheann Walsh, Clinical Research Associate.

Verena Murphy (Left), Clinical Program Lead with Luke Heaphy, Clinical Trials Administrator.



Ausra Teiserskiene, Clinical Research Associate II.

Catherine Dolphin, Clinical Research Associate II.



Andrés Hernando, Clinical Project Manager.

Research teams gather for lively development day

The second Development Programme Day for members of the cancer trials research teams from around the country and head office (GCO) staff took place in Dublin in late January.

This recent get together built on the very successful first meeting held last September and saw the attendance levels rise to 50—it was a great turn and thank you for your attendance.

The main topic of discussion for the day was focused around preparing and setting up Phase 1b studies and it resulted in plenty of discussion and lively debate.

Amanda Bray and Jess Walsh from the Blood Cancer Network Ireland in Galway and Keith Egan from Beaumont Hospital made very insightful presentations and engaged with the teams in very informative questions and answer sessions.

Kathleen Scott, our Clinical Program Lead, provided professional guidance for the day which all went like clockwork thanks to Siobhan Collins our Operations Officer.

Shane Ring, Business Development Manager.

The date for the next Development Programme event is 1st June 2017, which we hope to hold outside Dublin. Full details will be forwarded in the coming weeks. I look forward to seeing you then.

Kyra Callinan, Data Manager, St. James's Hospital, Snehal Prabhukeluskar, Clinical Nurse Manager, St James Hospital, and April Spollen, Data Manager, St. James's Hospital.

Liz Lenihan, Research Nurse, Cork University Hospital, Anna Cole, Data Manager, Cork University Hospital, Debra O'Hare, Team Leader, Cork University Hospital, and Kathleen Scott, Clinical Program Lead, Cork Trials Ireland.

Lucy Short, Data Manager, Clinical Trials Ireland, and Margaret Burke, Research Nurse, Sligo University Hospital.

Jillian Burns, Clinical Research Associate, Cancer Trials Ireland, Ausra Teiserskiene, Clinical Research Associate,Cancer Trials Ireland, and Mary Dunne, Biostatistician, St Luke's Hospital.

Elaine McCarthy, Research Nurse, Limerick University Hospital, and Maureen O'Grady, Clinical Nurse Manager 3, Limerick University Hospital.

Siobhan Collins, Cancer Trials Ireland, and Deirdre Wynne, Business Manager, Clinical Trials Research Unit, Mater University Hospital.

Mary Byrne, Clinical Trials Unit, University Hospital Galway, and Shauni Fitzgerald, Clinical Research Unit Blood Cancer Network Ireland, Galway .

Lillie Broderick, Galway University Hospital, Jess Walsh, Clinical Research Unit, Blood Cancer Network Ireland, Galway, and Helena Desmond, Clinical Trials Pharmacist, Mater Private Hospital.

Lorraine Weymes, Data Manager, Mater Hospital, Shane Ring, Business Development Manager, Cancer Trials Ireland, Martina Smith, Clinical Trials Manager, Mater University Hospital, and Keith Egan, Clinical Trials Manager, Beaumont Hospital.

Thanks to our sponsors

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

abbvie astellas BAYER Bristol-Myers Squibb

Genomic Health LIFE. CHANGING. janssen MSD NOVARTIS Roche

Cancer Trials Ireland studies open to accrual

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

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual	AMNCH	Beacon	BH	BonS	CUH
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	1565			644		455
Breast	Trans	10-11	Circulating miRNA	192			6	18	
Breast	Trans	10-15	Exosomal HER2	250	47	Open	56	50	11
Breast	Trans	10-16	Ovarian Reserve	142	20	Open	33	21	21
Breast	Trans	12-09	CharactHer	189			6		
Breast	Trans	12-30	TAILORx Tissue Bank	567	23		33	14	72
Breast	Trans	12-40	EORTC 10085	14			3		4
Breast	Clinical	14-01	EMBRACA/ MDV 673-301 (TRIO 023)	5					
Breast	Clinical	15-17	PALLAS	4			1		Initiated
Breast	Clinical	15-49	NeoTRIP	0			Open		Open
Breast	Clinical	14-11	PENELOPE-B	26			2	1	1
Breast	Clinical	14-21	NALA	3					Open
Breast	Clinical	14-22	16298 Radium 223 in BC (Bayer)	0					Open
Breast	Clinical	15-02	PantHER	5			4		
Breast	Clinical	15-33	KEYNOTE-119 in mTNBC (MSD)	7					
Breast	Radio	15-03	NSABP B-51	3					
Breast	Clinical	15-16	FLIPPER	7			TBI	1	
Breast	Clinical	16-03	PEARL	0			TBI	TBI	TBI
Breast	Clinical	16-20	POSITIVE	1					TBI
CNS	Trans	08-13	Serum Protein Markers for Glioma	75			75		
CNS	Clinical	15-28	M13-813 INTELLANCE 1	5			5		
GI	Clinical	10-14	Neo-AEGIS	153			1		1
GI	Clinical	11-32	Lithium Autophagy Study	0			TBI		TBI
GI	Trans	12-27	CRAC Plasma Biomarkers	77	3	Open	24	13	
GI	Trans	12-31	PDAC Plasma Biomarkers	98	37	Open	6	10	
GI	Radio	12-38	TRI-LARC	33					
GI	Clinical	14-19	BMS CA209-142 (CheckMate 142)	19			2		
GI	Clinical	14-20	GERCOR STRATEGIC-1	0	Open			Open	Open
GI	Clinical	14-17	Exelixis Celestial Study	2					
GI	Clinical	16-28	MK 3475-177	1	1				
GI	Clinical	16-73	BMS CA209-577	0			Open		Open
GI	Clinical	16-29	MK 3475-181	3	2				
GU	Clinical	13-09	PEACE-1	30	2				10
GU	Clinical	13-21	Radium-223 & Enzalutamide mCRPC	41	24				7
GU	Clinical	13-23	Neo-adjuvant Abiraterone prostate	6					1
GU	Trans	14-04	iPROSPECT	55	26	Open	Open		3
GU	Clinical	14-06	ENZAMET	169	27	Open	3		
GU	Clinical	11-34	Tiger	0					
GU	Clinical	14-07	ENZARAD	74		11			15
GU	Trans	15-21	ExPeCT study	29	11		1		
GU	Trans	16-07	IPCOR	1589	39	70	101	119	100
GU	Clinical	16-27	Keynote 426	0	Open				
GU	Clinical	15-19	CARD	1	1				
GU	Clinical	16-70	BMS CA209-274	1	Open				1
Gynae	Radio	09-06	Endometrial - IMRT v 3D RT	65					
Gynae	Clinical	11-29	ICON8B	17				3	
Gynae	Clinical	14-02	SHAPE	10					
Gynae	Clinical	15-22	JAVELIN 200	0					
Gynae	Clinical	16-04	PRIMA	0					TBI
Gynae	Clinical	16-05	JAVELIN 100	0				Open	TBI
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)	2					Open
H & L	Clinical	15-09	ARROVEN Brentixumab Vedotin PASS Study in HL (Millennium)	10			6		
H & L	Clinical	15-10	OPTIMISMM Pomalidomide Study in rel/ref MM (Celgene)	10					
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	15-36	Rigosertib versus Physicians Choice in MDS (Onconova)	0	Open				Open
H & L	Clinical	16-08	Millennium P2001 Pevonedistat	1	1				
H & L	Clinical	16-10	KEYNOTE 185	1			1		
H & L	Clinical	16-02	CyBorD with Daratumumab in transplant eligible patients with newly diagnosed MM	3			TBI		TBI
H & L	Clinical	16-09	Astellas 2215 CL 0301	0			Open		
H & L	Clinical	16-79	M15-550 (VENICE 1)	1			Open		
Head & Neck	Clinical	16-54	BMS CA209-714	0					
Head & Neck	Clinical	16-11	NRG HN-002	1					
Lung	Clinical	12-53	ETOP SPLENDOUR	24	1		Open		4
Lung	Radio	15-05	Oligo-Recurrent Metastatic Disease	15		15			
Lung	Clinical	15-27	BMS CA209-227 (CheckMate 227)	17			2		
Lung	Radio	15-47	INTENSE	0					
Lung	Clinical	16-18	BMS CA209-451 (CheckMate 451)	5	1				3
Lung	Clinical	16-16	MSD MK3475-189	6			TBI		Open
Lung	Clinical	15-40	MSD MK3475-091 (PEARLS)	4					Open
Melanoma	Trans	13-22	SYS-ACT	8			TBI		TBI
Melanoma	Clinical	16-13	Keynote-252	3					Open
Melanoma	Clinical	16-14	CheckMate 401	12			5		1
Basket	Trans	08-40	SNP Study	123	17		4	29	1
Basket	Clinical	15-42	LOXO-101	0					
Basket	Clinical	16-64	Roche MO29518	7					

Open Studies | Studies To Be Initiated | Studies Pending | Studies Initiated but not activated

UHG	LUH	Mater	MRH	MRH	MUH	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites	Other
						385		11		Open	70			
128								30	8	Open	2			
	7							2	30	36	11			
								6	11	22	8			
		6						6		153			Italy 18	
66	14	79			Open	Open		37	32	167	30			
		Open						1		4	2			
1		3				Closed				1				
		Open						Initiated		Initiated	3			
Open		Open						TBI		TBI	Open			
9		4				TBI		5		3	1			
Open		Open				Open		2		1				
		Open												
Open										1				
		7								Open				
Open							3							
Open		2				TBI		Open		TBI	4			
TBI		TBI						TBI		TBI				
TBI		TBI				TBI		TBI		1	TBI			
1							Open	79					71	
								TBI						
11	3	3						Open	10	2	8			
3	TBI									35	7			
							33							
1										16				
Open		TBI						Open		Open	Open			
		2												
								0						
TBI														
								1						
1		14								3				
		2					Open			8				
1							4							
TBI		5						Open	6	14	1			
2		19						Open		10	11		UK 10 sites (97)	
								Open						
2		2					8					TBI	UK 10 sites (36)	
		4					1	12					UK 18	
381		251			142	9		64		76	1			236
		TBI												
		TBI								TBI				
		Open												
				TBI			65							
1		9						0			4			
								10						
		Open						Open		TBI	Open			
		TBI						TBI			TBI			
		TBI						TBI		TBI				
2		1												
Open		Open						1		1				
		1						3						
3		4						3						
		Open												
1		1						Open		Open				
Open											Open			
Open		Open												
3														
								1						
								Open						
							1							
2		1				7		6		Closed	3			
5						5		5						
							Open							
1						TBI								
						2		2		2				
		1				Open		3		Open	Open			
2										6	TBI			
Open		Open								3				
Open		6						Open		TBI				
21		2							19	Pend	30			
										0				
								1		6				

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
NALA **CTRIAL-IE (ICORG) 14-21** PI: Prof John Crown Type: Industry Sponsored Sponsor: PUMA	Global: Mar 2013 **Ireland** Feb 2016	CUH, UHG, Mater, UHL, SJH, SVUH.	600	N/A	18	**3** SVUH 1 SJH 2	Jun 2017
Title: 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. **Comment:** Accrual extended. Global accrual figures not released by company.							
Penelope B **CTRIAL-IE (ICORG) 14-11** PI: Dr Cathy Kelly Type: Collaborative Group Sponsor: German Breast Group	Global: Apr 2013 **Ireland** Sept 2015	BH, BonS, CUH, UHG, Mater, UHL, SJH, SVUH, UHW	800	624	20	**26** UHG 9, BH 2, Mater 4, Bons 1, SJH 5, UHW 1 , CUH 1, SVUH 3	Oct 2017
Title: 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”. **Comment:** 8 sites activated. Accrual ahead of target.							
MDV 673-301/ TRIO 023 / EMBRACA Study **CTRIAL-IE (ICORG) 14-01** PI: Prof John Crown Type: Industry Sponsored/ Collaborative Group Sponsor: Medivation in collaboration with TRIO	Oct 2013 **Ireland** June 2014	UHG, Mater, SVUH	429	361	2 Pts per site per year	**5** Mater 3, SVUH 1, UHG 1	April 2017
Title: 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. **Comment:** Referral of patients to open sites encouraged. Study planned to close soon.							
PantHER **CTRIAL-IE (ICORG) 15-02** PI: Prof Bryan Hennessy Type: In-House Sponsor: cancer trials ireland	August 2016	BH, SVUH, UHG	N/A	N/A	31	**5** BH 4 SVUH 1	Dec 2019
Title: Phase Ib/II clinical trial of copanlisib in combination with trastuzumab in pretreated recurrent or metastatic HER2-positive breast cancer. **Comment:** Referral of patients to open sites encouraged.							
Protocol 16298 Radium **CTRIAL-IE (ICORG) 14-22** PI: Dr Jennifer Gilmore Type: Industry Sponsored Sponsor: Bayer	**Ireland** Feb 2016	MPH, CUH, SLRON	227	26	5	**0**	October 2017
Title: 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 **Comment:** 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
FLIPPER **CTRIAL-IE (ICORG) 15-16** PI: Dr Miriam O'Connor Type: Collaborative Group Sponsor: GEICAM	May 2016	SJH, Mater, BH, SVUH, BonS, UHG, UHW, UHL	190	52	40	**7** UHW 4 MMUH 2 BonS 1	February 2018
Title: A randomized, double-blind, parallel-group, multicentre, phase II study to compare the efficacy and tolerability of fulvestrant (FaslodexTM) 500mg with placebo and fulvestrant (FaslodexTM) 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 that 12 months following its completion or have "de novo" metastatic disease. **Comment:** 5 sites initiated to date (SJH, Mater, BonS, UHW and UHG).							
PALLAS **CTRIAL-IE (ICORG) 15-17** PI: Dr Patrick Morris Type: Collaborative Group Sponsor: ABCSG	Sep 2015	BH, CUH, MMUH, SJH, SVUH, UHW	4600	617	30/year	BH 1, UHW 3	Q3 2018
Title: A randomized phase III trial of palbociclib with adjuvant endocrine therapy versus endocrine therapy alone for hormone receptor positive (HR+)/HER2 negative early breast cancer. **Comment:** All sites initiated, 4 sites activated to date (BH, MMUH, UHW and CUH).							
NeoTRIP **CTRIAL-IE (ICORG) 15-49** PI: Dr Catherine Kelly Type: Collaborative Group Sponsor: Fondazione Michelangelo	Oct 2016	BH, CUH, MMUH, SJH, SVUH, UHG, UHW	272	22	30	BH 0, CUH 0, MMUH 0, UHG 0, UHW 0	Expected Q3 2018
Title: Open-label, international, randomized phase III neoadjuvant study of MPDL3280A, carboplatin and nab-paclitaxel compared to the control arm of carboplatin and abraxane **Comment:** 5 sites initiated to date (CUH, BH, Mater, UHW and UHG).							
PEARL **CTRIAL-IE (ICORG) 16-03** PI: Dr Janice Walshe Type: Collaborative Group Sponsor: GEICAM	Feb 2017	BH, BonS, CUH, SJH, SVUH, UHG, MMUH	300	75	31	0	Expected Q4 2018
Title: Phase III study of Palbociclib (PD-0332991) in combination with Endocrine therapy (exemestane or fulvestrant) versus chemotherapy (capecitabine) in Hormonal Receptor (HR) positive/HER2 negative Metastatic Breast Cancer (MBC) patients with Resistance to non-steroidal aromatase inhibitors. "The PEARL Study" **Comment:** In study set up.							
KEYNOTE 119 **CTRIAL-IE (ICORG) 15-33** PI: Dr Cathy Kelly Type: Industry Sponsored Sponsor: MSD	Global: Oct 2015 **Ireland** Dec 2015	SVUH, Mater	600	358	8	**7** Mater 7, SVUH 0.	TBC 2017
Title: 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) **Comment:** Patient referrals welcome.							

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
NSABP B51 **CTRIAL-IE (ICORG) 15-03** PI: Dr Joseph Martin Type: Collaborative Group Sponsor: cancer trials ireland	Global: Aug 2013 **Ireland** Feb 2016	SLRON, UHG	1636	520	Not specified	**3** SLRON 3, UHG 0	Aug 2018
Title: 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 **Comment:** Recruitment is slow globally due to strict inclusion criteria.							
EORTC 10085 Male Breast Cancer **CTRIAL-IE (ICORG) 12-40** PI: Dr Cathy Kelly Type: Collaborative Group Sponsor: EORTC	Feb 2014	BH, CUH, Mater, SJH, SVUH, UHW	N/A	387	N/A	**14** BH 3, CUH 4, SJH 1, SVUH 4, UHW 2	Feb 2017
Title: EORTC 10085 – Male Breast Cancer: Clinical and biological characterization of Male Breast Cancer: an international EORTC, BIG, TBCRC and NABCG intergroup study. **Comment:** Study will close to recruitment on 28-Feb-2017.							
Proteomic/Molecular Breast **CTRIAL-IE (ICORG) 09-07** PI: Prof Leonie Young & Prof Bryan Hennessy Type: In-House Sponsor: cancer trials ireland	Jan 2013	BH, CUH, SJH, SVUH, UHL, UHW	N/A	N/A	N/A	**1565** BH 644; CUH 455; SJH 11; UHL 385; UHW 70	N/A
Title: Breast cancer proteomics and molecular heterogeneity. **Comment:** SVUH now open.							
Circulating miRNA **CTRIAL-IE (ICORG) 10-11** PI: Prof Michael Kerin Type: In-House Sponsor: cancer trials ireland	May 2011	BH, BonS, UHG, SJH, SUH, SVUH, UHW	N/A	N/A	Cohort 1: 122 (closed) Cohort 2: 122 Cohort 3: 122	**192** BH 6, BonS 18, UHG 128, SJH 30, SUH 8, UHW 2	TBC
Title: Circulating miRNAs: Novel breast cancer biomarkers and their use for guiding and monitoring response to therapy. **Comment:** Increase in accrual required.							
Exosomal HER2 **CTRIAL-IE (ICORG) 10-15** PI: Dr Lorraine O'Driscoll & Prof John Crown Type: In-House Sponsor: cancer trials ireland	Oct 2012	AMNCH, Beacon, BH, BonS, CUH, LUH, SJH, SUH, SVUH, UHW	N/A	N/A	HER2+: 300 HER2-: 30 (closed)	**250** AMNCH 47, BH 56, BonS 50, CUH 11, LUH 7, SJH 2, SUH 30, SVUH 36, UHW 11	TBC
Title: Exosomal and Free Extracellular RNAs and Proteins as Predictive Biomarkers for HER2 Therapies in Breast Cancer. **Comment:** HER2+ accrual is excellent.							

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
Ovarian Reserve **CTRIAL-IE (ICORG) 10-16** PI: Dr Janice Walshe & Prof Bryan Hennessy Type: In-House Sponsor: cancer trials Ireland	Oct 2012	AMNCH, Beacon, BH, BonS, CUH, SJH, SUH, SVUH, UHW	N/A	N/A	250	**142** AMNCH 20, BH 33, BonS 21, CUH 21, SJH 6, SUH 11, SVUH 22, UHW 8	TBC
Title: A study to determine alteration of hormone levels in premenopausal patients receiving adjuvant or neo-adjuvant chemotherapy for breast cancer. **Comment:** Accrual going well.							
CharactHER **CTRIAL-IE (ICORG) 12-09** PI: Prof Giuseppe Gullo & Prof John Crown Type: In-House Sponsor: cancer trials Ireland	May 2014	BH, Mater, SJH, SUH, SVUH, Milan Italy	N/A	Cohort 1&3: 91 Cohort 2: 98	Cohort 1&3: 100 Cohort 2: 200	**171** BH 6, Mater 6, SJH 6, SVUH 153 **18** Milan	TBC
Title: A study of the molecular and cytogenetic characteristics of HER2-positive breast cancers to predict durable complete response after chemo-therapy and trastuzumab. **Comment:** SUH recently opened. Additional Italian site will open soon.							
TAILORx Tissue Bank **CTRIAL-IE (ICORG) 12-30** PI: Dr Cathy Kelly & Dr Darran O'Connor Type: In-House Sponsor: cancer trials Ireland	May 2014	AMNCH, BH, BonS, CUH, UHG, LUH, Ma-ter, SJH, SUH, SVUH, UHW	N/A	N/A	691	**567** AMNCH 23, BH 33, BonS 14, CUH 72, UHG 66, UHL 14, Mater 79, SJH 37, SUH 32, SVUH 167, UHW 30	TBC
Title: TAILORx Tissue Bank: Breast Cancer Bank of Tissue from Trial Assigning Individualized Options for Treatment. **Comment:** All FFPE blocks should be sent to Dr Darran O'Connor.							

Basket Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
CTRIAL-IE (ICORG) 15-42 **Loxo101** PI: Prof Ray McDermott Type: Industry sponsored Sponsor: Loxo Oncology	US Sept 2015 **EU** May 2016	SVUH	226 (18 per cohort + 25 Other Tu-mour NOS)	Ahead of target of 1 patient per month	7 patients (across all 8 cohorts)	**0**	May 2018
Title: A Phase II Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects With NTRK Fusion-Positive Tumours **Comment:** This is a basket study encompassing 8 cohorts; NSC lung, thyroid, sarcoma, colorectal, salivary, biliary, primary CNS, and all other solid tumours - all of which are currently open and recruiting at SVUH. No local accruals to date. Study recruiting ahead of target globally.							

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

Basket Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
CTRIAL-IE 16-64 MO29518 PIs: Dr Dearbhaile O'Donnell / Prof John Crown Type: Industry sponsored Sponsor: Roche	2015	SVUH SJH	600	341	SVUH 10 SJH 5	**SVUH 6** **SJH 1**	TBC
Title: An open-label, multicohort, phase II study of atezolizumab in advance solid tumours **Comment:** This is a basket study encompassing 16 cohorts; the opening and closing of cohorts is fluid. Please contact Cancer Trials Ireland for latest details.							
SNP study **CTRIAL-IE (ICORG) 08-40** PI: Dr Michael Martin Type: In-House Sponsor: cancer trials ireland	May 2011	AMNCH, BH, BonS, CUH, Mater, SUH, UHG, UHW	N/A	N/A	150	**123** AMNCH 17, BH 4, BonS 29, CUH 1, Mater 2, SUH 19, UHG 21, UHW 30	TBC
Title: 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. **Comment:** 8 patients accrued since last DSSG meeting. Accrual has increased since the last DSSG.							
CRQ Survey **CTRIAL-IE (ICORG) 15-43** PI: Dr Cathy Kelly Type: In-House Sponsor: cancer trials ireland	April 2016	AMNCH, Beacon, BH, BonS, CUH, LUH, Mater, OLLHD, SJH, SLRON, SUH, SVUH, UHG, UHW	N/A	N/A	1000	**1090** All Research Units AMNCH 100, Beacon 46, BH 100, BonS 100, CUH 50, LUH 50, Mater 100, OLLHD 50, SJH 100, SLH 47, SUH 99, SVUH 100, UHG 48, UHW 100	CLOSED
Title: CRQ Study: Clinical Research Questionnaire of Oncology Patients – A Nationwide Survey. **Comment:** Study is now closed to recruitment and data analysis is ongoing.							

Melanoma Cancer Trials

Chair of Melanoma DSSG: Dr Paul Donnellan 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
CheckMate 401 **CTRIAL-IE 16-14** PI: Dr. Derek Power Type: Industry Sponsor: BMS	August 2016	SVUH, BH, MPH, MMUH, UHG, CUH, SJH.	768 enrolled, 615 treated	382	Cap of 5 patients per site	**12 enrolled** BH 5, CUH 1, MPH 1, MMUH 5	June 2017
Title: 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. **Comment:** SVUH to be opened soon, all other sites are now open (SJH and UHG opened since the last DSSG). Accrual has been extended until June 2017.							

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

Melanoma Cancer Trials

Chair of Melanoma DSSG: Dr Paul Donnellan 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
SYS-ACT **CTRIAL-IE (ICORG) 13-22** PI: Dr Markus Rehm Type: In-House Sponsor: cancer trials ireland	August 2014	SVUH, UHG	N/A	N/A	Case: 60 Controls: ~20	**8** SVUH 6, UHG 2	TBC
KEYNOTE-252 **CTRIAL-IE 16-13** PI: Prof. John Crown Type: Industry Sponsor: MSD	**July 2016** (May 2016 globally)	SVUH, MPH, MMUH, CUH, UHG.	600	Closed	16	**3** (SVUH)	20-Jan-17

Title: SYS-ACT: A Translational Systems Medicine Approach to provide Predictive Capacity for Therapy Responsiveness in Advanced or Metastatic Malignant Melanoma.

Comment: SVUH and UHG have developed working models for inter-departmental collaboration that could be replicated at other sites.

Title: 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.

Comment: As global recruitment was ahead of schedule, accrual closed early on 20-Jan-17 (instead of June 2017).

Lung Cancer Trials

Chair of Lung DSSG: Dr Linda Coate Clinical Project Manager: Lisa Tucker 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
ETOP 5-12 SPLENDOUR **CTRIAL-IE (ICORG) 12-53** PI: Dr Linda Coate Type: Collaborative Group Sponsor: ETOP	International Q1 2015 **Ireland Q3 2015**	AMNCH, BH, CUH, UHG, Mater, UHL, SJH, UHW, SVUH	1000	455	70	**24** 7 UHL, 6 SJH, 4 CUH, 3 UHW, 2 MMUH, 2 UHG, 1 AMNCH	Feb 2018

Title: A randomized phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC.

Comment: Recruitment is behind target both globally and nationally. Continue to screen and recruit patients for this trial.

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

Lung Cancer Trials

Chair of Lung DSSG: Dr Linda Coate Clinical Project Manager: Lisa Tucker 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
MK3475-091 PEARLS Study **CTRIAL-IE (ICORG) 15-40** PI: Dr Linda Coate Type: Industry Sponsor: MSD	International Nov 2015 **Ireland Jan 2016**	MMUH, UHL, SVUH, UHW, SJH, CUH	1380	117	20/site	**4** 3 SJH, 1 MMUH	Jan 2021
Title: 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). **Comments:** A number of patients are in screening across the sites. Forthcoming protocol amendment will relax inclusion criteria.							
BMS CA 209-227 Study **CTRIAL-IE (ICORG) 15-27** PI: Dr Sinead Cuffe Type: Industry Sponsored Sponsor: BMS	International Aug 2015 **Ireland Q1 2016**	SJH, UHL, BH, UHG	2475 enrolled 1980 treated	2923 enrolled 1740 randomised	20	**17** 5 SJH, 5 UHG, 5 UHL, 2 BH	Part 1: closed Part 2: May/ June 2017
Title: 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) **Comment:** Part two of this study will open shortly in SJH, UHL and UHG with a target of 5 patients in Ireland.							
BMS CA209-451 (CheckMate-451) SCLC study **CTRIAL-IE (ICORG) 16-18** PI: Dr Deirdre O'Mahony Type: Industry Sponsored Sponsor: BMS	International Sep 2015 **Ireland Q2 2016**	AMNCH, CUH, UHL, UHG	810	400	16	5 3 CUH, 1 GUH, 1 AMNCH	July 2017
Title: 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. **Comments:** Recruitment period has been extended to July 2017. A number of patients are currently in screening. UHL to open in February.							
MK3475-189 Study **CTRIAL-IE (ICORG) 16-16** PI: Dr Emer Hanrahan Type: Industry sponsored Sponsor: MSD	International Jan 2016 **Ireland Q3 2016**	UHL, SJH, BH, SVUH, CUH	570	266	16	**6** 2 SVUH, 2 SJH, 2 UHL	Feb 2017
Title: 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) **Comments:** Recruitment scheduled to close mid-February.							
Javelin Lung 100 study **CTRIAL-IE (ICORG) 16-15** PI: Dr Emer Hanrahan Type: Industry sponsored Sponsor: Merck Serono	International Q1 2016 **Ireland Q1 2017**	SVUH, AMNCH	420	327	2	**0**	TBC
Title: 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 **Comments:** Recruitment on hold pending an amendment. Irish sites will open Q2 2017.							

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

Lung Cancer Trials

Chair of Lung DSSG: Dr Linda Coate Clinical Project Manager: Lisa Tucker 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
INTENSE **CTRIAL-IE (ICORG) 15-47** PI: Prof John Armstrong Type: In-house Sponsor: cancer trials ireland	Jul 2016 (currently on hold)	SLRON	104	N/A	104	**0**	Q2 2020
Title: A Phase I/II Study of Inhomogeneous Targeted Dose Escalation in Non-Small Cell Lung Cancer **Comments:** Study is on hold pending an amendment to the protocol. Study should reopen in March/April 2017.							
UPCI 10-028 **Oligo-Recurrent Stereotactic Radiotherapy** **CTRIAL-IE (ICORG) 15-05** PI: Dr Alina Mihai Type: Collaborative Group Sponsor: cancer trials ireland	International Jun 2011 **Ireland Jan 2016**	Beacon	175	132	TBC	**15** Beacon 15	TBC
Title: Phase II study of stereotactic radiosurgery for patients with oligo-recurrent disease. **Comments:** Study recruiting very well in the Beacon Hospital. Study was due to close Q4 2016 but has been extended. Closure date to be confirmed.							

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
TIGER **CTRIAL-IE (ICORG) 11-34** PI: Dr. Dearbhaile O'Donnell Type: Collaborative Sponsor: Alliance, EORTC	Mar 2015	SJH	420	34	7 / year	0	TBC
Title: A Randomized phase III trial comparing conventional-dose chemotherapy using paclitaxel, ifosfamide, and cisplatin (TIP) with high dose chemotherapy using mobilizing paclitaxel plus ifosfamide followed by high-dose carboplatin and etoposide (TI-CE) as first salvage treatment in relapsed or refractory germ cell tumors. **Comment:** SJH initiated in Nov 2016, site activated by Alliance on 18-Jan-2017.							
CARD **CTRIAL-IE (ICORG) 15-19** PI: Prof Ray McDermott Type: Industry Sponsor: Sanofi	International: Nov 2015 Ireland: Nov 2016	AMNCH, Mater, SVUH.	270	62	20	1 AMNCH 1	Oct 2017
Title: A randomized, open label, multicenter study of Cabazitaxel versus an Androgen Receptor (AR)-targeted agent (abiraterone or enzalutamide) in mCRPC patients previously treated with Docetaxel and who rapidly failed a prior AR-targeted agent. **Comment:** Initiations pending at Mater and SVUH.							

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
iProspect **CTRIAL-IE (ICORG) 14-04** PI: Prof Ray McDermott Type: In-House Sponsor: cancer trials ireland	Feb 2015	AMNCH, Beacon, BH, CUH, UHG, Mater, SJH, SUH, SVUH, UHW	N/A	N/A	Cohort 1: 15 (closed); Cohort 2: 45	**55** AMNCH 26, CUH 3, Mater 5, SUH 6, SVUH 14, UHW 1	TBC
Title: Irish Programme for Stratified Cancer Therapy. **Comment:** Accrual on hold pending protocol amendment.							
ENZAMET **CTRIAL-IE (ICORG) 14-06** PI: Prof Ray McDermott Type: Collaborative Sponsor: ANZUP	International Feb 2014 **Ireland** Dec 2014, UK 2015	AMNCH, BH, UHG, Beacon, Mater, SJH, SVUH, UHW UK sites	1100	989	275	**169** AMNCH 27, BH 3, UHG 2, Mater 19, SVUH 10, UHW 11, UK 97.	March 2017
Title: Randomised Phase III trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer. **Comment:** Accrual going very well, expect study to finish accrual by end of Feb or early March 2017.							
CA209-274 **CTRIAL-IE 16-70** PI: Prof. Ray McDermott Type: Industry Sponsor: BMS	23-Mar-2016	AMNCH, Mater, CUH	640	203	8	**1** **CUH 1.**	24-Mar-2019
Title: A Phase 3 Randomized, Double-blind, Multi-center Study of Adjuvant Nivolumab Versus Placebo in Subjects With High Risk Invasive Urothelial Carcinoma (CheckMate 274: CHECKpoint Pathway and nivoluMAb Clinical Trial Evaluation 274). **Comment:** Accrual open in Ireland since 31-Aug-16.							
IPCOR **CTRIAL-IE (ICORG) 16-07** PI: Mr David Galvin Type: Collaborative Sponsor: IPCOR	Feb 2016	17 Irish sites	N/A	N/A	>3000 per annum	**1589**	TBC
Title: IPCOR – Irish Prostate Cancer Outcome Research **Comment:** Please address queries for this study to IPCOR.							
Neo-adjuvant abiraterone prostate study **CTRIAL-IE (ICORG) 13-23** PI: Dr Pierre Thirion Type: In-House Sponsor: cancer trials ireland	**Ireland** May 2015	CUH, SLRON (SLH), UHG	N/A	N/A	36 evaluable	**6** SLRON (SLH) 4, UHG 1, CUH 1.	Q4 2017
Title: 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. **Comment:** Recruitment behind target for this study. Active sites requested to aim for 1 patient per month.							
ExPeCT study **CTRIAL-IE (ICORG) 15-21** PI: Prof Stephen Finn Type: Collaborative Sponsor: cancer trials ireland	**Ireland** Jan 2016	AMNCH, BH, Mater, SJH, SLRON , UK sites	200	47	133	**29** AMNCH 11, BH 1, Mater 4, SJH 12, SLRON 1,	March 2017
Title: ExPeCT: Exercise, Prostate Cancer and Circulating Tumour Cells. **Comment:** SLRON site opened December 2016.							

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
PEACE-1 study **GETUG-AFU 21** **CTRIAL-IE (ICORG) 13-09** PI: Prof Ray McDermott Type: Collaborative Sponsor: UNICANCER	**Ireland** Oct 2014	AMNCH, CUH, UHG, Mater , SLRON, SVUH	916	599	60	**30** AMNCH 2, CUH 10, UHG 1, Mater 14, SVUH 3	May 2017
Title: A prospective randomised Phase III study of androgen deprivation therapy with or without local radiotherapy with or without abiraterone acetate and prednisone in patients. **Comment:** Accrual has increased since the last DSSG. Study on track to complete by May 2017.							
Radium-223 & Enzalutamide mCRPC study **CTRIAL-IE (ICORG) 13-21** PI: Prof Ray McDermott Type: In-house Sponsor: cancer trials ireland	**Ireland** June 2015	AMNCH, CUH, UHG, Mater, SLRON, SVUH	N/A	N/A	44	**41** AMNCH 24, CUH 7, Mater 2, SVUH 8	Feb 2017
Title: A Phase II Study of Radium-223 in Combination with Enzalutamide in Progressive Metastatic Castrate-Resistant Prostate Cancer. **Comment:** Accrual expected to close on this study by end of Jan 17 / early Feb 17.							
Spinal Cord Retreat study **CTRIAL-IE (ICORG) 07-11** PI: Dr Pierre Thirion Type: In-House Sponsor: cancer trials ireland	Oct 2007	SLRON (3 sites), UHG	N/A	N/A	25 evaluable	**22** (11 evaluable) SLRON 19, UHG 3.	2016
Title: 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. **Comment:** Study closed on the 08-Dec-2016 due to the difficulties in recruitment.							
ENZARAD **CTRIAL-IE (ICORG) 14-07** PI: Dr Paul Kelly Type: Collaborative Sponsor: ANZUP	International March 2014 **Ireland** April 2015 UK Sept 2015	CUH, UHG, Mater, Beacon, SLRON, Whitfield, UK sites	800	380	200	**74** CUH 15, Mater 2, Beacon 11, UHG 2, SLRON 8, UK 36.	2018
Title: Randomised Phase III trial of enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised, prostate cancer. **Comment:** Accrual going well, 1 IRL and 3 UK sites remain to be initiated.							
Keynote 426 **CTRIAL-IE (ICORG) 16-27** PI: Prof. Ray McDermott, Prof. John McCaffrey Type: Industry Sponsor: Merck	Sept 2016	AMNCH, Mater	840	66	20	**0**	Q1 2017
Title: A Phase III Randomized, Open-label, Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) in Combination with Axitinib versus Sunitinib Monotherapy as a First-line Treatment for Locally Advanced or Metastatic Renal Cell Carcinoma (mRCC). **Comment:** AMNCH site opened in December 16, Mater pending initiation.							

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

Head & Neck Cancer Trials

Chair of Head & Neck DSSG: Dr Sinead Brennan

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
De-ESCALaTE HPV **CTRIAL-IE (ICORG) 12-39** PI: Dr Sinéad Brennan Type: Collaborative Group Sponsor: University of Warwick	International Oct 2012 **Ireland** Jan 2015	SLRON (SLH & BH)	304	334	**20**	**17** SLH 14 BH 3	Closed
Title: 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. **Comment:** Study closed to accrual in October 2016.							
DARS **CTRIAL-IE 16-23** PI: Dr Sinéad Brennan Type: Collaborative Group Sponsor: cancer trials ireland	International May 2016 **Ireland** Q1 2017	SLRON	102	15	**TBC**	**0**	Q2 2018
Title: 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 . **Comment:** Awaiting contracts for site activation.							
NRG-HN002 **CTRIAL-IE (ICORG) 16-11** PI: Dr Sinéad Brennan Type: Collaborative Group Sponsor: cancer trials ireland	International Oct 2014 **Ireland** Q4 2016	SLRON (SLH)	296	280	**8 -12**	**1**	Q1 2017
Title: A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer **Comment:** Study opened for accrual in November 2016. Study is recruiting well globally and will likely close in February 2017.							
BMS CA209-714 1st Line Nivo Vs. Nivo+Ipi **CTRIAL-IE 16-54** PI: Dr Clíona Grant Type: Industry sponsored Sponsor: BMS	International Oct 2016 **Ireland** Dec 2016	SJH	315	19	**5**	**0**	14-Oct-2017
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:** Trial opened in SJH on 22-Dec-2016. One patient is in screening and a number of other potential patients have been identified.							

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
AALL0932 **CTRIAL-IE 16-31** PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group **Title:** 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	**35**	N/A
AALL1131 **CTRIAL-IE 16-32** PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group **Title:** A Phase III Randomised Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukiemia (B-ALL) Testing a Purine Nucleoside Anti-metabolite in the Very High Risk Stratum.	**Ireland** May 2015	OLCHC	N/A	N/A	N/A	**18**	N/A
UKALL2011 **CTRIAL-IE 16-33** PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group **Title:** 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	**107**	N/A
Interfant 06 **CTRIAL-IE 16-53** PI: Dr Owen Smith Type: Collaborative Group **Title:** 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	**4**	N/A
NBL—HR-NBL-1.7/SIOPEN **CTRIAL-IE 16-38** PI: Dr Cormac Owens Type: Collaborative Group **Title:** High Risk Neuroblastoma Study 1.7 of SIOP-EUROPE (SIOPEN).	Ireland Sep 2004	OLCHC	N/A	N/A	N/A	**62**	N/A
NBL LTI Study **CTRIAL-IE 16-39** PI: Dr Cormac Owens Type: Collaborative Group **Title:** 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	**8**	N/A
NBL BEACON **CTRIAL-IE 16-40** PI: Dr Cormac Owens Type: Collaborative Group **Title:** 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	**5**	N/A
NBL LINES **CTRIAL-IE 16-41** PI: Dr Cormac Owens Type: Collaborative Group **Title:** European Low and Intermediate Risk Neuroblastoma - A SIOPEN Study.	Ireland Feb 2016	OLCHC	N/A	N/A	N/A	**2**	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
EpSSG / RMS 2005 **CTRIAL-IE 16-47** PI: Dr Cormac Owens Type: Collaborative Group	Ireland Oct 2011	OLCHC	N/A	N/A	N/A	**20**	N/A
Title: A protocol for non-metastatic rhabdomyosarcoma (incorporates RMS-MET2008: Treatment Arm for Metastatic Disease).							
EpSSG / NRSTS 2005 **CTRIAL-IE 16-48** PI: Dr Jane Pears Type: Collaborative Group	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	**4**	N/A
Title: A Protocol for Non-Rhabdomyosarcoma Soft Tissue Sarcomas.							
LLR Cell Bank **CTRIAL-IE 16-34** PI: Drs Aengus O'Marcaigh/ Owen Smith Type: Collaborative Group	Ireland Feb 2013	OLCHC	N/A	N/A	N/A	**87**	N/A
Title: Leukaemia and Lymphoma Research (LLR) Childhood Leukaemia Cell Bank.							
JMML-Mesrat Study **CTRIAL-IE 16-51** PI: Dr Owen Smith Type: Collaborative Group	Ireland June 2015	OLCHC	N/A	N/A	N/A	**1**	N/A
Title: DNA methylation signatures and response to the azacitidine therapy in juvenile myelomonocytic leukaemia (JMML)Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) - AALL08B1.							
HD Interim Study **CTRIAL-IE 16-36** PI: Dr Jane Pears Type: Collaborative Group	Ireland Mar 2013	OLCHC	N/A	N/A	N/A	**27**	N/A
Title: EuroNet Paediatric Hodgkin's Lymphoma Interimphase study following closure of EuroNet PHL-C1 (HD 2007 10) Trial.							
EWOG-MDS-2006 **CTRIAL 16-37** PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group	Ireland Jan 2012	OLCHC	N/A	N/A	N/A	**3**	N/A
Title: Prospective non-randomised multi-center study for epidemiology and characterisation of Myelodysplastic Syndrome (MDS) and Juvenile Myelomonocytic Leukemia (JNML) in childhood.							
Renal IMPORT **CTRIAL-IE 16-42** PI: Dr Jane Pears Type: Collaborative Group	Feb 2015	OLCHC	N/A	N/A	N/A	**17**	N/A
Title: Improving Population Outcomes for Renal Tumours of Childhood.							
OLCHC Tumour Bank **CTTRIAL-IE 16-43** PI: N/A Type: Collaborative Group	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	**122**	N/A
Title: Procedure agreed for Tumour tissue and matched blood-DNA banking at OLCHC.							

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
EU-RHAB **CTRIAL-IE 16-44** PI: Dr Michael Capra Type: Collaborative Group	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	**7**	N/A
Title: European Rhabdoid Registry. A Multinational registry for rhabdoid tumours of any anatomical site.							
AALL08B1 **CTRIAL-IE 16-30** PI: Drs Aengus O'Marcaigh/ Owen Smitth Type: Collaborative Group	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	**46**	N/A
Title: Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL)							
FACT Study **CTRIAL-IE 16-45** PI: N/A Type: Collaborative Group	Ireland April 2006	OLCHC	N/A	N/A	N/A	**33**	N/A
Title: Factors associated with Childhood Tumours Study.							
EWOG-SAA-2010 **CTRIAL 16-46** PI: Dr Owen Smith Type: Collaborative Group	Ireland April 2012	OLCHC	N/A	N/A	N/A	**19**	N/A
Title: Genetic & Immunological Characterisation of Acquire Severe Aplastic Anaemia (SAA) in Children & Adolescents.							
NBL Registry **CTRIAL-IE 16-49** PI: Dr Cormac Owens Type: Collaborative Group	Ireland April 2015	OLCHC	N/A	N/A	N/A	**2**	N/A
Title: Prospective Study Registry of Peripheral Neuroblastic Tumours Presenting with Spinal Canal Involvement (SCI).							
AZA-JMML-001 **CTRIAL-IE 16-50** PI: Dr Owen Smith Type: Industry sponsored Sponsor: Celgene	Ireland June 2015	OLCHC	N/A	N/A	N/A	**1**	N/A
Title: 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.							
EBMT **CTRIAL-IE 16-35** PI: Dr Owen Smith Type: Collaborative Group	Ireland April 2015	OLCHC	N/A	N/A	N/A	**1**	N/A
Title: EBMT.							
EURO-Ewing 2012 **CTRIAL-IE 16-52** PI: Dr Cormac Owens Type: Collaborative Group	Ireland April 2015	OLCHC	N/A	N/A	N/A	**1**	N/A
Title: International Randomised Controlled Trial for the Treatment of Newly Diagnosed Ewing's Sarcoma Family of Tumours							

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
Serum Protein Markers for Glioma **CTRIAL-IE (ICORG) 08-13** PI: Dr Verena Murphy Type: In-House Sponsor: cancer trials ireland	July 2009	BH	N/A	N/A	Cohort 1: 100 Cohort 2: 30	**75** Cohort 1: 71 Cohort 2: 4	TBC
M14-483 INTELLANCE-2 **CTRIAL-IE (ICORG) 15-29** PI: Dr Patrick Morris Type: Industry sponsored Sponsor: AbbVie	**Ireland** Jul 2015 International Feb 2015	BH, CUH	240	260	8-12	**7** BH 5, CUH 2	Q3 2016
M13-813 INTELLANCE 1 **CTRIAL-IE (ICORG) 15-28** PI: Dr Patrick Morris Type: Industry sponsored Sponsor: AbbVie	Q1 2016	BH	720	84	10	**5** BH 5	Q3 2017
ROAM **CTRIAL-IE (ICORG) 15-41** PI: Dr David Fitzpatrick Type: Collaborative Group Sponsor: cancer trials ireland	**Ireland** Q1 2017 International Q2 2016	SLRON BH	190	2	0	**0**	Q1 2020

Title: Glioma Study: Are gliomas in adults associated with a unique identifying serum protein signature?

Comment: Accrual going well.

Title: ABT-414 alone or ABT-414 plus temozolomide versus lomustine for recurrent glioblastoma: a randomised phase II study of the EORTC Brain Tumour Group

Comment: Trial closed to recruitment in July 2016. Ireland treated 3% of global patients. Paediatric trial commencing (Ireland not participating).

Title: A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 in Subjects with Newly Diagnosed Gliobastoma Multiforme (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification.

Comment: Only 1 site in Ireland has been selected—Beaumont Hospital. Still the 2nd Top recruiting site in the world, ahead of global Chief Investigator

Title: Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial

Comment: SLRON BH expected to be activated by end of Q1 2017 once contracts have been finalised with the UK Cooperative Group

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

Gastrointestinal Cancer Trials

Chairs of GI DSSG: Dr Gregory Leonard & Dr Brian O'Neill 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
NeoAEGIS **CTRIAL-IE (ICORG) 10-14** PI: Prof John Reynolds Type: In-House / Investigator Led Sponsor: cancer trials ireland	January 2013	SJH, SLH, BH, CUH, GUH, UK (53); Denmark (18); France (0)	594	153	180	**82** SJH/SLH 79, BH 1, GUH 1, CUH 1.	2018

Title: 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.

Comment: Full regulatory approval received in France, sites to open soon. Accrual needs to increase.

CRAC Plasma Biomarker Study **CTRIAL-IE (ICORG) 12-27** PI: Prof Ray McDermott Type: In-House Sponsor: cancer trials ireland	October 2013	AMNCH, BH, BonS, UHG, Mater, SUH, SVUH, UHW, LUH, OLLOH (TBI), Beacon, SJH	N/A	N/A	150	**77** AMNCH 3, BH 24, BonS 13, LUH 3, Mater 3, SUH 10, UHG 11, UHW 8, SVUH 2,	2017

Title: Identification of Plasma Biomarkers in Early Detection of Colorectal Adenocarcinoma Recurrence (CRAC Plasma Biomarker Study).

Comment: Protocol version 4 received 7 out of 10 REC approvals. Protocol version 5 is currently underway. 3 patients recruited since the last DSSG.

PDAC Plasma Biomarker Study **CTRIAL-IE (ICORG) 12-31** PI: Prof Ray McDermott Type: In-House Sponsor: cancer trials ireland	October 2013	AMNCH, Beacon, BH, BonS, UHG, LUH (TBI), OLLOH (TBI), SVUH, UHW	N/A	N/A	290	**98** AMNCH 37, BH 6, BonS 10, SVUH 35, UHG 3, UHW 7	2018

Title: Identification of Predictive Plasma Biomarkers in Pancreatic Ductal Adenocarcinoma.

Comment: Only two centres (LUH and OLLOH) remaining to be initiated. Protocol amendment is ongoing.

TRI-LARC **CTRIAL-IE (ICORG) 12-38** PI: Dr Brian O'Neill Type: In-House Sponsor: cancer trials ireland	August 2014	SLRON BH	N/A	N/A	268	**33** SLRON BH 33	August 2020

Title: 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.

Comment: Study is recruiting approx. 1 patient/month . Opening of SLRON SLH and SJH is being prioritised and it is hoped recruitment will increase as a result. Nonetheless likely accrual end date will need to be extended.

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

Gastrointestinal Cancer Trials

Chairs of GI DSSG: Dr Gregory Leonard & Dr Brian O'Neill 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
Exelixis Celestial **CTRIAL-IE (ICORG) 14-17** PI: Dr David Gallagher Type: Industry sponsored Sponsor: Exelixis	Unknown	Mater	760	N/A	N/A	**2** Mater 2	October 2016
Title: Phase III Placebo Controlled Trial evaluating a tyrosine kinase inhibitor in HCC patients previously treated with Sorafenib. **Comment:** No update provided by Exelixis. No new patients recruited to the study in Ireland last eight months.							
BMS CA209-142 **CTRIAL-IE (ICORG) 14-19** PI: Prof Ray McDermott Type: Industry sponsored Sponsor: Bristol-Myers Squibb	March 2014	BH, SVUH, UHG	300	277	8	**19** BH 2, SVUH 16, UHG 1	July 2017
Title: A Phase II Clinical Trial of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Microsatellite High (MSI-H) Colon Cancer **Comment:** No new accruals since last DSSG due to no cohorts being open. Cohort 3 due to open by February 2017 amendment fully approved.							
STRATEGIC-1 **CTRIAL-IE (ICORG) 14-20** PI: Dr Greg Leonard Type: Collaborative Group Sponsor: GERCOR & cancer trials Ireland	January 2015	UHG, UHW, AMNCH, BonS, SVUH, CUH, Mater, SJH	500	236	40	0	June 2017
Title: Multi-line Therapy Trial in Unresectable Wild-Type RAS Metastatic Colorectal Cancer. **Comment:** 7 sites re-opened to recruitment since November. Mater to be initiated January 2017. No accruals to date.							
MK 3475-177 **CTRIAL-IE (ICORG) 16-28** PI: Dr David Gallagher Type: Industry Sponsor: Merck	July 2016	AMNCH, SJH	270	44	4	1 AMCH 1	September 2017
Title: Phase II/III Study of Pembrolizumab vs. Chemotherapy in MSI-H CRC **Comment:** No accruals globally or locally in the last four months. Difficult patient population. Study due to close in September.							
BMS CA209-577 **CTRIAL-IE 16-73** PI: Dr Patrick Morris Type: Industry sponsored Sponsor: Bristol-Myers Squibb	July 2016 (global) November 2016 (Ireland)	BH, CUH, UHG	760	33	12	0	August 2017
Title: A Randomized, multicenter, double blind, phase III study of adjuvant nivolumab or placebo in patients with resected lower oesophageal, or gastroesophageal junction cancer **Comment:** BH site recently activated and has begun screening. CUH and UHG sites opening soon (CUH initiated Jan 2017).							
MK 3475-181 **CTRIAL-IE 16-21** PI: Dr Sinéad Cuffe Type: Industry Sponsor: Merck	September 2016	AMNCH, SJH	600	229	6	**3** AMNCH 2, SJH 1	October 2017
Title: Phase III Study of Pembro vs. Chemo in Subjects with Esophageal Cancer **Comment:** Opened since last DSSG (September). Recruiting well to date.							

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
Endometrial IMRT **CTRIAL-IE (ICORG) 09-06** PI: Dr Charles Gillham Type: In-House Sponsor cancer trials ireland	Feb 2010	SLRON (3 sites)	N/A	N/A	154 (142 evaluable)	**65** SLRON (SLH 54, BH 7, SJH 4)	TBC
Title: Prospective Randomised Phase II Study evaluating Adjuvant Pelvic Radiotherapy using either IMRT or 3-Dimensional Planning for Endometrial Cancer. **Comment:** One patient only recruited since the previous DSSG.							
ICON8B **CTRIAL-IE (ICORG) 11-29** PI: Dr Dearbhaile O'Donnell Type: Collaborative Group Sponsor: MRC	Sep 2015	BonS, UHG, Mater, SJH, UHW	1170	340	30	**17** BonS 3, UHG 1, Mater 9, UHW 4,	2019
Title: 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. **Comment:** Global accrual is currently ahead of schedule.							
SHAPE **CTRIAL-IE (ICORG) 14-02** PI: Dr Noreen Gleeson Type: Collaborative Group Sponsor: NCIC	Sep 2014	SJH	700	275	10	**10** SJH 10	2019
Title: 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. **Comment:** Country target accrual reached at SJH.							
JAVELIN 200 **CTRIAL-IE 15-22** PI: Prof. J. McCaffrey Type: Industry Sponsored Sponsor: Pfizer	Sep 2016	SJH, Mater, UHW, SVUH	550	263	23	**0**	June 2017
Title: 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. **Comment:** SVUH planned to be activated in March 2017.							
JAVELIN 100 **CTRIAL-IE 16-05** PI: Dr Dearbhaile O'Donnell Type: Industry Sponsored Sponsor: Pfizer	Dec-2016	BonS, CUH, Mater, SJH, SVUH	951	110	TBC	**0**	Mid 2017
Title: A randomized, open-label, multicenter, phase 3 study to evaluate efficacy and safety of Avelumab (MSB0010718C) in combination with and/or following chemotherapy in patients with previously untreated epithelial ovarian cancer. **Comment:** CUH, Mater, SJH, SVUH planned to be activated shortly.							

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
PRIMA **CTRIAL-IE 16-04** PI: Dr P. Calvert Type: Industry Sponsored Sponsor: Tesaro	Q1 2017	UHW, CUH, Mater, SJH	305	11	12	**0**	2020
Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients with HRD-Positive Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy **Comment:** All sites to be activated shortly.							

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
ROBUST **CTRIAL-IE (ICORG) 15-08** PI: Dr Cliona Grant Type: Industry Sponsored Sponsor: Celgene	**Ireland** Feb 2015	CUH, Mater, SJH, SVUH, UHG	560	363	15	**2** SJH 1, SVUH 1	Oct 2017
Title: 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. **Comment:** No new patients enrolled since last DSSG meeting.							
ARROVEN PASS Study **CTRIAL-IE (ICORG) 15-09** PI: Prof Elisabeth Vandenberghe Type: Industry Sponsored Sponsor: Millennium	**Ireland** Sep 2015	SJH, BH, Mater	500	250	9 (3 per site)	**10** BH 6, SJH 3, Mater 1	Mar 2018
Title: 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. **Comment:** Recruitment extended until March 2018.							
CHRONOS-2 **CTRIAL-IE (ICORG) 15-37** PI: Prof Liam Grogan Type: Industry Sponsored Sponsor: Bayer	Feb 2016	BH, Mater	189	18	4	0	Dec 2018
Title: 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) **Comment:** Mater to open.							

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
CHRONOS-3 **CTRIAL-IE (ICORG) 15-38** PI: Prof Elisabeth Vandenberghe Type: Industry Sponsored Sponsor: Bayer	Oct 2015	UHG, SJH, Mater, SVUH, BH	567	92	18	**2** UHG 1; Mater 1	Jun 2019
Title: 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) **Comment:** To screen 29 for 18 randomised patients. Recruitment is slower than planned.							
P2001 **CTRIAL-IE (ICORG) 16-08** PI: Prof Helen Enright Type: Industry Sponsored Sponsor: Millennium	Sep 2016	AMNCH, Mater, UHG	117	67	1-2 patients per site	**1** AMNCH 1	Apr 2017
Title: 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 **Comment:** AMNCH and Mater activated.							
Protocol 04-30 **CTRIAL-IE (ICORG) 15-36** PI: Prof Helen Enright Type: Industry Sponsored Sponsor: Onconova	May 2016	AMNCH, CUH, UHG, UHW	225	71	12	0	Dec 2017
Title: A Phase III International Randomised Controlled Study of Rigosertib versus Physicians Choice in MDS After Failing A Hypermethylating Agent **Comment:** Protocol Amendment 3 submitted to the HPRA and CEC in Jan 2017, pending approval. Recruitment behind schedule.							
2215 CL 0301 **CTRIAL-IE (ICORG) 16-09** PI: Prof Michael O'Dwyer Type: Industry Sponsor: Astellas	Global: Oct 2015	UHG, BH, CUH	369	TBC	TBC	0	Apr 2017
Title: A Phase 3 Open-Label, Multicenter, Randomized Study of ASP2215 versus Salvage Chemotherapy in Patients with Relapsed or Refractory Acute Myeloid Leukemia (AML) with FLT3 Mutation **Comment:** Study open at BH.							
M15-550 (VENICE 1) **CTRIAL-IE (ICORG) 16-79** PI: Dr Patrick Thornton Type: Industry Sponsor: AbbVie	Dec/16	SJH, BH	250	31	3 to 10 patients for each site.	**1** SJH 1	Oct 2018
Title: Open-Label, Single Arm, Phase 3b, Multi-Center Study Evaluating the Efficacy of Venetoclax (ABT-199) in Relapsed/Refractory Subjects with Chronic Lymphocytic Leukemia (CLL) Including Those with the 17p Deletion or TP53 Mutation OR Those Who Are Refractory or Intolerant to B-Cell Receptor Inhibitors **Comment:** SJH opened in Dec 16. Beaumont to open Feb 17.							

Cancer Trials Round Up—Spring 2017

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
ECOG E3A06 **CTRIAL-IE (ICORG) 12-02** PI: Prof Michael O'Dwyer Type: Collaborative Group Sponsor: ECOG-ACRIN	International Oct 2010 **Ireland** Mar 2014	UHG, Mater	224	207	10	**3** MMUH 1, UHG 2	Apr 2017
Title: Randomised Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma. **Comment:** Protocol Addendum 12 has been approved by EC and HPRA.							
KEYNOTE 185 **CTRIAL-IE (ICORG) 16-10** PI: Dr John Quinn Type: Industry Sponsored Sponsor: MSD	Sep 2016	BH	640	123	4	**1** BH 1	Mar 2018
Title: A phase III study of Lenalidomide and low-dose Dexamethasone with or without Pembrolizumab (MK3475) in newly diagnosed and treatment naïve Multiple Myeloma **Comment:** Study recently opened.							
CyBorD-DARA **CTRIAL-IE (ICORG) 16-02** PI: Prof Michael O'Dwyer Type: Collaborative Sponsor: NUIG	Oct 2016	UHG, CUH, BH	18	3	18	**3** UHG 3	Mar 2018
Title: Phase Ib study of weekly Cyclophosphamide-Bortezomib-Dexamethasone (CyBorD) with Daratumumab (DARA) in transplant eligible patients with newly diagnosed Multiple **Comment:** Study open at UHG, to open at CUH Feb 2017.							
MMY3008 **CTRIAL-IE (ICORG) 15-11** PI: Prof Michael O'Dwyer Type: Industry Sponsored Sponsor: Janssen	**Ireland** Feb 2016	UHG, Mater	730	736	15	**7** UHG 5 Mater 2	Dec 2016
Title: 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 **Comment:** Accrual closed in Dec 16.							
OPTIMISMM **CTRIAL-IE (ICORG) 15-10** PI: Dr Patrick Hayden Type: Industry Sponsored Sponsor: Celgene	Jun 2015	UHG, Mater, SJH	544	549	18	**10** UHG 3, Mater 4, SJH 3	Feb 2017
Title: 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 **Comment:** Accrual to close Feb 2017.							

DSSG NOTES—Spring 2017

Just Ask!

2016 IRISH HEALTHCARE AWARDS

Cancer Trials Ireland has won an Irish Healthcare Award for its "Just Ask!" campaign.

The campaign was designed to encourage patients and their families to ask their doctor about cancer trials.

It won the award for the Best Patient Education Project – Non pharmaceutical.

The "Just Ask!" campaign was also part of the organisation's name change programme from ICORG to Cancer Trials Ireland which was kindly supported by the Irish Cancer Society, the Health Research Board, Bayer, Amgen and Merck Serono. Attendance at the awards event was supported by Bayer and MSD.

Pictured presenting the award to Eibhlin Muloe, CEO of Cancer Trials Ireland, is Darina Sexton, Head of Communication at MSD, which sponsored the award category.

2017 DSSG Meetings

Friday, 23rd June

Friday, 20th October

Venue will be confirmed closer to the date

Cancer Trials Ireland, Charity No. CHY12492
60 Fitzwilliam Square, Dublin 2, Ireland
Tel: +353 (0)1 6677211 Fax: +353 (0)1 6697869
info@cancertrials.ie www.cancertrials.ie
Twitter: @cancertrials_ie

Promotions and new staff

Staff Promotions

Luke Heaphy promotion to CTA
Luke joined us in 2016 as an intern and has assisted with a number of study trials. He recently graduated with first class honours in his science degree from Maynooth University.

Emma Farrell promotion to tCRA
Emma Farrell joined us a year ago as Clinical Trial Administrator. She has played a vital role in supporting the set up and running of studies managed and sponsored by TRIO (Translational Research In Oncology).

Jillian Burns promotion to CRA
Jillian joined us in 2016 as a tCRA and made a smooth transition from her previous role as a Radiation Therapist. Since joining the RT team she has gained considerable experience as a CRA on RT trials. She has also taken on additional responsibilities including co-ordination of the lung DSSG.

Fiona Martin promotion to CRA
Fiona joined our translational team in 2015 as a tCRA. She has worked on several complex translational studies within many disease subgroups with particular focus on biomarker studies. She has also gained CRA experience on clinical studies, in particular the ANZUP prostate studies.

Jacinta Marron promotion to Data Project Lead
Jacinta Marron has taken over leadership of the Clinical Data Management team. She has over 13 years' clinical research experience in both the CRO and pharmaceutical business in Ireland and abroad. Jacinta will also take on the responsibility of liaising with the CRFG, our Data Management partners in Galway.

New staff

Lydia Sullivan – rtCRA
Lydia joins us with over 8 years' experience working as a Research Radiation Therapist/Clinical Trials Coordinator in St Luke's Hospital, Rathgar. She is completing her MSc in Radiotherapy and Oncology. She brings great expertise and experience to the Radiotherapy Team and Cancer Trials Ireland.

Ann Ryan – Finance Manager
Ann is an experienced Chartered Accountant at Finance Manager level and has extensive commercial experience both in large and small enterprises. She also has a background in not-for-profit enterprises having been a director of SPADE Enterprise Centre for many years. Ann will be responsible for the day to day Operations of the Finance Dept.