

# DSSG DIGEST

## Summer 2016

### Vol. 10 ISSUE 2



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## DSSG NOTES—Summer 2016

# Welcome from

## Prof Bryan Hennessy

### Clinical Lead



Cancer Trials Ireland's network is a unique health research infrastructure. We offer a world class one stop shop for cancer trials.

Over the past 20 years we have built a huge reservoir of scientific knowledge and expertise. This expertise is very important in what is a highly complex, challenging and regulated environment. Our plan is to build on this expertise and develop it further.

Our key objective is to increase patient participation on cancer drug trials to 5% from the current 3%. This is the figure that reflects our country's commitment to finding answers to the disease that is the second biggest killer in Ireland and will double between now and 2040. It is the figure that tells patients and their families how serious we are about tackling cancer.

To achieve this objective, we want to initiate and support more investigator led studies, broaden our impact across more cancer types and grow the opportunities to work with international collaborative groups and pharmaceutical companies. We want to enhance further the very positive reputation we have developed on the global stage through more collaboration with cancer experts around the world.

In achieving these goals we can help bring diagnostics and treatments to patients and the wider community, which will enhance lives and save lives.

These ambitions are consistent with many working in the field. For example, the expectations of the HRB in its current strategy document are for “more intervention-focused health research, resulting in better outcomes for individuals, and increased quality and safety in the healthcare system”.

In the context of an increase of cancer incidences, of cancer related death rates and the positive impact cancer

trials can have on these two factors, it is also critical that we address our funding model.

Given our ambition and the need for more cancer trials in Ireland we will naturally have to increasingly supplement our already reduced exchequer funding and focus on finding and opening up new funding sources.

In this context we also seek to strengthen our ties with the pharmaceutical industry to enable more cancer trials to be opened.

We have set up a Business Development function to help our cancer trials research units around the country identify and pursue opportunities, work together and learn from each other's best practice.

I would like to take this opportunity to thank all consultants, doctors, nurses and staff in our research units around the country and all our office staff in Dublin for their dedication and commitment to cancer research at the highest standard.

It is also important to recognise the support that we get from the exchequer which we receive through the Department of Health and in turn through the HRB. I would also like to thank the Irish Cancer Society for its generous support.

We appreciate the opportunity to work with the pharmaceutical industry and wish to develop further our relationship with it during the years ahead.

Finally I want to thank the international collaborative groups that we work with - we are working with these groups on some very exciting trials from across the world and leading the European leg of some trials. This reflects the high regard for our cancer trials teams across the country.

# Welcome from

## Eibhlin Mulroe

### CEO



*Eibhlin Mulroe with John Lawlor, author of the DKM Economic Consultants Report*

I would like to begin with a very special thank you to all who got behind our activities for International Clinical Trials Day.

We marked the start of this year's activities to a packed audience in The Mansion House in Dublin. Around the country, cancer trials research units organised a whole variety of local information activities to highlight their work and the value of cancer trials – our new posters and information leaflet featured prominently (see page 6).

To spread the word far and wide many organised local media events and participated in local radio interviews. Collectively these activities helped us greatly in raising our profile, promoting our new look, new name and the impact of cancer trials for patients today and tomorrow.

John Lawlor and his team at DKM Economic Consultants quantified this impact and his revealing findings are outlined on page 7. The report is available at [cancertrials.ie](http://cancertrials.ie). I encourage you to read it. The findings highlight the tangible benefits for participating patients, but also that for every euro the exchequer invests in cancer trials we generate many multiples of this investment.

I would like to thank our colleagues around the country for welcoming and engaging so positively with our newly appointed Business Development Manager, Shane Ring. Shane has been out and about meeting with many of you and getting to know how you can build on your success and how we can support you.

We operate in a highly regulated, complex and demanding environment. It is critical for our continued and future success that we are equipped to respond effectively to what the industry, collaborators and our investigators require. Our business development function is here to support you in meeting these requirements.

Related to this is the development of the next strategic plan for Cancer Trials Ireland. It is being developed on foot of the organisational review that was completed in 2014 and the International Panel Review carried out in 2015.

We have made a number of strategic changes over the past year supported by a series of operational initiatives such as more rigorous performance measurement and management, and clinical oversight. These changes, which are ongoing, are designed to enable us operate as a fit for purpose organisation.

The new strategic plan will provide us with a road map for the next stage in our growth and development. It will outline the key strategic objectives we will work toward achieving over the next four years. It will outline what we need to do at an operational level to achieve these objectives, and it will also outline the various risks and opportunities on the horizon. We will be informed by feedback from our membership through the Executive, the HRB International Panel Review, and will be working closely with our Chairman, Clinical Lead and Board over the coming months to complete it.

Finally, I would like to thank all who have contributed to the development of our new name. We initiated considerable consultation and the feedback was invaluable.

Our old name served us very well for 20 years in the global research environment and we have a job to do to communicate our new identity. However, back at home through feedback from our membership, the HRB International Panel Review and our Patient Advocate Advisory Group we needed to do better in reaching and connecting with the general public. We need to communicate in language that is easily understood. Our new name will, I believe, help us make these connections.



# New name and Just Ask! launched at International Clinical Trials Day

Cancer Trials Ireland's new look and logo along with the Just Ask! Campaign were part of the celebrations for the launch of the recent International Clinical Trials Day (20th May). The new campaign was developed to encourage people diagnosed with cancer to just ask their doctor or healthcare professional about cancer trials.

Announcing the background to the two initiatives Eibhlin Mulroe, CEO, said that the changes were informed by the membership through consultations and discussions since 2014, particularly at Executive and Board level.

They were also informed by the findings from the International Panel Review 2015 commissioned by the Health Research Board. While the panel's findings overall were very positive, it said that it was "critical" that the organisation became more outward-looking, more focused on connecting and engaging with patients. "We have reflected carefully on these suggestions", Eibhlin said.

*A new information leaflet which answers key questions about cancer trials is now available in research units across the country.*



"One of the initiatives we took last year was setting up the first Patient Advocacy Advisory Group.

The second is our new name developed through a series of consultations.

"The new name says exactly what we do – cancer trials. The icon selected, a stylised question mark, reflects what cancer trials do – they ask questions and seek answers.

"Both our new name and the icon are supported with our strap line – *Together*, which reflects the fact that patients and researchers are working together, *we are finding answers to cancer* – which is the counter point to the question.

"This reflects that our endeavour is a collective enterprise – it requires working together not only within Ireland but on a global scale," she said.



*Pictured at the launch (l to r) Dr Graham Love, CEO of the HRB, Professor Bryan Hennessy, Clinical Lead, Cancer Trials Ireland, Oliver O'Connor, CEO of IPHA, John McCormack CEO of the Irish Cancer Society, Dr Jonathan Westrup, Chairman, and Eibhlin Mulroe, CEO, Cancer Trials Ireland and Dr Robert O'Connor, Head of Research, Irish Cancer Society.*



## Research Units get behind International Clinical Trials Day



**Cork:** (l to r) Elaine Sheehan, Niamh Mullane, Elaine Cronin, Niamh Crowley, Fiona Lowe and Liz Lenihan



**Limerick:** (l to r) Maureen O'Grady, Dr Linda Coate, Munster Head Coach Anthony Foley who kindly supported the hospital's events and Breda Fallon.



**Galway:** (l to r) Sue Hennessey, Mary Byrne, Danielle Nicholson.



**Cork:** (l to r) Karen Molan, Katrina Falvey, Niamh Mullane and Sarah Thompson.



**Galway:** (l to r) Olive Forde, Mary Byrne, Marian Jennings, Carmel O'Toole, Swapnil Gaware.



**AMNCH, Dublin:** (l to r) Ruth Mc Ginn, Rhonda Mooney and Maria Gillespie.



**Beacon Hospital, Dublin:** Sacha Liu and Gavin Lawler.



**Beaumont Hospital, Dublin:** (l to r) Derval Kehily, Stephen Shovlin, Keith Egan, Marieke Amerlynck, Andrea Klincse and Kevin Browne.



**Mater Hospital, Dublin:** (l to r) Louise Cusack, Brian Whelan, Karen Geraghty, Deirdre Wynne, Sandra Flynn, Martina Smith and Orna Harraghy.

# Cancer trials save Government €6.5m annually



*The independent report  
Health and Economic  
Impacts of Cancer Trials in  
Ireland by DKM Economic  
Consultants is available to  
download from [cancertrials.ie](http://cancertrials.ie)*

An independent report commissioned by Cancer Trials Ireland estimates that the €3.63m funding from the Exchequer, and other grants, allocated to cancer trials in 2016 will save the HSE at least €6.5m in cancer drugs costs, generate almost €6m in tax revenues, contribute €16.5m to Ireland's GDP and support over 230 jobs, mostly high quality specialist positions. In addition, Cancer Trials Ireland is expected to generate more than €3.85m from international sources.

Based on a small sample of case studies, the report, prepared by DKM Economic Consultants, estimates that cancer trials can add 6 to 15 quality adjusted years of life (QALYs) collectively for trial participants with a related economic benefit ranging from €0.28m to €0.65m per trial. The report notes that subsequent benefits would be a multiple of these values when proven therapies are made available to patients generally. These benefits are in addition to the early access to drugs and treatments and the extra care cancer trials participants receive.

One case study in the report demonstrated that in the breast cancer trial known as TAILORx 110 Irish patients collectively avoided 27 years of chemotherapy which generated a saving of €0.766m for the HSE in avoided treatment costs. The test that resulted from this trial means that each year hundreds of patients do not have to undergo chemotherapy which saves the HSE over €0.5m annually. Another cancer trial in the area of advanced melanoma added a combined 6.3 quality adjusted years of life to the 27 participants which generated an economic benefit of over €0.28m.

During 2015, cancer trials research units were working on 154 cancer trials involving over 6500 patients. There were more than 50 collaborations with pharmaceutical companies, collaborative groups and universities worldwide and were mentioned in 33 articles in high impact medical journals.

Speaking at the report's publication to mark International Clinical Trials Day, Eibhlin Mulroe, CEO, Cancer Trials Ireland, said: "This report highlights the impact our very well developed network of 14 cancer trials research units is having. They give patients early access to medicines not yet available. They can contribute significantly to their wellbeing all the while finding answers to cancer. They also represent a highly effective network for investigator led studies and attracts cancer trials from around the world and from leading pharmaceutical companies."

Prof Bryan Hennessy, Clinical Lead, Cancer Trials Ireland and Consultant Oncologist, Beaumont Hospital, said: "While I was naturally aware of the impact cancer trials can have on health outcomes and our battle against cancer, I was surprised by the multiple returns that the investments in trials generate. When you think of the hundreds of trials we are working on the impact is enormous," he said.

## Collaborations support Foreign Direct Investment

The independent report *Health and Economic Impacts of Cancer Trials in Ireland* notes that Cancer Trials Ireland's success with international collaborations helps the IDA build and broaden linkages with its existing clients and opens up opportunities for discussions with new clients interested in cancer. "These deepened relationships and positive perceptions of Ireland as an innovative location have the potential to increase our chances of winning high-value foreign direct investment in the biopharma space, especially as innovation in oncology is moving at such a fast pace," Barry Heavey, Global Head of Life Sciences, Engineering & Industrial Tech at IDA.



## New Board appointments

Dr Jonathan Westrup, Chairman of Cancer Trials Ireland, is delighted to announce the appointment of four new board members.

Dr Jerome Coffey, Director of the National Cancer Control Programme (NCCP), Dr Cathy Kelly, Consultant Medical Oncologist in the Mater University Hospital, Dublin, Dr Paul Kelly, Consultant Radiation Oncologist in Cork University Hospital and Darren Byrne, (Chair of Audit Committee) Non Executive Director and Experienced Chartered Accountant / CFO.

Dr Westrup thanked the outgoing Board members, Prof Mike O'Dwyer, Dr Susan O'Reilly and Prof Liam Grogan, very sincerely for their invaluable contribution, insights and for giving their time so generously to Cancer Trials Ireland during a period of particularly significant strategic change.

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

Christine Dalton, Clinical Research Associate  
David Higgins, Trainee Quality Assurance Auditor  
Jillian Burns, Trainee Clinical Research Associate  
Karl Anderson, Communication Adviser  
Laura Maher, Clinical Project Manager  
Luke Heaphy, Administrative Assistant  
Lorraine Carrabine, Senior Clinical Research Associate  
Orla Casey, Translational Research Coordinator  
Shane Ring, Business Development Manager

## Generous donation for Glioma research

We would like to warmly thank Shona Tarrant and Neil Kennedy for their generous donation for Glioma research given on the occasion of their wedding in June 2016. We wish the couple a bright, happy and successful future together.

Date for your Diary

**Next DSSG Meeting**

**Friday, 14th October 2016**

**The Gibson Hotel, Point Village, Dublin 1**

## Fond Farewell



Derval Kehily, Clinical Trials Program Manager of the Cancer Trials Unit at Beaumont Hospital in Dublin has retired after 14 years leading the trials team.

Derval was new to both oncology and clinical research when she

*Derval pictured with Dr Patrick Morris, Medical Director, Cancer Clinical Trials and Research Unit at Beaumont Hospital.*

first took up the challenge to build the trials team alongside Professor Liam Grogan. Derval's commitment to quality and getting the job done has left a lasting legacy. We offer Derval a very big thank you for her dedication to her role and wish her the very best for the future!

## New Name—New Numbers

In line with our new name we have introduced a new numbering system for trials. There will naturally be a transition period where we will be using both the old and new numbering system.

### New Trials

When numbering new trials (including those in development) which were adopted and/or started after International Clinical Trials Day (20th May 2016) the acronym ICORG will be replaced with CTRIAL-IE.

For example instead of using the number ICORG 16-01 we will use CTRIAL-IE 16-01. The first number denotes the year the study was adopted into the Cancer Trials Ireland study portfolio and the second denotes the order the trial was adopted that year.

### Open Trials

Open studies which opened before International Clinical Trials Day (20th May 2016) will use the new acronym with ICORG in brackets, e.g. CTRIAL-IE (ICORG) 10-09.

### Old trials

Old trials (closed, close to closure or in long term follow up) will be unchanged and continue to use the old acronym.

For further information contact your study contact in Cancer Trials Ireland.



## Update Lung Cancer

The lung cancer trials portfolio has expanded significantly in recent months with several new and exciting trials both opening and in the planning phase. A brand new international collaboration has also been formed with the **Thoracic Alliance for Cancer Trials (TACT)** which held its inaugural meeting at ASCO, 2016. Lung DSSG Chair, Dr Linda Coate presented an overview of Cancer Trials Ireland as a new member group of TACT which brings together more than 20 international cancer collaborative groups specialising in thoracic oncology clinical research and aims to conduct high quality large scale trials and translational research in this field. We look forward to being involved in this exciting international initiative.

### Spotlight on Open Lung Trials:

The **ETOP 5-12 SPLENDOUR Study** is a randomised Phase III trial evaluating the addition of denosumab to standard first-line anti-cancer treatment in advanced NSCLC sponsored by the European Thoracic oncology Platform (ETOP). Accrual is progressing very well with 19 patients enrolled across 7 active sites with a further 3 sites open in Ireland. The target in Ireland is 70 patients by January 2018.

The **EORTC 1416 PEARLS Study** is an international Phase III trial investigating immunotherapy treatment with an anti-PD-1 monoclonal antibody versus placebo for patients with early NSCLC after resection and completion of standard adjuvant therapy. This study has recently been initiated and activated in 5 Irish sites with 2 patients enrolled to date.

The industry sponsored **BMS CA209-227 (CHECKMATE-227) Study**, a Randomised Phase III 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) has accrued faster than anticipated to the PDL1 positive cohort and anticipated to close by the end of this summer. 5 patients have been enrolled in Ireland and sites are reminded to refer suitable patients to open centres including SJH, UHL, BH and UHG.

The lung cancer trials group has utilised referral as a model successfully on other trials, including the **AstraZeneca ASCEND 5 Study**, a Phase III, Multicenter, Randomized, open-label Study of Oral LDK378 versus standard



*Dr Linda Coate speaking at the TACT meeting held during ASCO, June 2016.*

chemotherapy in Adult Patients With ALK rearranged (ALK positive) advanced Non-small Cell Lung Cancer who have been treated previously with chemotherapy (platinum doublet) and crizotinib, which enrolled 6 patients at 2 open sites in Ireland, exceeding our accrual target.

For further details on the lung cancer trials portfolio please contact: Dr Linda Coate, Chair of Lung DSSG:

[linda.coate@cancertrials.ie](mailto:linda.coate@cancertrials.ie) or Kathleen Scott PhD, Clinical Program Leader: [Kathleen.scott@cancertrials.ie](mailto:Kathleen.scott@cancertrials.ie).

## Fond Farewell

Carmel O'Shea, Research Project Manager in St Luke's Radiation Oncology Network (SLRON), is leaving after 21 years.

Carmel started in St. Luke's in 1995 under its Director of Research, Dr Michael Moriarty. A successful grant application to the HRB in early 2000 formed the base for the St. Luke's Institute of Cancer Research under the Directorship of Professor John Armstrong.

Carmel together with Valerie Owens started to build up the clinical trials unit and her organisational talent and commitment to quality was instrumental to the success of the unit.

One of the greatest challenges was to open the additional two new SLRON radiation oncology centres on the North & South side of the city, which are forming the St Luke's Radiation Oncology Network (SLRON), which is now the hub for a large number of radiotherapy clinical trials.

A warm thank you to Carmel for her dedication to clinical trials and all the best wishes for the future!

## Update: Radiotherapy (RT)

### Newly opened RT trials:

#### **NSABP B-51 / RTOG 1304 CTRIAL-IE (ICORG) 15-03 —CI Dr Joseph Martin**

Study 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

The primary aim of this trial is to evaluate whether the addition of chestwall + regional nodal RT after mastectomy or breast + regional nodal RT after breast conserving surgery will significantly reduce the rate of events for invasive breast cancer recurrence-free interval, in patients who present with histologically positive axillary nodes – but convert to histologically negative nodes following neoadjuvant chemotherapy. The study has been described as the most important breast cancer RT Study in years, and is open at American sites since August 2013 – with 353 of 1636 patients enrolled to date. Via Cancer Trials Ireland's collaboration with NSABP/NRG, UHG and SLRON were the first sites to open outside of America; site initiation visits took place at both sites in February 2016. To date, 2 SLRON patients have been successfully registered and randomised to the study.

#### **UPCI #10-028 Phase II study of stereotactic radiosurgery for patients with oligo-recurrent disease CTRIAL-IE (ICORG) 15-05—CI Dr Alina Mihai**

The trial was initiated by UPMC in the Beacon Hospital on 07-Jan-2016. To date, 4 patients have been enrolled onto the study at the Beacon; the first patients to join the trial outside of the US. Later this year, it is anticipated that UPCI #10-027 Phase II study for curative intent treatment for patients presenting with oligometastatic disease (CTRIAL-IE 15-06) will also open at the Beacon Hospital.

### RT Studies in Development / Pending:

#### **IMRIS: Phase II study of intensity modulated radiotherapy (IMRT) in primary bone and soft tissue sarcoma CTRIAL-IE 15-48—CI Dr Charles Gillham**

This international trial will be Cancer Trials Ireland's first RT trial for patients with sarcoma; a rare type of cancer. Cancer Trials Ireland submitted to SLRON REC on 19-May-2016. Cancer Trials Ireland is awaiting the Research Agreement and Roles and Responsibilities documents from University College London to take over as local sponsor in

Rep. Ireland, and it is anticipated that the trial will open in SLRON in Q3 2016. The current global accrual is 17 patients to date. Accrual is expected to remain open until Q1 2018.

#### **INTENSE: A Phase 1 Study of Inhomogeneous Targeted Dose Escalation in Non-Small Cell Lung Cancer CTRIAL-IE 15-47—CI Prof John Armstrong**

This Cancer Trials Ireland in-house trial will open in SLRON. SLRON REC approval was granted on 29-Mar-2016. The study is expected to open in Q2 2016.

#### **PACE: A trial comparing surgery, conventional radiotherapy and stereotactic radiotherapy for localised prostate cancer (Phase 3) CTRIAL-IE 15-46—CI Prof John Armstrong**

Cancer Trials Ireland submitted to SLRON REC on 19-May-2016 and Beacon REC on 25-May-2016. It is awaiting the necessary paperwork from the Royal Marsden NHS Foundation Trust to take over as local sponsor for this international trial in Rep. Ireland. The study is expected to open in SLRON and Beacon in Q3 2016, and accrual will remain open until Q3 2018.

#### **ROAM: Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial (the ROAM trial) – EORTC protocol 1308 CTRIAL-IE 15-41—CI Dr David Fitzpatrick**

Cancer Trials Ireland submitted ROAM to SLRON REC on 19-May-2016 and Beaumont REC on 20-May-2016 as some trial-specific assessments will take place on the main Beaumont Hospital campus also. The study is expected to open in Ireland in Q3 2016 once all the necessary paperwork from the Walton Centre NHS Foundation Trust at University of Liverpool has been received and finalised. Accrual will remain open until Q3 2019.

#### **PLATO ACT5: Personalising Anal cancer RadioTherapy dose – Anal cancer trials (ACT) CTRIAL-IE 15-18—CI Dr Brian O'Neill**

The pilot study (limited access) for this international trial is due to open in June 2016, and will close to accrual after 12 months, following which the phase II/III study will open. The participation of SLRON in the pilot study is yet to be confirmed. The PLATO UK group will retain sponsorship in the Rep. of Ireland. All interested Cancer Trials Ireland sites should be able to participate in the main trial from June 2017.

Please contact Niall.Fox@cancertrials.ie (CRA) or Jillian.Burns@cancertrials.ie (tCRA) for queries regarding RT studies.

## Update GU: ENZAMET and ENZARAD ASCO 2016



The ENZAMET and ENZARAD trials were both selected for the Genito-Urinary poster presentation session at ASCO 2016. The trials are being conducted by the NHMRC Clinical Trials Centre, University of Sydney, in collaboration with ANZUP (Australian and New Zealand Urogenital and Prostate Cancer Trials Group) and sponsored in Australia by the University of Sydney. The trial is funded by Astellas Pharma Inc.

Cancer Trials Ireland is the European sponsor and running the studies within Europe. To date the Ireland and UK sites have successfully recruited a total of 117 patients (ENZAMET 96 patients; ENZARAD 21 patients). The Cancer Trials Ireland study team continues actively to conduct site initiations in IRL and the UK with the goal to reach the study recruitment targets as defined below. EORTC will join ENZARAD in the coming months opening the trial in 5 more European Countries.

### ENZAMET Trial

**Aim:** to determine the effectiveness of androgen deprivation therapy (ADT) + enzalutamide versus ADT + conventional non-steroidal anti-androgen (NSAA), as 1st line endocrine therapy for metastatic prostate cancer.

**Trial Design:** open label, randomised, stratified, 2-arm, multicentre, phase 3 trial including ANZ, Canada, UK, Ireland and USA.

**Eligibility:** metastatic prostate cancer starting 1st line ADT.

**Stratification:** volume of disease, anti-resorptive therapy, co-morbidities, early docetaxel use, study site.

**Endpoints:** overall survival (primary), PSA progression free survival (PFS), clinical PFS, health related quality of life (HRQOL), adverse events and cost-effectiveness.

**Treatment:** LHRHa or surgical castration plus either enzalutamide 160mg daily orally, or conventional oral NSAA until disease progression or prohibitive toxicity.

**Assessments** will be performed at baseline, days 29 and 85 then 12 weekly until clinical progression; imaging prior to randomisation and on progression (PSA and clinical).

**Tertiary objectives:** identify predictive biomarkers from archived tissue and fasting bloods. 1100 target participants, 79 sites open globally with total accrual of 620 participants on 26th May 2016.

**Recruitment:** closing Q2 2017.

### ENZARAD Trial

**Aim:** to determine the effectiveness of enzalutamide as part of adjuvant ADT with LHRHa in men planned for radiotherapy for localised prostate cancer at high risk of recurrence.

**Trial Design:** open label, randomised, stratified, 2-arm multicentre, phase 3 clinical trial including ANZ, Europe and USA.

**Primary endpoint:** OS.

**Secondary endpoints:** cause-specific survival, PSA PFS, clinical PFS, time to subsequent hormonal therapy, time to castration-resistant disease, metastasis free survival, adverse events and HRQOL.

**Treatment:** LHRHa for 24 months and EBRT (78Gy/39F) starting after week 16 for all participants and randomised 1:1 to enzalutamide 160mg daily for 24 months versus conventional NSAA for first 6 months.

**Assessments:** baseline, weeks 4, 12, 16, 20 and 24, then 3-4 monthly until year 5, 6-monthly until year 7, then annually. CT/MRI and bone scan at baseline, PSA progression, 6 monthly until re-initiation of ADT and 3 monthly until evidence of metastases.

**Tertiary objectives:** identify predictive biomarkers from archived tissue and fasting research bloods. Target of 800 participants, 46 sites open globally with total accrual of 210 participants as of 26th May 2016.

**Recruitment:** closing Q4 2018.

For more information on Ireland and UK site participation please contact Cancer Trials Ireland on [enza@cancertrials.ie](mailto:enza@cancertrials.ie).



Proudly pictured at the ENZAMET and ENZARAD study posters at ASCO 2016 GU Poster Session were (l to r) Prof Ian Davis, ANZUP Chair, Eibhlín Mulroe, CEO, Cancer Trials Ireland, Olwyn Deignan, CPM, Cancer Trials Ireland and Dr Scott Williams, ANZUP Study Chair.



# Cancer Trials Ireland studies open to accrual

Purple = Industry studies


Green = Cancer Trials Ireland studies

Orange = Collaborative Group studies

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual	AMNCH	Beacon	BH	BonS
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	1355			510	
Breast	Trans	10-11	Circulating miRNA	182			3	15
Breast	Trans	10-15	Exosomal HER2	219	41	Open	49	44
Breast	Trans	10-16	Ovarian Reserve	111	16	Open	24	15
Breast	Trans	12-09	CharactHER	181			5	
Breast	Trans	12-30	TAILORx Tissue Bank	567	23		33	14
Breast	Trans	12-40	EORTC 10085	12			3	
Breast	Clinical	14-01	EMBRACA/ MDV 673-301 (TRIO 023)	5				
Breast	Clinical	14-11	PENELOPE-B	7			1	Open
Breast	Clinical	14-21	NALA	1				
Breast	Clinical	14-22	16298 Radium 223 in BC (Bayer)	0				
Breast	Clinical	15-02	PanTHER	0			TBI	
Breast	Clinical	15-33	KEYNOTE-119 in mTNBC (MSD)	5				
Breast	Radio	15-03	NSABP B-51	2				
Breast	Clinical	15-16	FLIPPER	0			TBI	TBI
CNS	Trans	08-13	Serum Protein Markers for Glioma	69			69	
CNS	Clinical	15-28	M13-813 INTELLANCE 1	3			3	
CNS	Clinical	15-29	M14-483 INTELLANCE 2	w			5	
GI	Clinical	10-14	Neo-AEGIS	110			1	
GI	Clinical	11-32	Lithium Autophagy Study	0			TBI	
GI	Trans	12-27	CRAC Plasma Biomarkers	75	3	Open	24	10
GI	Trans	12-31	PDAC Plasma Biomarkers	58	24	Open	4	TBI
GI	Radio	12-38	TRI-LARC	28				
GI	Clinical	14-17	Exelixis Celestial Study	2				
GI	Clinical	14-19	BMS CA209-142 (CheckMate 142)	9			1	
GI	Clinical	14-20	GERCOR STRATEGIC-1	0	Initiated			Initiated
GU	Radio	07-11	Spinal Cord Retreat	21				
GU	Radio	08-17	IMRT Prostate	250		22		
GU	Trans	12-29	IMPACT study	23				
GU	Clinical	13-09	PEACE-1	24	1			
GU	Clinical	13-21	Radium-223 & Enzalutamide mCRPC	23	13			
GU	Clinical	13-23	Neo-adjuvant Abiraterone prostate	4				
GU	Trans	14-04	iPROSPECT	55	25	Open	Open	
GU	Clinical	14-06	ENZAMET	96	22	Open	2	
GU	Clinical	14-07	ENZARAD	22		6		
GU	Trans	15-21	ExPeCT study	21	6		Open	
GU	Trans	16-35	IPCOR	425		30	28	38
Gynae	Radio	09-06	Endometrial - IMRT v 3D RT ( <i>on hold</i> )	64				
Gynae	Clinical	11-29	ICON8B	9				2
Gynae	Clinical	14-02	The SHAPE Trial	5				
H & L	Clinical	12-02	E3A06 Lenalidomide in Smoldering Myeloma (ECOG-ACRIN)	3				
H & L	Clinical	15-08	ROBUST Lenalidomide plus RCHOP in ABC DLBCL (Celgene)	1				
H & L	Clinical	15-09	ARROVEN Brentixumab Vedotin PASS Study in HL (Millennium)	5			4	
H & L	Clinical	15-10	OPTIMISM Pomalidomide Study in rel/ref MM (Celgene)	6				
H & L	Clinical	15-37	CHRONOS-2 Copanlisib v placebo in rituximab refractory INHL (Bayer)	0			Open	
H & L	Clinical	15-38	CHRONOS-3 Copanlisib v placebo + rituximab in relapsed INHL (Bayer)	2			Open	
H & L	Clinical	15-11	MMY3008 Daratumumab in Multiple Myeloma (Janssen)	7				
H & L	Clinical	15-36	Rigosertib versus Physicians Choice in MDS (Onconova)	0	TBI			
Head & Neck	Clinical	12-39	De-ESCALaTE HPV	11			Open	
Lung	Clinical	12-53	ETOP SPLENDOR	19	1		Open	
Lung	Radio	15-05	Oligo-Recurrent Metastatic Disease	4		4		
Lung	Clinical	15-27	CA209-227 (CheckMate 227) 1st line NSCLC study (BMS)	4			1	
Lung	Radio	15-47	INTENSE	0				
Lung	Clinical	16-18	CA209-451 (CheckMate-451) 2nd line SCLC study (BMS)	1	TBI			
Lung	Clinical	15-39	ASTRIS (D5160C00022) 2nd Line T790m NSCLC study (AstraZeneca)	3				
Lung	Clinical	15-40	EORTC 1416 (PEARLS) study	1				
Melanoma	Trans	13-22	SYS-ACT	8			TBI	
Other	Trans	15-43	CRQ Survey	150	50	Open	Open	Open
Other	Trans	08;40	SNP Study	111	17		3	23
Other	Clinical	15-42	LOXO-101	0				

Open Studies	Studies To Be Initiated	Studies Pending	Studies Initiated but not activated
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## Breast Cancer Trials


Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	
<b>NALA</b> <b>CTRIAL-IE (ICORG) 14-21</b> PI: Prof John Crown Type: Industry Sponsored Sponsor: PUMA	Global: Mar 2013  <b>Ireland</b> Feb 2016	CUH, UGH, Mater, UHL, SJH, SVUH.	600	N/A	18	<b>1</b> SVUH 1	Dec 2016
<b>Summary:</b> Randomized, multi-center, multinational, open-label, active-controlled, parallel design study of the combination of neratinib plus capecitabine versus the combination of lapatinib plus capecitabine in HER2+ MBC patients who have received two or more prior HER2 directed regimens in the metastatic setting.							
<b>Comment:</b> Accrual extended to December 2016. Global accrual figures not released by company.							
<b>Penelope B</b> <b>CTRIAL-IE (ICORG) 14-11</b> PI: Dr Catherine Kelly Type: Collaborative Group Sponsor: German Breast Group	April 2013  <b>Ireland</b> Sept 2015	BH, BonS, CUH, UHG, Mater, UHL, SJH, SVUH, UHW	800	494	20	<b>7</b> UHG 3; Mater 2; BH 1; SJH 1	Q4 2016
<b>Summary:</b> Phase III study evaluating palbociclib (PD-0332991), a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor-positive, HER2-normal primary breast cancer with high relapse risk after neo-adjuvant chemotherapy “Penelope B”.							
<b>Comment:</b> 8 sites activated.							
<b>MDV 673-301/ TRIO 023 /</b> <b>EMBRACA Study</b> <b>CTRIAL-IE (ICORG) 14-01</b> PI: Prof John Crown Type: Industry Sponsored/ Collaborative Group Sponsor: MEDIVATION in collaboration with TRIO	Oct 2013  <b>Ireland</b> June 2014	UHG, Mater, SVUH	429	235	2 Pts per site per year	<b>5</b> Mater 3; SVUH 1; UHG 1	Dec 2016
<b>Summary:</b> A Phase III, Open-Label, Randomised, Parallel, 2-Arm, Multicentre Study of BMN 673 versus Physician’s Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, who have received no more than 2 prior Chemotherapy Regimens for Metastatic Disease.							
<b>Comment:</b> Referral of patients to open sites encouraged.							
<b>PantHER</b> <b>CTRIAL-IE (ICORG) 15-02</b> PI: Prof Bryan Hennessy Type: In-House Sponsor:	June 2016	BH, SVUH, UHG	N/A	N/A	29	0	To Open
							
<b>Summary:</b> Phase Ib/II clinical trial of copanlisib in combination with trastuzumab in pretreated recurrent or metastatic HER2-positive breast cancer.							
<b>Comment:</b> Site initiations projected June/July 2016.							



## 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-ordinator: Paulina Lawner/Andrés Hernando




Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	
<b>Protocol 16298</b> <b>CTRIAL-IE (ICORG) 14-22</b> PI: Dr Jennifer Gilmore Type: Industry Sponsored Sponsor: Bayer <b>Summary:</b> A phase II randomized, double-blind, placebo-controlled trial of radium-223 dichloride vs. placebo when administered to Her 2 negative hormone receptor positive breast cancer with bone metastases treated with standard of care hormonal treatment <b>Comment:</b> Study opened in CUH and Mater.	Ireland Feb 2016	Mater, CUH, UHG, SLRON	227	42	8	0	Jun 2017
<b>KEYNOTE 119</b> <b>CTRIAL-IE (ICORG) 15-33</b> PI: Dr Catherine Kelly Type: Industry Sponsored Sponsor: MSD <b>Summary:</b> A Randomized Open-Label Phase III Study of Single Agent Anti-PD1 versus Single Agent Chemotherapy per Physician's Choice for Metastatic Triple Negative Breast Cancer (mTNBC) <b>Comment:</b> Patient referrals welcome.	Global: Oct 2015  Ireland Dec 2015	SVUH, Mater	600	166	8	5 Mater 5; SVUH 0.	Oct 2016
<b>NSABP B51</b> <b>CTRIAL-IE (ICORG) 15-03</b> PI: Dr Joseph Martin Type: Collaborative Group Sponsor:  <b>Summary:</b> A Randomised Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy <b>Comment:</b> Two patients registered and randomised to the trial in SLRON since SIV Feb 2016. Both patients randomised to Group 1A.	Aug 2013  Ireland Feb 2016	SLRON, UHG	1636	353	Not specified	2 SLRON 2	2018
<b>EORTC 10085 Male Breast Cancer</b> <b>CTRIAL-IE (ICORG) 12-40</b> PI: Dr Cathy Kelly Type: Collaborative Group Sponsor: EORTC <b>Summary:</b> Clinical and biological characterization of Male Breast Cancer: an international EORTC, BIG, TBCRC and NABCG intergroup study. <b>Comment:</b> Accrual going well.	Feb 2014	BH, CUH, Mater, SJH, SVUH, UHW	N/A	372	N/A	12 BH 3; CUH 3; SJH 1; SVUH 4; UHW 1	Feb 2017

## Breast Cancer Trials

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

Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	
<b>FLIPPER</b> <b>CTRIAL-IE (ICORG) 15-16</b> PI: Dr Miriam O'Connor Type: Collaborative Group Sponsor: GEICAM	May 2016	SJH, Mater, BH, SVUH, BonS, UHG, UHW, UHL	190	16	40	0	February 2017
<b>Summary:</b> A randomized, double-blind, parallel-group, multicentre, phase II study to compare the efficacy and tolerability of fulvestrant (Faslodex™) 500mg with placebo and fulvestrant (Faslodex™) 500mg in combination with PD-0332991 (Palbociclib) as first line treatment for postmenopausal women with hormone receptor-positive metastatic breast cancer, who have completed at least 5 years of adjuvant endocrine therapy and remained disease free for more that 12 months following its completion or have “de novo” metastatic disease.							
<b>Comment:</b> 2 site initiated to date (SJH and Mater).							
<b>Proteomic/Molecular</b> <b>Breast</b> <b>CTRIAL-IE (ICORG) 09-07</b> PI: Prof Leonie Young & Prof Bryan Hennessy Type: In-House Sponsor: 	Jan 2013	BH, CUH, SJH, SVUH, UHL, UHW	N/A	N/A	N/A	<b>1355</b>  BH 510; CUH 379; SJH 11; UHL 385; UHW 70	N/A
<b>Summary:</b> Define the proteomic and molecular characteristics of primary and recurrent/metastatic breast tumours.							
<b>Comment:</b> SVUH is now open and will begin recruitment soon.							
<b>Circulating miRNA</b> <b>CTRIAL-IE (ICORG) 10-11</b> PI: Prof Michael Kerin Type: In-House Sponsor: 	May 2011	BH, BonS, UHG, SJH, SUH, SVUH, UHW	N/A	N/A	Cohort 1: 122 (closed)  Cohort 2: 122  Cohort 3: 122	<b>182</b> BH 3; BonS 15; UHG 125; SJH 29; S UH 8; UHW 2	TBC
<b>Summary:</b> Novel breast cancer biomarkers and their use for guiding and monitoring response to therapy.							
<b>Comment:</b> Recent improvements in accrual need to continue.							
<b>Exosomal HER2</b> <b>CTRIAL-IE (ICORG) 10-15</b> PI: Dr Lorraine O'Driscoll & Prof John Crown Type: In-House Sponsor: 	Oct 2012	AMNCH, Beacon, BH, BonS, CUH, LUH, SJH, SUH, SVUH, UHW	N/A	N/A	HER2+: 300  HER2-: 30 (closed)	<b>219</b> AMNCH 41; BH 49; BonS 44; CUH 8; LUH 6; SJH 2; SUH 22; SVUH 36; UHW 11	TBC
<b>Summary:</b> Exosomal and free extracellular RNAs and proteins as predictive biomarkers for HER2 therapies in breast cancer.							
<b>Comment:</b> HER2+ accrual is excellent.							

## Breast Cancer Trials

Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	
<b>Ovarian Reserve</b> <b>CTRIAL-IE (ICORG) 10-16</b> PI: Dr Janice Walshe & Prof Bryan Hennessy Type: In-House Sponsor: 	Oct 2012	AMNCH, Beacon, BH, BonS, CUH, SJH, SUH, SVUH, UHW	N/A	N/A	250	<b>111</b> AMNCH 16; BH 24; BonS 15; CUH 18; SJH 6; SUH 8; SVUH 18; UHW 6	TBC
<b>Summary:</b> A study to determine alteration of hormone levels in premenopausal patients receiving adjuvant or neo-adjuvant chemotherapy for breast cancer.							
<b>Comment:</b> Accrual has more than doubled in less than 1 year since the most recent protocol amendment.							
<b>CharactHER</b> <b>CTRIAL-IE (ICORG) 12-09</b> PI: Prof Giuseppe Gullo & Prof John Crown Type: In-House Sponsor: 	May 2014	BH, Mater, SJH, SVUH,  Milan, Italy	N/A	181	Cohort 1&3: 100  Cohort 2: 200	<b>167</b> BH 5; Mater 6; SJH 6; SVUH 150;  <b>14</b> Milan	TBC
<b>Summary:</b> Using molecular and cytogenetic characteristics of HER2+ breast cancer to predict durable complete response after chemotherapy and trastuzumab.							
<b>Comment:</b> Additional Italian site will open soon.							
<b>TAILORx Tissue Bank</b> <b>CTRIAL-IE (ICORG) 12-30</b> PI: Dr Cathy Kelly & Dr Darran O'Connor Type: In-House Sponsor: 	May 2014	AMNCH, BH, BonS, CUH, UHG, LUH, Mater, SJH, SUH, SVUH, UHW	N/A	N/A	691	<b>567</b> AMNCH 23; BH 33; BonS 14; CUH 72; UHG 66, LUH 14; Mater 79; SJH 37; SUH 32; SVUH 167; UHW 30	TBC
<b>Summary:</b> Identify candidate/novel biomarkers prognostic for disease relapse and predictive for endocrine and/or chemotherapy resistance from patients involved in the ICORG 06-31 TAILORx study.							
<b>Comment:</b> All FFPE blocks should be sent to Dr Darran O'Connor.							




## Translational Cancer Trials

Co-ordinator: Ronan Feighery

## Melanoma Cancer Trials

Co-ordinator: Catherine Dolphin

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>SYS-ACT CTRIAL-IE (ICORG) 13-22</b> PI: Dr Markus Rehm Type: In-House Sponsor: 	August 2014	SVUH, UHG	N/A	N/A	Case: 60 Controls: ~20	8 SVUH 7; UHG 1	2017
<b>Summary:</b> A Translational Systems Medicine Approach to provide Predictive Capacity for Therapy Responsiveness in Advanced or Metastatic Malignant Melanoma (SYS-ACT).							
<b>Comment:</b> SVUH has accrued 7 patients. Dr Fabre (pathologist), Mr Evoy (surgeon) and Dr Gullo (oncologist) have developed a working model that could be replicated at other sites. UHG has been initiated and has recruited its first patient since the last DSSG in February 2016.							

## Basket Cancer Trials

## Lung Cancer Trials

Co-ordinators: Glenn Webb / Jillian Burns

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Abbvie M11-089 Veliparib squamous NSCLC study CTRIAL-IE (ICORG) 14-14</b> PI: Dr Linda Coate Type: Industry Sponsored Sponsor: ABBVIE	Q3 2014	BH, CUH, SJH, UHL, UHW	975	975	29	<b>12</b> BH 2; CUH 1; UHL 3; SJH 4; UHW 2	Closed
<b>Summary:</b> A Randomized, Double-Blind, Multicenter, Phase 3 Study Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Placebo Plus Carboplatin and Paclitaxel in Previously Untreated Advanced or Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)							
<b>Comments:</b> 12 ICORG patients randomised (17 screened, 5 screen failures). 1 patient recruited since the last DSSG. Study now closed with global target met.							
<b>BMS CA209-171 CTRIAL-IE (ICORG) 16-17</b> PI: Dr Sinead Cuffe Type: Industry Sponsored Sponsor: BMS	Oct 2015	SJH, UHG	800	800	10	<b>2</b> SJH	Closed
<b>Summary:</b> A single arm, open-label, multicentre clinical trial with Nivolumab (BMS 936558) Monotherapy in Subjects with advanced or metastatic Sqamous Cell (Sq) Non-Small Cell Lung Cancer (NSCLC) who have received at least one prior systemic regimens for the treatment of Stage IIb/IV SqNSCLC.							
<b>Comments:</b> Study is closed to accrual having met the global target.							

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

### Lung Cancer Trials

Chair of Lung DSSG: Dr Linda Coate

Co-ordinator: Glenn Webb / Jillian Burns

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>ETOP 5-12 SPLENDOUR</b> <b>CTRIAL-IE (ICORG) 12-53</b> PI: Dr Linda Coate Type: Collaborative Group Sponsor: ETOP <b>Summary:</b> A randomized phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC. <b>Comment:</b> All sites in Ireland open, 7 actively recruiting. Protocol amendment planned for release July 2016. 24 patients registered, 19 patients randomized (5 ineligible), 9 patients since the last DSSG.	Q3 2015	AMNCH, BH, CUH, UHG, Mater, UHL, SJH, UHW, SVUH	1000	367	70	<b>19</b> UHL 5; CUH 3; SJH 6; AMNCH 1; Mater 1; UHW 1; UHG 2	Jan 2018
<b>'ASTRIS' (D5160C00022)</b> <b>CTRIAL-IE (ICORG) 15-39</b> PI: Dr Emer Hanrahan Type: Industry Sponsored Sponsor: AstraZeneca <b>Summary:</b> Open Label, Multinational, Multicenter, Real World Treatment Study of Single Agent AZD9291 for Patients with Advanced/Metastatic Epidermal Growth Factor Receptor (EGFR) T790M Mutation-Positive Non-Small Cell Lung Cancer (NSCLC) Who Have Received Prior Therapy with an EGFR Tyrosine Kinase Inhibitor (EGFR-TKI). <b>Comment:</b> 3 patients enrolled and 1 patient currently in screening. Accrual will close on the 01-Aug-2016.	Q1 2016	SVUH	1325	TBC	5	3	Aug 2016
<b>UPCI 10-028</b> <b>Oligo-Recurrent Stereotactic Radiotherapy</b> <b>CTRIAL-IE (ICORG) 15-05</b> PI: Dr Alina Mihai Type: Collaborative Group Sponsor: UPMC <b>Summary:</b> Phase II study of stereotactic radiosurgery for patients with oligo-recurrent disease. <b>Comments:</b> Study re-opened following EC approval of PIL amendment.	Jan 2016	Beacon	175	110	TBC	<b>4</b> Beacon 4	Q4 2016
<b>BMS CA209-451 (CheckMate-451) SCLC study.</b> <b>CTRIAL-IE (ICORG) 16-18</b> PI: Dr Deirdre O'Mahony Type: Industry Sponsored Sponsor: BMS <b>Summary:</b> A Randomized, Multicenter, Double-Blind, Phase 3 Study of Nivolumab, Nivolumab in Combination with Ipilimumab, or Placebo as Maintenance Therapy in Subjects with Extensive-Stage Disease Small Cell Lung Cancer (ED-SCLC) after Completion of Platinum-based First Line Chemotherapy. <b>Comments:</b> UHG enrolled 1st patient in northern European hub of 4 countries.	Oct 2015	AMNCH, CUH, SVPH, UHG	810 randomized	160 enrolled / 88 randomised	16	<b>1</b> UHG 1	Apr 2017



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

### Lung Cancer Trials

Chair of Lung DSSG: Dr Linda Coate

Co-ordinator: Glenn Webb / Jillian Burns

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

**EORTC 1416 (PEARLS) Study** Jan 2016 MMUH, UHL, SVUH, UHW, SJH, CUH 1380 25 20/site **1** Jan 2021  
**CTRIAL-IE (ICORG) 15-40**  
 PI: Dr Linda Coate  
 Type: Collaborative Group  
 Sponsor: EORTC

**Summary:** 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:** Study has been initiated and activated in SJH, Mater, SVUH, UHL and UHW. Globally 97 sites initiated.

**BMS CA 209-227 (CheckMate-227) Study** Q1 2016 SJH, UHL, BH, UHG 2475 enrolled Enrolled: 970 20 **5** Aug/Sep 2016  
**CTRIAL-IE (ICORG) 15-27**  
 PI: Dr Sinead Cuffe  
 Type: Industry Sponsored  
 Sponsor: BMS

**Summary:** 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:** Beaumont, UHG, SJH and UHL open. Given the faster than expected accrual into the PDL1+ cohort, it is anticipated that the study will close in Aug-Sep 2016. Please ensure to refer suitable patients for recruitment.

### Paediatric Cancer Trials

Chair of Paediatric DSSG: Dr Aengus O'Marcaigh

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

**AALL0932** Ireland May 2015 OLCCHC N/A N/A N/A **21** N/A  
 Type: Collaborative Group

**Summary:** Treatment of Patients with Newly Diagnosed Standard Risk B-Lymphoblastic Leukemia (B-ALL) or Localized B-lineage Lymphoblastic Lymphoma (B-LLy).

**AALL1131** Ireland May 2015 OLCCHC N/A N/A N/A **14** N/A  
 Type: Collaborative Group

**Summary:** A Phase III Randomised Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Testing a Purine Nucleoside Anti-metabolite in the Very High Risk Stratum.




## Paediatric Cancer Trials

Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	
<b>UKALL2011</b> Type: Collaborative Group	Ireland April 2013	OLCHC	N/A	N/A	N/A	<b>102</b>	N/A
<b>Summary:</b> United Kingdom National Randomised Trial for Children and Young Adults with Acute Lymphoblastic Leukaemia and Lymphoma 2011.							
<b>Interfant 06</b> Type: Collaborative Group	Ireland Nov 2014	OLCHC	N/A	N/A	N/A	<b>3</b>	N/A
<b>Summary:</b> International collaborative treatment protocol for Infants under one year with Acute Lymphoblastic or Biphenotypic Leukemia.							
<b>NBL—HR-NBL-1.7/SIOPEN</b> Type: Collaborative Group	Ireland Sep 2004	OLCHC	N/A	N/A	N/A	<b>60</b>	N/A
<b>Summary:</b> High Risk Neuroblastoma Study 1.7 of SIOP-EUROPE (SIOPEN).							
<b>NBL LTI Study</b> Type: Collaborative Group	Ireland Aug 2013	OLCHC	N/A	N/A	N/A	<b>7</b>	N/A
<b>Summary:</b> A Phase I/II Dose Schedule Finding Study of Monoclonal Antibody Continuous Infusion Combined With Subcutaneous Aldesleukin (IL-2) in Patients with Primary or Relapsed Neuroblastoma.							
<b>NBL BEACON</b> Type: Collaborative Group	Ireland May 2014	OLCHC	N/A	N/A	N/A	<b>4</b>	N/A
<b>Summary:</b> A randomised phase IIb trial of trial of VEGF Inhibitor added to Temozolomide ± IrinOtecan for children with refracto-ry/relapsed Neuroblastoma.							
<b>NBL LINES</b> Type: Collaborative Group	Ireland Feb 2016	OLCHC	N/A	N/A	N/A	<b>1</b>	N/A
<b>Summary:</b> Low and Intermediate Risk Neuroblastoma European Study (LINES). A SIOPEN Study.							
<b>RMS 2005</b> Type: Collaborative Group	Ireland Oct 2011	OLCHC	N/A	N/A	N/A	<b>17</b>	N/A
<b>Summary:</b> A protocol for non-metastatic rhabdomyosarcoma (incorporates RMS-MET2008: Treatment Arm for Metastatic Disease).							
<b>NRSTS 2005</b> Type: Collaborative Group	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	<b>4</b>	N/A
<b>Summary:</b> A Protocol for Non-Rhabdomyosarcoma Soft Tissue Sarcomas.							
<b>LLR Cell Bank</b> Type: Collaborative Group	Ireland Feb 2013	OLCHC	N/A	N/A	N/A	<b>85</b>	N/A
<b>Summary:</b> Leukaemia and Lymphoma Research (LLR) Childhood Leukaemia Cell Bank.							
<b>Mesrat Study</b> Type: Collaborative Group	Ireland June 2015	OLCHC	N/A	N/A	N/A	<b>1</b>	N/A
<b>Summary:</b> DNA methylation signatures and response to the azacitidine therapy in juvenile myelomonocytic leukaemia (JMML)							



## Paediatric Cancer Trials

Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	
<b>HD Interim Study</b> Type: Collaborative Group	Ireland Mar 2013	OLCHC	N/A	N/A	N/A	<b>26</b>	N/A
<b>Summary:</b> EuroNet Paediatric Hodgkin’s Lymphoma Interimphase study following closure of EuroNet PHL–C1 (HD 2007 10) Trial.							
<b>EWOG–MDS–2006</b> Type: Collaborative Group	Ireland Jan 2012	OLCHC	N/A	N/A	N/A	<b>3</b>	N/A
<b>Summary:</b> Prospective non–randomised multi–center study for epidemiology and characterisation of Myelodysplastic Syndrome (MDS) and Juvenile Myelomonocytic Leukemia (JNML) in childhood.							
<b>Renal Import</b> Type: Collaborative Group	Feb 2015	OLCHC	N/A	N/A	N/A	<b>14</b>	N/A
<b>Summary:</b> Improving Population Outcomes for Renal Tumours of Childhood.							
<b>OLCHC Tumour Bank</b> Type: Collaborative Group	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	<b>92</b>	N/A
<b>Summary:</b> Procedure agreed for Tumour tissue and matched blood–DNA banking at OLCHC.							
<b>EU–RHAB</b> Type: Collaborative Group	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	<b>6</b>	N/A
<b>Summary:</b> European Rhabdoid Registry. A Multinational registry for rhabdoid tumours of any anatomical site.							
<b>FACT Study</b> Type: Collaborative Group	Ireland April 2006	OLCHC	N/A	N/A	N/A	<b>28</b>	N/A
<b>Summary:</b> Factors associated with Childhood Tumours Study.							
<b>EWOG–SAA–2010</b> Type: Collaborative Group	Ireland April 2012	OLCHC	N/A	N/A	N/A	<b>15</b>	N/A
<b>Summary:</b> Genetic & Immunological Characterisation of Acquire Severe Aplastic Anaemia (SAA) in Children & Adolescents.							
<b>NBL Registry</b> Type: Collaborative Group	Ireland April 2015	OLCHC	N/A	N/A	N/A	<b>1</b>	N/A
<b>Summary:</b> Prospective Study Registry of Peripheral Neuroblastic Tumours Presenting with Spinal Canal Involvement (SCI).							
<b>AALL08B1</b> Type: Collaborative Group	Ireland May 2015	OLCHC	N/A	N/A	N/A	<b>27</b>	N/A
<b>Summary:</b> Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) – AALL08B1.							
<b>AZA–JMML–001</b> Type: Collaborative Group	Ireland June 2015	OLCHC	N/A	N/A	N/A	<b>1</b>	N/A
<b>Summary:</b> A Phase 2, multicenter, open–label study to evaluate the pharmacokinetics, pharmacodynamics, safety and activity of azacitidine and to compare azacitidine to historical controls in pediatric subjects with newly diagnosed advanced MDS or JMML before HSCT.							

## Genitourinary Cancer Trials




Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	
<b>Pazopanib study</b> <b>CTRIAL-IE (ICORG) 10-01</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	Dec 2010	AMNCH, BH, Mater, CUH, UHG, UHL, UHW, Sweden (Karolinska)	N/A	N/A	43 evaluable	<b>54</b> AMNCH 18; BH 5; CUH 4; UHG 1; Mater 13; UHL 5; UHW 5; Karolinska 3	Feb 2016 (closed)
<b>Summary:</b> A phase II study of second line pazopanib in patients with metastatic or unresectable Renal Cell Carcinoma who have failed prior therapy with sunitinib.							
<b>Comment:</b> Total number of evaluable patients achieved, study accrual closed Feb 2016.							
<b>Taxotere Biomarkers in</b> <b>HRPC CTRIAL-IE (ICORG)</b> <b>08-08</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	Sep 2008	BH, Mater, SJH, AMNCH	N/A	N/A	70	<b>73</b> AMNCH 17; BH 13; Mater 41; SJH 2	March 2016 (closed)
<b>Summary:</b> Biomarkers of Response to Taxotere in Hormone-Refractory Prostate Cancer.							
<b>Comment:</b> Accrual closed in March 2016. All sites are asked to send CRFs to CRFG as soon as possible. TCD will organise shipment of frozen samples.							
<b>IMRT Prostate</b> <b>CTRIAL-IE (ICORG) 08-17</b> PI: Prof John Armstrong Type: In-House Sponsor: 	<b>Ireland</b> Jan 2009	SLRON, Beacon, CUH (closed)	N/A	N/A	248	<b>250</b> SLRON 213; Beacon 22; CUH 15	Q3 2016
<b>Summary:</b> A Prospective Phase II Dose Escalation Study using IMRT for High Risk No Mo Prostate Cancer.							
<b>Comment:</b> CUH closed to accrual. 49 patients registered on the translational sub-studies. 08-17 is expected to close to accrual when 50 evaluable patients have been recruited to the translational sub-studies. Accrual expected to close Q3 2016.							
<b>IMPACT study</b> <b>CTRIAL-IE (ICORG) 12-29</b> PI: Dr David Gallagher Type: Collaborative Group Sponsor: ICR	<b>Ireland</b> Oct 2005	Mater, SJH	BRCA >1700 + Lynch 1140	BRCA 2943 + Lynch 441	N/A	<b>23 (BRCA)</b> Mater 1; SJH 22	TBC
<b>Summary:</b> Identification of Men With a Genetic Predisposition to ProstAte Cancer: Targeted Screening in BRCA1/2 Mutation Carriers & Controls.							
<b>Comment:</b> Lynch control open until 31.12.2016.							

## Genitourinary Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>iProspect CTRIAL-IE (ICORG) 14-04</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	Feb 2015	AMNCH, Beacon, BH, CUH, UHG, Mater, SJH, SUH, SVUH, UHW	N/A	N/A	Cohort 1: 15 (closed); Cohort 2: 45	<b>55</b> AMNCH 25; Mater 5; SJH 1; SUH 6; SVUH 14; UHW 1; CUH 3	TBC
<b>Summary:</b> Irish Programme for Stratified Cancer Therapy.							
<b>Comment:</b> Cohort 1 closed to accrual. Protocol amendment underway. UHG initiation pending. Request all CRFs to be completed and submitted.							
<b>ENZAMET CTRIAL-IE (ICORG) 14-06</b> PI: Prof Ray McDermott Type: Collaborative Sponsor: ANZUP	International Feb 2014  <b>Ireland</b> Dec 2014  UK 2015	AMNCH, BH, UHG, Beacon, Mater, SJH, SVUH, UHW  UK sites	1100	620	275	<b>96</b> AMNCH 22; BH 2; Mater 8; SVUH 7; UHW 7; UK Sites 50	Q2 2017
<b>Summary:</b> Randomised Phase III trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer.							
<b>Comment:</b> UHG pending initiation. 11 sites approved in the UK, 10 active, 1 activation pending.							
<b>ENZARAD CTRIAL-IE (ICORG) 14-07</b> PI: Dr Pierre Thirion Type: Collaborative Sponsor: ANZUP	International March 2014  <b>Ireland</b> April 2015 UK Sept 2015	CUH, UHG, Mater, Beacon, SLRON, Whitfield,  UK sites	800	210	200	<b>22</b> CUH 11; Mater 1, Beacon 6, UK sites 4	2018
<b>Summary:</b> Randomised Phase III trial of enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised, prostate cancer.							
<b>Comment:</b> Whitfield pending initiation. 14 sites approved in the UK, 3 active, 5 further sites pending activation, 6 pending initiations.							
<b>Neo-adjuvant abiraterone prostate study CTRIAL-IE 13-23</b> PI: Dr Pierre Thirion Type: In-House Sponsor: 	<b>Ireland</b> May 2015	CUH, SLRON (SLH), UHG	N/A	N/A	36 evaluable	<b>4</b> SLRON (SLH) 3, UHG: 1	Q2 2017
<b>Summary:</b> Phase II Non-randomised single arm study evaluating Neo-adjuvant (pre-radical radiotherapy) Abiraterone acetate (plus prednisolone) and Gonadotropin-releasing hormone (GnRh) agonist in Localised Prostate Cancer.							
<b>Comment:</b> Protocol Version 4.0 (01-Apr-2016) approved by Central Ethics on 19-Apr-2016 and HPRA 11-May-2016.							



## Genitourinary Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>ExPeCT study</b> <b>CTRIAL-IE (ICORG) 15-21</b> PI: Prof Stephen Finn Type: In-House Sponsor: 	<b>Ireland</b> Jan 2016	AMNCH, BH, Mater, SJH, SLRON (SLH),  UK sites	200 (UK 67, IRL 133)	34	133	<b>21</b> AMNCH 6; Mater 3; SJH 12	TBC
<b>Summary:</b> The ExPeCT Trial (Exercise, Prostate cancer and Circulating Tumour Cells): Evasion of immune editing by circulating tumour cells is an exercise-modifiable mechanism underlying aggressive behaviours in obese men with prostate cancer. <b>Comment:</b> Pending SLRON REC approval.							
<b>PEACE-1 study</b> <b>GETUG-AFU 21</b> <b>CTRIAL-IE 13-09</b> PI: Prof Ray McDermott Type: Collaborative Sponsor: UNICANCER	<b>Ireland</b> Oct 2014	AMNCH, CUH, UHG, Mater , SLRON, SVUH	916	447	60	<b>24</b> AMNCH 1; CUH 9; UHG 1; Mater 11; SVUH 2	Oct 2016
<b>Summary:</b> A prospective randomised Phase III study of androgen deprivation therapy with or without local radiotherapy with or without abiraterone acetate and prednisone in patients. <b>Comment:</b> Accrual has slowed in Ireland since Jan 2016.							
<b>Radium-223 &amp; Enzalutamide mCRPC study</b> <b>CTRIAL-IE (ICORG) 13-21</b> PI: Prof Ray McDermott Type: In-house Sponsor: 	<b>Ireland</b> June 2015	AMNCH, CUH, UHG, Mater, SLRON, SVUH	N/A	N/A	44	<b>23</b> AMNCH 13; CUH 3; Mater 2; SVUH 5	Dec 2016
<b>Summary:</b> A Phase II Study of Radium-223 in Combination with Enzalutamide in Progressive Metastatic Castrate-Resistant Prostate Cancer. <b>Comment:</b> UHG is pending initiation.							
<b>Spinal Cord Retreat study</b> <b>CTRIAL-IE (ICORG) 07-11</b> PI: Dr Pierre Thirion Type: In-House Sponsor: 	Oct 2007	SLRON (3 sites), UHG	N/A	N/A	25 evalua- ble	<b>21</b> (10 evaluable) SLRON 18; UHG 3.	TBC
<b>Summary:</b> A Phase II trial evaluating the efficacy of a radio-biological based re-irradiation strategy for patient with malignant spinal cord compression. A palliative cancer trial. <b>Comment:</b> Once 14 evaluable patients enrolled, an interim analysis will be performed.							

## 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-ordinator: Olwyn Deignan/Ausra Teiserskiene

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Merck Keynote 52 CTRIAL-IE (ICORG) 15-32</b> PI: Prof Ray McDermott Type: Industry sponsored Sponsor: Merck <b>Summary:</b> Study using pembrolizumab (MK-3475) for first-line treatment of participants with advanced/unresectable (inoperable) or metastatic urothelial cancer who are ineligible for cisplatin-based therapy <b>Comment:</b> Study closed to recruitment 20-May-16	<b>Ireland</b> Jun 15  <b>Globally</b> Feb 15	AMNCH	350	343	4	4	Closed May 2016
<b>IPCOR CTRIAL-IE (ICORG) 16-35</b> PI: Dr David Galvin Type: Collaborative Sponsor: IPCOR <b>Summary:</b> IPCOR – Irish Prostate Cancer Outcome Registry <b>Comment:</b> Please address queries for this study to IPCOR which runs the registry.	Feb 2016	17 Irish sites	N/A	N/A	>3000 per annum	425	TBC

### Head & Neck Cancer Trials

Chair of Head & Neck DSSG: Dr Sinead Brennan

Co-ordinator: Niall Fox


Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>De-ESCALaTE HPV CTRIAL-IE (ICORG) 12-39</b> PI: Dr Sinéad Brennan Type: Collaborative Group Sponsor: University of Warwick <b>Summary:</b> Determination of Epidermal growth factor receptor-inhibitor (cetuximab) versus Standard Chemotherapy (cisplatin) early And Late Toxicity Events in Human Papillomavirus-positive oropharyngeal squamous cell carcinoma. <b>Comment:</b> SLRON Beaumont hospital SIV took place 07-Mar-2016. Site activation occurred on 22-Apr-2016.	Oct 2012  <b>Ireland</b> Jan 2015	SLRON (SLH & BH)	304	273	20	11 SLH 11	Q1 2017
<b>MK-3475 Versus Standard of Care CTRIAL-IE (ICORG) 15-13</b> PI: Dr Cliona Grant Type: Industry sponsored Sponsor: Merck <b>Summary:</b> A Phase III Randomised Trial of MK-3475 Versus Standard Treatment in Subjects with Recurrent or Metastatic Head and Neck Cancer. <b>Comment:</b> Study closed to accrual April 2016.	<b>Ireland</b> Dec 2014  <b>Globally</b> Nov 2014	SJH	466	495	5	4 SJH 4	Closed April 2016

## 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: Norah Cassidy

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Serum Protein Markers for Glioma CTRIAL-IE (ICORG) 08-13</b> PI: Dr Verena Murphy Type: In-House Sponsor: 	July 2009	BH	N/A	N/A	Cohort 1: 100 Cohort 2: 30	<b>69</b> Cohort 1: 53, Cohort 2: 1, Control: 15	TBC
<b>Summary:</b> Are malignant gliomas in adults associated with a unique identifying serum protein signature? <b>Comment:</b> Protocol amendment and submitted to REC.							
<b>M14-483 INTELLANCE-2 CTRIAL-IE (ICORG) 15-29</b> PI: Dr Patrick Morris Type: Industry sponsored Sponsor: ABBVIE	Ireland Jul 2015 International Feb 2015	BH, CUH	240	195	18	<b>7</b> BH 5; CUH 2	Q3 2016
<b>Summary:</b> ABT-414 alone or ABT-414 plus temozolomide versus lomustine for recurrent glioblastoma: a randomised phase II study of the EORTC Brain Tumour Group <b>Comment:</b> Trial expected to close by mid July 2016							
<b>M13-813 INTELLANCE 1 CTRIAL-IE (ICORG) 15-28</b> PI: Dr Patrick Morris Type: Industry sponsored Sponsor: ABBVIE	Q1 2016	BH	720	18	20	<b>3</b> BH 3	Q3 2017
<b>Summary:</b> A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 in Subjects with Newly Diagnosed Glioblastoma Multiforme (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification. <b>Comment:</b> Beaumont is the top recruiting site in the world.							

## Gastrointestinal Cancer Trials




Co-ordinator: Grainne O'Dowd

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>CTRIAL-IE (ICORG) 12-31 PDAC</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	Oct 2013	AMNCH, Beacon, BH, BonS (TBI), UHG, LUH (TBI), SVUH, UHW	N/A	N/A	290	<b>58</b> AMNCH 24, BH 4, SVUH 21, UHW 6, UHG 3	2018
<b>Summary:</b> Identification of Predictive Plasma Biomarkers in Pancreatic Ductal Adenocarcinoma.							
<b>Comment:</b> Protocol amendment approved. Only two centres remaining to be initiated.							
<b>NeoAEGIS CTRIAL-IE (ICORG) 10-14</b> PI: Prof John Reynolds Type: In-House / Investigator Led Sponsor: 	Jan 2013	SJH, SLH, BH, CUH, UHG, UK (27); Denmark (8); France (0)	594	110	180	<b>75</b> SJH 73, BH 1, UHG 1	2018
<b>Summary:</b> Randomised Clinical Trial of neoadjuvant and adjuvant chemotherapy (Modified MAGIC regimen) vs. neoadjuvant chemoradiation (CROSS protocol) in adenocarcinoma of the oesophagus and oesophago-gastric junction.							
<b>Comment:</b> Protocol version 8 approved in Ireland and UK. CRF version 7 and eCRF release pending.							
<b>Exelixis Celestial CTRIAL-IE (ICORG) 14-17</b> PI: Dr David Gallagher Type: Industry sponsored Sponsor: Exelixis	Unknown	Mater	760	N/A	N/A	<b>2</b> Mater 2	Oct-2016
<b>Summary:</b> Phase III Placebo Controlled Trial evaluating a tyrosine kinase inhibitor in HCC patients previously treated with Sorafenib							
<b>Comment:</b> Mater now open and recruiting.							
<b>CRAC Plasma Biomarker Study CTRIAL-IE (ICORG) 12-27</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	Oct 2013	AMNCH, BH, BonS, UHG, Mater, SUH, SVUH, UHW, LUH, Beacon, SJH	N/A	N/A	150	<b>75</b> AMNCH 3; BH 24; BonS 10; UHG 11; LUH 3; Mater 3; SUH 9; SVUH 2; UHW 10.	2017
<b>Summary:</b> Identification of Plasma Biomarkers in Early Detection of Colorectal Adenocarcinoma Recurrence (CRAC Plasma Biomarker Study).							
<b>Comment:</b> Protocol version 3 approved.							



## Gastrointestinal Cancer Trials

Co-ordinator: Grainne O' Dowd

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>STRATEGIC-1 CTRIAL-IE (ICORG) 14-20</b> PI: Dr Greg Leonard Type: Collaborative Group Sponsor: GERCOR & 	Jan 2015	UHG, UHW, AMNCH, BonS, SVUH, CUH, Mater, SJH	500	223	40	0	Q2 2017 or later
<b>Summary:</b> Multi-line Therapy Trial in Unresectable Wild-Type RAS Metastatic Colorectal Cancer. <b>Comment:</b> Study currently on hold at all sites pending HPRA and EC approval of protocol version 7 and group specific appendix.							
<b>BMS CA209-142 CTRIAL-IE (ICORG) 14-19</b> PI: Prof Ray McDermott Type: Industry sponsored Sponsor: Bristol-Myers Squibb	Mar-2014	BH, SVUH, UHG	115	96	8	9 BH 1, SVUH 7, UHG 1.	Jul 2017
<b>Summary:</b> A Phase II Clinical Trial of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Microsatellite High (MSI-H) Colon Cancer <b>Comment:</b> None.							
<b>TRI-LARC CTRIAL-IE (ICORG) 12-38</b> PI: Dr Brian O'Neill Type: In-House Sponsor: 	Aug 2014	SLRON (BH & SJH)	N/A	N/A	268	28 SLRON (BH) 28	Aug 2020
<b>Summary:</b> Randomised Phase II Clinical Study; 3-D Conformal Chemo-Radiotherapy (current standard) versus IMRT (Intensity Modulated Radiotherapy) for Pre-operative Chemo-Radiotherapy for Locally Advanced Rectal Cancer. <b>Comment:</b> Protocol being amended.							
<b>CTRIAL-IE (ICORG) 15-15 Pre0204</b> PI: Dr Werner Scheithauer Type: Collaborative Group Global Sponsor: PrECOG European Sponsor: 	Sep 2015	Vienna	70	70	5	3 Vienna 3.	Closed April 2016
<b>Summary:</b> A Multi-Institutional, Single Arm, Two-Stage Phase II Trial of an Antimicrotubular Cytotoxic and Gemcitabine for First-Line Treatment of Patients with Advanced or Metastatic Cholangiocarcinoma. <b>Comment:</b> Study accrued ahead of schedule in the US therefore Cancer Trials Ireland's target accrual was reduced to 5 (15 initially). Recruitment closed early; 3 patients were enrolled in total.							

## 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
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<b>Endometrial IMRT CTRIAL-IE (ICORG) 09-06</b>	Feb 2010	SLRON (3 sites)	N/A	N/A	154 (142 evaluable)	<b>64</b> SLRON (SLH 53; BH 7; SJH 4)	Accrual suspended 6 Oct 2015
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PI: Dr Charles Gillham

Type: In-House

Sponsor



**Summary:** Prospective Randomised Phase II Study evaluating Adjuvant Pelvic Radiotherapy using either IMRT or 3-Dimensional Planning for Endometrial Cancer.

**Comment:** Recruitment on hold.

<b>ICON8B CTRIAL-IE (ICORG) 11-29</b>	Sep 2015	BonS, UHG, Mater, SJH, UHW	1170	188	30	<b>9</b> BonS 2; Mater 6; UHW 1	2019
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PI: Dr Dearbhaile O'Donnell

Type: Collaborative Group

Sponsor: MRC

**Summary:** 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:** UHL to be initiated. Global accrual ahead of schedule.

<b>The SHAPE Trial CTRIAL-IE (ICORG) 14-02</b>	Sep 2014	SJH	700	107	10	<b>5</b> SJH 5	2019
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PI: Dr Noreen Gleeson

Type: Collaborative Group

Sponsor: NCIC

**Summary:** 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:** Sites are encouraged to refer eligible patients to SJH.

<b>The MILO Study ICORG 14-03</b>	Sep 2014	SJH	360	341	2 per year	<b>0</b>	Closed
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PI: Dr Dearbhaile O'Donnell

Type: Collaborative Group,

Industry Sponsored

Sponsor: BGOG

**Summary:** The MILO Study (MEK Inhibitor in Low-grade Serious Ovarian Cancer): A Multinational, Randomised, Open-label Phase III Study of MEK Inhibitor vs. Physician's Choice Chemotherapy in Patients with Recurrent or Persistent Low-grade Serious Carcinomas of the Ovary, Fallopian Tube, or Primary Peritoneum.

**Comment:** Recruitment closed on 1st Apr 2016 following results of an interim analysis.

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

### Lymphoma/Haematology Cancer Trials

Chair of Lymphoma/Haematology DSSG: Prof Michael O'Dwyer Co-ordinator: Marzena Wiczorkowska

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

<b>ECOG E3A06</b> <b>CTRIAL-IE (ICORG) 12-02</b> PI: Prof Michael O'Dwyer Type: Collaborative Group Sponsor: ECOG	International Oct 2010  <b>Ireland</b> Mar 2014	UHG, Mater	180 (revised from 380)	164	10	3  MMUH 1; UHG 2	April 2017
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**Summary:** Randomised Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma.

**Comment:** Sample size revised to 180. Patient referral encouraged.

<b>Amgen Multiple Myeloma Study</b> <b>CTRIAL-IE (ICORG) 12-10</b> PI: Prof Peter O'Gorman Type: Industry Sponsored Sponsor: AMGEN	Ireland May 2012	AMNCH, Mater, MRH, UHL, SJH	1700	1642	15	14 Mater 4; MRH 7; UHL 2; SJH 1	Closed
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**Summary:** A Randomised, Double-Blind, Multicentre study of Denosumab Compared with zoledronic acid (Zometa) in the treatment of Bone Disease in Subjects with Newly Diagnosed Multiple Myeloma.

**Comment:** Recruitment closed.

<b>RsqVD Study</b> <b>CTRIAL-IE (ICORG) 13-17</b> PI: Prof Peter O'Gorman Type: In-House Sponsor:	Ireland Nov 2014	AMNCH, BH, CUH, UHG, Mater, MRH, UHL, SJH	N/A	N/A	42	42 BH 5; CUH 6; UHG 11; Mater 14; MRH 2; UHL 1; SJH 2; UHW1	Closed
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**Summary:** A phase II study of the Efficacy and Safety of lenalidomide, subcutaneous bortezomib, and dexamethasone combination therapy for patients with newly diagnosed multiple myeloma.

**Comment:** Recruitment closed.

<b>KEYNOTE-087</b> <b>CTRIAL-IE (ICORG) 15-24</b> PI: Dr Larry Bacon Type: Industry Sponsored Sponsor: MSD	Ireland July 2015	SJH	180	183	Screened 6  Randomised 4	0	Closed
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**Summary:** MK-3475-087: A Phase II clinical trial of Anti PDI in HL in subjects with relapsed or refractory (R/R) classical Hodgkin Lymphoma (cHL).

**Comment:** Study accrued globally ahead of schedule.

## Cancer Trials Round Up—Summer 2016

### Lymphoma/Haematology Cancer Trials

Chair of Lymphoma/Haematology DSSG: Prof Michael O'Dwyer Co-ordinator: Marzena Wieczorkowska

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>ROBUST CTRIAL-IE (ICORG) 15-08</b> PI: Dr Cliona Grant Type: Industry Sponsored Sponsor: Celgene <b>Summary:</b> Phase III Randomised, Double-Blind, Placebo Controlled, Multicentre Study to Compare the Efficacy and Safety of Lenalidomide (CC-5013) Plus R-CHOP Chemotherapy (R2-CHOP) Versus Placebo Plus R-CHOP Chemotherapy in Subjects With Previously Untreated Activated B-Cell Type Diffuse Large B-Cell Lymphoma. <b>Comment:</b> Protocol amendment released to improve accrual. Additional sites opened- SVUH and UHG planned.	Ireland Feb 2015	CUH, Mater, SJH, SVUH	560	184	15	1 SJH 1	October 2017
<b>ARROVEN Brentuximab Vedotin PASS Study CTRIAL-IE (ICORG) 15-09</b> PI: Prof Elisabeth Vandenberghe Type: Industry Sponsored Sponsor: MILLENNIUM <b>Summary:</b> Observational Cohort Study of the Safety of Brentuximab Vedotin in the Relapsed of Refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma. <b>Comment:</b> Mater to be initiated in June 2016.	Ireland Sep 2015	SJH, BH, Mater	500	208	15 (3 per site)	5 BH 4; SJH 1	June 2016
<b>OPTIMISMM CTRIAL-IE (ICORG) 15-08</b> PI: Dr Patrick Hayden Type: Industry Sponsored Sponsor: CELGENE <b>Summary:</b> A Phase III, Multicentre, Randomised, Open-Label Study to compare the Efficacy and Safety of Pomalidomide, Bortezomib and Low-Dose Dexamethasone Versus Bortezomib and Low-Dose Dexamethasone in Subjects with Relapsed or Refractory Multiple Myeloma <b>Comment:</b> Sample size reduced, planned to close earlier. Screening/referral of patients encouraged to meet country target.	June 2015	UHG, Mater, SJH	450	313	18	6 UHG 2; Mater 1; SJH 3	Jan 2017
<b>CHRONOS-3 CTRIAL-IE (ICORG) 15-28</b> PI: Prof Elisabeth Vandenberghe Type: Industry Sponsored Sponsor: Bayer <b>Summary:</b> 17067: A Phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of copanlisib in combination with rituximab in patients with relapsed indolent B-cell non-Hodgkin's lymphoma (iNHL) <b>Comment:</b> To screen 29 for 18 patients randomised.	Oct 2015	UHG, SJH, Mater, SVUH, BH	567	19	11	2 UHG 1; Mater 1	Jan 2017

## Cancer Trials Round Up—Summer 2016

### Lymphoma/Haematology Cancer Trials

Chair of Lymphoma/Haematology DSSG: Prof Michael O'Dwyer Co-ordinator: Marzena Wieczorkowska

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>MMY3008</b> <b>CTRIAL-IE (ICORG) 15-11</b> PI: Prof Michael O'Dwyer Type: Industry Sponsored Sponsor: Janssen  <b>Summary:</b> A Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Previously Untreated Multiple Myeloma who are Ineligible for High Dose Therapy.  <b>Comment:</b> 2 sites open in Ireland, referrals encouraged.	Ireland Feb 2016	UHG, Mater	730	TBC	TBC	7	TBC
<b>CHRONOS-2</b> <b>CTRIAL-IE (ICORG) 15-37</b> PI: Prof Liam Grogan Type: Industry Sponsored Sponsor: Bayer  <b>Summary:</b> Bayer 17322: A randomized, double-blind phase III study of copanlisib versus placebo in patients with rituximab-refractory indolent B-cell non-Hodgkin lymphoma (iNHL)  <b>Comment:</b> 1 site open in Ireland.	Feb 2016	BH	189	8	2	0	April 2017
<b>Protocol 04-03</b> <b>CTRIAL-IE (ICORG) 15-36</b> PI: Prof Helen Enright Type: Industry Sponsored Sponsor: Onconova  <b>Summary:</b> A Phase III International Randomised Controlled Study of Rigosertib versus Physicians Choice in MDS After Failing A Hypermethylating Agent  <b>Comment:</b> CUH initiated to date, 3 additional sites in progress.	May 2016	AMNCH, CUH, UHG, UHW	225	10	12	0	Dec 2017