Research Nurses Sarah Thompson (left) and Katrina Falvey, from the Cancer Trials Research Unit at Cork University Hospital, celebrating International Clinical Trials Day 2017— (See pages 5 to 7)

cancer trials ireland
Together, we're finding answers to cancer.

DSSG Digest

Summer 2017 – Vol. 12 ISSUE 2

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 and Health Research Board

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

Target to double the number of patients who can access cancer drug trials from 3% to 6%

Our purpose is to enable the opening of as many cancer trials in Ireland, and indeed in European countries, and oversee the running of these trials.

These trials have three tangible benefits:

- They take us closer to finding life enhancing treatments.
- They enable patients to get access to new and novel treatments which are only available to people who are on trials.
- They save the HSE millions in drugs costs. Last year's saving is estimated to be more than €6 million.

Given these concrete benefits, there is absolutely no justification for not trying to open more cancer trials. It could in fact be argued that it would be irresponsible not to.

At the moment only about 3% of patients with cancer take part in cancer drug trials. These are trials that involve testing the efficacy and safety of promising new drugs or combinations of drugs. Sometimes they involve testing drugs already licensed for certain disease types and conditions, as a potential new treatment for other disease types. In both situations they offer people with cancer early access to promising treatment options.

Over the past few years, Cancer Trials Ireland has been making important strategic changes to grow the number of people who can take part in cancer drug trials.

We have modernised the way we are organised; strengthening our governance and oversight.

We have broadened our portfolio to include more trials in more disease areas.

We are expanding, for example, our translational research portfolio.

We've started work on a national integrated cancer trials management system.

We are providing greater support to our cancer trials research units around the country.

We are strengthening our links with our pharmaceutical partners.

We have done all of this against the backdrop of a 20% cut in our 3 year grant from the State.

When this cut came into effect last year we did not create a fuss. We simply got on with our work.

However, it is time for the State to not only reverse these cuts but increase its original commitment to cancer trials.

We also want the State to commit to doubling the number who can access cancer drug trials from 3% to 6%. This will involve increasing its investment in cancer trials by €2.5 million a year. This investment will save twice as much in drugs costs.

This investment will enable our teams of committed researchers around the country to forge new ground and enable us to attract international trials to Ireland which are run by European and global research organisations, and major pharmaceutical organisations.

In addition, we want the health service to redefine the role of cancer trials within the health service. We want it to accept that cancer trials are treatment options that people with cancer are entitled to choose from. They are not outliers.

I ask all of you, our members, to use your influence to enable us to double the number of people with cancer who are participating in cancer drug trials.

The alternative is that we will miss out on the opportunities that are waiting for us on the horizon.

Reaching out and growing our impact beyond Ireland

Eibhlin Mulroe, CEO, Cancer Trials Ireland.

ASCO

ASCO (the American Society of Clinical Oncology) is the world's leading professional organisation for physicians and oncology professionals caring for people with cancer. Its annual conference is the most important date in the diary of a cancer clinical researcher. Many of the delegates are world leaders in their fields and published in high impact journals.

It's an event that brings together the brightest and the best in the world. The Cancer Trials Ireland team of Oncologists, Researchers and two staff members did their very best at this meeting to solidify partnerships with collaborative groups like ECOG, ANZUP, GEICAM, etc. It was also an opportunity to forge new partnerships and bring new trials into Ireland for our patients. We did much work on that and we will discuss this further in our DSSG meeting.

The backdrop to all of this networking and future planning is the research and the announcements of exciting results and not so exciting results. In every session, the research question is important because it informs our future directions in cancer trials. I want to thank all our members who wore the Irish jersey for the weekend and did their very best to up our game in Ireland.

Data Analytics is clearly on the agenda in the cancer research space, particularly in light of the "Moonshot" Program initiated by the then USA Vice President, Joe Biden. ASCO has created the Center for Research and Analytics (CENTRA). Like many other groups we met over the weekend, ASCO recognises the potential value of its data assets and its growing expertise in conducting research. They plan to make these resources available to ASCO members and other organisations.

This is on our agenda, but a little further away. In a climate of new EU Data Regulations, there are challenges but it is our hope that we can work towards the infrastructure needed in valuing the research potential of data in Ireland.

(See back page for more details.)

Just Ask Your Doctor!

On International Clinical Trials Day 2017 we launched our Just Ask Your Doctor! campaign.

Thanks to the support of our pharmaceutical partners; MSD, Bayer, Janssen, Abbvie, Roche, Merck, and Novartis, this is our biggest ever public information campaign.

It builds on the campaign we introduced last year to coincide with our name change and we hope it will become a regular feature of our calendar.

There are four main elements to the campaign. For the first time we've run local and national radio advertising. Our thanks to broadcaster Bobby Kerr for the voice over.

We have been actively generating media coverage of cancer trials, with a number of patients generously advocating publicly for cancer trials. We greatly appreciate this invaluable support.

Cancer trials units in hospitals across the country held a series of information events which we supported with marketing packs consisting of our new brochures, posters, etc. Thank you all for your enthusiasm.

And we have revamped our website. It now provides a comprehensive listing of cancer trials open in Ireland. It also includes a full listing of Cancer Trials Ireland's academic publications dating back to 2006 which is a very valuable resource.

We will be keeping the momentum going during the year with another series of profile raising activities.

Integrated Trials Management

An important action noted in our Strategy 2020 is the need to develop an integrated trial management system capable of monitoring and reporting on all aspects of all trials, across the entire portfolio.

Implementing such a system is a major undertaking. Thanks to the support of the Irish Cancer Society we have started the first phase which will involve the development of a robust business case for a preferred system.

We hope that through the development and implementation of an integrated trials management system in the cancer trials environment we will be able to contribute to the wider clinical trials community, and hopefully the project will act as an exemplar for the way forward.

Our network carries out more trials than all other research organisations in Ireland combined.

Speaking at our International Clinical Trials Day recognition event, Dr Linda Coate, Cancer Trials Ireland's Vice Clinical Lead highlighted the importance of having cancer trials units around the country that are well staffed and equipped.

Dr Coate is an Oncologist based at University Hospital Limerick. She is also the Chair of the Lung DSSG group and is actively growing trials in this disease area.

"Cancer is not location specific", Dr Coate said. "It affects people from Malin Head to Mizen Head.

"And while the evidence clearly shows that treatments are more effective when delivered through centres of excellence, to deliver the benefits of cancer trials we need cancer trials research units that are also centres of excellence."

Dr Coate took the opportunity to thank all of our colleagues in our research units across the country, many of which were represented at the recognition event.

"I thank our principal investigators, team leaders, research nurse specialists, data managers and pharmacists and general staff for your commitment to your patients and your commitment to uncovering cancer's secrets.

"We are absolutely committed to supporting you as best we can to grow and develop your teams." Dr Coate also thanked pharmaceutical companies which were enabling more training and development support to be provided to the units around the country (see pages 14 - 15).

She went on to point out that the integrated trial management system that was being worked on will enable the network to be integrated further, making it more attractive to conduct potentially ground breaking trials.

Following on from Prof Bryan Hennessy's comments on the need to reframe cancer trials as integral to the treatment options available to people with cancer and not as an outlier,

Dr Linda Coate

Dr Coate emphasised that our network of research units has a huge role to play in supporting this shift in mind set.

"It is a cliché to use the word unique. But this network provides a unique superstructure to enable our medical, surgical and radiation oncologists to open up new novel options for patients which would otherwise remain unexplored.

"They have a reservoir of knowledge, experience and clinical and research know-how which is unmatched in any other area of research in Ireland.

"Combined, our cancer trial research units around the country are carrying out more clinical trials than all other research organisations," she said.

She said that the network has been 20 years in the making and its importance and relevance is growing every year as the challenges of getting to grips with cancer remains as acute as ever.

"It is a powerful resource in our collective effort to remove the devastation that cancer can deliver and it needs your generous support," she said.

To mark this year's International Clinical Trials Day 2017, we launched the Just Ask Your Doctor! public information campaign.

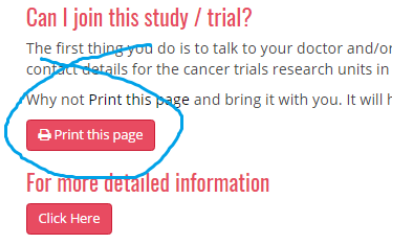
The campaign includes national and local events across our network of cancer trials research units, radio advertising, social media advertising and advertising in the medical press.

It is designed to encourage people with cancer to ask their doctor if there's a cancer trial that they might be able to join. There are three ways to Just Ask!

1. Ask — Just Ask Your Doctor!

2. Visit — cancertrials.ie

3. Call — Irish Cancer Society Cancer Nurseline Freephone 1800 200 700

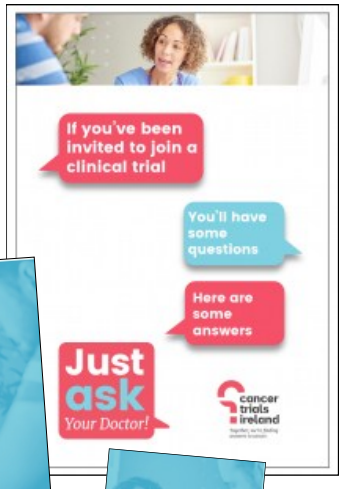


There's lots of information about trials posted on our revamped website and a full listing of all open cancer trials. If you would like to discuss a trial with a patient, you can print off the trial information using the PRINT THIS PAGE button that is located on each trial's listing page, and bring it along to their next appointment.

Our thanks to our industry partners for supporting the campaign.

Industry sponsors of the Just Ask Your Doctor! campaign. *Pictured at the launch were (L-R) Liz O'Donnell, Director of Policy, Government Affairs and Communications, MSD; Blánaid O'Connell, Medical Science Liaison, Merck; Michelle Gartland, Therapeutic Area Manager Oncology, Bayer; Leisha Daly, Country Director, Janssen; and Janet Culbert, Disease Area Manager, Novartis; with Eibhlin Mulroe, CEO, Cancer Trials Ireland (seated).*

Right (L-R): Prof Bryan Hennessy, Clinical Lead; Eibhlin Mulroe, CEO; Dr Linda Coate, Vice Clinical Lead; all from Cancer Trials Ireland with Rory Goodbody, Senior Medical Manager, Abbvie.



Examples of support material (brochures, posters and advertisements) for the campaign.

Celebrating International Clinical Trials Day 2017 at Dublin's Mansion House and in research units across the country

Dr Jonathan Westrup, Chair of Cancer Trials Ireland.

(Below) Evelyn O'Rourke, Member of the Board of Cancer Trials Ireland and RTÉ.

Advocates for cancer trials (L-R) Mary Coyne, Co Clare; Noel Barrins, Co Sligo; Robert Phayre, Co Dublin; Emily Hourican, journalist and cancer survivor and guest speaker at the launch; Tara Devon, Co. Meath; Esther

(Right) Eibhlin Mulroe, CEO, Cancer Trials Ireland; Muiris O'Connor, Head of R&D &Health Analytics, Dept. of Health; Dr Linda Coate, Vice Clinical Lead and Consultant Oncologist, University Hospital Limerick; Dr. Jerome Coffey, Member of the Board of Cancer Trials Ireland and Director of the National Cancer Control Programme, HSE; Oonagh Ward, Lead Programme Manager - Infrastructure, Networks & Interventions at the Health Research Board.

(Right) Back row L-R: John McCormack, Chief Executive, Irish Cancer Society; Liz O'Donnell, Director of Policy, Government Affairs and Communications, MSD; Michelle Gartland, Therapeutic Area Manager Oncology, Bayer; Dr Linda Coate, Vice Clinical Lead and Consultant Oncologist, University Hospital Limerick; Dr Jerome Coffey, Member of the Board of Cancer Trials Ireland and Director of the National Cancer Control Programme, HSE; Leisha Daly, Country Director, Janssen and Member of the Board of Cancer Trials Ireland; Evelyn O'Rourke, Member of the Board of Cancer Trials Ireland and RTÉ broadcaster; Dr Jonathan Westrup, Chair of Cancer Trials Ireland; Janet Culbert, Disease Area Manager, Novartis.

Front row L-R: Eibhlin Mulroe, CEO Cancer Trials Ireland; Blánaid O'Connell, Medical Science Liaison, Merck; Dr Robert O'Connor, Head of Research, Irish Cancer Society; and Prof Bryan Hennessy, Clinical Lead, Cancer Trials Ireland.

Tallaght Hospital *(L to R) Ruth McGinn, Data Manager; Dr Fergal Kelleher, Consultant Oncologist; Ashley Bazin, Team Leader; Maria Gillespie, CNM II; Prof Ray Mc Dermott, Consultant Oncologist; Rhonda Mooney, Data Manager and Annmarie O'Shea, CNM II.*

University Hospital Limerick *(L to R) Susie Nagle, Research Study Co-ordinator; Siobhain O' Brien, Data Manager; Lorraine O'Connell, Research Study Co-ordinator; Dr Grzegorz Korpanty, Locum Consultant Oncologist and Maureen O' Grady, CNM III/Team Leader.*

Bon Secours Hospital, Cork *(L to R) Colette Hussey, Irish Cancer Society; Dr Gul Ahmed, Sub-Investigator; Emma Daly, Laboratory Reception Manager; Dr Raimundas Galiauskas, Sub-Investigator; Dr Brian Bird, Principal Investigator; Siobhan Finn, Data Manager; Aofie O'Shea, Study Co-ordinator; Dr Conleth Murphy, Principal Investigator and Dr Eamon Carmody, Lead Radiologist.*

University Hospital Waterford *(L to R) Flordeliza Calacsan, Team Leader; Helena Dwyer, Research Nurse; Dr Paula Calvert, Dr Miriam O'Connor, Dr Anne Horgan and Elaine Shanahan, Data Manager.*

Cork University Hospital *(L to R) Elaine Cronin, Data Manager; Liz Lenihan, Research Nurse and Debra O'Hare, Team Leader.*

Mater Hospital *(L to R) Brian Whelan, Data Manager; Louise Cusack, Research Nurse; Martina Smith, Clinical Trials Manager; Orna Harraghy, Data manager; Miriam Coffey, Patient; Prof Michaela Higgins, Consultant Medical Oncologist; Karen Geraghty, Administrator; Jane Lynch, Research Nurse and John Heeney, Data Coordinator.*

UPMC Whitfield Cancer Centre *(L to R) Dr. Dayle Hacking and Kathleen Kearns, Clinical Specialist Radiation Therapist.*

St. Vincent's University Hospital *(L to R) Giulio Calzaferri, Study Co-ordinator and Jessica-Clare Long, Data Manager.*

We're on the move

Later this year Cancer Trials Ireland is relocating its head office to the Dublin City University's Innovation Campus, DCU ALPHA, in Glasnevin, on Dublin's northside.

DCU ALPHA offers a young dynamic business environment designed to promote invention and inspire innovation. It is a hub of cutting edge development across many industries serving global markets.

There are currently 350 people working across the campus in a range of different sized organisations from small incubator enterprises to global companies such as Siemens. The long term plan is to have 1000 people working on the campus.

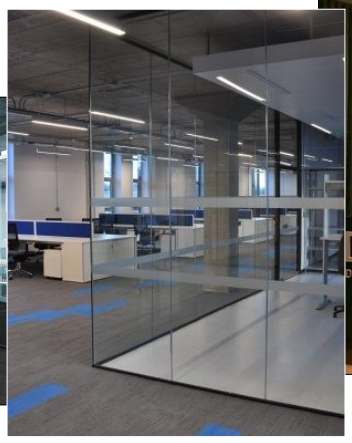
Commenting on the move, Cancer Trials Ireland's CEO, Eibhlin Mulroe said that DCU was the perfect fit at the right time.

"Our city centre office has served us well and was up to now competitively priced. With the city's changing fortunes we naturally had to seek somewhere more suitable to not only meet our limited purse but also to provide a more modern work environment which reflects our team's approach", she said.

"DCU ALPHA is an energetic and vibrant community which is built on a foundation of discovery and innovation, values which are central to our work.

"It offers a wonderful bright and welcoming environment which will meet all our needs in a very accessible location," she said.

The businesses located at DCU ALPHA work independently in their own self contained facilities yet are connected with other innovators through shared services such as meeting rooms, on site restaurant, theatre / conference facilities, common reception, circulation areas, security, maintenance and over flow desk facilities. They are also connected to the wider DCU campus and all it has to offer. We look forward to welcoming you to our new home.



Terms of Reference for Clinical Executive Committee approved

At a very well attended meeting held in April, the Clinical Executive Committee voted to revise the Committee's Terms of Reference. The new terms were subsequently approved by the Board of Cancer Trials Ireland on 25th April.

Prof Bryan Hennessy is the Chair of the Clinical Executive Committee and he explains the background to the change.

In 2014, the Board of Cancer Trials Ireland was established. It is designated the organisation's ultimate decision-making authority.

The organisation's governance structures spanning out from the Board have matured very well. This is consistent with the recommendations of the HRB International Panel Review (2012) and in keeping with good governance in the context of the Charities Act (2009).

As part of this ongoing development process we needed clear Terms of Reference for the Clinical Executive Committee, which is described in the Memorandum and Articles of Association.

Following consultation within the organisation, we prepared a draft Terms of Reference which was circulated to all members of the committee.

In April, we held an extraordinary meeting of the committee at which the Terms of Reference were accepted and approved.

The Clinical Executive Committee is now clearly recognised within the organisation's governance structure as the clinical leadership body of Cancer Trials Ireland.

Its overarching aims are to advise and provide guidance to the Board on ***equity*** of access for clinicians and patients to cancer research, ***access*** to novel therapeutics for Irish cancer patients, and to promote ***excellence*** in all types of cancer research in Ireland.

It is the key forum for engagement between clinicians working in cancer medicine in leadership roles in designated Cancer Trials Research Units (including, but not limited to the eight HSE designated cancer centres) and Cancer Trials Ireland's Group Central Office (GCO). It provides a forum for discussion and knowledge exchange and consideration of strategic issues of importance to Cancer Trials Ireland between personnel at Cancer Trials Research Units around the country, GCO and the Board.

It enables the organisation's clinical leadership, which is ultimately responsible for the execution of cancer trials in each participating Cancer Trials Research Unit, to have structured and accountable engagement with the most active clinicians engaged in cancer research in Ireland and have collective and effective representation at the organisation's apex.

The Clinical Executive Committee also advises and makes recommendations to the Board on important issues related to clinical and operational aspects of cancer care delivery relevant to cancer trial execution.

The Clinical Executive Committee is an important voice of Irish cancer care research leadership.

Governance

The Clinical Executive Committee is a sub-committee of the Board of Directors of Cancer Trials Ireland.

The Committee reports to the Board and has the authority to represent and make recommendations to the Board on behalf of the Cancer Trials Research Units.

The Committee is Chaired by the Clinical Lead and represented on the Board by the Clinical Lead and Vice Clinical Lead.

Membership:

Membership of the Committee includes the following:

- Clinical Lead
- Vice Clinical Lead
- One Consultant representative from each of the 11 HRB supported Cancer Trials Research Units:

1. St Luke's Hospital (SLH)
2. Our Lady's Children's Hospital Crumlin (OLCHC)
3. Beaumont Hospital (BH)
4. Mater Misericordiae University Hospital (MMUH)
5. St Vincent's University Hospital (SVUH)
6. St James's Hospital (SJH)
7. Adelaide and Meath Hospital (AMNCH)
8. University Hospital Waterford (UHW)
9. Cork University Hospital (CUH)
10. University Hospital Limerick (UHL)
11. University Hospital Galway (UHG).

- One Consultant representative from each linked Cancer Trials Research Unit:

1. LUH (Letterkenny) linked to UHG
2. SUH (Sligo) linked to UHG
3. Bon Secours Hospital, Cork linked to CUH
4. Beacon Hospital linked to SLH
5. Midlands Regional Hospital, Tullamore linked to SJH.

- The following modality and specialty representation will be included if not already represented:

1. Three radiation oncology representatives (inclusive of the representative for SLH)
2. One surgical oncology representative
3. One haematology representative
4. One translational representative.

The next meeting of the Committee will be held on 29th August 2017.

Ireland very well represented at ASCO—GU 2017

Olwyn Deignan, Senior Clinical Project Manager with Cancer Trials Ireland, reports on the 2017 Genitourinary Cancers Symposium organised by the American Society of Clinical Oncology (ASCO) held during February in Florida.

Ireland was very well represented at this year's symposium. The Chairs of our Genitourinary DSSG, Prof Ray McDermott and Dr Paul Kelly, were there along with Dr Miriam O'Connor, Dr Richard Bambury, Prof John McCaffrey, Prof Paul Donnellan, Prof Liam Grogan, Dr Michael Maher and Dr John Greene, to name just a few.

There were many highlights during the conference, including a session I attended called 'Prostate Cancer Evolution and Progression'. During this session 'The Prostate Cancer Project'[(1)] which is a patient driven project was presented. Launching soon, this project is a Broad Institute/Dana Farber Cancer Institute research initiative that partners with patients to accelerate and share discoveries in advanced Prostate Cancer. This could certainly be the future for some cancer trials, particularly translational.

I also attended the Poster sessions where a poster of the trial 'Prospectively-collected baseline Erectile Function in 1,173 consecutive newly diagnosed prostate cancer patients referred for radiotherapy' [(2)] conducted by Cork University Hospital and University College Cork in collaboration, and led by Dr Jill Nicholson and Dr Paul Kelly was displayed. This is a fantastic achievement for all of the teams involved.

A Keynote Lecture was given by Prof Lawrence H Einhorn, a Distinguished Professor of Medicine at Indiana University School of Medicine and an Oncologist. Prof Einhorn pioneered the development of the life-saving medical treatment in 1974 for testicular cancer[(3)] involving the addition of platinum therapy. This increased the cure rate from 10% to 95%. Only for his work, platinum therapies may no longer have been used. BEP is a chemotherapy treatment still used to treat testicular cancer 30 years later. BEP is named after the initials of the drugs used: **b**leomycin, **e**toposide and cisplatin (**p**latinum). It was inspirational to hear the Professor in person. We currently have two cancer trials in testicular cancer in our portfolio. The first study is a collaboration with the EORTC called TIGER. The other, called P3BEP, is currently in development and is in collaboration with ANZUP. At the end of his lecture Prof Einhorn provided his contact details so that any oncologist / medical professional in the world could contact him if they needed any advice on how to treat their patients. Prof McDermott and Dr Paul Kelly both confirmed that they have made contact with Prof. Einhorn in the past and received very helpful answers and advice.

I also attended a session where the results of the trial 'Standard-of-care versus computer-assisted response evaluation (CARE)' [(3)] were presented. The study proved the hypothesis that computer-assisted tumour response evaluation reduced errors and time of evaluation, indicating better overall effectiveness than manual tumour response evaluation methods, which are the current standard-of-care. Tumour measurements are critical endpoints in patients with metastatic disease and these measurements are relied on for the results and analysis of the trial. This is another area to watch for in the future as technology continues to improve.

Prior to the conference, we successfully scheduled a number of external meetings relating to our ongoing Genitourinary trials portfolio. Prof Ray McDermott and Dr Paul Kelly attended each of these in their capacities as Chief Investigators and the Genitourinary DSSG Chairs.

Together we attended the International Trial Steering Committee (ITSC) for the ENZAMET and ENZARAD studies and met the global sponsor ANZUP and the NHMRC CTC.

ENZAMET and ENZARAD International Trial Steering Committee meeting 15th Feb 2017, Orlando, Florida.

The ECOG-ACRIN group held an investigator meeting for the upcoming PROSPER trial 'A **P**hase 3 **R**and**O**mized **S**tudy Comparing **PER**ioperative Nivolumab vs. Observation in Patients with Localized **R**enal **C**ell **C**arcinoma Undergoing Nephrectomy'. This meeting was very well attended by our Irish investigators and reflected their commitment to the trial. I look forward to the Cancer Trials Ireland head office continuing to facilitate our hospitals involvement by project managing, planning, activating and running the trials we are responsible for in Europe within the agreed timelines. Within the area of adjuvant Renal Cell Carcinoma another important trial called Immoticon 010 is currently open in Ireland; it is an industry led trial.

The conference also provided a good opportunity to meet with some of our industry partners ROCHE and Bayer.

Lastly we attended the IRONMAN Investigator meeting. The IRONMAN registry[(4)] is sponsored by the Prostate Cancer Clinical Trials Consortium, LLC (PCCTC) [(5)] Cancer Trials Ireland is collaborating to run this translational study in Ireland.

Continued on Page 11.

Dr Kathleen Scott appointed Head of Operations and Clinical Programs

Dr Kathleen Scott has been appointed to the newly created position of Head of Operations and Clinical Programs within Cancer Trials Ireland. In this role, she will manage all aspects of the organisation's cancer trials portfolio.

Kathleen joined the organisation in 2012 and more recently was a Clinical Program Leader. Kathleen has more than 20 years cancer clinical research experience in academic, clinical, and pharmaceutical settings in the UK, Australia, and Ireland.

In her role at Cancer Trials Ireland, Kathleen will lead a team of approximately 40 clinical research staff working across a diverse range of clinical trials portfolios and functional areas and support the work of the cancer trials research units across the country. Kathleen will continue to have program responsibility for haematology trials including multiple myeloma. She has worked proactively with lead haematologists in Ireland, international collaborators and pharmaceutical partners to design and develop new trials and bring new myeloma treatments to patients in Ireland. Kathleen published a Cochrane Review in 2016 titled 'Bortezomib for the treatment of multiple myeloma'.

Welcoming the appointment, Prof Bryan Hennessy, Cancer Trials Ireland's Clinical Lead said that Kathleen brought to the position a great combination of clinical and operations experience and leadership.

Dr Kathleen Scott, newly appointed Head of Operations and Clinical Programs, and Prof Bryan Hennessy, Clinical Lead.

"Kathleen has played a really important role in the development of the organisation during the past five years. She has great drive and energy and a deep understanding of cancer trials. Coupled with her excellent management skills, she will continue to make an enormous contribution to our development and the development of our highly committed teams," he said.

Continued from Page 10.

'IRONMAN Registry' Investigator meeting 17th Feb 2017.

I would like to thank our leadership team for giving me the opportunity to attend this very worthwhile conference.

I would also like to thank Prof McDermott and Dr Kelly in particular for their support during the conference. Witnessing the enthusiasm of our Irish Medical and Radiation Oncologists and their work at these conferences to promote and bring research to Ireland is very inspiring. As the GU Project Manager and DSSG operations lead, they are my Prof. Einhorns as they always take the time to answer the medical and sometimes logistical questions that we need to open and progress trials in Ireland and internationally. Equally, the hard work and dedication of each of the research teams at each of our hospitals participating in our trials never ceases to amaze me on a daily basis. Our close interaction and vested interest with them at every stage of the trials makes Cancer Trials Ireland a very unique place to work.

References:

1. https://www.pcproject.org/
2. http://meetinglibrary.asco.org/record/140577/video
3. https://medicine.iu.edu/faculty/4942/einhorn-lawrence/
4. http://ascopubs.org/doi/abs/10.1200/JCO.2017.35.6_suppl.432
5. http://pcctc.org/

Quality and Training unit provides an important service to all members

Cancer Trials Ireland's Quality and Training team is centrally involved in ensuring that all trials are carried out to the highest clinical and ethical standards and comply with the rigorous legislation and regulation. Here Olivia McLoughlin, Quality and Training Manager, Sandra Boldrin, Quality and Training Associate II, and David Higgins, Quality Assurance Auditor describe the key areas of their unit's work.

Regulatory research

Clinical trials operate in a highly regulated environment and regulations and guidance come in many forms.

In Ireland, we are under the jurisdiction of both domestic and European regulations. Regulatory research involves reading and interpreting regulations and guidance documents which are issued by regulators and other professional organisations. The regulatory body in Ireland, the Health Products Regulatory Authority (HPRA), hosts information days or sessions related to the conduct of clinical trials in Ireland from time to time.

The European Regulator (EMA: European Medicines Agency) issues guidance documents on important topics and hosts public consultations on practices across Europe.

The UK regulator, the MHRA, also offers guidance and best practice through both their "Grey" Good Clinical Practice Guide and regularly updated blog.

The UK-based Research Quality Association (RQA) also provides regular updates on changes and developments.

There are also online forums where people can share their experience, ask questions and invite others to submit their views. These resources are incredibly useful and can offer insights which may not be obvious from a reading of the regulations.

One of our team's responsibilities involves keeping up to date with regulations and guidance and comparing them to our current practices which we document in Standard Operating Procedures (SOPs). One such guidance document – the International Conference on Harmonisation (ICH) Guidance on Good Clinical Practice (GCP) initially issued in 1995 - has been updated recently and is effective in Europe from the 14th June 2017. The upcoming European Clinical Trial Regulation (CTR) (536/2014) expected to be in force from the 1st October 2018 will have a significant impact on our work. It is vital that we are preparing for these changes now so that we are compliant when they come into force.

Training

Training is fundamental to ensuring that clinical research is conducted according to current regulations and guidelines.

We run regular GCP training courses, which all members, our staff at the Head Office and staff in Cancer Trials Research Units around the country can attend. The schedule is available at cancertrials.ie.

We also run specific courses for Research Units when requested.

Once a training date and location is confirmed and all required attendees are notified, we start preparing or updating the training course slide deck and other material, such as workshops, knowledge assessments, and feedback forms.

Although we have developed a lot of training material over the years, it must be reviewed to ensure it is up to date before each new course to include any changes to regulations or guidance, changes in "best practice", as well as consideration of any feedback received from previous courses. For example, we recently updated our GCP courses to include the recently issued GCP update (ICH GCP E6 (R2)).

Participants on a recent GCP training course.

A typical training course would involve participants from our Head Office and Research Units and involve presentations and practical group work sessions.

Audit preparation

Conducting audits is one of the ways that we check that all our work complies with regulations and guidance. Audits can be conducted internally to look at the procedures we use to manage trials; at Research Units which may focus on a specific trial or specific aspects of different trials; or at other organisations we work with on our trials.

The preparation for an audit at Research Units is an intense process. While the regulations and guidance are generally the same, the trials themselves can be very different. For example, a blood cancer trial has entirely different types of laboratory tests compared to a trial in a solid tumour, such as breast or prostate cancer.

Members of our audit team may need training on a specific disease type to thoroughly understand the trial protocol, manuals and documents. We also need to request access to, and train, on any electronic systems, as well as prepare materials to conduct the audit efficiently.

Continued on page 13.

Conference data suggests new standard of care recommendation

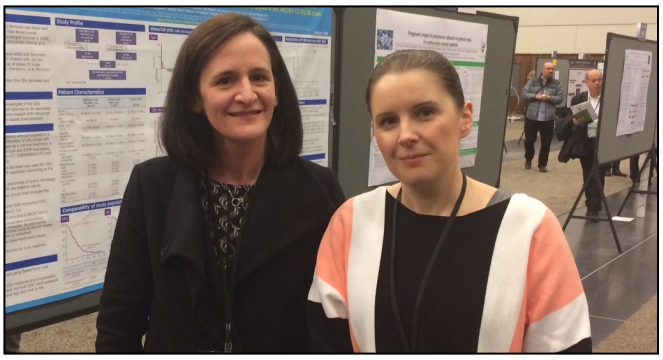
Laura Maher, Clinical Project Manager with Cancer Trials Ireland, reports that data from an international trial in which Cancer Trials Ireland research units are participating has led to a new standard of care recommendation for metastatic colorectal cancer.

The data was presented by Dr Michael J. Overman from The University of Texas MD Anderson Cancer Center at the 2017 Gastrointestinal (GI) Cancers Symposium held in San Francisco in January.

Dr Overman presented updated data for single-agent nivolumab within the phase II CheckMate 142 study, which is currently open for recruitment at St. Vincent's University Hospital, Beaumont Hospital and University Hospital Galway. This study, which is being conducted in heavily pre-treated patients with metastatic colorectal cancer featuring high microsatellite instability or DNA mismatch repair deficiency, showed that nivolumab is showing marked improvements in objective responses, disease control, long-term survival, and patient quality of life. According to the study investigators, single-agent nivolumab should be considered a new standard of care for these individuals.

The three day meeting, co-sponsored by the American Gastroenterological Association Institute, the American Society of Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO), and the Society of Surgical Oncology (SSO), encompassed the latest science in cancers of the oesophagus and stomach; the pancreas, small bowel, and hepatobiliary tract; and the colon, rectum, and anus.

Immunotherapy featured strongly at the meeting, with positive results reported from the ONO-4538-12 (ATTRACTION-2) phase III trial of nivolumab in patients with advanced gastric or gastroesophageal junction cancer and also positive interim results from the large phase I/II CheckMate 040 study of nivolumab given as first or second line monotherapy to patients with advanced hepatocellular carcinoma. It also heard promising results for targeted therapies with data from a small prospective phase II trial



Dr Anne Horgan, University Hospital Waterford, and Laura Maher, Clinical Project Manager, at the GI Cancer Symposium 2017.

suggesting that cabozantinib confers marked clinical benefit in patients with progressive, well-differentiated neuroendocrine tumours—lesions that historically are very difficult to treat given their chemoresistant nature. Interim results of the phase II SWOG 1406 trial revealed that the addition of vemurafenib to cetuximab and irinotecan significantly prolonged progression free survival and the disease control rate in patients with $BRAF^{V600E}$-mutated metastatic colorectal cancer.

In spite of these successes, there were also some negative results reported at the conference. The results of the prospective phase III PRODIGE 12–ACCORD 18 trial turned out negative, showing no statistical difference between gemcitabine plus oxaliplatin and surveillance with regards to recurrence free survival or patient quality of life in localized biliary tract cancer following resection. The addition of the mTOR inhibitor everolimus (RAD001) to paclitaxel failed to significantly improve overall survival, progression free survival or overall response rate compared with paclitaxel alone among patients with gastric cancer who progressed after fluoropyrimidine/platinum-based therapy within the large randomized, double-blind, multicentre, phase III RADPAC trial.

Laura Maher, Clinical Project Manager and Coordinator of the GI DSSG, was able to attend this meeting thanks to generous support from Roche Products (Ireland).

Continued from page 12.

We also consider both our own internal SOPs and the Research Unit's SOPs in reviewing compliance along with the applicable regulations and guidance documents.

Audits at Research Units are usually conducted over 2-3 days. We prepare an audit schedule and send it to the Research Unit in advance so that they know what will be involved and which personnel we would like to meet, including whether a pharmacy and/or laboratory audit is planned. It is important that the Principal Investigator who is responsible for the trial is available to meet the audit team to review and discuss any issues that may arise. Careful planning by both the audit team and the Research Unit should mean less disruption to normal working practices at the Research Unit during the audit.

Participants on a recent GCP training course

We acknowledge the extra work involved for a Research Unit undergoing audit and greatly appreciate the cooperation and participation of the Research Unit teams.

Summer Development Day for Research Units

Shane Ring, Business Development Manager.

We completed the Third Development Programme Day for members of the Cancer Trials Research units from around the country on Thursday 15th June.

This meeting was our first 'out of Dublin' meeting and we selected Portlaoise as a central location with good road and rail links.

The meeting was well supported with 8 Cancer Trials Research Units represented with a good mix of specialties in attendance.

We began the day with a presentation from Olivia McLoughlin, Quality and Training Manager, Cancer Trials Ireland on the recent ICH Good Clinical Practice E6 (R2) Addendum and then shifted our focus onto 4 workshops for the remainder of the day;

Workshop 1: *Training, Delegation, and Investigational Site Staff documentation*

Workshop 2: *Informed Consent and Eligibility*

Workshop 3: *Adverse Event Capture*

Workshop 4: *Site File Maintenance, Version Control, SOPs, and Audits*

All attendees spent time working on each of the 4 workshops, sharing insights on their own unit experiences relating to each topic and listening to the experiences of colleagues from other research units.

There was excellent discussion and lively debate across the workshops and during the feedback session with many participants willing to share best practices from their own research units with the wider network.

It was decided that the area to capture and share these 'best practices' was in the **Trials Unit Login** section of the newly redesigned Cancer Trials Ireland website. Usernames and passwords were distributed to the attendees during the meeting. This portal will become a valuable repository for the research units over time.

The date for the next Development Programme event is provisionally pencilled in for Thursday 28th September 2017.

This meeting will see us return to Dublin. Confirmation of the date and full details will be forwarded in the coming weeks. I look forward to seeing you then.

(L to R) Moira Maxwell and Margaret Burke (Sligo University Hospital); Sharon Curran-Rae, Rhonda Mooney, Maria Gillespie, Ruth McGinn, and Ashley Bazin (AMNCH).

The Development Day involved a series of lively workshops.

(Right) (L to R) Aileen Walsh (Midland Regional Hospital, Tullamore); Orlaith Cormican and Olive Forde, (University Hospital Galway) and Keith Egan (Beaumont Hospital).

(Bottom) (L to R) Jessica-Clare Long, Deirdre Collison, Mary Doyle, Katherine Hoey and Geraldine Schofield (St Vincent's University Hospital, Dublin).

(Bottom right) (L to R) Lorraine O'Connell, Maureen O'Grady, Siobhain O'Brien and Ciara Cantrell (University Hospital Limerick).

(L to R) Elaine Cronin, Anna Cole (Cork University Hospital), Claire Temple, Siobhan Warren, Andrea Ferguson and Helen Buckley (St James's Hospital, Dublin).

Thanks to our sponsors

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

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Cancer Trials Ireland studies open to accrual

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

DSSG	General Group	Cancer Trials Ireland No:	Study Name:
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity
Breast	Trans	10-11	Circulating miRNA
Breast	Trans	10-15	Exosomal HER2
Breast	Trans	10-16	Ovarian Reserve
Breast	Trans	12-09	CharactHer
Breast	Trans	12-30	TAILORx Tissue Bank
Breast	Trans	15-34	Recurrence Score
Breast	Trans	12-40	EORTC 10085
Breast	Clinical	14-01	EMBRACA/ MDV 673-301 (TRIO 023)
Breast	Clinical	15-17	PALLAS
Breast	Clinical	15-49	NeoTRIP
Breast	Clinical	14-11	PENELOPE-B
Breast	Clinical	14-21	NALA
Breast	Clinical	14-22	16298 Radium 223 in BC (Bayer)
Breast	Clinical	15-02	PantHER
Breast	Clinical	15-33	KEYNOTE-119 in mTNBC (MSD)
Breast	Radio	15-03	NSABP B-51
Breast	Clinical	15-16	FLIPPER
Breast	Clinical	16-20	POSITIVE
Breast	Clinical	17-08	KEYNOTE-522 in TNBC (MSD)
CNS	Trans	08-13	Serum Protein Markers for Glioma
CNS	Clinical	15-28	M13-813 INTELLANCE 1
GI	Clinical	10-14	Neo-AEGIS
GI	Trans	12-27	CRAC Plasma Biomarkers
GI	Trans	12-31	PDAC Plasma Biomarkers
GI	Radio	12-38	TRI-LARC
GI	Clinical	14-17	Exelixis Celestial Study
GI	Clinical	14-19	BMS CA209-142 (CheckMate 142)
GI	Clinical	14-20	GERCOR STRATEGIC-1
GI	Clinical	16-28	MK 3475-177
GI	Clinical	16-29	MK 3475-181
GI	Clinical	16-73	BMS CA209-577
GU	Clinical	11-34	TIGER
GU	Clinical	13-09	PEACE-1
GU	Clinical	13-21	Radium-223 & Enzalutamide mCRPC
GU	Clinical	13-23	Neo-adjuvant Abiraterone prostate
GU	Trans	14-04	iPROSPECT
GU	Clinical	14-06	ENZAMET
GU	Clinical	14-07	ENZARAD
GU	Clinical	15-19	CARD

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:
GU	Trans	15-21	ExPeCT study
GU	Radio	15-46	PACE
GU	Trans	16-07	IPCOR
GU	Clinical	16-27	Keynote 426
GU	Clinical	16-62	Roche MO29983 (SAUL)
GU	Clinical	16-63	Roche IMmotion010
GU	Clinical	16-70	BMS CA209-274
GU	Clinical	17-05	MSD MK-3475-361/ KEYNOTE-361
Gynae	Radio	09-06	Endometrial - IMRT v 3D RT
Gynae	Clinical	11-29	ICON8B
Gynae	Clinical	14-02	SHAPE
Gynae	Clinical	15-22	JAVELIN 200
Gynae	Clinical	16-04	PRIMA
Gynae	Clinical	16-05	JAVELIN 100
H & L	Clinical	12-02	E3A06 Lenalidomide in Smoldering Myeloma (ECOG-ACRIN)
H & L	Clinical	15-08	ROBUST Lenalidomide plus RCHOP in ABC DLBCL (Celgene)
H & L	Clinical	15-09	ARROVEN Brentixumab Vedotin PASS Study in HL (Millennium)
H & L	Clinical	15-10	OPTIMISMM Pomalidomide Study in rel/ref MM (Celgene)
H & L	Clinical	15-37	CHRONOS-2 Copanlisib v placebo in rituximab refractory iNHL (Bayer)
H & L	Clinical	15-38	CHRONOS-3 Copanlisib v placebo + rituximab in relapsed iNHL (Bayer)
H & L	Clinical	15-36	Rigosertib versus Physicians Choice in MDS (Onconova)
H & L	Clinical	16-08	Millennium P2001 Pevonedistat
H & L	Clinical	16-10	KEYNOTE 185
H & L	Clinical	16-02	CyBorD with Daratumumab in transplant eligible patients with newly diagnosed MM
H & L	Clinical	16-09	Astellas 2215 CL 0301
H & L	Clinical	16-79	M15-550 (VENICE 1)
Head & Neck	Clinical	16-54	BMS CA209-714
Head & Neck	Clinical	16-11	NRG HN-002
Lung	Clinical	12-53	ETOP SPLENDOUR
Lung	Radio	15-05	Oligo-Recurrent Metastatic Disease
Lung	Clinical	15-27	BMS CA209-227 (CheckMate 227) (Parts 1 and 2)
Lung	Radio	15-47	INTENSE
Lung	Clinical	16-18	BMS CA209-451 (CheckMate 451)
Lung	Clinical	16-16	MSD MK3475-189
Lung	Clinical	15-40	MK3475-091 (PEARLS)
Lung	Clinical	16-24	Roche IMpower 132
Melanoma	Trans	13-22	SYS-ACT
Melanoma	Clinical	16-14	CheckMate 401
Basket	Trans	08-40	SNP Study
Basket	Clinical	15-42	LOXO-101
Basket	Clinical	16-64	Roche MO29518

CEO appointed to HSE Steering Group

Cancer Trials Ireland's CEO, Eibhlin Mulroe has been appointed to the HSE's Electronic Health Records Programme Steering Group.

The Group is chaired by Dr Áine Carroll, the HSE's National Director for Clinical Strategy and Programmes Division, with the HSE's Chief Information Officer, Richard Corbridge, as Deputy Chair.

The Steering Group is responsible for maintaining a programme view of the sub-programmes, projects and work streams that comprise the Electronic Health Records Programme.

New staff

David Baxter, Senior Pharmacovigilance Associate

Celine Cadogan, Pharmacovigilance Associate

Alison Bowes, Clinical Data Manager

Anne Maguire, CRA II

Hilary Smyth, CRA (Radiotherapy)

Howard Foye, CRA

Position changes

Kathleen Scott to Head of Operations and Clinical Programs

Verena Murphy to Translational Research Leader

Orla Casey to Translational Project Manager

David Higgins to Quality Assurance Auditor / trainee CRA

Carrie Gilligan to trainee CRA

Welcome back

Aoife Shannon CPM (Radiotherapy) has returned from Maternity leave. Welcome back Aoife.

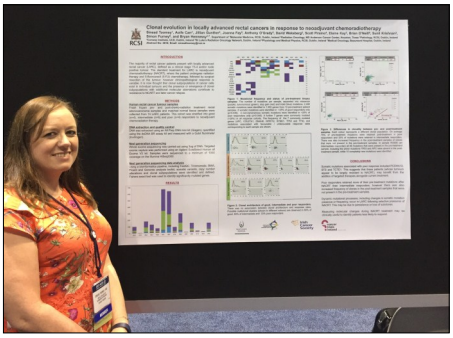
Next DSSG Meeting

Friday, 20th October

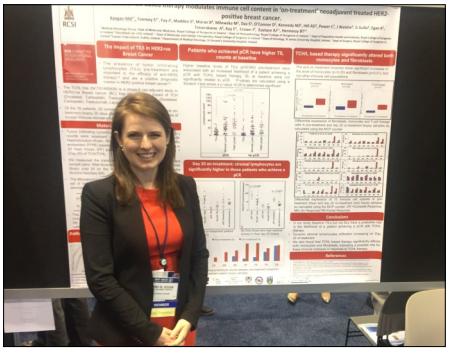
Venue to be confirmed closer to the date

Out and about at ASCO 2017

With leading melanoma expert Prof John Kirkwood (right) Director, Melanoma and Skin Cancer Program, University of Pittsburgh, were Eibhlin Mulroe, CEO, Prof Ray McDermott, Consultant Medical Oncologist, and Dr Kathleen Scott, Head of Operations and Clinical Programs.



Sinead Toomey, Dept of Molecular Medicine, RCSI.



Dr Niamh Keegan, Research Registrar, Beaumont Hospital / RCSI.

Planning meeting with ECOG – ACRIN and GEICAM.