

Annual Report 2015



Name change

In May 2016 the All-Ireland Cooperative Oncology Research Group (ICORG) changed its trading name to Cancer Trials Ireland. (The company is registered with the Company Registration Office as Irish Clinical Oncology Research Group (ICORG)).

The name change followed considerable consultation and the feedback from our membership, the Health Research Board's International Panel Review carried out during 2015, and our Patient Advocate Advisory Group, that we needed to do better in reaching and connecting with the general public. To do this we needed to communicate in language that is more easily understood. Our new name will help us make these connections.

While the name change did not take place until 2016, for the convenience of readers the new name, Cancer Trials Ireland, is used throughout this report, except for the names of trials.

Cover photo

Promoting clinical trials during International Clinical Trials Day in May 2015 were (l to r) Prof. Ray McDermott (Board Member and in 2015 Cancer Trials Ireland's Clinical Lead), Anne Cody (Head of Clinical and Applied Biomedical Research at the Health Research Board) and Evelyn O'Rourke (Board Member and patient advocate).



I am delighted to present our Annual Report for 2015 and have the opportunity to publicly thank many of the people who contributed to the success of Cancer Trials Ireland during that year.

I would like to take this opportunity to thank my colleagues on the Board who give of their time and expertise generously and freely.

I would like to thank our CEO, management team and our head office staff all of whom are very diligent and committed to the highest standards of professionalism. I would like to thank the clinical leadership and their support teams that are very busy across the country planning and initiating new trials and delivering very valuable findings.

I would like to thank our funders; donors, the Exchequer, the Health Research Board and the Irish Cancer Society.

I would like to thank the many pharmaceutical companies and international collaborative groups with whom we work closely.

Finally I would like to express a particular thanks to people who have cancer and their families for making such an enormous community contribution by taking part in cancer trials and advancing us closer toward diagnostics and treatments that will save and enhance the lives of millions of others around the world.

Dr Jonathan Westrup, Chair of Cancer Trials Ireland

Other Members of the Cancer Trials Ireland Board 2015



Dr Leisha Daly



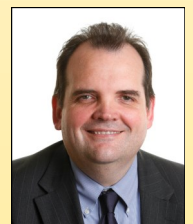
Berchmans Gannon



Prof. Liam Grogan



Prof. Bryan Hennessy



Prof. Ray McDermott



Prof. Patrick Murray



Dr. Robert O'Connor



Prof. Michael
O'Dwyer



Dr. Susan O'Reilly



Evelyn O'Rourke



Cancer Trials Ireland was established in 1996 and since that time has revolutionised cancer trials in Ireland.

More than 15,000 people have participated in cancer trials. This participation has not only provided early access to promising diagnostics and treatments, enhanced and extended lives, it has saved the Exchequer many millions of euro in drugs costs.

Thanks to the commitment and dedication of the organisation's founders to engage with colleagues and stakeholders and establish a network of research units around the country, cancer trials in Ireland are thriving.

Building on this stellar achievement, 2015 was an important year for Cancer Trials Ireland. It signalled the start of a new stage in the organisation's growth and development.

Governance structures have been developed to meet best practice standards, facilitate the growth of the organisation and ensure that all of its various strands are strategically aligned.

To ensure the organisation is fit for purpose we have focused on leadership development, staff development, training and internal succession supported by a dedicated IT resource and a disease specific model with associated efficiencies.

We are working more closely on an integrated basis with cancer trials research units around the country, strengthening strategic alliances with pharmaceutical companies and international collaborative groups, and enhancing our relations with key stakeholders such as the HRB, Irish Cancer Society, NCCP and Dept of Health and other stakeholders such as the wider cancer research community, cancer patients and the public where possible.

We continue to work with the Clinical Research Facility Galway (CRFG) on the assigned studies and engage with the Irish Cancer Society and work together on research initiatives which are of common interest.

I would like to take this opportunity to thank the Board for its direction, advice and support.

And finally I would like to thank staff at the Group Central Office for their commitment to their work and the ideals of Cancer Trials Ireland.

Eibhlin Mulroe, CEO, Cancer Trials Ireland

*154 trials
involving 6312
patients*

Clinical Trial Activity

- 14 hospital based cancer trials research units around the country were working on 154 trials involving 6312 patients; 66 were recruiting patients and 88 were in the follow up stage. There were also 16 paediatric cancer trials.
- Of these 154 trials, 123 involved drugs and/or treatments, 29 were translational trials which involved analysing tissue and/or blood samples and 2 involved questionnaires/surveys.
- These trials resulted in patients being able to access more than 25 new cancer drugs and treatments, thereby saving the state millions of euros annually.
- There were 33 articles published in high impact medical journals.
- There were more than 50 collaborations with pharmaceutical companies, collaborative groups and universities worldwide.
- Exciting new opportunities were explored in Gastrointestinal, Genitourinary, Lung and Blood cancers.

Organisational Activities

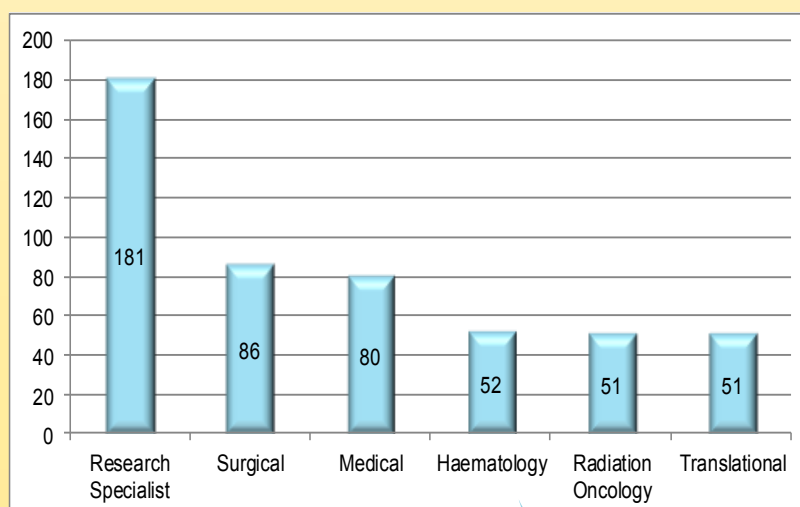
- During 2015, a sub group of the Clinical Executive was established to develop Site Metrics. The group consisted of personnel from Group Central Office (GCO) and research units around the country.
- Cancer Trials Ireland hosted International Clinical Trials Day in May and, with Patient Champions, highlighted through the media the importance of providing access to clinical trials.
- A presentation and written submission was made to the Department of Health's Steering Group on the development of Cancer Strategy 2016-2025. This submission recommended that a target of 5% be set for the number of cancer patients who should be participating in cancer drug trials.
- A stakeholder event was held during Autumn 2015 to mark Cancer Week which included a round table with patients at the Irish Cancer Society.
- Stakeholder Engagement meetings, open to non members, were introduced as part of the Disease Specific Sub Group (DSSG) meetings in June and October.
- The Board and CEO engaged with the IDA and Science Foundation Ireland to explore partnership opportunities.
- The CEO was appointed to the eHealth Ireland Committee and the Board of the Blood Cancer Network of Ireland.
- Meetings with global teams from pharmaceutical companies and clinical research organisations were organised to explore new collaborations.
- Cancer Trials Ireland continued to attract studies from international research groups such as ANZUP (collaborated on the ENZAMET (ICORG 14-06) and ENZARAD (ICORG 14-07) trials) and PreCOG, a sister Foundation to ECOG-ACRIN.

The General Central Office (GCO) supports cancer trials across the country

- Prof. Ray McDermott, Clinical Lead, acted as Interim CEO after the departure of long time CEO, Dr Brian Moulton in November 2014. The Board recruitment process took place in early 2015 and in June 2015, Eibhlin Mulroe took up the full time position of CEO.
- New line management structures were introduced, facilitating clear career pathways for staff.
- A Leadership Team was established with representatives from the clinical operations, finance, HR, data management, and quality and training functions.
- Dedicated Clinical Program Leaders were appointed to oversee and manage the organisation's clinical portfolios and teams.
- A bi-weekly Medical Oversight Meeting was established to review the trials portfolio. This is led by the Clinical Lead with the Vice Clinical Lead in attendance as appropriate. The various operations functions are represented at this meeting.
- An ethics and regulatory resource has been established providing a specialised expertise to all staff and members.
- The organisation's HR capability was expanded and its processes streamlined. It also developed operational and management training for staff.
- Personnel were aligned to disease specific areas.
- The Data Management team was expanded from one staff member to five which was an important strategic appointment in the context of regulatory requirements .

Membership

- Total membership on 31 December 2015 was 501 (31 new members joined since 01 January 2015) broken down as follows:



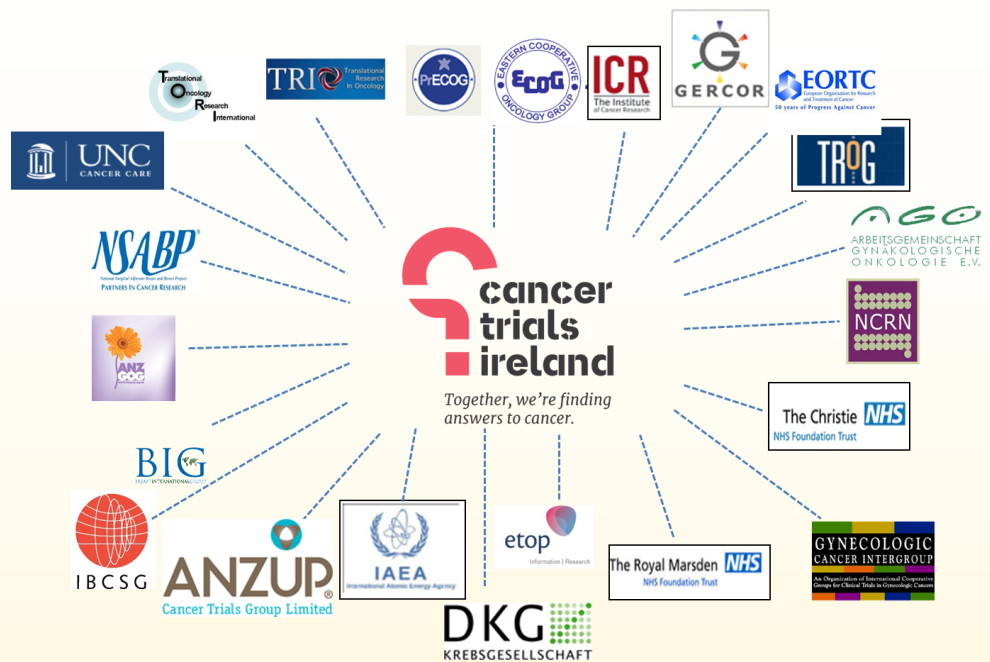


Diagram 1: Examples of international collaborative groups Cancer Trials Ireland is engaging with.



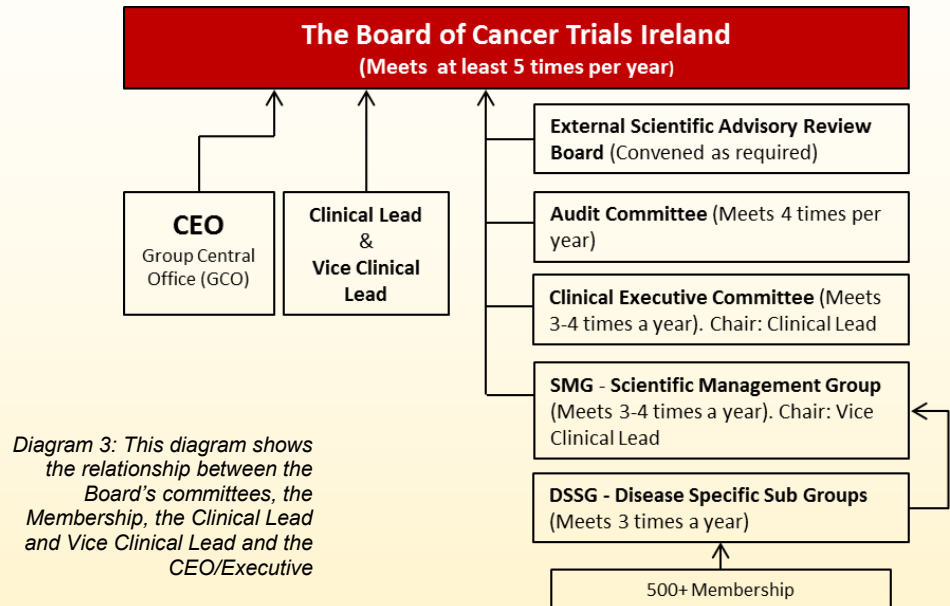
Diagram 2: Examples of pharmaceutical companies Cancer Trials Ireland is working with.

More than 50 collaborations with pharmaceutical companies, collaborative groups and universities worldwide

Governance

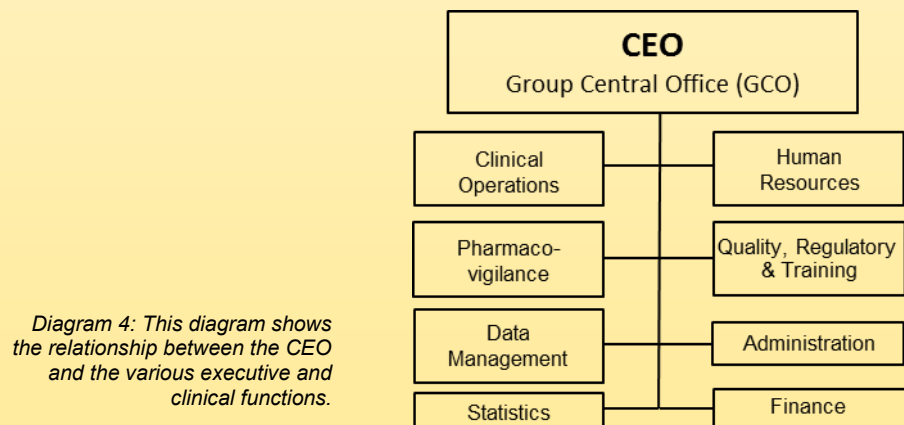
The organisation's Articles of Association were adopted at an Extraordinary General Meeting on the 28th November 2014 and a Board was elected at a subsequent Annual General Meeting in November 2014 under said Articles.

The Board met five times in 2015; 26 Mar 2015, 14 May 2015, 09 July 2015, 08 Oct 2015 and 03 Dec 2015.



General Central Office

On 31st December 2015 the General Central Office (GCO) consisted of 44 employees (43 employees on 31 December 2014).



Disease Specific Programmes

Cancer Trials Ireland's scientific activities and direction are determined by its Disease Specific Sub Groups (DSSG). These groups are open to all members; they meet regularly (minimum three times per year) and set priorities by way of appraisal of in-house studies and critical analysis of potential collaborations. The DSSGs fulfil three main functions:

- Review all studies currently open in the disease area, discuss issues and troubleshoot problems arising.
- Review protocol concepts submitted by members, decide on their merit, and advise how they should be developed further.
- Review collaborative group and industry protocols and prioritise these for Group adoption.

In 2015 there were eleven active DSSGs which have been prioritised on the basis of need. These are:

Breast	Gastrointestinal	Genitourinary
Gynaecological	Head and Neck	Lung
Lymphoma/Haematology	Melanoma	Translational
Paediatric	Central Nervous System (CNS)	

Each group has trials which are currently open or at various stages of development. The table below shows the number of trials in the portfolio (without the follow up); studies open and closed to accrual; number of new study proposals; and number of studies in follow-up for each DSSG.

DSSG	Number Of Studies in portfolio (without the follow up)	Number Of Studies Open to accrual	Number Of Studies Closed to accrual	Number Of New Study proposals (opened and discussed)	Number Of Studies In Follow-Up
Breast	16	6	3	18	34
CNS	3	2	0	7	0
Gastro-intestinal	14	9	2	10	7
General	3	1	0	3	0
Genito-urinary	17	8	3	6	19
Gynaecology	7	5	1	15	1
Head and Neck	4	4	2	2	1
Lung	10	7	5	22	9
Lymphoma/ Haematology	20	15	5	18	9
Melanoma	5	3	3	10	9
Translational	30	14	6	10	2
Other		1	0		1
Paediatric	19	16	3	19	24

DSSG meetings

During 2015 the DSSGs continued to provide a slide set for each specific research area detailing what was to be presented at the upcoming meetings. This helped facilitate preparatory discussions, and to increase efficiency and productivity of these meetings as well as enabling members who could not attend in person to discuss their views via teleconference.

During 2015, significant work was done to develop a Stakeholder Engagement Meeting (SEM) with representatives from the HRB, the Irish Cancer Society, the Irish Pharmaceutical Healthcare Association, Science Foundation Ireland, IDA Ireland, ICON and the Department of Jobs, Enterprise and Innovation.

The Scientific Management Group (SMG)

The SMG is responsible for the development of research priorities and the resourcing of these priorities within the Cancer Trials Ireland's allocated funding.

The SMG's role is planning scientific development, keeping in mind under-served disease areas, while at the same time maximising accrual and meeting agreed targets. The SMG took on the role of study ratification so that more detailed discussion and analysis could take place. All trials and studies must be ratified at the SMG prior to initiation.

The Chair of the SMG during 2015 was Prof. Bryan Hennessy (Vice Clinical Lead during 2015). Other Clinical members include:

Breast DSSG	Dr. Cathy Kelly and Dr Patrick Morris
Central Nervous System DSSG	Dr. Stephen MacNally
Lung DSSG	Dr. Linda Coate,
Gastrointestinal DSSG	Prof. Seamus O'Reilly and
	Dr. Gregory Leonard
Genitourinary DSSG	Prof. Ray McDermott and Dr Paul Kelly
Gynaecology DSSG	Dr. Dearbhaile O'Donnell
Head and Neck DSSG	Dr. Sinead Brennan
Lymph/Haem DSSG	Prof. Michael O'Dwyer
Translational DSSG	Prof. William Watson
Melanoma DSSG	Dr. Paul Donnellan
Paediatrics DSSG	Dr. Aengus O'Marcaigh

Data Safety Monitoring Board (DSMB)

Cancer Trials Ireland has established a system for convening and managing DSMBs for in-house studies that require this level of oversight. Broadly, study oversight is carried out through the DSSGs and day to day trial management groups, with additional oversight for higher risk studies provided by a DSMB and a Trial Steering Committee (TSC).

Studies requiring the involvement of a DSMB and a TSC are identified at protocol development/ risk assessment stage, and for each study requiring a DSMB and TSC a committee is formed according to standard procedures.

In 2015 there were two open studies involving an active DSMB (ICORG 11-10:TH vs THL and ICORG 10-14: Neo-AEGIS). The DSMBs have oversight of these studies and meet as defined in the study protocol and recommendations are issued to the Sponsor (Cancer Trials Ireland), the Chief Investigator and Clinical Lead.

Safety Monitoring Committee (SMC)

During 2015, Cancer Trials Ireland set up a Safety Monitoring Committee. Its primary role is to review the continuing benefit/risk of Cancer Trials Ireland sponsored clinical studies. Studies which require DSMB oversight are not reviewed by this committee. The Chairperson of this committee is Dr. Patrick Morris, Consultant Medical Oncologist and the membership includes the Clinical Lead, Vice Clinical Lead, Radiation Oncology, Surgical Oncology, Haematology, and Pharmacy representatives and a former HPRA Director of Scientific Affairs.

Meetings occur on a quarterly basis and specific data reports for each study are produced and reviewed (as per SMC Charter). A quorum must be present for the meeting to occur and following a review of the information provided, the committee provides recommendations based on the continuing benefit/risk assessment of the studies. The Study Chief Investigators have defined timelines to review and respond to the recommendations.

Medical Oversight Meetings (MOM)

Bi-weekly Medical Oversight meetings were established during 2015 to review and discuss current issues relative to the medical oversight and continuing benefit/risk monitoring of ongoing studies. These meetings are led by the Clinical Lead with the Operations Team in attendance. For studies where the Clinical Lead is the study Chief Investigator, the Vice Clinical Lead reviews the continuing benefit/risk of the study. Any actions required regarding the benefit/risk status of the study are communicated to the relevant parties.

Trial Steering Committee (TSC)

For clinical studies where a DSMB is required or multiple countries are involved, a Trial Steering Committee (TSC) is required. The primary focus of this committee is to review the scientific integrity of the study on an ongoing basis.

The TSC members comprise the Chief Investigator, Country Lead Investigators, Clinical Lead and other members of the Operations Study Team. The meetings occur as defined in the trial protocol and Committee Charter and review all aspects of the study including any recommendations from the study DSMB and required actions discussed.

Standard Operating Procedures (SOPs)

SOPs which are vital to ensuring that we operate according to regulatory requirements, international standards and best practices, were implemented or updated in the areas of Pharmacovigilance, Medical Oversight and Benefit-Risk Monitoring, Risk Assessment and Management of trials, and in Data Management.

Regulatory Activities

A HPRA inspection took place in April 2015 which triggered the following improvements:

1. Implementation of a Medical Oversight process which involves bi-weekly meetings with the operations team, Clinical Lead and Vice Clinical Lead.
2. The establishment of a Safety Monitoring Committee chaired by Dr. Patrick Morris to oversee Cancer Trials Ireland sponsored trials.

International Peer Review

International peer review became a standard process for all new trials (except trials which had been previously peer-reviewed). Between January and December 2015, 5 concepts were issued for review; 2 were approved in 2015 and 3 were approved in 2016.

Clinical Research Facility Galway and Cancer Trials Ireland

In 2015, the CRFG continued to be tasked by the Health Research Board, in partnership with Cancer Trials Ireland, to be responsible for statistics and data management activities for selected Cancer Trials Ireland in-house trials.

This included:

- Undertaking data management and processing functions for selected in-house trials.
- Providing statistical support for activities such as protocol development, abstracts and study reports.

Accrual Monitoring System

Each research unit submits their accrual information to the CRFG on a monthly basis. This group ensures timely submission of data from sites, cross checks the data submitted, collates the data across trials, disease areas and the group as a whole, and produces a variety of reports for different audiences internally and externally in conjunction with the GCO.

Group Activity Reports between 1st January – 31st December 2015

During 2015 Group Activity Reports were compiled by the CRFG and the Data Management Unit. Reports were submitted to the HRB for the first six months of the year on 31 August 2015 and for the full year on 15 February 2016

Publication Policy

A Cancer Trials Ireland publication policy was drafted during 2015 to be finalised in 2016. This specifies the requirements relating to the publication of any study where Cancer Trials Ireland has been involved and also include requirements for external third parties where this is applicable.

Pharmacovigilance

This table summarises Cancer Trials Ireland's pharmacovigilance activities for the period 01 January 2015 – 31 December 2015.

Pharmacovigilance Activity	Number
SAEs Received and Tracked by Cancer Trials Ireland (includes follow-ups)	239
SAEs received through Cancer Therapy Evaluation Program's Adverse Event Reporting System (CTEP AERS) (includes follow-ups).	75
SAEs received on Medwatch forms.	51
SUSARs Entered onto Eudravigilance Database by Cancer Trials Ireland.	64
PhV SOPs updated.	1
Annual Development Safety Update Reports (produced in-house) distributed to relevant Ethics Committees and Competent Authorities by Cancer Trials Ireland.	22
Annual Development Safety Update Reports (received from another sponsor) distributed to relevant Ethics Committees and Competent Authorities by Cancer Trials Ireland.	7
Safety and clinical database reconciliations	5

Accruals

The trials portfolio continued to grow during 2015 and accruals increased.

In 2015, 35% of the overall portfolio were Breast cancer trials(38% in 2014 and 41% in 2013). 29% of all patients enrolled onto a trial were recruited to Breast cancer trials (it was 53% in 2013).

In consultation with the Health Research Board, four disease areas were selected for particular attention. These were GI, GU, Lung and Lymph/Haem. In 2015, all four groups exceeded 50 patients recruited to trials. The respective totals were: GI = 135, GU = 185, Lung = 63, Lymph/ Haem = 61.

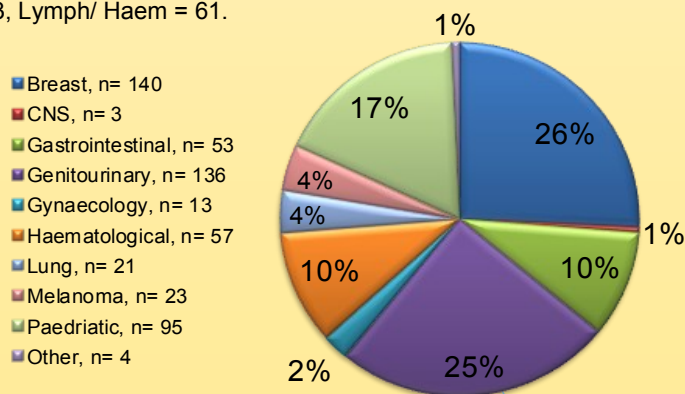


Diagram 5: Accrual to trials by disease area during 2015.

Note:

Why do these number not correspond with the tables on the next few pages?

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Group Accrual

Accrual to Cancer Trials Ireland studies and trials from 01 January 2015 to 31 December 2015.

Disease Area	Study Type	Protocol Number	Study (Acronym)	Patients Recruited
Breast	Clinical Trial / Translational	ICORG 06-31	ECOG – TAILORx (Step 3)	40
Breast	Clinical Trial	ICORG 11-24	NSABP B-47	7
Breast	Clinical Trial	ICORG 12-01	SWOG S1007 (step 1)	87
Breast	Clinical Trial	ICORG 12-01	SWOG S1007 (step 2)	(37)
Breast	Clinical Trial	ICORG 12-45	IBCSG 42-12 / BIG 2-12 SNAP study	10
Breast	Clinical Trial	ICORG 13-05	KATHERINE study/(Roche adjuvant BO27938/ NSABP B-50i/ GBG 77)	19
Breast	Clinical Trial	ICORG 13-11	Medivation 'TNBC' (enzalutamide) study/MDV-3100-11	0
Breast	Clinical Trial	ICORG 14-12	Medivation MDV-3100-12 study	6
Breast	Clinical Trial	ICORG 14-08	Novartis MONALEESA-2 study	1
Breast	Questionnaire	ICORG 13-01	ABC Survey	118
Breast	Translational	ICORG 12-40	EORTC 10085	7
Breast	Translational	ICORG 09-07	Proteomics and Molecular Heterogeneity	198
Breast	Translational	ICORG 10-11	Circulating miRNA's	31
Breast	Translational	ICORG 10-15	Predictive Biomarker Breast (cohort 1) Exosomal	64
Breast	Translational	ICORG 10-16	Anti-Mullerian Hormone (Ovarian Reserve)	43
Breast	Translational	ICORG 12-09	CharactHer	31
Breast	Translational	ICORG 12-30	TailorX Tissue Bank	446
Breast	Clinical Trial	ICORG 14-01	Biomarin 673-301 study	2
Breast	Clinical Trial	ICORG 14-11	PENELOPE-B	1
Breast Total				1111

Disease Area	Study Type	Protocol Number	Study (Acronym)	Patients Recruited
CNS	Clinical Trial	ICORG 15-29	M14-483 - Step 1	15
CNS	Clinical Trial	ICORG 15-29	M14-483 - Step 2	3
CNS	Translational	ICORG 08-13	Serum Markers Primary Brain Tumours 1	42
CNS Total				60

Disease Area	Study Type	Protocol Number	Study (Acronym)	Patients Recruited
Gastrointestinal	Clinical Trial	ICORG 10-14	Neo-AEGIS	16
Gastrointestinal	Clinical Trial	ICORG 12-07	LCCC 1029	10
Gastrointestinal	Translational	ICORG 08-40	SNP	20
Gastrointestinal	Translational	ICORG 12-16	AngioPredict	5
Gastrointestinal	Translational	ICORG 12-27	CRAC Plasma Biomarkers	34
Gastrointestinal	Translational	ICORG 12-31	PDAC Plasma Biomarkers	22
Gastrointestinal	Clinical Trial	ICORG 14-18	APACT	2
Gastrointestinal	Clinical Trial	ICORG 14-19	BMS CA209-142	3
Gastrointestinal	Clinical Trial	ICORG 15-30	MK3475-061 Gastric	12
Gastrointestinal	Clinical Trial	ICORG 15-45	BMS CA209-214	10
Gastrointestinal	Observational	ICORG 14-17	XL184-309 Celestial	1
Gastrointestinal Total				135
General	Translational	ICORG 07-12	Collaborative Biomarkers Study	123
General Total				123
Genitourinary	Clinical Trial	ICORG 08-17	IMRT Prostate	34
Genitourinary	Clinical Trial	ICORG 10-01	Phase II 2nd line pazopanib metastatic RCC study	2
Genitourinary	Clinical Trial	ICORG 12-38	TRI-LARC Rectal	18
Genitourinary	Clinical Trial	ICORG 13-09	PEACE-1 study	22
Genitourinary	Clinical Trial	ICORG 13-21	Radium-223 & Enzalutamide mCRPC study	9
Genitourinary	Clinical Trial	ICORG 13-23	Neo-adjuvant abiraterone prostate study	2
Genitourinary	Clinical Trial	ICORG 14-06	ANZUP ENZAMET study	34
Genitourinary	Clinical Trial	ICORG 14-07	ANZUP ENZARAD study	8
Genitourinary	Translational	ICORG 08-08	Biomarkers of Response Taxotere	4
Genitourinary	Translational	ICORG 08-17	IMRT Prostate Sub-Study 1	(29)
Genitourinary	Translational	ICORG 08-17	IMRT Prostate Sub-Study 2	(30)
Genitourinary	Translational	ICORG 14-04	iPROSPECT study	45
Genitourinary	Translational	ICORG 14-04	iPROSPECT sub-study A	(7)
Genitourinary	Translational	ICORG 14-04	iPROSPECT sub-study B	(6)
Genitourinary	Translational	ICORG 14-04	iPROSPECT sub-study C	(8)
Genitourinary	Clinical Trial	ICORG 15-31	MK3475-045 Bladder	4
Genitourinary	Clinical Trial	ICORG 15-32	MK3475-052 Bladder	3
Genitourinary Total				185
Gynaecological	Clinical Trial	ICORG 09-06	Endometrial IMRT	10
Gynaecological	Clinical Trial	ICORG 13-07	AEZS-108-050	1
Gynaecological	Clinical Trial	ICORG 14-02	SHAPE study	2
Gynaecological	Observational	ICORG 11-29	ICON 8B	5
Gynaecological Total				18

Disease Area	Study Type	Protocol Number	Study (Acronym)	Patients Recruited
Haematological	Clinical Trial	ICORG 12-02	E3A06 Lenalidomide	2
Haematological	Clinical Trial	ICORG 12-10	Amgen Denosumab/Zometa myeloma	1
Haematological	Clinical Trial	ICORG 13-17	RsQVD	32
Haematological	Clinical Trial	ICORG 13-18	TOWER study	4
Haematological	Clinical Trial	ICORG 14-10	GSK TRC112121 SUPPORT study	4
Haematological	Clinical Trial	ICORG 14-09	Roche MO28543 GREEN study	11
Haematological	Observational	ICORG 15-09	MA25101 - ARROVEN	2
Haematological	Clinical Trial	ICORG 15-10	OPTIMISMM	5
Haematological	Clinical Trial	ICORG 12-47	CC-4047-MM-010 Celgene Pomalidomide	0
Haematological Total				61
Head & Neck	Clinical Trial	ICORG 12-39	De-ESCALaTE HPV Head & Neck	4
Head & Neck	Clinical Trial	ICORG 15-13	MK-3475-040 (Keynote 040)	2
Head and Neck Total				6
Lung	Clinical Trial	ICORG 12-53	ETOP SPLENDOUR	4
Lung	Clinical Trial	ICORG 14-13	MSD Pembrolizumab	7
Lung	Clinical Trial	ICORG 14-14	Abbvie M11-089/Veliparib mNSCLC study	10
Lung	Translational	ICORG 07-12	Collaborative Biomarkers Study (Lung cohort)	42*
Lung Total				63
Melanoma	Clinical Trial	ICORG 12-51	ROCHE GO27826-BRIM 8	3
Melanoma	Clinical Trial	ICORG 14-15	BMS CA209-172 Nivolumab advanced Melanoma study	11
Melanoma	Clinical Trial	ICORG 14-24	BMS CA209-238	9
Melanoma	Translational	ICORG 13-22	SYS-ACT	2
Melanoma Total				25
Other	Clinical Trial	ICORG 05-03	SCC - In House	4
Other Total				7
Paediatric	Translational	N/A	AALL08B1	18
Paediatric	Clinical Trial	N/A	AALL0932	14
Paediatric	Clinical Trial	N/A	AALL1131	9
Paediatric	Clinical Trial	N/A	BEACON Neuroblastoma	1
Paediatric	Clinical Trial	N/A	EU-RHAB	1
Paediatric	Clinical Trial	N/A	EuroNet PHL-C1 (HD 2007 10)	9
Paediatric	Other	N/A	EWOG-SAA 2010	4
Paediatric	Clinical Trial	N/A	FACT	3
Paediatric	Clinical Trial	N/A	IMPORT	9
Paediatric	Clinical Trial	N/A	LLR Cell Bank	17
Paediatric	Clinical Trial	N/A	LTI Study	4
Paediatric	Registry	N/A	NBL-SCI Registry	1
Paediatric	Clinical Trial	N/A	SIOP Europe	6
Paediatric	Clinical Trial	N/A	STS 2006 04 - RMS 2005	2
Paediatric	Tumour Banking	N/A	Tumour Banking Study	30
Paediatric	Clinical Trial	N/A	UKALL 2011	20
Paediatric Total				148
Total Cancer Trials Ireland Accrual				1897

Other developments

Twitter

Cancer Trials Ireland has been active on twitter since April 2012. In December 2015 it had over 600 followers, up from 435 in December 2014. According to Google Analytics, in 2015, its twitter domain was recording an average of 2000 twitter impressions per month and 50 twitter mentions. Although a private account, one of our staff members frequently tweeted about Cancer Trials Ireland and the related twitter impressions were averaging 15,000 per month and 50 related mentions.

A number of our important study-related tweets have been frequently re-tweeted by Cancer Trials Ireland's followers, broadening further their reach.

Newsletter

The purpose of Cancer Trials Ireland's newsletter in 2015 was to inform Members of progress regarding trials, as well as keeping them up to date on issues such as training opportunities and DSSG news.

Newsletters were issued before the DSSG meetings. The format of the newsletter is undergoing significant re-development in 2016 to maintain it as an effective way to communicate to stakeholders. Now its eight year of production, the newsletters have received a lot of positive feedback from Members.

Cancer Trials Ireland Short Films

In 2015, Cancer Trials Ireland developed 6 short films interviewing staff, clinical investigators, patient champions and stakeholders. The videos are available on the Cancer Trials Ireland website (cancertrials.ie) and have been pushed out through social media channels.

This was an important step in further explaining the value of Cancer Trials Ireland's offering to the public and patients with cancer. Staff, patients and investigators talk through the importance of investigator-led studies, paediatric studies and the need for patient involvement in the development of Cancer Trials Ireland research.

Communications Adviser

Cancer Trials Ireland was awarded the HRB KEDs grant in late 2015 to employ a part-time Communications Adviser and host an International Clinical Trials Conference in Dublin in May 2016. The Communications Adviser will work to enhance Cancer Trials Ireland's internal communication channels between research units and GCO staff and also develop relationships with medical media and health media to further raise the profile of clinical trials to the Irish public.

International Clinical Trials Day

Held on 14th May Cancer Trials Ireland's profile raising activities for International Clinical Trials Day won a Commendation from the Irish Medical Times' Irish Healthcare Awards in the "best patient education non-pharma" category.

The campaign featured Cancer Trials Ireland's 'Clinical Trial Champions' who were patients ranging from a six year old boy to gentlemen in their seventies who shared their stories about taking a proactive approach to their treatments and participating in clinical trials. The campaign also included representatives from the HRB, the Irish Cancer Society and our Clinical Lead.

Irish Clinical Oncology Research Group CLG
(A company limited by guarantee, without a share capital)
INCOME AND EXPENDITURE ACCOUNT
for the year ended 31 December 2015

	Notes	2015 €	2014 €
Income	6	2,979,287	2,459,509
Expenditure		<u>(2,882,264)</u>	<u>(2,468,569)</u>
Surplus/(deficit) on ordinary activities before interest		97,023	(9,060)
Interest receivable and similar income	8	<u>11,657</u>	<u>41,507</u>
Total Comprehensive Income		<u>108,680</u>	<u>32,447</u>

The company has no recognised gains or losses other than the surplus for the year. The results for the year have been calculated on the historical cost basis. The company's income and expenses all relate to continuing operations.

Approved by the board on _____ and signed on its behalf by:

Prof. Bryan Hennessy
Director

Prof. Ray McDermott
Director

BALANCE SHEET

as at 31 December 2015

	Notes	2015 €	2014 €
Fixed Assets			
Tangible assets	10	<u>36,052</u>	<u>28,067</u>
Current Assets			
Debtors	11	182,490	338,070
Cash and cash equivalents		<u>5,360,326</u>	<u>3,787,775</u>
		5,542,816	4,125,845
Creditors: Amounts falling due within one year	12	<u>(4,625,079)</u>	<u>(3,308,803)</u>
Net Current Assets		<u>917,737</u>	<u>817,042</u>
Total Assets less Current Liabilities		<u>953,789</u>	<u>845,109</u>
Reserves			
Income and expenditure account		<u>953,789</u>	<u>845,109</u>
Equity attributable to owners of the company		<u>953,789</u>	<u>845,109</u>

Approved by the board on _____ and signed on its behalf by:

Prof. Bryan Hennessy
Director

Prof. Ray McDermott
Director

Publications in 2015
Peer Reviewed Papers Published

Breast

ICORG 06-31: TAILORx study

The New England Journal of Medicine, November 19, 2015, vol. 373 no. 21
Prospective Validation of a 21-Gene Expression Assay in Breast Cancer

J.A. Sparano, R.J. Gray, D.F. Makower, K.I. Pritchard, K.S. Albain, D.F. Hayes, C.E. Geyer, Jr., E.C. Dees, E.A. Perez, J.A. Olson, Jr., J.A. Zujewski, T. Lively, S.S. Badve, T.J. Saphner, L.I. Wagner, T.J. Whelan, M.J. Ellis, S. Paik, W.C. Wood, P. Ravdin, **M.M. Keane**, H.L. Gomez Moreno, P.S. Reddy, T.F. Goggins, I.A. Mayer, A.M. Brufsky, D.L. Toppmeyer, V.G. Kaklamani, J.N. Atkins, J.L. Berenberg, and G.W. Sledge

Appendix: The authors' full names and academic degrees are as follows: Joseph A. Sparano, M.D., Robert J. Gray, Ph.D., Della F. Makower, M.D., Kathleen I. Pritchard, M.D., Kathy S. Albain, M.D., Daniel F. Hayes, M.D., Charles E. Geyer, Jr., M.D., Elizabeth C. Dees, M.D., Edith A. Perez, M.D., John A. Olson, Jr., M.D., Ph.D., JoAnne Zujewski, M.D., Tracy Lively, Ph.D., Sunil S. Badve, M.D., Thomas J. Saphner, M.D., Lynne I. Wagner, Ph.D., Timothy J. Whelan, M.D., Matthew J. Ellis, M.B., B.Chir., Ph.D., Soonmyung Paik, M.D., William C. Wood, M.D., Peter Ravdin, M.D., **Maccon M. Keane, M.D.**, Henry L. Gomez Moreno, M.D., Pavan S. Reddy, M.D., Timothy F. Goggins, M.D., Ingrid A. Mayer, M.D., Adam M. Brufsky, M.D., Ph.D., Deborah L. Toppmeyer, M.D., Virginia G. Kaklamani, M.D., James N. Atkins, M.D., Jeffrey L. Berenberg, M.D., and George W. Sledge, M.D.

The authors' affiliations are as follows: the Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY (J.A.S., D.F.M.); Dana-Farber Cancer Institute, Boston (R.J.G.); Sunnybrook Research Institute, Toronto (K.I.P.) and Juravinski Cancer Center, Hamilton, ON (T.J.W.) — both in Canada; Loyola University Medical Center, Maywood (K.S.A.), and Northwestern University, Chicago (L.I.W., V.G.K.) — both in Illinois; University of Michigan, Ann Arbor (D.F.H.); Virginia Commonwealth University School of Medicine and the Massey Cancer Center, Richmond (C.E.G.); University of North Carolina, Chapel Hill (E.C.D.), Duke University Medical Center, Durham (J.A.O.), Wake Forest University Health Service, Winston-Salem (L.I.W.), and Southeast Clinical Oncology Research Consortium, Goldsboro (J.N.A.) — all in North Carolina; Mayo Clinic, Jacksonville, FL (E.A.P.); University of Maryland School of Medicine, Baltimore (J.A.O.), and National Institutes of Health, Bethesda (J.Z., T.L.) — both in Maryland; Indiana University School of Medicine (S.S.B.) and Indiana University Hospital (G.W.S.) — both in Indianapolis; Vince Lombardi Cancer Clinic, Two Rivers (T.J.S.), and Fox Valley Hematology and Oncology, Appleton (T.F.G.) — both in Wisconsin; Baylor College of Medicine, Houston (M.J.E.), and University of Texas, San Antonio (P.R.) — both in Texas; Washington University, St. Louis (M.J.E.); Allegheny General Hospital (S.P.) and University of Pittsburgh (A.M.B.) — both in Pittsburgh; the Department of Medical Oncology and Breast Center, Yonsei University College of Medicine, Seoul, South Korea (S.P.); Emory University, Atlanta (W.C.W.); **Irish Clinical Oncology Research Group, Dublin** (M.M.K.); Instituto Nacional de Enfermedades Neoplásicas, Lima, Peru (H.L.G.M.); Cancer Center of Kansas, Wichita (P.S.R.); Vanderbilt University, Nashville (I.A.M.); Rutgers Cancer Institute of New Jersey, New Brunswick (D.L.T.); University of Hawaii Cancer Center, Honolulu (J.L.B.); and Stanford University, Stanford, CA (G.W.S.).

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DOI: 10.1056/NEJMoa1510764
Impact score: 55.873

ICORG 06-31: TAILORx study

J Clin Oncol 33, 2015 (suppl; abstr 533)

Recurrence score and clinicopathologic characteristics of TAILORx participants by race and ethnicity.

Author(s): Maria M Zlobinsky Rubinstein, Robert James Gray, Joseph A. Sparano, JoAnne Zujewski, Timothy Joseph Whelan, Kathy S. Albain, Daniel F. Hayes, Charles E. Geyer, Elizabeth Claire Dees, Edith A. Perez, **Maccon M. Keane**, Carlos Vallejos, Timothy F. Goggins, Ingrid A. Mayer, Adam Brufsky, Deborah Toppmeyer, Virginia G. Kaklamani, James Norman Atkins, Jeffrey L. Berenberg, George W. Sledge;

Montefiore Medical Center, Bronx, NY; Dana-Farber Cancer Inst, Boston, MA; National Institutes of Health, Bethesda, MD; Cancer Care Ontario, Hamilton, ON, Canada; NRG Oncology/NSABP, SWOG, and Loyola University Chicago Stritch School of Medicine, Maywood, IL; University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; Virginia Commonwealth University Massey Cancer Center, Richmond, VA; UNC Chapel Hill, Chapel Hill, NC; Mayo Clinic, Jacksonville, FL; **West of Ireland Cancer Center, Galway, Ireland**; Instituto Nacional de Enfermedades Neoplásicas, Lima, Peru; Fox Valley Hem Onc, Appleton, WI; Vanderbilt-Ingram Cancer Center, Nashville, TN; NRG Oncology/NSABP, and Magee Women's Hospital, Pittsburgh, PA; The Cancer Inst of New Jersey, New Brunswick, NJ; Northwestern University Division of Hematology/Oncology, Chicago, IL; Southeastern Medcl Ctr, Goldsboro, NC; Tripler Army Medcl Ctr, Honolulu, HI; Stanford Univ Med Ctr, Stanford, CA

[Dr Maccon Keane was the Cancer Trials Ireland Chief Investigator for this study on behalf of the Cancer Trials Ireland participating Investigators]

Impact score: 18.428

Publications in 2015

Peer Reviewed Papers Published

ICORG 05-09: IBIS-II DCIS study

The Lancet: www.thelancet.com Published online December 11, 2015

[http://dx.doi.org/10.1016/S0140-6736\(15\)01129-0](http://dx.doi.org/10.1016/S0140-6736(15)01129-0)

See Online/Comment [http://dx.doi.org/10.1016/S0140-6736\(15\)01219-2](http://dx.doi.org/10.1016/S0140-6736(15)01219-2)

Anastrozole versus tamoxifen for the prevention of locoregional and contralateral breast cancer in postmenopausal women with locally excised ductal carcinoma in situ (IBIS-II DCIS): a double-blind, randomised controlled trial

John F Forbes, Ivana Sestak, Anthony Howell, Bernardo Bonanni, Nigel Bundred, Christelle Levy, Gunter von Minckwitz, Wolfgang Eiermann, Patrick Neven, Michael Stierer, Chris Holcombe, Robert E Coleman, Louise Jones, Ian Ellis, Jack Cuzick, **on behalf of the IBIS-II investigators***

[Supplementary appendix to The Lancet 2015; published online Dec 11 lists the participating IBIS-II DCIS Irish ICORG Investigators & study coordinators]:

Principal Investigators [Ireland] :

Deirdre O'Hanlon (Dept of Surgery, Cork, Ireland), Henry Paul Redmond (Department of surgery, Cork, Ireland), Arnold Hill (Surgical Professorial Unit, Beaumont Dublin, Ireland), Denis Evoy (Department of Surgery, UC Dublin, Ireland), Michael Kerin (University College Hospital, Galway, Ireland), Rajnish Gupta (Midwestern Cancer Centre, Limerick, Ireland), Michael J. Martin (Sligo General Hospital, Sligo, Ireland)

Local Coordinating Centres [Ireland]:

Anna Cole (All Ireland Cooperative Clinical Research Group (ICORG), Cork, Ireland),
Debra O'Hare (All Ireland Cooperative Clinical Research Group (ICORG), Cork, Ireland),
Elaine Cronin (All Ireland Cooperative Clinical Research Group (ICORG), Cork, Ireland),
Trudi Roche (All Ireland Cooperative Clinical Research Group (ICORG), Dublin, Ireland),
Emer Kennedy (All Ireland Cooperative Clinical Research Group (ICORG), Dublin, Ireland),
Jo Ballot (All Ireland Cooperative Clinical Research Group (ICORG), Dublin, Ireland),
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Marian Jennings (All Ireland Cooperative Clinical Research Group (ICORG), Galway, Ireland),
Laura Lowry (All Ireland Cooperative Clinical Research Group (ICORG), Limerick, Ireland),
Moira Maxwell (All Ireland Cooperative Clinical Research Group (ICORG), Sligo, Ireland),
Margaret Burke (All Ireland Cooperative Clinical Research Group (ICORG), Sligo, Ireland)

Impact score: 45.217

J Clin Oncol 33, 2015 (suppl; abstr e11586)

Low oncotype recurrence score (RS) and poor clinical outcomes: An Irish multicentre experience.

Author(s): Emily Harrold, Niamh Keegan, Ciara Marie Kelly, Susie Conlon, Connor Gerard O'Leary, Rachel Collins, **Janice Maria Walshe, M. John Kennedy, Seamus O'Reilly;**

St James's Hospital, Dublin, Ireland; Waterford University Hospital, Waterford, Ireland; Mater Misericordiae University Hospital, Dublin, Ireland; Department of Medical Oncology, Cork University Hospital, Cork, Ireland; Cork University Hospital, Cork, Ireland; St Vincent's University Hospital, Dublin, Ireland; **ICORG, Dublin, Ireland;** Cork Univ Hosp, Cork, Ireland.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr e11604)

Effect of adjuvant trastuzumab (Tad) therapy (Tx) for early-stage breast cancer (ESBC) on demographics, survival and likelihood of durable complete response (DCR) of HER2+ metastatic breast cancer (HMBC): A 15-year study.

Author(s): Alessandra Zacchia, **Giuseppe Gullo, Imelda Parker,** Annamaria De Giorgi, **David William Fennelly,** Daniele Zannoni, **Janice Maria Walshe,** Anne Marie Defrein, Nuno Silva, **Norma O'Donovan, Josephine Ballot, Enda McDermott, John P Crown;**

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Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr e11582)

Pneumocystis jirovecii pneumonia (PJP) in metastatic breast cancer (MBC) patients (pts) treated with mTOR inhibitor everolimus (EVE) and exemestane (AI).

Author(s): Geoffrey Watson, **Giuseppe Gullo,** Alessandra Zacchia, Daniele Zannoni, **John Crown;** St Vincent's University Hospital, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland.**

Impact score: 18.428

Publications in 2015

Peer Reviewed Papers Published

J Clin Oncol 33, 2015 (suppl; abstr 615)

Effect of somatic mutations in the four genes of the HER family on occurrence in HER2-positive breast cancer, cell proliferation rates, and resistance to HER2-targeted therapies in vitro.

Author(s): Naomi Elster, Alex J Eustace, Yue Fan, Jarushka Naidoo, Joanna Fay, Elaine Kay, Aoife Carr, **Oscar S. Breathnach, Patrick G. Morris, William Grogan, Arnold D. Hill,** Colm Power, Michael J Allen, Susan Kennedy, **John Crown, William M. Gallagher,** Sinead Toomey, **Bryan Hennessy;** Medical Oncology, Royal College of Surgeons in Ireland, Dublin, Ireland; Smurfit Institute of Genetics, Dublin, Ireland; Memorial Sloan Kettering Cancer Center, New York, NY; Pathology, Royal College of Surgeons in Ireland, Dublin, Ireland; Beaumont Hospital, Dublin, Ireland; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Beaumont Hospital, Royal College of Surgeons in Ireland, Dublin, Ireland; LRCP & SI MB BCh NUI, Beaumont Hospital, Dublin, Ireland; St. Vincent's University Hospital, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland;** University College Dublin, Dublin, Ireland; Medical Oncology, Royal College of Surgeons in Ireland and Beaumont Hospital, Dublin, Ireland.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr e12072)

PRIMA-1MET (APR-246): A novel targeted therapy for triple negative breast cancer?

Author(s): Naoise C Synnott, Patricia M. McGowan, Aisling Pierce, Maeve Kiely, **Norma O'Donovan, John Crown,** Patrick A Kiely, Michael J. Duffy; Education and Research Centre, St.Vincent's University Hospital and School of Medicine and Medical Science, University College Dublin, Dublin, Ireland; University of Limerick, Limerick, Ireland; Molecular Therapeutics for Cancer Ireland, National Institute for Cellular Biotechnology, Dublin City University, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland;** Department of Life Sciences, University of Limerick, Limerick, Ireland; Clinical Research Centre, St.Vincent's University Hospital and School of Medicine and Medical Science, University College Dublin, Dublin, Ireland.

Impact score: 18.428

ICORG 09-01: TRIO-18 study

The Lancet Oncology: Volume 16, No. 1, p25–35, January 2015

DOI: [http://dx.doi.org/10.1016/S1470-2045\(14\)71159-3](http://dx.doi.org/10.1016/S1470-2045(14)71159-3)

The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of oestrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18): a randomised phase 2 study

Richard S Finn, MD¹, **Prof John P Crown, MD²,** Istvan Lang, MD³, Katalin Boer, MD⁴, Prof Igor M Bondarenko, MD⁵, Sergey O Kulyk, MD⁶, Johannes Ettl, MD⁷, Ravindranath Patel, MD⁸, Tamas Pinter, MD⁹, Marcus Schmidt, MD¹⁰, Yaroslav Shparyk, MD¹¹, Anu R Thummala, MD¹², Nataliya L Voytko, MD¹³, Camilla Fowst, MD¹⁴, Xin Huang, PhD¹⁵, Sindy T Kim, BS¹⁵, Sophia Randolph, MD¹⁵, Prof Dennis J Slamon, MD¹

Affiliations: ¹University of California Los Angeles, Los Angeles, CA, USA; ²**Irish Cooperative Oncology Research Group, Dublin, Ireland;** ³Orszagos Onkologiai Intezet, Budapest, Hungary; ⁴Szent Margit Korhaz, Onkologia, Budapest, Hungary; ⁵Dnipropetrovsk Medical Academy, City Multiple-Discipline Clinical Hospital, Dnipropetrovsk, Ukraine; ⁶Municipal Treatment and Prophylactic Institution, Donetsk, Ukraine; ⁷Technical University of Munich, Munich, Germany; ⁸Comprehensive Blood and Cancer Center, Bakersfield, CA, USA; ⁹Petz Aladar Megyei Oktato Korhaz, Gyor, Hungary; ¹⁰University Hospital Mainz, Mainz, Germany; ¹¹Lviv State Oncologic Regional Treatment and Diagnostic Centre, Lviv, Ukraine; ¹²Comprehensive Cancer Centers of Nevada, Las Vegas, NV, USA; ¹³Kyiv City Clinical Oncology Centre, Kyiv, Ukraine; ¹⁴Pfizer Oncology, Milan, Italy; ¹⁵Pfizer Oncology, San Diego, CA, USA.

Impact score: 24.69

Publications in 2015

Peer Reviewed Papers Published

J Clin Oncol 33, 2015 (suppl; abstr 570)

Long-term safety profile of palbociclib (P) in combination with letrozole (L) as first-line treatment for postmenopausal patients with ER+ and HER2- advanced breast cancer (ABC) (PALOMA-1/TRIO-18).

Author(s): Dennis J. Slamon, **John Crown**, Istvan Lang, Sergey O. Kulyk, Marcus Schmidt, Ravi Patel, Anu Thummala, Nataliya L. Voytko, Sophia Randolph, Sindy Kim, Xin Huang, Cynthia Huang Bartlett, Patrick Schnell, Richard S. Finn; School of Medicine/Translational Oncology Research Laboratory, University of California, Los Angeles, Los Angeles, CA; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; National Institute of Oncology, Budapest, Hungary; Municipal Treatment-and-Prophylactic Institution, Donetsk, Ukraine; University Hospital Mainz, Mainz, Germany; Comprehensive Blood and Cancer Center, Bakersfield, CA; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Kyiv City Clinical Oncology Center, Kyiv, Ukraine; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, New York, NY; University of California, Los Angeles Medical Center, Los Angeles, CA.

J Clin Oncol 33, 2015 (suppl; abstr 571)

Efficacy and safety of first-line palbociclib plus letrozole compared with letrozole alone in patients aged ≥ 65 years with estrogen receptor-positive, HER2-negative advanced breast cancer: A subgroup analysis by age of the PALOMA-1/TRIO-18 trial.

Author(s): **John Crown**, **Richard S. Finn**, Johannes Ettl, Katalin Boer, Ravi Patel, Anu Thummala, Sophia Randolph, Sindy Kim, Xin Huang, Sashi Nadanaciva, Patrick Schnell, Cynthia Huang Bartlett, Dennis J. Slamon;

Irish Cooperative Oncology Research Group, Dublin, Ireland; University of California, Los Angeles Medical Center, Los Angeles, CA; Technical University of Munich, Munich, Germany; Szent Margit Korhaz, Onkologia, Budapest, Hungary; Comprehensive Blood and Cancer Center, Bakersfield, CA; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, Groton, CT; Pfizer Oncology, New York, NY; School of Medicine/Translational Oncology Research Laboratory, University of California, Los Angeles, Los Angeles, CA.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr 572)

The effect of palbociclib (P) in combination with letrozole (L) on bone metastases in women with ER+/HER2- metastatic breast cancer (MBC): Subanalysis from a randomized phase II study.

Author(s): **Richard S. Finn**, **John Crown**, Istvan Lang, Sergey O. Kulyk, Marcus Schmidt, Ravi Patel, Anu Thummala, Igor Bondarenko, Sophia Randolph, Sindy Kim, Xin Huang, Erling Donnelly, Cynthia Huang Bartlett, Dennis J. Slamon;

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Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr 575)

Clinical efficacy and safety profile of palbociclib (P) in combination with letrozole (L) as first-line treatment in patients (pts) with ER+ and HER2- advanced breast cancer (ABC) who have not received any systemic treatment (ST): A subgroup analysis of PALOMA-1/TRIO-18.

Author(s): **Richard S. Finn**, **John Crown**, Johannes Ettl, Tamas Pinter, Anu Thummala, Yaroslav V. Shparyk, Ravi Patel, Sophia Randolph, Sindy Kim, Xin Huang, Yuqiu Jiang, Cynthia Huang Bartlett, Dennis J. Slamon; University of California, Los Angeles Medical Center, Los Angeles, CA; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; Technical University of Munich, Munich, Germany; Petz Aladar Megyei Oktato Korhaz, Győr, Hungary; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Lviv State Oncologic Regional Treatment and Diagnostic Center, Lviv, Ukraine; Comprehensive Blood and Cancer Center, Bakersfield, CA; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, New York, NY; School of Medicine/Translational Oncology Research Laboratory, University of California, Los Angeles, Los Angeles, CA.

Impact score: 18.428

Publications in 2015

Peer Reviewed Papers Published

J Clin Oncol 33, 2015 (suppl; abstr 1071)

Enzalutamide: A new hormonal treatment for triple-negative breast cancer?

Author(s): Francesco Caiazza, Alyson Murray, Stephen F. Madden, Naoise C Synnott, **Norma O'Donovan, John Crown**, Michael J. Duffy;
Education and Research Centre, St.Vincent's University Hospital and School of Medicine and Medical Science, University College Dublin, Dublin, Ireland; Molecular Therapeutics for Cancer Ireland, National Institute for Cellular Biotechnology, Dublin City University, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; Clinical Research Centre, St.Vincent's University Hospital and School of Medicine and Medical Science, University College Dublin, Dublin, Ireland.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr e12517)

Exome sequencing of an Irish familial breast cancer family.

Author(s): Judith Conroy, Sean Ennis, C. Nolan, R. M. Clarke, Eileen Berkley, Dhafir Alazawi, E. M. Connolly, Terence Boyle, **M. John Kennedy, David J. Gallagher**;
University College Dublin, Dublin, Ireland; St. James's Hospital, Dublin, Ireland; St. James Hospital, Dublin, Ireland; **ICORG, Dublin, Ireland**.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr 614)

Neuromedin U to increase IL-6 levels and to expand cancer stem cells in HER2-positive breast cancer cells.

Author(s): Vanesa Gabriela Martinez, Sweta Rani, Claire Corcoran, **John Crown, Lorraine O'Driscoll**;
School of Pharmacy & Pharmaceutical Sciences & Trinity Biomedical Sciences Institute, Trinity College Dublin, Dublin, Ireland; School of Pharmacy and Pharmaceutical Sciences & Trinity Biomedical Sciences Institute, Trinity College Dublin, Dublin, Ireland; School of Pharmacy & Pharmaceutical Sciences & Trinity Biomedical Sciences Institute, Trinity College, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**.

Impact score: 18.428

Gastrointestinal

J Clin Oncol 33, 2015 (suppl; abstr e15282)

Correlation of the SOX9 FGFR2b feed forward loop with prognostic variants and survival in resected pancreatic cancer.

Author(s): Shereen Rafee, **Ray McDermott**, Niall Swan, Maire Lavelle, Brianan McGovern, Jean Murphy, **Fergal C Kelleher**;
St. James's Hospital, Dublin, Ireland; **ICORG, Dublin, Ireland**; St. Vincent's University Hospital, Dublin, Ireland.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl 3; abstr 615)

Mutational analysis of clinically relevant cancer related genes in colorectal cancer.

Author(s): Aine O'Reilly, Colin Barr, Aoife Carr, Elaine Kay, Susan Kennedy, **Ray McDermott, William Grogan, David William Fennelly, Oscar S. Breathnach**, Des C Winter, Deborah A McNamara, **Fergal C Kelleher, John Crown, Bryan Hennessy**, Sinead Toomey;
Beaumont Hospital, Dublin, Ireland; Department of Pathology and Laboratory Services, St. Vincent's University Hospital, Dublin, Ireland; Medical Oncology, Royal College of Surgeons in Ireland, Dublin, Ireland; St. Vincent's University Hospital, Dublin, Ireland; **ICORG, Dublin, Ireland**; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Centre for Colorectal Disease, St. Vincent's University Hospital, Dublin, Ireland; Department of Colorectal Surgery, Beaumont Hospital, Dublin, Ireland; **Irish Clinical Oncology Research Group** and Molecular Therapeutics for Cancer Ireland, Dublin, Ireland.

Impact score: 18.428

Publications in 2015

Peer Reviewed Papers Published

J Clin Oncol 33, 2015 (suppl 3; abstr 525)

Routine screening for mismatch repair proteins: The impact on genetic testing.

Author(s): Grainne O'Kane, Delia Flannery, Katrina O'Connor, Carmel Nolan, Michael P. Farrell, Andrew J. Green, Brian Meighan, Paul McCormick, **M. John Kennedy**, C. Muldoon, David James Gallagher;
St. James's Hospital, Dublin, Ireland; Department of Cancer Genetics, Dublin, Ireland; Mater Private Hospital and Mater Misericordiae University Hospital, Dublin, Ireland; School of Medicine and Medical Science, University College Dublin, Dublin, Ireland; **ICORG, Dublin, Ireland**; Mater Hospital, St. James's Hospital, University College Dublin, Dublin, Ireland.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr e16121)

Impact of body composition parameters on clinical outcomes in patients with metastatic castration-resistant prostate cancer treated with docetaxel

Author(s): Derek Gerard Power, Samantha Cushen, Ray McDermott, Marvin Chang Jui Lim, Peter Mcneaney, Louise Daly, Brendan Griffin, Kevin P Murphy, Aoife M Ryan; Mercy University Hospital, Cork, Ireland; University College Cork, Cork, Ireland; **ICORG, Dublin, Ireland**; Tallaght Hospital, Dublin, Ireland; School of Pharmacy, University College Cork, Cork, Ireland; Department of Radiology, Mercy University Hospital, Cork, Ireland

Impact score: 18.428

Genitourinary

ICORG 14-06: ANZUP ENZAMET Trial (ANZUP 1304)

J Clin Oncol 33, 2015 (suppl; abstr TPS5077)

Randomised phase 3 trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer: the ANZUP ENZAMET Trial (ANZUP 1304).

Author(s): Ian D. Davis, Martin R. Stockler, Andrew James Martin, **Vittorio Marchesin, Olwyn Deignan, Ray McDermott**, Wendy R. Parulekar, Scott A. North, Barbara Graham, Anne Poh Long, Felicia T Roncolato, Sonia Yip, Wendy Hague, Carlo Dazo, Xanthi Coskinas, Christopher Sweeney; Monash University Eastern Health Clinical School, Box Hill, Australia; NHMRC Clinical Trials Centre, The University of Sydney, Sydney, Australia; NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia; **ICORG, Dublin, Ireland**; NCIC Clinical Trials Group, Cancer Research Institute, Queen's University, Kingston, ON, Canada; Cross Cancer Institute, Edmonton, AB, Canada; Queen's University, Kingston, ON, Canada; Royal Perth Hospital, Willetton, WA, Australia; NHMRC Clinical Trials Centre, Camperdown, Australia; Sydney Catalyst Translational Cancer Research Centre, Sydney, Australia; NHMRC Clinical Trials Centre, Sydney, Australia; Dana-Farber Cancer Institute, Boston, MA.

Impact score: 18.428

ICORG 14-07: ANZUP ENZARAD Trial (ANZUP 1303)

J Clin Oncol 33, 2015 (suppl; abstr TPS5078)

Randomised phase 3 trial of enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised prostate cancer: The ANZUP ENZARAD Trial (ANZUP 1303).

Author(s): Scott G. Williams, Ian D. Davis, Christopher Sweeney, Martin R. Stockler, Andrew James Martin, **Vittorio Marchesin, Olwyn Deignan, Ray McDermott**, Anne Poh Long, Felicia T Roncolato, Sonia Yip, Wendy Hague, Emily Tu, Xanthi Coskinas, Paul Linh Nguyen; Peter MacCallum Cancer Centre, East Melbourne, Australia; Monash University Eastern Health Clinical School, Box Hill, Australia; Dana-Farber Cancer Institute, Boston, MA; NHMRC Clinical Trials Centre, The University of Sydney, Sydney, Australia; NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia; **ICORG, Dublin, Ireland**; Royal Perth Hospital, Willetton, WA, Australia; NHMRC Clinical Trials Centre, Camperdown, Australia; Sydney Catalyst Translational Cancer Research Centre, Sydney, Australia; NHMRC Clinical Trials Centre, Sydney, Australia; Brigham and Women's Hospital, Dana-Farber Cancer Institute, Boston, MA.

Impact score: 18.428

Publications in 2015

Peer Reviewed Papers Published

ICORG 06-15: ICORG Proteomic Prostate study:

J. Proteome Res., 2015, 14 (7), pp 2769–2783

DOI: 10.1021/acs.jproteome.5b00041

Publication Date (Web): May 26, 2015

Discovery and Longitudinal Evaluation of Candidate Protein Biomarkers for Disease Recurrence in Prostate Cancer

Claire L. Tonry,^{*,†,§} Darren Doherty[†], **Carmel O'Shea[‡]**, Brian Morrissey[†], Lisa Staunton[†], Brian Flatley[†], **Aoife Shannon[‡]**, John Armstrong[‡], and **Stephen R. Pennington[†]**

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Impact score: 4.245

J Clin Oncol 33, 2015 (suppl; abstr e16121)

Impact of body composition parameters on clinical outcomes in patients with metastatic castration-resistant prostate cancer treated with docetaxel

Author(s): Derek Gerard Power, Samantha Cushen, **Ray McDermott**, Marvin Chang Jui Lim, Peter Mceneaney, Louise Daly, Brendan Griffin, Kevin P Murphy, Aoife M Ryan; Mercy University Hospital, Cork, Ireland; University College Cork, Cork, Ireland; **ICORG, Dublin, Ireland**; Tallaght Hospital, Dublin, Ireland; School of Pharmacy, University College Cork, Cork, Ireland; Department of Radiology, Mercy University Hospital, Cork, Ireland.

Impact score: 18.428

Gynaecological

ICORG 09-03: AGO-OVAR16 study

Gynecol Oncol. 2015 Dec 29. pii: S0090-8258(15)30230-4.

DOI: 10.1016/j.ygyno.2015.12.027. [Epub ahead of print]

BRCA1/2 mutations associated with progression-free survival in ovarian cancer patients in the AGO-OVAR 16 study.

Harter P¹, Johnson T², Berton-Rigaud D³, Park SY⁴, Friedlander M⁵, Del Campo JM⁶, Shimada M⁷, Forget F⁸, Mirza MR⁹, Colombo N¹⁰, Zamagni C¹¹, Chan JK¹², Imhof M¹³, Herzog TJ¹⁴, **O'Donnell D¹⁵**, Heitz F¹⁶, King K¹⁷, Stinnett S¹⁷, Barrett C¹⁸, Jobanputra M¹⁹, Xu CF2, du Bois A¹⁶.

Author information: ¹Department of Gynecology & Gynecologic Oncology, Kliniken Essen Mitte, Essen, Germany. Electronic address: p.harter@gmx.de. ²GlaxoSmithKline, Gunnels Wood Road, Stevenage SG1 2NY, UK. ³Institut de Cancérologie de l'Ouest, Centre René Gauducheau, Saint-Herblain, France. ⁴National Cancer Center, Goyang, Republic of Korea. ⁵The Prince of Wales Clinical School University of New South Wales, Randwick, NSW, Australia. ⁶Department of Medical Oncology, Vall d'Hebron University Hospital, Barcelona, Spain. ⁷Department of Obstetrics and Gynecology, Tottori University School of Medicine, Nishimachi, Yonago, Japan. ⁸Centre Hospitalier de l'Ardenne, Libramont, Belgium. ⁹Department of Oncology, Rigshospitalet, Copenhagen, Denmark. ¹⁰Gynecologic Oncology, University of Milan-Bicocca and European Institute of Oncology, Milan, Italy. ¹¹S. Orsola-Malpighi University Hospital, Bologna, Italy. ¹²California Pacific and Palo Alto Sutter Cancer Research Institute, San Francisco, CA, USA. ¹³Regional Hospital Korneuburg, Medical University of Vienna, Austria. ¹⁴University of Cincinnati Cancer Institute, Cincinnati, OH, USA. ¹⁵**All Ireland Cooperative Oncology Research Group, Dublin, Ireland.** ¹⁶Department of Gynecology & Gynecologic Oncology, Kliniken Essen Mitte, Essen, Germany. ¹⁷Parexel International, Durham, NC, USA. ¹⁸Novartis Pharma AG, Basel, Switzerland. ¹⁹Biogen Idec, Berkshire, UK.

Impact score: 3.774

Haematology & Lymphoma:

ICORG 07-01: CLL study

December 3, 2015; Blood: 126 (23)

Detection of Mutations in SF3B1 in Chronic Lymphocytic Leukaemia Patients By Reverse Transcription (Rt) Polymerase Chain Reaction and High Resolution Melt Curve Analysis, an Alternative Approach to Next Generation Sequencing for Routine Molecular Diagnostic Laboratories?

Fiona M Quinn, PhD¹, Deirdre Waldron, M.Sc.¹, David O'Brien, FAMLs², Johanna Kelly, BSc³, **Kathleen Scott, PhD⁴**, Amjad Hayat, MBBS, MRCP, FRCPath, PhD⁵, and **Elisabeth A. Vandenberghe, MB, PhD⁶**

Author Affiliations: ¹ Cancer Molecular Diagnostics Dept., St. James's Hospital, Dublin, Ireland

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⁶ Dept. of Cancer Molecular Diagnostics and Haematology, St. James's Hospital, Dublin, Ireland.

Impact score: 10.452

Lung

ICORG 12-25: ETOP 3-1 EMPHASIS study

J Clin Oncol 33, 2015 (suppl; abstr 8049)

Randomized phase III trial of erlotinib vs. docetaxel in patients with advanced squamous cell non-small cell lung cancer (SqNSCLC) failing first line platinum based doublet chemotherapy stratified by VeriStrat Good vs VeriStrat Poor: The European Thoracic Oncology Platform (ETOP) EMPHASIS trial.

Author(s): Solange Peters, Egbert F. Smit, Urania Dafni, Santiago Ponce Aix, Bartomeu Massuti, Oliver Gautschi, **Linda Coate**, Ana López Martín, Robbert van Heemst, Thierry Berghmans, Peter Meldgaard, Manuel Cobo Dols, Javier Garde Noguera, Irene Claudia Floriani, Marie Kassapian, Yojena Chittazhathu Kurian Kuruvilla, Adriana Gasca-Ruchti, Christoph Zielinski, Vanesa Gregorc, Rolf A. Stahel, EMPHASIS Collaborative Group; University Hospital of Lausanne (CHUV), Lausanne, Switzerland; Cancer Center Amsterdam, Department of Pulmonary Diseases, VU University Medical Center, Amsterdam, Netherlands; Frontier Science Foundation-Hellas & University of Athens, Athens, Greece; Hospital 12 de Octubre, Madrid, Spain; Alicante University Hospital, Alicante, Spain; Cantonal Hospital Lucerne and Swiss Group for Clinical Cancer Research SAKK, Luzern, Switzerland; **Mid-Western Regional Hospital, Limerick, Ireland**; Hospital Universitario Severo Ochoa, Madrid, Spain; Deventer Ziekenhuis, Deventer, Netherlands; Institut Jules Bordet, Brussels, Belgium; Aarhus University Hospital, Aarhus, Denmark; Hospital Universitario Regional y Virgen de la Victoria Málaga, Málaga, Spain; Hospital Arnau Vilanova Valencia, Valencia, Spain; Istituto di Ricerche Farmacologiche Mario Negri, Milano, Italy; Frontier Science Foundation-Hellas, Athens, Greece; European Thoracic Oncology Platform (ETOP) Coordinating Office, Bern, Switzerland; Medical University Vienna - General Hospital, Vienna, Austria; Department of Oncology, San Raffaele Scientific Institute, Milan, Italy; University Hospital Zurich, Zurich, Switzerland

[Dr Linda Coate was ICORG Chief Investigator for this study on behalf of the ICORG participating Investigators]

Impact score: 18.428

ICORG 13-19: ETOM-1 study

J Clin Oncol 33, 2015 (suppl; abstr 6536)

Emergency Diagnosis of Lung Cancer: A European Problem

Thomas Newsom-Davis^{1*}, Rosanna Beradi², **Norah Cassidy**³, **Linda Coate**³, Ana Figueiredo⁴, Gabriele Gamerith⁵, Gareth Giblin³, Marko Jakopović⁶, Cor van der Leest⁸, Damien Pouessel⁸, Marcello Tiseo⁹, Anne-Claire Toffart¹⁰ and Cathy Hughes¹

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¹Chelsea & Westminster Hospital, London, UK; ²Università Politecnica Marche, Ancona, Italy; ³**All Ireland Co-operative Oncology Research Group, Dublin, Ireland**; ⁴Porto, Portugal; ⁵Medizinische Universität Innsbruck, Austria; ⁶University Hospital Centre Zagreb, Croatia; ⁷Amphia Hospital, Breda, Netherlands; ⁸Hopital Saint-Louis, Paris, France; ⁹University Hospital of Parma, Italy; ¹⁰Centre Hospitalier Universitaire de Grenoble, France.

Impact score: 18.428

ICORG 12-24: ETOP 2-11 BELIEF study

Eur J Cancer 51 (suppl 3):S711

DOI: [http://dx.doi.org/10.1016/S0959-8049\(15\)30068-X](http://dx.doi.org/10.1016/S0959-8049(15)30068-X)

A phase II trial of erlotinib (E) and bevacizumab (B) in patients with advanced non-small-cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations with and without T790M mutation. The Spanish Lung Cancer Group (SLCG) and the European Thoracic Oncology Platform (ETOP) BELIEF trial.

Stahel RA, Dafni U, Gautschi O, Felip E, Curioni-Fontecedro A, Peters S, Massutí B, Cardenal F, Aix SP, Früh M, Pless M, Popat S, Kotsakis A, **Cuffe S**, Bidoli P, Favaretto A, Carcereny E, Sanchez Ronco M, Molina MA, Rosell R.

Impact score: 5.417

Publications in 2015

Peer Reviewed Papers Published

J Clin Oncol 33, 2015 (suppl; abstr 11077)

Protein tyrosine phosphatase non receptor 11 (PTPN11/Shp2) as a driver oncogene and a novel therapeutic target in non-small cell lung cancer (NSCLC).

Author(s): Yasir Elamin, Sinead Toomey, Aoife Carr, Kathy Gately, Shereen Rafee, **William Grogan, Patrick G. Morris, Oscar S. Breathnach, John Crown, Kenneth O'Byrne, Bryan Hennessy**; Education Centre Beaumont Hospital, Dublin, Ireland; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Medical Oncology, Royal College of Surgeons in Ireland, Dublin, Ireland; Trinity College Dublin & St. James's Hospital, Dublin, Ireland; St. James's Hospital, Dublin, Ireland; Beaumont Hospital, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; Princess Alexandra Hospital and Queensland University of Technology, Brisbane, Australia; Royal College of Surgeons in Ireland, Dublin, Ireland.

Impact score: 18.428

J Clin Oncol 33, 2015 (suppl; abstr 11078)

Identifying driver mutations in squamous cell lung cancer (SCC): The Lung Cancer Genomics Ireland (LCGI) study.

Author(s): Shereen Rafee, Sinead Toomey, Yasir Elamin, Aoife Carr, Kathy Gately, **Stephen Finn, Siobhan Nicholson, Sinead Cuffe, John Crown, Patrick G. Morris, William Grogan, Oscar S. Breathnach**, Elaine Kay, Anthony O'Grady, **Bryan Hennessy**, Kenneth O'Byrne; St. James's Hospital, Dublin, Ireland; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Education Centre Beaumont Hospital, Dublin, Ireland; Medical Oncology, Royal College of Surgeons in Ireland, Dublin, Ireland; Trinity College Dublin & St. James's Hospital, Dublin, Ireland; St. James's Hospital, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; Beaumont Hospital, Dublin, Ireland; Department of Histopathology, Beaumont Hospital, Dublin, Ireland; Dept of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Princess Alexandra Hospital and Queensland University of Technology, Brisbane, Australia.

Impact score: 18.428

Melanoma

J Clin Oncol 33, 2015 (suppl; abstr e20091)

Pattern of systemic relapse and outcome of patients (pts) with ocular melanoma (OM) after curative local therapy (Rx): Results of an active surveillance strategy.

Author(s): Niamh Coleman, **Giuseppe Gullo**, Ciara Marie Kelly, Megan Grealley, Barry Power, Susan Kennedy, Emir Hoti, Noel Horgan, **John P Crown**; Beaumont Hospital, Marino, Ireland; St Vincent's University Hospital, Dublin, Ireland; Mater Misericordiae University Hospital, Dublin, Ireland; Beaumont Hosp, Dublin, Ireland; St. Vincent's University Hospital, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**.

Impact score: 18.428

Publications in 2015

Posters/oral poster presentations

Breast

Meeting: European Cancer Congress 2015 in Vienna, Austria.

ICORG 08-10: TC-AVASTIN study

Poster number 1964

Pilot study of bevacizumab (Bev) in combination with docetaxel (T) and cyclophosphamide (C) as adjuvant treatment (AdjRx) for patients (pts) with early stage (ES) HER-2 normal breast cancer (BrCa) ICORG 08-10.

G.Gullo¹, J.Kennedy², O.Beathnach³, J.McCaffrey⁴, M.Keane⁵, M.Martin⁶, R.Gupta⁷, G.Leonard⁸, P.Calvert⁹, P.Donnellan⁵, 7.Walshe¹, E.McDermott⁹, S.Cairney¹⁰, R.Bose¹, K.Scott¹¹, A.Hernando¹¹, I.Parker¹², D.Tryfonopoulos¹, B.Moulton¹¹, J.Crown¹. ¹St. Vincent's University Hospital, medical Oncology, Dublin, Ireland; ²St.James' Hospital, Medical Oncology, Dublin Ireland; ³Beaumont Hospital, Medical Oncology, Dublin, Ireland; ⁴Mater Misericordiae University Hospital, Medical Oncology, Dublin, Ireland; ⁵Galway University Hospital, Medical Oncology, Galway, Ireland; ⁶Sligo Regional Hospital, Medical Oncology, Sligo, Ireland; ⁷University Hospital Limerick, Medical Oncology, Limerick, Ireland; ⁸Waterford Regional Hospital, medical Oncology, Waterford, Ireland; ⁹St. Vincent's University Hospital, General and Breast Surgery, Dublin, Ireland; ¹⁰St Vincent's University Hospital, Oncology Clinical Research Unit, Dublin, Ireland, ¹¹ICORG, Oncology Clinical Research, Dublin, Ireland; ¹²ICORG, Medical Statistics, Dublin, Ireland.

Publications in 2015

Posters/oral poster presentations

Meeting: 2015 San Antonio Breast Cancer Symposium

ICORG 01-03: BCIRG 006 study

Poster Publication Number: S5-04

Ten year follow-up of the BCIRG-006 trial comparing doxorubicin plus cyclophosphamide followed by docetaxel (AC@T) with doxorubicin plus cyclophosphamide followed by docetaxel and trastuzumab (AC@TH) with docetaxel, carboplatin and trastuzumab (TCH) in HER2+ early breast cancer patients

Slamon DJ J, Eiermann W, Robert NJ J, Giermek J, Martin M, Jasiowka M, Mackey JR R, Chan A, Liu M-C, Pinter T, Valero V, Falkson C, Fornander T, Shiftan TA A, Bensfia S, Hitier S, Xu N, Bée-Munteanu V, Drevot P, Press MF F and **Crown J**.
 UCLA, Los Angeles, CA; GBG, Munchen, Germany; USO, The Woodlands, TX; Maria Sklodowska-Curie Centre, Warsaw, Poland; GEICAM, Madrid, Spain; Maria Sklodowska-Curie Memorial Cancer Institute, Krakow, Poland; Cross Cancer Institute, Edmonton, Canada; Breast Cancer Research Centre - WA & Curtin University, Perth, Australia; Sun Yat-Sen Cancer Center, Taipei, Taiwan; Petz Aladar Megyei Oktato Korhaz Onkoradiologica, Gyor, Hungary; The University of Texas MD Anderson Cancer Centre, Houston, TX; University of Alabama, Birmingham, AL; Karolinska University Hospital, Stockholm, Sweden; Sharp Memorial Hospital, San Diego, CA; Sanofi, Cambridge; Sanofi, Chilly-Mazarin, France; Genentech, South San Francisco, CA; TRIO, Paris, France; USC/ Norris Comprehensive Cancer Center, Los Angeles, CA and **ICORG, Dublin, Ireland**.

Meeting: 2015 ASCO Annual Meeting

ICORG 06-31: TAILORx study

Session Type and Session Title: Poster Session, Breast Cancer—HER2/ER

Category: Breast Cancer—HER2/ER,

Subcategory: ER+

Abstract Number: 533

Poster Board Number: Board #21

Recurrence score and clinicopathologic characteristics of TAILORx participants by race and ethnicity.

Author(s): Maria M Zlobinsky Rubinstein, Robert James Gray, Joseph A. Sparano, JoAnne Zujewski, Timothy Joseph Whelan, Kathy S. Albain, Daniel F. Hayes, Charles E. Geyer, Elizabeth Claire Dees, Edith A. Perez, **Maccon M. Keane**, Carlos Vallejos, Timothy F. Goggins, Ingrid A. Mayer, Adam Brufsky, Deborah Toppmeyer, Virginia G. Kaklamani, James Norman Atkins, Jeffrey L. Berenberg, George W. Sledge;

Montefiore Medical Center, Bronx, NY; Dana-Farber Cancer Inst, Boston, MA; National Institutes of Health, Bethesda, MD; Cancer Care Ontario, Hamilton, ON, Canada; NRG Oncology/NSABP, SWOG, and Loyola University Chicago Stritch School of Medicine, Maywood, IL; University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; Virginia Commonwealth University Massey Cancer Center, Richmond, VA; UNC Chapel Hill, Chapel Hill, NC; Mayo Clinic, Jacksonville, FL; **West of Ireland Cancer Center, Galway, Ireland**; Instituto Nacional de Enfermedades Neoplasicas, Lima, Peru; Fox Valley Hem Onc, Appleton, WI; Vanderbilt-Ingram Cancer Center, Nashville, TN; NRG Oncology/NSABP, and Magee Women's Hospital, Pittsburgh, PA; The Cancer Inst of New Jersey, New Brunswick, NJ; Northwestern University Division of Hematology/Oncology, Chicago, IL; Southeastern Medcl Ctr, Goldsboro, NC; Tripler Army Medcl Ctr, Honolulu, HI; Stanford Univ Med Ctr, Stanford, CA

[Dr Maccon Keane was ICORG Chief Investigator for this study on behalf of the ICORG participating Investigators]

Meeting: 2015 San Antonio Breast Cancer Symposium

ICORG 06-31: TAILORx study

Poster Publication Number: P2-08-01

Prospective trial of endocrine therapy alone in patients with estrogen receptor positive, HER2-negative, node-negative breast cancer: Results of the TAILORx low risk registry

Sparano JA A, Gray RJ J, Makower DF F, Pritchard KI I, Albain KS S, Hayes DF F, Geyer Jr CE E, Dees EC C, Perez EA A, Olson Jr JA A, Zujewski J, **Keane MM M**, Gomez Moreno HL L, Reddi RP P, Goggins TF F, Mayer IA A, Brufsky AM M, Toppmeyer DL L, Kaklamani VG G, Atkins JN N, Berenberg JL L and Sledge Jr GW W. Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY; Dana Farber Cancer Institute, Boston, MA; Sunnybrook Research Institute, Toronto, ON, Canada; Loyola University Medical Center, Maywood, IL; University of Michigan, Ann Arbor, MI; Virginia Commonwealth University School of Medicine and the Massey Cancer Center, Richmond, VA; University of North Carolina, Chapel Hill, NC; Mayo Clinic, Jacksonville, FL; Duke University Medical Center, Durham, NC; National Cancer Institute, Bethesda, MD; **University College Hospital, Galway, Ireland**; Oncosalud SAC, Lima, Peru; Via Christi Regional Medical Center, Wichita, KS; Fox Valley Hematology and Oncology, Appleton, WI; Vanderbilt University, Nashville, TN; University of Pittsburgh, Pittsburgh, PA; Rutgers Cancer Institute of New Jersey, New Brunswick, NJ; Northwestern University, Chicago, IL; Southeast Clinical Oncology Research Consortium, Goldsboro, NC; University of Hawaii Cancer Center, Honolulu, HI and Stanford University, Stanford, CA.

[Dr Maccon Keane was ICORG Chief Investigator for this study on behalf of the ICORG participating Investigators]

Publications in 2015

Posters/oral poster presentations

Meeting: 2015 San Antonio Breast Cancer Symposium
ICORG 14-12: Medivation MDV-3100-12 study, NCT01889238
Poster Publication Number: P3-07-25

Improved clinical outcomes on enzalutamide observed in patients with PREDICT AR+ triple-negative breast cancer: prognosis or prediction?

Miller K, Krop I, Schwartzberg L, Abramson V, Garcia-Estevez L, Eakle J, Nanda R, Yardley D, Ademuyiwa F, Chan S, **Crown J**, Danso M, Gelmon K, Ma L, Martinez-Janez N, Gradishar W, Steinberg J, Tudor IC, Uppal H, Paton VE E, Parker J, Hudis CA A and Traina TA A.
Indiana University School of Medicine, Indianapolis, IN; Dana-Farber Cancer Institute, Boston, MA; The University of Tennessee Health Science Center, Memphis, TN; Vanderbilt Ingram Cancer Center, Nashville, TN; Comprehensive Cancer Center Clara Campal, Madrid, Spain; Florida Cancer Specialists, Sarasota, FL; The University of Chicago Medicine, Chicago, IL; Tennessee Oncology PLCC, Nashville, TN; Washington University School of Medicine, St. Louis, MO; Brigham and Women's Hospital, Boston, MA; **All Ireland Co-operative Oncology Research Group, Dublin, Ireland**; Virginia Oncology, Norfolk, VA; BC Cancer Agency, Vancouver, BC, Canada; Rocky Mountain Cancer Centers, Lakewood, CO; Hospital de Madrid Norte Sanchinarro, Madrid, Spain; Northwestern University Feinberg School of Medicine, Chicago, IL; Astellas Pharma Global Development, Inc., Northbrook, IL; Medivation, Inc., San Francisco, CA; UNC-Chapel Hill, Chapel Hill, NC and Memorial Sloan Kettering Cancer Center, NY, NY.

Meeting: 2015 San Antonio Breast Cancer Symposium
ICORG 09-01: PALOMA-1/ TRIO-18 study
Publication Number: P4-13-02

Treatment patterns of post-disease progression in the PALOMA-1/TRIO-18 trial

Finn RS S, Crown JP P, Ettl J, Pinter T, Thummala A, Shparyk Y, Patel R, Randolph S, Kim S, Huang X, Nadanaciva S, Huang, Bartlett C and Slamon DJ J.
University of California Los Angeles, Los Angeles, CA; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; Technical University of Munich, Munich, Germany; Petz Aladar Megyei Oktató Kórház, Győr, Hungary; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Lviv State Oncologic Regional Treatment and Diagnostic Center, Lviv, Ukraine; Comprehensive Blood and Cancer Center, Bakersfield, CA; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, Groton, CT and Pfizer Oncology, NY, NY.

Meeting: 2015 ASCO Annual Meeting
ICORG 09-01: PALOMA-1/ TRIO-18 study
Session Type and Session Title: Poster Session, Breast Cancer—HER2/ER
Subcategory: ER+
Abstract Number: 570
Poster Board Number: Board #58

Long-term safety profile of palbociclib (P) in combination with letrozole (L) as first-line treatment for postmenopausal patients with ER+ and HER2- advanced breast cancer (ABC) (PALOMA-1/TRIO-18).

Author(s): Dennis J. Slamon, **John Crown**, Istvan Lang, Sergey O. Kulyk, Marcus Schmidt, Ravi Patel, Anu Thummala, Nataliya L. Voytko, Sophia Randolph, Cindy Kim, Xin Huang, Cynthia Huang Bartlett, Patrick Schnell, **Richard S. Finn**;
School of Medicine/Translational Oncology Research Laboratory, University of California, Los Angeles, Los Angeles, CA; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; National Institute of Oncology, Budapest, Hungary; Municipal Treatment-and-Prophylactic Institution, Donetsk, Ukraine; University Hospital Mainz, Mainz, Germany; Comprehensive Blood and Cancer Center, Bakersfield, CA; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Kyiv City Clinical Oncology Center, Kyiv, Ukraine; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, New York, NY; University of California, Los Angeles Medical Center, Los Angeles, CA

Publications in 2015

Posters/oral poster presentations

Meeting: 2015 ASCO Annual Meeting

ICORG 09-01: PALOMA-1/ TRIO-18 study

Session Type and Session Title: Poster Session, Breast Cancer—HER2/ER

Subcategory: ER+

Abstract Number: 571

Poster Board Number: Board #59

Efficacy and safety of first-line palbociclib plus letrozole compared with letrozole alone in patients aged ≥ 65 years with estrogen receptor-positive, HER2-negative advanced breast cancer: A subgroup analysis by age of the PALOMA-1/TRIO-18 trial.

Author(s): John Crown, Richard S. Finn, Johannes Ettl, Katalin Boer, Ravi Patel, Anu Thummala, Sophia Randolph, Sindy Kim, Xin Huang, Sashi Nadanaciva, Patrick Schnell, Cynthia Huang Bartlett, Dennis J. Slamon; **Irish Cooperative Oncology Research Group, Dublin, Ireland;** University of California, Los Angeles Medical Center, Los Angeles, CA; Technical University of Munich, Munich, Germany; Szent Margit Korhaz, Onkologia, Budapest, Hungary; Comprehensive Blood and Cancer Center, Bakersfield, CA; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, Groton, CT; Pfizer Oncology, New York, NY; School of Medicine/Translational Oncology Research Laboratory, University of California, Los Angeles, Los Angeles, CA

Meeting: 2015 ASCO Annual Meeting

ICORG 09-01: PALOMA-1/ TRIO-18 study

Session Type and Session Title: Poster Session, Breast Cancer—HER2/ER

Category: Breast Cancer—HER2/ER

Subcategory: ER+

Abstract Number: 572

Poster Board Number: Board #60

The effect of palbociclib (P) in combination with letrozole (L) on bone metastases in women with ER+/HER2- metastatic breast cancer (MBC): Subanalysis from a randomized phase II study.

Author(s): Richard S. Finn, John Crown, Istvan Lang, Sergey O. Kulyk, Marcus Schmidt, Ravi Patel, Anu Thummala, Igor Bondarenko, Sophia Randolph, Sindy Kim, Xin Huang, Erling Donnelly, Cynthia Huang Bartlett, Dennis J. Slamon; University of California, Los Angeles Medical Center, Los Angeles, CA;

Irish Cooperative Oncology Research Group, Dublin, Ireland; National Institute of Oncology, Budapest, Hungary; Municipal Treatment-and-Prophylactic Institution, Donetsk, Ukraine; University Hospital Mainz, Mainz, Germany; Comprehensive Blood and Cancer Center, Bakersfield, CA; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Dnipropetrovsk City Multiple-Discipline Clinical Hospital, Dnipropetrovsk, Ukraine; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, Boston, MA; Pfizer Oncology, New York, NY; School of Medicine/Translational Oncology Research Laboratory, University of California, Los Angeles, Los Angeles, CA

Meeting: 2015 ASCO Annual Meeting

ICORG 09-01: PALOMA-1/ TRIO-18 study

Session Type and Session Title: Poster Session, Breast Cancer—HER2/ER

Subcategory: ER+

Abstract Number: 575

Poster Board Number: Board #63

Clinical efficacy and safety profile of palbociclib (P) in combination with letrozole (L) as first-line treatment in patients (pts) with ER+ and HER2- advanced breast cancer (ABC) who have not received any systemic treatment (ST): A subgroup analysis of PALOMA-1/TRIO-18.

Author(s): Richard S. Finn, John Crown, Johannes Ettl, Tamas Pinter, Anu Thummala, Yaroslav V. Shparyk, Ravi Patel, Sophia Randolph, Sindy Kim, Xin Huang, Yuqiu Jiang, Cynthia Huang Bartlett, Dennis J. Slamon;

University of California, Los Angeles Medical Center, Los Angeles, CA; **Irish Cooperative Oncology Research Group, Dublin, Ireland;** Technical University of Munich, Munich, Germany; Petz Aladar Megyei Oktato Korhaz, Gyor, Hungary; Comprehensive Cancer Centers of Nevada, Las Vegas, NV; Lviv State Oncologic Regional Treatment and Diagnostic Center, Lviv, Ukraine; Comprehensive Blood and Cancer Center, Bakersfield, CA; Pfizer Oncology, La Jolla, CA; Pfizer Oncology, New York, NY; School of Medicine/Translational Oncology Research Laboratory, University of California, Los Angeles, Los Angeles, CA

Publications in 2015

Posters/oral poster presentations

Meeting: 2015 ASCO Annual Meeting

Category: Breast Cancer—Triple-Negative/Cytotoxics/Local Therapy

Subcategory: Triple-Negative Breast Cancer

Session Type and Session Title: Poster Session, Breast Cancer—Triple-Negative/Cytotoxics/Local Therapy

Abstract Number: 1071

Enzalutamide: A new hormonal treatment for triple-negative breast cancer?

Author(s): Francesco Caiazza, Alyson Murray, Stephen F. Madden, Naoise C Synnott, **Norma O'Donovan, John Crown**, Michael J. Duffy; Education and Research Centre, St.Vincent's University Hospital and School of Medicine and Medical Science, University College Dublin, Dublin, Ireland; Molecular Therapeutics for Cancer Ireland, National Institute for Cellular Biotechnology, Dublin City University, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; Clinical Research Centre, St.Vincent's University Hospital and School of Medicine and Medical Science, University College Dublin, Dublin, Ireland

Meeting: 2015 ASCO Annual Meeting

Session Type and Session Title: Poster Session, Breast Cancer—HER2/ER

Category: Breast Cancer—HER2/ER

Subcategory: HER2+

Abstract Number: 614

Poster Board Number: Board #104

Neuromedin U to increase IL-6 levels and to expand cancer stem cells in HER2-positive breast cancer cells.

Author(s): Vanesa Gabriela Martinez, Sweta Rani, Claire Corcoran, **John Crown, Lorraine O'Driscoll**; School of Pharmacy & Pharmaceutical Sciences & Trinity Biomedical Sciences Institute, Trinity College Dublin, Dublin, Ireland; School of Pharmacy and Pharmaceutical Sciences & Trinity Biomedical Sciences Institute, Trinity College Dublin, Dublin, Ireland; School of Pharmacy & Pharmaceutical Sciences & Trinity Biomedical Sciences Institute, Trinity College, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**

Meeting: 2015 ASCO Annual Meeting

Session Type and Session Title: Poster Session, Breast Cancer—HER2/ER

Subcategory: HER2+

Abstract Number: 615

Poster Board Number: Board #105

Effect of somatic mutations in the four genes of the HER family on occurrence in HER2-positive breast cancer, cell proliferation rates, and resistance to HER2-targeted therapies in vitro.

Author(s): Naomi Elster, Alex J Eustace, Yue Fan, Jarushka Naidoo, Joanna Fay, Elaine Kay, Aoife Carr, **Oscar S. Breathnach, Patrick G. Morris, William Grogan, Arnold D. Hill**, Colm Power, Michael J Allen, Susan Kennedy, **John Crown, William M. Gallagher**, Sinead Toomey, **Bryan Hennessy**;

Medical Oncology, Royal College of Surgeons in Ireland, Dublin, Ireland; Smurfit Institute of Genetics, Dublin, Ireland; Memorial Sloan Kettering Cancer Center, New York, NY; Pathology, Royal College of Surgeons in Ireland, Dublin, Ireland; Beaumont Hospital, Dublin, Ireland; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Beaumont Hospital, Royal College of Surgeons in Ireland, Dublin, Ireland; LRCP & SI MB BCh NUI, Beaumont Hospital, Dublin, Ireland; St. Vincent's University Hospital, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; University College Dublin, Dublin, Ireland; Medical Oncology, Royal College of Surgeons in Ireland and Beaumont Hospital, Dublin, Ireland.

Publications in 2015

Posters/oral poster presentations

Gastrointestinal

Meeting: European Cancer Congress 2015 in Vienna, Austria.
ICORG 09-11: PAVES 20080259 study (NCT00911170)

Poster number 1609

Final results from PAVES, a phase 3, randomized, double-blind, placebo-controlled study of pegfilgrastim in patients (pts) receiving first-line FOLFOX or FOLFIRI and bevacizumab for locally advanced or metastatic colorectal cancer (LA/mCRC) (NCT00911170)

T.Pinter¹, P.K.Morrow², A.Cesas³, A.Croitoru⁴, J.Decaestecker⁵, P.Gibbs⁶, Y.Hotko⁷, J.Jassem⁸, G.Kurteva⁹, J.Novotny¹⁰, **S.O'Reilly**¹¹, T.Salek¹², L.Khosrowshahi¹³, M.Reiner¹³, Z.Klippel², C.Blanke¹⁴.

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Meeting: 2015 ASCO Gastrointestinal Cancers Symposium

Session Type and Session Title: General Poster Session C: Cancers of the Colon, Rectum, and Anus

Category: Cancers of the Colon, Rectum, and Anus

Subcategory: Prevention, Diagnosis, and Screening

Abstract Number: 525

Poster Board Number: General Poster Session C (Board #A19)

Routine screening for mismatch repair proteins: The impact on genetic testing.

Author(s): Grainne O'Kane, Delia Flannery, Katrina O'Connor, Carmel Nolan, Michael P. Farrell, Andrew J. Green, Brian Meighan, Paul McCormick, **M. John Kennedy**, C. Muldoon, David James Gallagher; St. James's Hospital, Dublin, Ireland; Department of Cancer Genetics, Dublin, Ireland; Mater Private Hospital and Mater Misericordiae University Hospital, Dublin, Ireland; School of Medicine and Medical Science, University College Dublin, Dublin, Ireland; **ICORG, Dublin, Ireland**; Mater Hospital, St. James's Hospital, University College Dublin, Dublin, Ireland

Meeting: 2015 ASCO Gastrointestinal Cancers Symposium

Session Type and Session Title: General Poster Session C: Cancers of the Colon, Rectum, and Anus

Category: Cancers of the Colon, Rectum, and Anus

Subcategory: Translational Research

Abstract Number: 615

Poster Board Number: General Poster Session C (Board #C7)

Mutational analysis of clinically relevant cancer related genes in colorectal cancer.

Author(s): Aine O'Reilly, Colin Barr, Aoife Carr, Elaine Kay, Susan Kennedy, **Ray McDermott, William Grogan, David William Fennelly, Oscar S. Breathnach**, Des C Winter, Deborah A McNamara, **Fergal C Kelleher, John Crown, Bryan Hennessy**, Sinead Toomey; Beaumont Hospital, Dublin, Ireland; Department of Pathology and Laboratory Services, St. Vincent's University Hospital, Dublin, Ireland; Medical Oncology, Royal College of Surgeons in Ireland, Dublin, Ireland; St. Vincent's University Hospital, Dublin, Ireland; **ICORG, Dublin, Ireland**; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Centre for Colorectal Disease, St. Vincent's University Hospital, Dublin, Ireland; Department of Colorectal Surgery, Beaumont Hospital, Dublin, Ireland; **Irish Clinical Oncology Research Group** and Molecular Therapeutics for Cancer Ireland, Dublin, Ireland

Publications in 2015
Posters/oral poster presentations

Genitourinary

Meeting: 30th Annual Congress of the European Association of Urology, 2015

ICORG 02-04: EORTC 22991 study

Session title: Treatment of high risk and oligometastatic prostate cancer

Session type: Poster Session 84

Presentation type: Extended presentation

Date: Monday, 23 March 2015 from 15:45 to 17:15

Abstract ID number: AM15-0703

New Number: 1021

Abstract Title: Effect of 6 months of androgen deprivation therapy on progression-free survival and quality of life in localized T1b/T2aN0M0 prostate cancer

Authors: M. Bolla¹, P. Maingon², A.C.M. Van Den Bergh³, C. Carrie⁴, S. Villa⁵, P. Kitsios⁶, P. Poortmans⁷, S. Sundar⁸, E.M. Van Der Steen-Banasik⁹, **J. Armstrong**¹⁰, J-F. Bosset¹¹, F. Herrera¹², B. Pieters¹³, C. Coens¹⁴, L. Collette¹⁴

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Meeting: 2015 ASCO Annual Meeting

ICORG 14-06: ANZUP ENZAMET Trial (ANZUP 1304)

Poster Session, Genitourinary (Prostate) Cancer

Poster Board Number: Board #67a

Abstract Number: TPS5077

Randomised phase 3 trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer: the ANZUP ENZAMET Trial (ANZUP 1304).

Author(s): Ian D. Davis, Martin R. Stockler, Andrew James Martin, **Vittorio Marchesin, Olwyn Deignan, Ray McDermott**, Wendy R. Parulekar, Scott A. North, Barbara Graham, Anne Poh Long, Felicia T Roncolato, Sonia Yip, Wendy Hague, Carlo Dazo, Xanthi Coskinas, Christopher Sweeney; Monash University Eastern Health Clinical School, Box Hill, Australia; NHMRC Clinical Trials Centre, The University of Sydney, Sydney, Australia; NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia; **ICORG, Dublin, Ireland**; NCIC Clinical Trials Group, Cancer Research Institute, Queen's University, Kingston, ON, Canada; Cross Cancer Institute, Edmonton, AB, Canada; Queen's University, Kingston, ON, Canada; Royal Perth Hospital, Willetton, WA, Australia; NHMRC Clinical Trials Centre, Camperdown, Australia; Sydney Catalyst Translational Cancer Research Centre, Sydney, Australia; NHMRC Clinical Trials Centre, Sydney, Australia; Dana-Farber Cancer Institute, Boston, MA

Meeting: 2015 ASCO Annual Meeting

ICORG 14-07: ANZUP ENZARAD Trial (ANZUP 1303)

Session Type and Session Title: Poster Session, Genitourinary (Prostate) Cancer

Category: Genitourinary (Prostate) Cancer

Abstract Number: TPS5078

Poster Board Number: Board #67b

Randomised phase 3 trial of enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised prostate cancer: The ANZUP ENZARAD Trial (ANZUP 1303).

Author(s): Scott G. Williams, Ian D. Davis, Christopher Sweeney, Martin R. Stockler, Andrew James Martin, **Vittorio Marchesin, Olwyn Deignan, Ray McDermott**, Anne Poh Long, Felicia T Roncolato, Sonia Yip, Wendy Hague, Emily Tu, Xanthi Coskinas, Paul Linh Nguyen; Peter MacCallum Cancer Centre, East Melbourne, Australia; Monash University Eastern Health Clinical School, Box Hill, Australia; Dana-Farber Cancer Institute, Boston, MA; NHMRC Clinical Trials Centre, The University of Sydney, Sydney, Australia; NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia; **ICORG, Dublin, Ireland**; Royal Perth Hospital, Willetton, WA, Australia; NHMRC Clinical Trials Centre, Camperdown, Australia; Sydney Catalyst Translational Cancer Research Centre, Sydney, Australia; NHMRC Clinical Trials Centre, Sydney, Australia; Brigham and Women's Hospital, Dana-Farber Cancer Institute, Boston, MA

Publications in 2015

Posters/oral poster presentations

Lung

Meeting: 16th World Conference on Lung Cancer (WCLC) hosted by the International Association of the Study of Lung Cancer (IASLC) in Denver, USA.

ICORG 06-36: ECOG 1505 study
PLENARY SESSION PRESENTATION

Date: Sept 9, 2015

PLEN04.03 - Randomized Phase III Trial of Adjuvant Chemotherapy with or without Bevacizumab in Resected Non-Small Cell Lung Cancer (NSCLC): Results of E1505 (Now Available) (ID 1608)

H.A. Wakelee, S.E. Dahlberg, S.M. Keller, W.J. Tester, D.R. Gandara, S.L. Graziano, A. Adjei, N. Leighl, S.C. Aisner, J.M. Rothman, J. Patel, M.D. Sborov, **S.R. McDermott**, R. Perez-Soler, A.M. Traynor, C. Butts, T. Evans, L. Horn, S.S. Ramalingam, J. Schiller

'Study chair Heather A. Wakelee, MD (Stanford University) presented the results of trial E1505 today at the 2015 World Conference on Lung Cancer in Denver, Colorado. *This phase III trial, chosen by the International Association of the Study of Lung Cancer (IASLC) as one of the top four most significant lung cancer research findings for 2015*, found that adding the monoclonal antibody bevacizumab to chemotherapy treatment does not improve overall survival for patients with early stage non-small cell lung cancer. Visit the IASLC website to read the press release'.

Meeting: 2015 ASCO Annual meeting, Chicago, USA

ICORG 12-25: ETOP 3-1 EMPHASIS study

Session Type and Session Title: Poster Session, Lung Cancer—Non-Small Cell Metastatic

Abstract Number: 8049

Poster Board Number: Board #372

Citation: *J Clin Oncol* 33, 2015 (suppl; abstr 8049)

A randomized phase III trial of erlotinib versus docetaxel in patients with advanced squamous cell non-small cell lung cancer who failed first line platinum based doublet chemotherapy stratified by VeriStrat Good vs VeriStrat Poor.

Author(s): Solange Peters¹, Egbert F. Smit², Urania Dafni³, Santiago Ponce Aix⁴, Bartomeu Massutí⁵, Oliver Gautschi⁶, **Linda Coate**⁷, Ana López Martín⁸, R. van Heemst⁹, Thierry Berghmans¹⁰, Peter Meldgaard¹¹, Manuel Cobo Dols¹², Javier Garde Noguera¹³, Irene C. Floriani¹⁴, Marie Kassapian³, Yojena Chittazhathu Kurian Kuruvilla¹⁵, Adriana Gasca-Ruchti¹⁵, Christoph C. Zielinski¹⁶, Vanesa Gregorc¹⁷, Rolf A. Stahel¹⁸, for the EMPHASIS Collaborative Group

¹ETOP and University Hospital of Lausanne (CHUV), Switzerland; ²NVALT and Cancer Center Amsterdam, VU University Medical Center, Netherlands; ³Frontier Science Foundation-Hellas & University of Athens, Greece; ⁴Hospital 12 de Octubre, Madrid, Spain; ⁵Alicante University Hospital, Spain; ⁶SAKK and Cantonal Hospital Lucerne, Switzerland; ⁷**ICORG and Mid-Western Cancer Centre, University Hospital Limerick, Ireland**; ⁸Hospital Universitario Severo Ochoa, Madrid, Spain; ⁹Deventer Ziekenhuis, Netherlands; ¹⁰Institut Jules Bordet, Brussels, Belgium; ¹¹Aarhus University Hospital, Aarhus, Denmark; ¹²Hospital Universitario Regional y Virgen de la Victoria Málaga, Spain; ¹³Hospital Arnau Vilanova Valencia, Spain; ¹⁴Istituto di Ricerche Farmacologiche "Mario Negri", Milano, Italy; ¹⁵Frontier Science Foundation-Hellas, Athens, Greece; ¹⁶ETOP Coordinating Office, Berne, Switzerland; ¹⁷CEGOC and Comprehensive Cancer Centre of the Medical University Vienna, Austria; ¹⁸IRCCS Ospedale San Raffaele, Milan, Italy; ¹⁸ETOP and University Hospital Zurich, Clinic of Oncology, Zurich, Switzerland

Meeting: European Cancer Congress 2015 in Vienna, Austria.

ICORG 12-24: ETOP 2-11 BELIEF study

Presidential Session III, Hall D1 - Best Abstract:

A phase II trial of erlotinib (E) and bevacizumab (B) in patients with advanced non-small-cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations with and without T790M mutation. The Spanish Lung Cancer Group (SLCG) and the European Thoracic Oncology Platform (ETOP) BELIEF trial. (ETOP 2-11 BELIEF)

Stahel RA, Dafni U, Gautschi O, Felip E, Curioni-Fontecedro A, Peters S, Massutí B, Cardenal F, Aix SP, Früh M, Pless M, Popat S, Kotsakis A, **Cuffe S**, Bidoli P, Favaretto A, Carcereny E, Sanchez Ronco M, Molina MA, Rosell R.

Publications in 2015

Posters/oral poster presentations

Meeting: 2015 ASCO Annual Meeting, Chicago, USA

ICORG 13-19: ETOM-1 study

Session Type and Session Title: Poster Session, Health Services Research and Quality of Care

Category: Health Services Research and Quality of Care

Subcategory: Access to Care/Care Delivery

Abstract Number: 6536

Poster Board Number: Board #93

Citation: *J Clin Oncol* 33, 2015 (suppl; abstr 6536)

Emergency diagnosis of lung cancer: An international problem.

Thomas Newsom-Davis^{1*}, Rosanna Beradi², **Norah Cassidy³**, **Linda Coate³**, Ana Figueiredo⁴, Gabriele Gamerith⁵, Gareth Giblin³, Marko Jakopović⁶, Cor van der Leest⁸, Damien Pouessel⁸, Marcello Tiseo⁹, Anne-Claire Toffart¹⁰ and Cathy Hughes¹

*Corresponding author: Department of Oncology, Chelsea & Westminster Hospital, 369 Fulham Road, London SW10 9NH. Tom.newsom-davis@chelwest.nhs.uk

¹Chelsea & Westminster Hospital, London, UK; ²Università Politecnica Marche, Ancona, Italy; ³**All Ireland Co-operative Oncology Research Group, Dublin, Ireland**; ⁴Porto, Portugal; ⁵Medizinische Universität Innsbruck, Austria; ⁶University Hospital Centre Zagreb, Croatia; ⁷Amphia Hospital, Breda, Netherlands; ⁸Hopital Saint-Louis, Paris, France; ⁹University Hospital of Parma, Italy; ¹⁰Centre Hospitalier Universitaire de Grenoble, France.

Meeting: 2015 ASCO Annual Meeting

Session Type and Session Title: Poster Session, Tumor Biology

Category: Tumor Biology

Subcategory: New Targets and New Technologies

Abstract Number: 11077

Poster Board Number: Board #291

Protein tyrosine phosphatase non receptor 11 (PTPN11/Shp2) as a driver oncogene and a novel therapeutic target in non-small cell lung cancer (NSCLC).

Author(s): Yasir Elamin, Sinead Toomey, Aoife Carr, Kathy Gately, Shereen Rafee, **William Grogan, Patrick G. Morris, Oscar S. Breathnach, John Crown, Kenneth O'Byrne, Bryan Hennessy**; Education Centre Beaumont Hospital, Dublin, Ireland; Department of Medical Oncology, Beaumont Hospital, Dublin, Ireland; Medical Oncology, Royal College of Surgeons in Ireland, Dublin, Ireland; Trinity College Dublin & St. James's Hospital, Dublin, Ireland; St. James's Hospital, Dublin, Ireland; Beaumont Hospital, Dublin, Ireland; **Irish Cooperative Oncology Research Group, Dublin, Ireland**; Princess Alexandra Hospital and Queensland University of Technology, Brisbane, Australia; Royal College of Surgeons in Ireland, Dublin, Ireland

Publications in 2015

External publication referencing ongoing ICORG study:

Gastrointestinal:

Reference to ICORG 10-14 study included:

World Journal of Gastroenterology

***World J Gastroenterol* 2015 June 28; 21(24): 7343-7612**

- Audrey H Choi, Joseph Kim, Joseph Chao. *Perioperative chemotherapy for resectable gastric cancer*

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