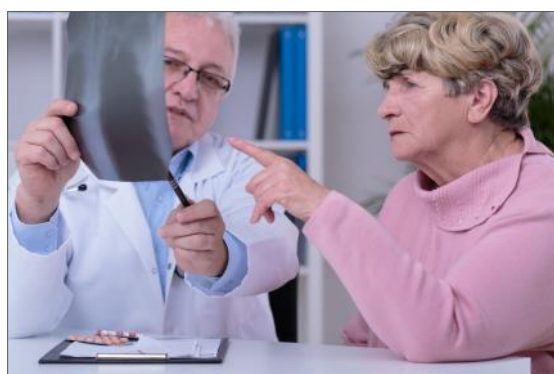
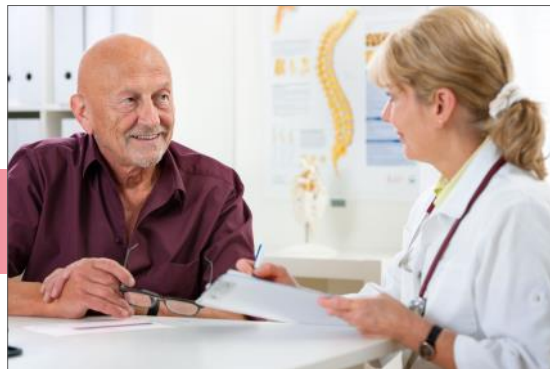


Annual Review 2016



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

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About Us

We are the only organisation in Ireland which is focused solely on cancer research trials.

Our vision is to provide people who have cancer with access to high-quality and potentially life enhancing cancer trials, and make Ireland a highly attractive location to open cancer trials.

To achieve this, **our mission** is to develop and provide access to a highly efficient and effective network of cancer trials research units, and clinical, professional, operational and administrative support services.

We work with the foremost Medical, Surgical and Radiation Oncologists, Haematologists and Research Specialists (i.e. Research Nurses, Research Radiation Therapists, Research Coordinators, Research Managers, Data Managers, Research Registrars, Research Pharmacists and Clinical Scientists) in Ireland. Almost all cancer treating specialists in Ireland are Members of Cancer Trials Ireland.

Since we were established in 1996, more than 15,000 patients have participated in over 350 cancer trials.

We work closely with local investigators, international collaborative groups such as ECOG-ACRIN, NRG, ANZUP and the main global pharmaceutical companies.

While the majority of our trials are carried out in Ireland some of our trials are also opened other countries in Europe.

We are a not-for-profit registered charity, partly funded by the Irish Cancer Society and the Health Research Board (HRB). We also receive greatly appreciated donations from members of the public.

Our everyday functions include planning, opening, coordinating, supporting, monitoring and auditing trials and publishing results.

We provide training, carry out feasibility studies, prepare and process ethics and regulatory submissions, facilitate cooperation between professionals working in the area and support the development of cancer trials research units in hospitals around the country.

We set policy and advocate for the opening of more cancer trials in Ireland through engagements with key stakeholders both in Ireland and internationally.

2016 at a glance

During 2016, the 11 hospital based cancer trials research units we fund directly (plus the 5 research units linked to these hospitals) were working on 178 cancer trials involving more than 6,000 patients. All the trials involved a highly cooperative effort between investigators, research teams in each hospital based research unit and the staff at our central office.

Of the 98 trials that were open and recruiting patients during 2016:

24% were **In-house** academic trials (which Cancer Trials Ireland initiates, manages, sponsors and monitors) and are generally funded by the grants received from the Health Research Board (HRB) and the Irish Cancer Society or pharmaceutical companies.

38% were **Collaborative** trials which involve working closely with other cancer research groups around the world.

38% were **Industry** trials which were initiated and managed by pharmaceutical companies and adopted into our trials portfolio.

■ In-house ■ Collaborative ■ Industry

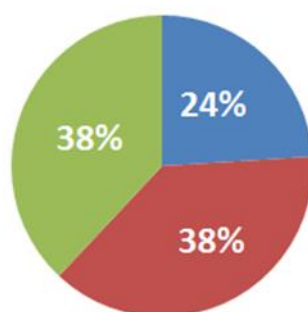


Fig 1: % of Open trials which were In-house, Collaborative and Industry trials.

There were 13 articles published in peer-reviewed journals and 30 oral and poster abstract conference presentations based on the findings of trials in which Members of Cancer Trials Ireland are, or have been, involved.

We were involved in 55 collaborations with pharmaceutical companies, collaborative groups and universities around the world.

Membership, which is open to Medical oncologists, Radiation oncologists, Surgical oncologists, Haematologists and Research Specialists exceeded 500, with 50 new Members admitted during 2016. Membership includes six affiliated universities, and 14 major affiliated hospital-based research units, which together treat more than 20,000 people with cancer annually in Ireland.



Dr Jonathan Westrup, Chairman

I am delighted to introduce our Annual Review for 2016.

I would like to say a sincere word of thanks to all members of the Board who give their time and valuable expertise voluntarily and generously to advancing our fundamental purpose which is to provide people who have cancer with access to potentially life enhancing cancer trials, and make Ireland a highly attractive location to open cancer trials.

I would like to thank our CEO, leadership team, operations team and our central office staff, all of whom are committed to exceptional standards of care and professionalism.

I would like to thank our clinical leadership and their support teams that are very busy across the country planning, initiating and running high quality trials.

I would like to thank our funders and donors, the Irish community through the HRB and the Irish Cancer Society. I would also like to acknowledge the many other groups and organisations that we engage with and which support the development of Ireland's potential as a key European hub for cancer trials.

I would like to thank the many international collaborative groups and pharmaceutical companies with whom we work closely for their ongoing and valuable support.

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 helping the collective effort to take us closer toward improved diagnostics and treatments that will save and enhance the lives of millions of others around the world during the decades ahead.

Board Members during 2016



Darren Byrne (Appointed 11 April 2016), Chartered Accountant / CFO and Non-Executive Director.



Dr Jerome Coffey (Appointed 19 Feb. 2016), Director of the National Cancer Control Programme (NCCP).



Dr Leisha Daly, Country Director of Janssen.



Berchmans Gannon, Formerly Beauchamps Solicitors.



Prof Liam Grogan (Up to 19 Feb. 2016), Consultant Medical Oncologist, Beaumont Hospital, Dublin.



Prof Bryan Hennessy, Clinical Lead, Consultant Medical Oncologist, Beaumont Hospital, Dublin, and Our Lady of Lourdes Hospital, Drogheda.



Dr Paul Kelly (Appointed 12 April 2016), Consultant Radiation Oncologist, Cork University Hospital.



Associate Prof Cathy Kelly (Appointed 19 Feb. 2016), Consultant Medical Oncologist, Mater Misericordiae University Hospital, Dublin.



Prof Ray McDermott, Consultant Medical Oncologist, Tallaght Hospital and St Vincent's University Hospital, Dublin.



Prof Patrick Murray, Professor of Clinical Pharmacology, UCD.



Dr Robert O'Connor, Head of Research, Irish Cancer Society.



Prof Michael O'Dwyer (Up to 19 Feb. 2016), Professor of Haematology, NUI Galway.



Dr Susan O'Reilly (Up to 19 Feb. 2016), Chief Executive, Dublin Midlands Hospital Group.



Evelyn O'Rourke, Radio and Television Broadcaster at RTE.



Dr Jonathan Westrup (Chairman), Head of Graduate Studies, Irish Management Institute.



Professor Bryan Hennessy, Clinical Lead

Over the past 20 years we have built a huge reservoir of scientific knowledge and expertise within our cancer trials research network.

As a result, our network is unique. It enables trial sponsors access Ireland's entire population through one point with the supports of highly qualified teams across the country. We are eager to work with colleagues at home and abroad who would like to access this network to take us closer to finding answers to cancer.

During 2016 we committed to initiating and supporting more investigator led studies, broaden our impact across more cancer types and grow the opportunities to work with international collaborative groups and pharmaceutical companies. These ambitions are consistent with many others working in the field. For example, the Health Research Board in its 2016-2020 strategy document calls for *"more intervention-focused health research, resulting in better outcomes for individuals, and increased quality and safety in the healthcare system"*.

We opened a number of exciting trials during the year. These include Flipper, LOXO 101, CheckMate 401, PEARLS, INTENSE, Nala, POSITIVE, PALLAS, NeoTRIP, PanTHER and CyBord-DARA. Our Members and their teams have been published in top line publications such as The New England Journal of Medicine and have had abstracts and posters presented at prestigious international conferences such as ASCO and ASH.

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

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

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

How we're organised

Chairman & Board of Directors

Committees of the Board

Audit Committee

Meets 4 times per year. Chaired by Board Member Darren Byrne.

Clinical Executive Committee

Meets 3-4 times a year. Chaired by Prof Bryan Hennessy, Clinical Lead.

SMG - Scientific Management Group

Meets 3-4 times a year. Chaired by Dr Linda Coate, Vice Clinical Lead. The work of the SMG is informed by the Disease Specific Sub Groups (DSSG) which meet 3 times a year, and are in turn informed by the 500+ Membership.

External Scientific Advisory Review Board

Convened as required.

Clinical Oversight

Prof Bryan Hennessy, Clinical Lead.

Dr Linda Coate, Vice Clinical Lead.

CEO and Central Office Team

Manages Cancer Trials Ireland's trials monitoring and business functions; clinical project management, pharmacovigilance, data management, on-site monitoring, quality management and training.

The team co-ordinates the activities of the Disease Specific Sub-Groups (DSSGs) through which the research portfolio is developed.

It provides local expertise in regulatory and ethics processes in Ireland, the UK and Europe as well as Pharmacovigilance - trained employees in this area who have direct access to the European safety database (Eudravigilance) for safety reporting purposes according to regulatory requirements.

The central office team has experience in drug distribution, accountability and labelling, which has facilitated our work with industry and our collaboration with international partners.

Location of hospital based Cancer Trials Research Units

Letterkenny University Hospital
 Sligo University Hospital
 University Hospital Galway
 University Hospital Limerick
 Cork University Hospital
 Bon Secours, Cork
 Midland Regional Hospital—Tullamore
 University Hospital Waterford
 Beaumont Hospital
 Mater Misericordiae University Hospital
 St James's Hospital
 Tallaght Hospital
 St Luke's Radiation Oncology Network
 St Vincent's University Hospital
 Beacon Hospital
 Our Lady's Children's Hospital Crumlin



Eibhlin Mulroe, CEO

The simplicity of our purpose, to provide people who have cancer with access to potentially life enhancing cancer trials, belies the complexity of cancer trials.

Each trial consists of many different and connected processes and procedures which must all dovetail together. Ensuring this occurs efficiently at all times involves a vast array of highly experienced and committed professionals all of whom are focused on the well being of people who have cancer.

A central focus for us during 2016 has been to ensure that all of our clinical governance, management and operational system and processes provide the maximum possible support for every trial within the funds available. This follows plans put in place during 2015.

This work has been achieved thanks to the commitment and support of Members across the country, coupled with the expertise of our highly committed team at central office and the teams in hospital-based research units across the country. We are all passionate in our collective pursuit of breakthrough findings.

The work of our central office team has been invaluable in the development of Ireland's capability to undertake cancer trials on par with the best in the world. While this work often occurs in the background and is unnoticed, it is work that is of pivotal importance. Our central office team not only enables each trial to successfully navigate the complex journey from idea, to approval, to opening, to patient recruitment, to data analysis, and results publication, it also provides important leadership at each stage. Without its experience, expertise and commitment many cancer trials would not get off the starting blocks.

Similarly, the research teams across the country are pivotal to making sure that trials run smoothly and the experience of participants is the best it can be.

I would like to thank you all for your commitment.

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

Clinical Highlights

During 2016 the number of trials opened in different disease areas exceeded expectations. However, there was an overall drop in the number who participated. This is not surprising in the context of the organisation's dependence on grants and the 20% cut to our HRB Grant (2016-18) allocation.

During the year

- 98 of the 119 trials that were open to recruitment, recruited patients.
- 2311 patients were recruited.
- Work was ongoing on 59 additional trials which had closed to patient recruitment.
- Exciting new opportunities were pursued in Gastrointestinal, Genitourinary, Lung & Blood Cancer diseases and Basket trials.
- We facilitated access for patients to more than 30 new cancer drugs and treatments, thereby saving the state millions of euros annually.
- There were 13 publications in high impact medical journals and 30 oral and poster abstract conference presentations.
- We were involved in more than 55 collaborations with pharmaceutical companies, collaborative groups and universities worldwide.



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

Strategic Highlights

- We made a number of key organisational changes to respond to the recommendations of the 2015 Health Research Board (HRB) Panel Review and the 2015 HPRA Regulatory Inspection Report. New medical oversight structures, departments and processes were established to respond to obligations and recommendations.
- “Towards 2020” the 2016-2020 Strategy for Cancer Trials Ireland was submitted to the HRB. The strategy outlines the vision and mission which is underpinned by 5 interconnected strategic pillars; governance, profile, funding model, organisational capabilities and clinical capabilities. This strategy complements our previous submissions to the HRB, particularly the 2016-18 funding application.
- The Scientific Management Group met three times during the year. The meetings review the scientific merit, resource requirements and budgets of all ‘new to approve’ trials and makes recommendations for consideration by the Clinical Executive Committee. This process is now applicable to all trials as part of the comprehensive approvals process.
- At the Board meeting in November 2016 a proposal for a Performance Assessment process for cancer trials research units was presented and endorsed. This assessment process includes metrics covering Timelines, Quality and Accruals.
- A special Stakeholder Meeting was organised during the Autumn Scientific Meeting (Disease Specific Sub Group – DSSG) and brought an audience of 100 together to discuss translational research and encourage researchers in this area to join Cancer Trials Ireland. The Clinical Executive Committee subsequently appointed a subgroup led by Prof Bryan Hennessy to develop the translational research portfolio.
- The Leadership Team in the central office facilitated monthly meetings between the NUI Galway Clinical Research Facility (CRFG) and Cancer Trials Ireland. These meetings were set up to support the collaboration between the CRFG and our central office team.
- The pre-2015 health budget cuts has led to increased workload for individual clinicians, difficulties in replacing departing research staff and delays in the appointment of Oncologists and Haematologists. These factors, coupled with the growing incidences of cancer, increases pressure on the ability of consultants to initiate and run Cancer Trials Ireland-sponsored studies.



Against this backdrop, the Board decided that the Vice Clinical Lead, in addition to the Clinical Lead, should have a portion of her time protected for research and allocated the necessary resources. It is hoped that with protected time, the clinical leadership will be able to develop more trial opportunities for patients.

Highlights

Strategic Highlights

- Stakeholder Engagement and Patient Advocate Advisory Group (PAAG) meetings became a permanent feature at our Scientific Meetings (Disease Specific Sub Group – DSSG meetings), with an average of 100 stakeholders and patients taking part. Topics discussed include Immunotherapy Trials, Translational Research and Patient-led research.
- For the first time members of the PAAG joined the closed Melanoma and Breast DSSG meetings to bring the patient perspective directly to these important conversations on the progress and development of our cancer trials portfolio.
- Our CEO and Clinical Lead presented and made a written submission to the Cancer Strategy Steering Group at the Department of Health. Among the Key Performance Measures proposed to the group was a target of 5% of patients with cancer to be enrolled in cancer drug trials. In 2017 the strategy was published and included a Key Performance Indicator to increase cancer drug trials to 6% by 2020.
- We also made a Pre-Budget Submission to the Department of Finance and a submission to the Future of Healthcare Committee.
- The Board and CEO engaged and met with senior executives in the IDA and Science Foundation Ireland (SFI) to explore partnership opportunities.
- The CEO continues to be an active member of the eHealth Ireland Committee and the Board of the Blood Cancer Network of Ireland (BCNI).
- A Communications Advisor was appointed with the support of a HRB Grant to raise the internal and external profile of the organisation, and the role and benefits of cancer trials generally.
- Following on from the recommendations of the International Panel Review we appointed a Business Development Manager to support our network of cancer trials research units, manage the Feasibility Study Service and engage with pharmaceutical industry colleagues.
- We continued to explore new partnerships with international collaborative groups, global teams from main pharmaceutical companies and Clinical Research Organisations.
- We continue to attract trials to Ireland from collaborative groups, for example BIG, EORTC, GEICAM, ETOP, NRG, CRUK and ECOG-ACRIN.



Cancer Trials Ireland's first pre-budget submission (above) and the submission to the Oireachtas Committee on the Future of Healthcare.



Pictured at the launch of our new name and rebrand in May 2016 were (l to r) Dr Graham Love, CEO of the HRB in 2016, Professor Bryan Hennessy, Clinical Lead, Cancer Trials Ireland, Oliver O'Connor, CEO of IPHA, John McCormack CEO of the Irish Cancer Society in 2016, Dr Jonathan Westrup, Chairman, Cancer Trials Ireland, Eibhlin Mulroe, CEO, Cancer Trials Ireland and Dr Robert O'Connor, Head of Research, Irish Cancer Society.

Name change and rebrand

We were established in 1996 as the Irish Clinical Oncology Research Group Limited (ICORG) by a group of cancer consultants committed to advancing cancer trials research in Ireland. ICORG's purpose was to create a formal infrastructure to make Ireland more attractive as a location to open cancer trials and create more opportunities for patients to access treatments available through trials but not yet available through the health service.

Following the signing of the 'Belfast Agreement' in 1999, the *Ireland-Northern Ireland – National Cancer Institute Cancer Consortium* was established to support initiatives to improve cancer care, research and training on an all-island basis. 'Clinical trials' was one of five priority areas selected for investment and development, and support by the Health Research Board (HRB).

In 2000 membership was expanded to include Northern Ireland.

In May 2016 ICORG changed its trading name to Cancer Trials Ireland and was rebranded. The rebrand was launched on International Clinical Trials Day in May alongside the publication of an Economic Impact Review on Cancer Trials activity in Ireland. (See page 15 for more details. [HERE](#) for full report)

The name change followed considerable consultation and feedback from our Members, the HRB's International Panel Review which was carried out during 2015, and our Patient Advocate Advisory Group, which suggested that we needed to do better in reaching and connecting with the general public. To do this we needed to communicate in language that was more easily understood. In tandem with our public facing communication programme (See pages 46-49 for more details) our new name has helped us make these connections.

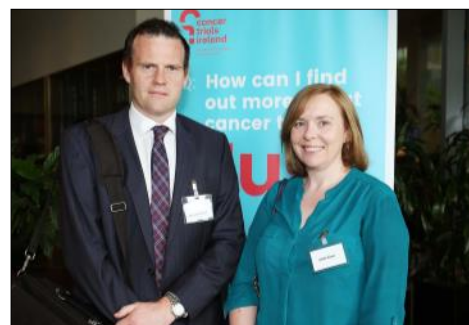
Summer 2016 Scientific Meeting

Summer 2016 Scientific Meeting

Our Summer 2016 Scientific Meeting (Disease Specific Sub Group – DSSG) started with a mini conference entitled *Cancer Immunotherapy – 2016 and beyond*.



Eibhlín Mulroe, CEO, Cancer Trials Ireland, Professor Seamus O'Reilly, Consultant Medical Oncologist, Cork University Hospital, and Kay Curtin, Patient Advocate.



Cathal O'Ceallaigh, MSD and Ashlin Dunne, MSD.



Melanie Sinson, Boehringer Ingelheim, and Aoife Kiely, Janssen.



Suzanne Ennis, Astellas with Pat Fortune, BMS and Dr. Siobhan Mitchell, BMS.



Dr Verena Murphy, Translational Research Leader, Cancer Trials Ireland, Prof. William Watson, Translational Research DSSG Chair, Cancer Trials Ireland, Dr Orla Casey, Translational Project Manager, Cancer Trials Ireland.

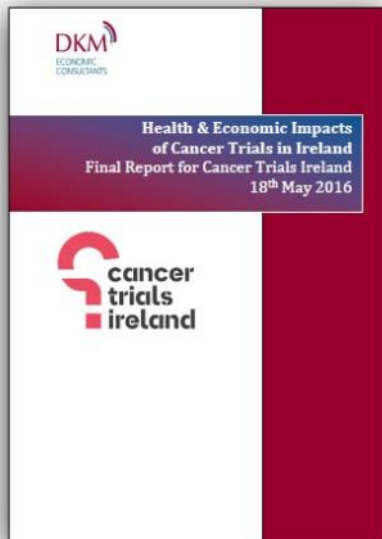


Aron O'Loughlin (left) with Ann Marie Cullen, Maureen Hannon, Killian MacDonld and Laura Kavanagh, Novartis



Every €1 invested in cancer trials generates €3

In May 2016 we published an independent report on the health and economic impacts of cancer trials in Ireland.



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

Based on a small sample of case studies, DKM Economic Consultants estimated that cancer trials could add 6 to 15 quality adjusted years of life (QALYs) collectively for trial participants with a related economic benefit ranging from €0.28m to €0.65m per trial. The report noted that subsequent benefits would be a multiple of these values when proven

therapies are made available to patients generally. These benefits are in addition to the early access to drugs and treatments and the extra care cancer trials participants receive.

A case study contained in the report demonstrated that in the breast cancer trial known as Tailor X, 110 Irish patients collectively avoided 27 years of chemotherapy which generated a saving of €0.766m for the HSE in avoided treatment costs. The outcome of this trial saves the HSE over €0.5m annually. Another cancer trial in the area of advanced melanoma added a combined 6.3 quality years of life to the 27 participants which generated an economic benefit of over €0.28m.

At the report's launch Professor Bryan Hennessy, Clinical Lead for Cancer Trials Ireland and Consultant Oncologist, Beaumont Hospital, said, "*Cancer Trials Ireland's network offers a world class infrastructure. Our key objective is to build on this and increase the number of patients on cancer drug trials from the current 3% to 5% of all patients. We want to initiate and support more investigator led studies, work with pharmaceutical companies and broaden our impact across more cancer types. This growth will further bolster the huge reservoir of scientific knowledge and expertise that we have built over the past 20 years and ensure that people living with cancer continue to access the latest medicines not yet widely available.*"

The report also noted that Cancer Trials Ireland's success with international collaborations helps the IDA build and broaden linkages with its existing clients and opens up opportunities for discussions with new clients with an interest in cancer.

The report can be downloaded [HERE](#).

Performance Metrics

Performance Metrics

In line with best practice among similar international collaborative research groups, we use a series of recognised metrics to measure our performance.

Our performance against these metrics is outlined on pages 17 to 41.

No	Performance Metric	Explanation
1	Accrual	Refers to the number of patients recruited to a trial.
2	Trials portfolio	The number and type of trials in our portfolio.
3	Cancer trials research unit monitoring	Monitoring activity of cancer trials research units includes a broad range of activities conducted from trial commencement until close-out.
4	Audits	The numbers of days spent preparing for and conducting audits and follow-up activity as well as active participation in external sponsor audits and regulatory inspections.
5	Training	The number of training courses conducted and attended.
6	Infrastructure Development	The number, organisation and staff contributing to the organisation's growth and development.
7	Participation	Attendances at scientific meetings, International Meetings, and trials introduced and developed by local Principal Investigators (PIs).
8	Membership	The number of Members of Cancer Trials Ireland.
9	Publications	The number of publications in peer-reviewed journals and abstracts accepted at top level international.

Performance Metric 1. Accruals

This metric records the number of patients recruited, or accrued, to trials. An accrual target set in 2015 was that the total of all patients recruited to breast cancer trials should not exceed the total number of patients recruited to all other trials. This target was exceeded during 2016.

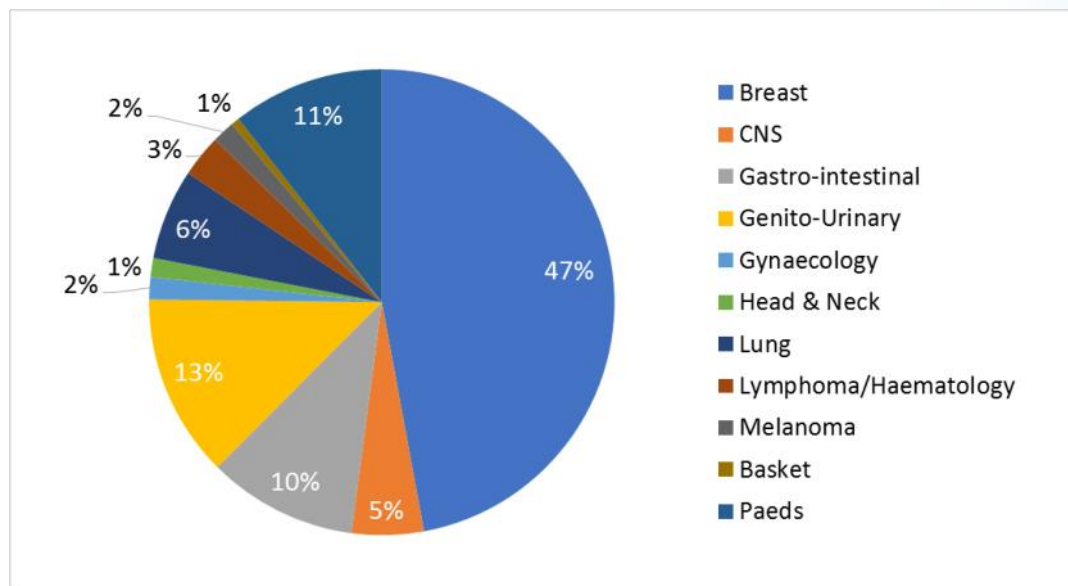


Fig. 2: % of patients accrued by Disease Area (excluding surveys).

Disease Area	Total patients accrued
Breast	575
Central Nervous System	61
Gastrointestinal	127
Genitourinary	155
Gynaecology	19
Head & Neck	16
Lung	77
Lymphoma / Haematology	36
Melanoma	19
Other (Survey & Basket)	1097
Paediatric	129
Grand Total	2311

Table 1: Number of patients accrued by Disease Area (including surveys):

Disease Area	Total Accrual	Collaborative	In-house	Industry
Breast	575	45	517	13
Non Breast	646	289	224	133
	1221	334	741	146

Table 2: Number of patients accrued to trials of breast disease and non breast disease areas by trial type (excluding surveys).

Trials Portfolio

This metric records the number and type of trials open and in development during 2016. In-house trials and Collaborative trials (which involve research organisations in other countries) were an important area of focus during 2016. Both In-house trials (which are funded by either HRB, Irish Cancer Society and other supports and/or directly by pharmaceutical companies) and Collaborative trials, are fully supported by our central office clinical, professional, operations and administrative teams. The third type of trials included in our portfolio are Industry trials. While these trials are carried out in the various cancer trials research units, central office staff are minimally involved.

Disease Specific Sub-Group	No. of trials in our portfolio	No. of new trials awaiting approval	No. of trials approved but not open to accrual	No. of trials open to accrual	No. of trials in follow-up	No. of trials awaiting closure
Breast	60	4	3	29	21	3
Central Nervous System	4	0	1	2	1	0
Gastrointestinal	32	2	8	10	4	8
Genitourinary	35	2	8	12	10	3
Gynaecology	15	3	4	6	2	0
Head & Neck	9	2	1	1	4	1
Lung	32	0	12	7	10	3
Lymphoma/Haematology	27	2	4	16	2	3
Melanoma	11	0	2	4	3	2
Paediatric	29	0	0	27	2	0
Basket	6	0	1	5	0	0
Total Number	260	15	44	119	59	23
The above includes Translational Studies in each disease area. See below for the breakdown for translational studies.						
Translational Total	42	5	4	29	2	2

Table 3: Status of overall trials portfolio by disease group.

In-house trials

Protocol Number	Trial Acronym	Protocol	Status @ end 2016
06-34	Palliative Lung	A clinical trial using 3-dimensional conformal radiation therapy to reduce the toxicity of palliative radiation for lung cancer	Fully closed out
07-01	CLL-Irl	A phase II study of fludarabine, cyclophosphamide and rituximab as initial therapy in chronic lymphocytic leukaemia	Follow-Up 54 Patients
07-11	SCC Retreat	Phase II trial evaluating the efficacy of a radio-biological based re-irradiation strategy for patients with malignant spinal cord compression	Follow-Up 20 Patients
08-01	CADY	Detection of Cardiac Dysfunction in patients treated with trastuzumab for HER2 Positive Breast cancer	Follow-Up 483 Patients
08-13	Malignant Gliomas	Are malignant gliomas in adults associated with a unique identifying serum protein signature?	Open Target: 130 Patients Cohort 1 = 100, Cohort 2 = 30 Current: 45 Patients (44 Cohort 1, 1 Cohort 2) Closing: 2016/7

Table 4: Cancer Trials Ireland In-house trials (Start-Up/Open/Treatment/Follow-Up)

Protocol Number	Trial Acronym	Protocol	Status @ end 2016
08-05	Adipose Tissue Bioresource development	The Development of Adipose Tissue Bioresource to Investigate the Link between Obesity and Cancer.	Open – this is a continuous collection of samples.
08-08	Biomarkers of Response Taxotere	Biomarkers of Response to Taxotere in Hormone-Refractory Prostate Cancer	Follow-Up 77 Patients
08-17	IMRT Prostate	A prospective phase 2 dose escalation trial using IMRT for T1a-T3cN0M0 prostate cancer	Follow-up 250 Patients
08-18	CHHiP	A phase III, multicentre, randomised controlled trial to see whether hypofractionated radiotherapy schedules for localised prostate cancer could improve the therapeutic ratio by either improving tumour control or reducing normal tissue side effects.	Follow-Up
08-40	SNP study	Correlation of Single Nucleotide Polymorphism (SNP) profile of domain III of EGFR to skin toxicity and disease response to treatment with Cetuximab or Panitumumab	Open Target: 150 Patients Current: 127 Patients Closing: 2017
09-06	Endometrial IMRT	Prospective Randomised Phase II Trial evaluating Adjuvant Pelvic Radiotherapy using either IMRT or 3-Dimensional Planning for Endometrial Cancer	Open Target: 154 Patients Current: 66 Patients
09-07	BC proteomics and molecular heterogeneity	Breast Cancer Proteomics and molecular heterogeneity	Open Target:5000 Patients Current: 1540 Patients Closing: 2020
10-01	Phase II second-line pazopanib metastatic RCC study	A phase II study of pazopanib in patients with metastatic or unresectable Renal Cell Carcinoma who have failed prior therapy with sunitinib	Follow-Up 53 Patients
10-05	TCHL Phase II	A Phase II neoadjuvant study assessing TCH versus TCL versus the combination of TCHL in ErbB2+ve breast cancer patients	Follow-Up 88 Patients
10-06	TROG DCIS	A randomised phase III study of radiation doses and fractionation schedules in non-low risk Ductal Carcinoma In Situ (DCIS) of the breast.	Follow-Up
10-10	CCLG tissue bank study	Tissue Bank (2008 BS 01)	Open – This is a continuous collection of samples
10-11	Circulating miRNA	Circulating miRNAs: Novel breast cancer biomarkers and their use for guiding and monitoring response to chemotherapy	Open Target: 366 Patients Current:199 Patients Closing: 2017/8
10-14	Neo-AEGIS	A Phase III trial of neoadjuvant chemotherapy (MAGIC) vs. neoadjuvant chemoradiation (Unit Standard) in adenocarcinoma of the oesophagus and oesophago-gastric junction	Open Target: 366 Patients Current: 77 Patients Closing: 2018
10-15	Exosomal and FE Predictive Biomarkers for HER2 Therapies	Exosomal and free extracellular RNAs and predictive biomarkers for HER2+ therapies in breast cancer	Open Cohort 1 Target: 300 Current = 260 Closing 2017 Cohort 2 Target: 30 Current = 30; Closed
10-16	Ovarian Reserve	A study to determine alteration hormone levels in premenopausal patients receiving adjuvant or neoadjuvant chemotherapy for breast cancer.	Open Target: 250 Patients Current: 149 Patient Closing: 2017
11-10	TH v THL: Phase II study in HER2+ Breast cancer	A Phase III randomised study of TH (Paclitaxel and Trastuzumab) versus THL (Paclitaxel, Trastuzumab, and Lapatinib) in first-line treatment of HER2 positive metastatic breast cancer	Follow-Up Current:75 Patients
11-32	Lithium Autophagy Phase 1 study	A Phase I Study of Lithium Combined With Oxaliplatin And Oral 5-Fluorouracil In Patients With Advanced Oesophago-gastric or Colorectal Cancer	Start-Up Target: 27 patients
12-09	CharactHer	A study of the molecular and cytogenetic characteristics of HER2-positive breast cancer to predict durable complete response after chemotherapy and trastuzumab	Open Target:300 Patients (3 Cohorts) Current:189 Patients Closing: 2016/7

Table 4: Cancer Trials Ireland In-house trials (Start-Up/Open/Treatment/Follow-Up)

Performance Metric 2. Trials Portfolio

Protocol Number	Study Acronym	Protocol	Status @ end 2016
12-27	Plasma BM in CRC	Identification of Plasma Biomarkers in Early Detection of Colorectal Adenocarcinoma Recurrence	Open Target: 150 Patients Current 84 Patient Closing: 2018
12-31	Predictive BM in PanCa	Identification of Predictive Plasma Biomarkers in Pancreatic Ductal Adenocarcinoma.	Open Target: 250 Patients Current: 102 Patients Closing: 2018
12-30	TAILORx tissue Bank	Breast Cancer Bank of Tissue from Trial Assigning Individualized Options for Treatment (TAILORx)	Open Target: 693 Samples Current: 567 Closing: 2018
12-38	TRI-LARC	Randomised Phase II Study of pre-operative 3-D Conformal Radiotherapy (3-DCRT) versus Intensity Modulated Radiation Therapy for Locally Advanced Rectal Cancer	Open Target: 267 Patients Current: 35 Patients
13-17	(RsqVD)	A Phase II Study of the Efficacy and Safety of lenalidomide, subcutaneous bortezomib and dexamethasone for Patients with Newly Diagnosed Multiple Myeloma	Follow-Up 42 Patients
13-21	Radium-223 & Enzalutamide mCRPC study	A Phase II Study of Radium-223 in Combination with Enzalutamide in Progressive Metastatic Castrate-Resistant Prostate Cancer	Open Target: 44 Patients Current: 43 Patients
13-22	SYSACT study	A translational systems medicine approach to provide predictive capacity for therapy responsiveness in metastatic malignant melanoma	Open Target: 40 Patients Current: 8 Patients
13-23	Neo-adjuvant abiraterone prostate	Phase II Single-arm Study evaluating Neo-adjuvant (pre-radical radiotherapy) Abiraterone acetate (plus prednisolone) and Gonadotropin-Releasing Hormone (GnRH) agonist in High Risk Localised Prostate Carcinoma	Open Target: 40 Patients Current: 8 Patients
14-04	iProspect	iPROSPECT: Irish Programme for Stratified Prostate Cancer Therapy.	Open Target: 60 Patients Current: 45 Patients
15-01	Neoadjuvant Breast Radiotherapy study	Trial of Neoadjuvant Radiotherapy in Women With Breast Cancer Treated With Neoadjuvant Chemotherapy and Mastectomy	Pre-Study Development
15-02	PanHER	Phase IB / II clinical trial of copanlisib in combination with Trastuzumab in pre-treated recurrent or metastatic HER2-positive breast cancer	Open Target: 27 Patients Current: 6
15-34	Recurrence Score LN-pos	The Impact of the 21 Gene Recurrence Score (RS) on Chemotherapy Prescribing in Estrogen Receptor Positive, Lymph Node Positive Early Stage Breast Cancer in Ireland	Open Target: 150 Patients Current: 0 Patients
15-43	Cancer Clinical Research Questionnaire	Understanding and Attitudes toward Cancer Clinical Research (CCR) among Patients with a Cancer Diagnosis: National Study through ICORG	Closed in 2016 1090 Patients
15-47	INTENSE	A Phase I/II Study of <u>I</u> nhomogeneous <u>T</u> argeted Dose <u>E</u> scalation in <u>N</u> on- <u>S</u> mall <u>C</u> ell Lung Cancer	Open (On Hold) Target: 48 Patients
16-01	Immune Biomarkers in DLBCL	Prospective validation of novel immune biomarkers in patients with Diffuse Large B Cell Lymphoma (DLBCL) treated with R-CHOP (DLBCL Biomarker Study)	Start-Up Target: 200 Patients
16-02	CyBord DARA	Phase Ib study of weekly Cyclophosphamide-Bortezomib-Dexamethasone (CyBorD) with Daratumumab (DARA) in transplant eligible patients with newly diagnosed Multiple Myeloma (MM). "The CyBorD-DARA study"	Open Target: 18 Patients Current: 6 Patients
16-06	Inecalcitol	Phase II, Open label clinical trial of Inecalcitol in combination with Gemcitabine/ Nab-Paclitaxel therapy in advanced pancreatic cancer	Start Up

Table 4: Cancer Trials Ireland in-house trials (Start-Up/Open/Treatment/Follow-Up)

Collaborations with international research groups

We maintain successful collaborations with many international research groups and organisations.

ACCOG—Anglo Celtic Cooperative Oncology Group

AGO-OVAR—Arbeitsgemeinschaft Gynaekologische Onkologie Ovarian Cancer Study Group

AIO—Arbeitsgruppe Internistische Onkologie

Alliance (former CALGB) - Alliance for Clinical Trials in Oncology (formed in March 2011 by the merger of three cooperative groups: the American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), and North Central Cancer Treatment Group (NCCTG)).

ANZGOG—The Australia New Zealand Gynaecological Oncology Group

ANZUP—The Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group

Assistance Publique – Hôpitaux de Paris

ABCSG—Austrian Breast and Colorectal Cancer Study Group

BIG—Breast International Group

Cardiff University (UK)

Dana Farber Cancer Institute—Major Cancer Centre linked to Harvard Medical School, Boston, MA.

EBMT—The European Group for Blood and Marrow Transplantation

ECOG - ACRIN—ECOG (Eastern Cooperative Oncology) and ACRIN (American College of Radiology Imaging Network) Research Group

ENGOT—The European Network for Gynaecological Oncological Trial groups

EORTC—European Organisation for Research and Treatment of Cancer

ETOP—European Thoracic Oncology Platform

Finnish Uro-Oncological Group

GBG—German Breast Group

GEICAM—Grupo Español de Investigación en Cáncer de Mama

GELA—Groupe d'Etude des Lymphomes de l'Adulte

GCLLSG—German CLL Study Group

GOG—Gynecologic Oncology Group

IBCSG—International Breast Cancer Study Group

ITCC—Innovative Therapies for Children with Cancer

LCCC UNC—Lineberger Comprehensive Cancer Center of the University of North Carolina

MARGIT—Mannheimer Arbeitsgruppe fuer Gastrointestinale Tumore

Michelangelo—Fondazione Michelangelo

NCIC CTG (Canada) - National Cancer Institute of Canada – Clinical Trials Group

NCRN—National Cancer Research Network UK (incorporating Cancer Research UK (CRUK), Clinical Trials Research Unit (CTRU) & Medical Research Council (MRC))

North Central Cancer Treatment Group

NRG Oncology

National Surgical Adjuvant Breast and Bowel Project (NSABP); the Radiation Therapy Oncology Group (RTOG); the Gynecologic Oncology Group (GOG).

PrECOG—Sister Foundation of ECOG

Royal Brompton and Harefield NHS Foundation Trust

Royal Marsden NHS Foundation Trust

Scandinavian Prostate Cancer Group

SCTU—Southampton Clinical Trial Unit

SIOPE—European Society for Paediatric Oncology

SWOG—Southwest Oncology Group

TRIO—Translational Research in Oncology

TROG—Trans-Tasman Radiation Oncology Group

UNICANCER (France)

University of Edinburgh

University of Leeds

University of Liverpool

University of Sheffield

University of Warwick

UPMC—University of Pittsburgh Medical Centre

Collaborations during 2016

ANZUP – The Australian New Zealand Urogenital and Prostate Cancer Trials Group

We started an important new collaboration with ANZUP in 2015. We are the EU sponsor on two large international phase III prostate trials (ENZAMET and ENZARAD). Both trials are open to accrual in 24 research units in Ireland and the UK and we are in the process of expanding to additional sites in Europe in partnership with the EORTC. Our partnership with ANZUP has the potential to expand to other global trials in Genitourinary cancers and enable us to continued growing our portfolio in this area.

ECOG - ACRIN

We have been a full member of ECOG-ACRIN since June 2008, and to date have participated in the breast cancer TAILORx trial, lung cancer E1505 trial, and prostate E2809 trial and via ECOG-ACRIN, the breast cancer SWOG S1007 trial, which accrued 385 patients to Step 1 and 141 patients to Step 2 before closing to accrual in 2015. The E3A06 high risk smouldering myeloma trial is also open.

We have expanded our role as a lead coordinating centre in collaboration with ECOG-ACRIN's sister foundation, PrECOG, acting as EU sponsor on the PrE0204 trial in cholangiocarcinoma which opened in the Vienna University Hospital in 2015 and enrolled 3 patients. During 2016 we were working with ECOG-ACRIN on new trials in renal cell carcinoma and melanoma.

NRG Oncology

The NSABP (National Surgical Adjuvant Breast and Bowel Project), RTOG (Radiation Therapy Oncology Group) and GOG (Gynaecologic Oncology Group) merged to form NRG Oncology in 2014. As we were an active member of NSABP we retained our membership in the new group.

In 2016 we had 5 NSABP studies in follow-up: B-38 (140 patients), B-39 (3 patients), B-42 (80 patients), B-46i (8 patients), B-47 (117 patients) and one open NSABP (B-51) study. The NSABP B-51 trial, a randomized phase III trial evaluating post-mastectomy chest wall and post-lumpectomy regional nodal radiotherapy in breast cancer patients after neoadjuvant chemotherapy, is also a niche study and is open in 2 Irish research units.

GBG – German Breast Group

We are participating in a Phase III study in HER2 negative Breast Cancer, Penelope B, led by GBG and under the auspices of BIG, providing access to the first-in-class cyclin-dependent kinase CDK 4/6 inhibitor, Palbociclib. Nine Irish research units are participating.

GEICAM

GEICAM is a Spanish non-profit organisation which specialises in Breast Cancer clinical trials and has been working with Cancer Trials Ireland on the 11-10/TH vs THL study conducted in Spain. We are participating in the GEICAM FLIPPER trial in hormone receptor-positive metastatic breast cancer.

Collaborations during 2016

BIG

We are taking part in the PALLAS trial, an international phase III trial evaluating palbociclib in adjuvant hormone receptor positive/HER2- early breast cancer which will include 4,600 women internationally. Six research units were open in Ireland, with the goal to enrol at least 50 patients.

European Thoracic Oncology Platform (ETOP)

ETOP specialises in European lung cancer research collaboration. We have opened and accrued to the ETOP EMPHASIS and the ETOP BELIEF trials in Ireland. Both of these studies have completed accrual and continue in the follow up phase. A third study, ETOP SPLENDOR, was initiated in Ireland in 2015 and opened in 9 research units.

NCRN

We collaborated with CRUK on the CHHiP, ART DECO, the IBIS-II Prevention and the DCIS studies, which are all in long-term follow up.

We also participated in the MRC led trial ICON 8 in ovarian cancer, enrolling 24 patients. The follow-on trial, ICON 8B opened in 5 research units in Ireland in 2015, with a target of 30 patients.

We will also open IMRiS, a phase II study of intensity modulated radiotherapy trial to treat sarcoma, the PACE study, a randomised study of laparoscopic prostatectomy or conventionally fractionated radiotherapy vs stereotactic body radiotherapy (SBRT) for early stage prostate cancer, and the large-scale ADD-Aspirin trial, which will enrol approximately 10,000 patients globally across breast, prostate and Gastrointestinal cancers.

TRIO – Translational Research in Oncology

Collaboration with TRIO has resulted in high patient accrual contribution by Cancer Trials Ireland to several TRIO studies: BCIRG 005 - 171 patients; BCIRG006 -129 patients; TRIO 012 – 10 patients; BETH - 41 patients; TRIO 018 - 18 patients; TRIO 019 - 12 patients; and TRIO 022 – 22 patients. We are also collaborating with TRIO on the TRIO 023/EMBRACA trial of a novel agent in women with BRCA positive metastatic breast cancer.

Fondazione Michelangelo

Michelangelo is a non-profit Italian oncology research group; leading the NeoTRIPaPDL1 study, of a PDL1-directed antibody in triple negative breast cancer in the neoadjuvant setting in combination with nav-paclitaxel and carboplatin. The study has opened in 6 Irish research units.

University of Edinburgh

The University of Edinburgh is an internationally renowned centre for teaching and research in Edinburgh which also fulfils the role of sponsor for studies which are investigator-led and where the Chief investigator is a University employee. SUPREMO (ICORG 04-11) is sponsored by the University of Edinburgh; this trial is closed and patients in Galway University Hospital, University Hospital Limerick, UPMC Whitfield Cancer Centre (Waterford) and Cork University Hospital are in 10 year follow up.

Specific collaborations during 2016

University of Warwick

University of Warwick (UK) is the sponsor for De-ESCALaTE HPV trial ICORG 12-39 which is open in St Luke's Radiation Oncology Network (SLRON) and has enrolled 16 patients.

Trans-Tasman Radiation Oncology Group (TROG)

TROG Cancer Research is Australia's and New Zealand's specialist clinical research group for cancers that can be treated with radiotherapy. TROG is a cooperative multi-disciplinary organisation dedicated to the control of a wide range of cancers through quality multi-centre research. TROG provides the infrastructure and governance for national and international collaborations to help ensure the development of more effective treatments for cancer.

Over 300 clinicians and other researchers and over 8000 patients have contributed to the TROG research program.

Through these collaborative efforts, involving more than 60 cancer treatment centres across Australia and New Zealand, as well as contributing centres internationally, TROG has launched over 50 cancer research trials and achieved significant improvements in patient care and outcomes.

The TROG study, ICORG 10-06 - The Radiation Doses and Fractionation Schedules in Non-Low Risk Ductal Carcinoma In Situ (DCIS) of the Breast closed to accrual in June 2014 and is now in long-term follow up at three research units (St Luke's Radiation Oncology Network (SLRON), Cork University Hospital, Galway University Hospital). We had the highest accrual per unit for this trial of all of the participating international cooperative groups.

Other key collaborations

Other important collaborations include the IBCSG – which coordinates and sponsor Breast Cancer Studies (SOLE, SOFT and POSITIVE); SCTU - Southampton Clinical Trial Unit - UK partner in the Phase III NeoAEGIS trial for Oesophageal Cancer; MARGIT, Cancer Trials Ireland's collaborator on a translational study in colorectal cancer, AC-Angiopredict (ICORG 12-16), with 28 patients enrolled in Germany and 48 patients enrolled in Ireland. The study is funded through a grant from the European Union. Collaborations with various universities in the UK allow participation in important radiotherapy trials, e.g. PLATO ACT5 (University of Leeds), ROAM (University of Liverpool).

Industry collaborations

During the last 21 years, we have established clinical research partnerships with many global pharmaceutical and biotechnology companies including Abbvie, Amgen, Astellas, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Eli-Lilly, Eisai, Inflection Biosciences, Novartis, Genomic Health, Janssen, Merck/Serono, MSD, Novartis, Pfizer, Roche/Genentech, Puma Biotechnology, Sanofi-Aventis (Genzyme), Takeda (Millennium Pharmaceuticals) and Teva (Cephalon). The breadth of studies includes early phase I/II clinical trials of novel anti-cancer agents through to large registration trials for more established treatments.

Our relationships with global pharmaceutical and biotechnology companies ranges from study development, to start-up through to follow-up, and therefore require varying degrees of input. Many of the trials are pivotal registration trials for the agents involved.

The contribution of the Cancer Trials Ireland network to the development of a number of breakthrough compounds has been acknowledged at many international meetings and in high impact peer reviewed journals. The publication listing for the group is detailed on pages 34-41.

Combined Study Code	Shortcode	Study (Acronym)	Disease Area	Company
CTRIAL-IE16-64	16-64	Roche MO29518 PDL1 Basket Study	Basket	ROCHE
CTRIAL-IE16-28	16-28	MK3475-177 Colorectal	Gastrointestinal	Merck
CTRIAL-IE16-29	16-29	MK3475-181 (Keynote 181)	Gastrointestinal	Merck
CTRIAL-IE16-27	16-27	KEYNOTE-426	Genitourinary	Merck
CTRIAL-IE16-05	16-05	Pfizer B9991010 JAVELIN 100	Gynaecology	Pfizer
CTRIAL-IE16-54	16-54	BMS CA209 714	Head and Neck	BMS
CTRIAL-IE16-18	16-18	BMS CA209-451 (Checkmate - 451)	Lung	BMS
CTRIAL-IE16-08	16-08	Millennium Pevonedistat P2001	Lymphoma/Haematology	Takada
CTRIAL-IE16-09	16-09	Astellas 2215-CL-0301	Lymphoma/Haematology	Astellas
CTRIAL-IE16-10	16-10	Merck KEYNOTE 185	Lymphoma/Haematology	Merck
CTRIAL-IE16-14	16-14	BMS 209-401 (Checkmate 401)	Melanoma	BMS
CTRIAL-IE16-50	16-50	AZA-JMML-001	Paediatrics	AZ
CTRIAL-IE16-67	16-67	BMS CA209-648	Gastrointestinal	BMS
CTRIAL-IE16-71	16-71	BMS CA209-848	Gastrointestinal	BMS
CTRIAL-IE16-69	16-69	E7080-G000-307	Genitourinary	Eisai
CTRIAL-IE16-70	16-70	CA209-274	Genitourinary	BMS
CTRIAL-IE16-66	16-66	MK3475-240 (KEYNOTE-240)	Gastrointestinal	Merck
CTRIAL-IE16-73	16-73	BMS CA 209-577	Gastrointestinal	BMS
CTRIAL-IE16-63	16-63	IMmotion010	Genitourinary	ROCHE
CTRIAL-IE16-79	16-79	Abbvie M15-550	Lymphoma/Haematology	AbbVie
CTRIAL-IE16-16	16-16	MK-3475-189/KEYNOTE-189	Lung	Merck
CTRIAL-IE16-17	16-17	BMS CA 209-171	Lung	BMS
CTRIAL-IE16-13	16-13	Melanoma MK 3475 Keynote 252	Melanoma	Merck

Table 5: Industry trials (no breast cancer trials opened during 2016).

Performance Metric 2. Trials Portfolio

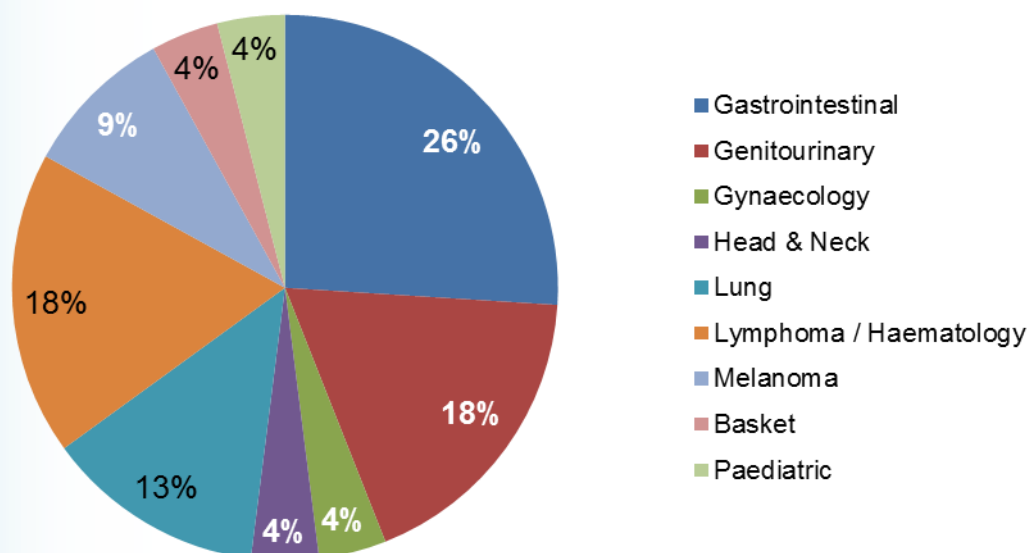


Figure 3: Distribution of the new Industry trials across the disease sub-groups opened during 2016 (no breast cancer trials opened during 2016).

We have also signed mutual agreements with some of the major Contract Research Organisations (CROs) including: ICON, COVANCE, PARAXEL, PPD, QUINTILES and CHROMOS. CROs are partnering with many of the companies listed in Table 5 and therefore approach Cancer Trials Ireland as a first step in assessing the feasibility of opening a new trial in Ireland.

Cancer trials research unit monitoring

Monitoring services provided to the cancer trials research units which are located in hospitals around the country includes a broad range of activities that are conducted from the commencement of a trial to close-out.

In 2016, we introduced a risk-based monitoring approach, in line with newly adopted clinical research practice by both the industry and similar research organisations, and as per guidelines published by regulatory authorities.

The level of monitoring activity and rationale for the chosen monitoring strategy are determined at the start of each trial according to a Standard Operating Procedure on Risk Assessment and Management Plan.

All our ongoing trials were reviewed in 2016 and a new risk-based monitoring plan per trial implemented. The monitoring level can be a combination of on-site and centralised monitoring activities as appropriate to the risk inherent to the type of study and other identified risks. Triggers for decreased or more frequent targeted on-site monitoring visits can be identified in the monitoring plan. The monitoring level can also be determined on a site-by-site basis depending on the previous or unknown experience of the investigational site.

Performance Metrics 4: Audits

Audits

Audit is a quality assurance tool to identify non-compliances with the regulatory requirements and guidelines applicable to trials as well as opportunities for improvement. It also plays an educational role as the auditors propose actions to secure compliance based on their knowledge and experience of the applicable regulatory requirements and guidelines.

Audit can also help prepare for regulatory inspections. This metric reports the numbers of days spent preparing for and conducting audits and follow-up activity as well as active participation in external sponsor audits and regulatory inspections both at our central office and at cancer trials research units around the country.

Audit Type	Preparation (days)	Audit (days)	Follow-up (days)
Regulatory Authority (HPRA) Inspection of Cancer Trials Ireland (central office)	13.25	9.5	13.75
External Sponsor audit of Cancer Trials Ireland research units	3	4	3.75
External Sponsor audit of Cancer Trials Ireland (central office)	9.25	10.25	8.5
Cancer Trials Ireland internal audit	3.5	12	0
Cancer Trials Ireland audit of research units	14	34.25	10
Total	43	70	36

Table 6: Trial Audits performed by Cancer Trials Ireland personnel as well as active participation in external sponsor audits and regulatory inspections conducted at central office and at research units around the country during 2016 and approximate amount of staff time spent on these activities.

Staff Training

Training Members and staff is a key part of our quality assurance and capacity building facilitated by our central office. This metric includes the training courses conducted by the central office training team along with attendance by central office staff and investigators/ investigational staff at research units, and significant external training courses attended by staff.

Type of training	Number of sessions	Number of attendees (Central office staff)	Number of attendees (Research unit staff)
Data Management training	3	50	-
Disease specific training	2	34	-
RECIST 1.1 Training	2	29	-
Audit Preparation Training	2	12	13
Chief Investigator/ Safety Monitoring Committee member training	15	6	32
SOP training	2	34	-
Patient confidentiality/ Data protection	4	41	-
Pharmacovigilance Training	5	30	14
Statistical Considerations	1	29	-
Time Management	1	21	-
Drug interactions: QT Intervals and CYP450	1	25	-
Investigational Medicinal Product Management	1	23	-
Monitoring vs auditing	1	25	-
GCP Basic Training for Pharmacists	1	-	2
GCP course Day 1	2	8	20
GCP course Day 2	2	12	20
GCP Basic/ Refresher Training (Sponsor/ Investigational research unit Staff)	1	15	-
GCP Basic/ Refresher Training (Investigational research unit)	5	1	34
Addendum to GCP E6 (R2)	2	42	-

Table 7: Training courses conducted by the central office training team attended by central office staff and investigators/ investigational staff at research units.

Date	Course	Attendees
13-Apr-2016	EFGCP: How to Ensure Optimal Ethical Review within the New Clinical Trials Regulation. Implementation of the new Clinical Trials Regulation in the EU with regards to EC requirements	Ethics and Regulatory Coordinator
27/28-Apr-2016	ECCRT: Responsibilities of the more mature monitor dealing with complex clinical trial and site management issues.	Clinical Research Associate
18/19-May-2016	TOPRA: Continuing Regulatory Education Development (CRED) Clinical Trials. Current requirements for an EU Clinical Trial Application (CTA) and information on how the introduction of the new clinical trial regulation will change things.	Ethics and Regulatory Coordinator
31-May-2016	Novartis: Overview of a Quality Management System	Trainee Quality Assurance Auditor
30-Jun-/01-Jul-2016	Research Quality Association (RQA): The Auditing Course. Designed to develop auditing skills and to give an insight into the role of the audit programme in achieving regulatory compliance and quality improvement.	Quality and Training Associate
11/12/13-Jul-2016	Research Quality Association (RQA): GCP Audits – Principles and Practice. Methods for assuring that GCP requirements have been met and practicalities of clinical trial audit.	Trainee Quality Assurance Auditor
24/25-Aug-/ 27-Sep-2016	Management Essentials	Line Managers: Quality and Training Manager Pharmacovigilance Manager Data Management Team Leader Clinical Project Manager (x7) Clinical Program Leader (x2) Business Development Manager Operations Officer Financial Controller HR Manager
20-Sep-2016	HRB-TMRN Webinar: Risk –based monitoring and the new ICH-GCP guideline	Pharmacovigilance Manager Quality and Training Associate Trainee Quality Assurance Auditor
21-Sep-2016	MHRA GCP symposium: Hot topics/ updates of regulatory and GCP requirements	Quality and Training Manager
22-Sep-2016	MHRA GLP/ GCP Laboratory symposium: Hot topics/ updates of regulatory and GLP/GCP requirements for laboratories	Quality and Training Manager
23-Sep-2016	EORTC: A One-Day Journey through EORTC Activities	Trainee Quality Assurance Auditor
21-Oct-2016	EMA: MedDRA: Safety Data Analysis and SMQs	Pharmacovigilance Manager
08-Nov-2016	Research Quality Association (RQA): Vendor and Sponsor Cooperation in Clinical Trials	Quality and Training Associate
09/10/11-Nov-2016	Research Quality Association (RQA): Annual Conference: Quality- Adding Value.	Quality and Training Associate

Infrastructure Development

Development of our capability and infrastructure for clinical trials is one of our key objectives.

Key organisational changes took place to respond to the recommendations of the 2015 HRB Panel Review and the 2015 HPRA Regulatory Inspection Report which include the establishment of new medical oversight structures, departments, and processes to respond to obligations and recommendations. The following appointments were made: A Communications Advisor was appointed through the HRB Knowledge Exchange and Dissemination Award (KEDS) to raise the profile of cancer trials.

Following on from the recommendations of the International Panel, we appointed a Business Development Manager to work with research units. The post holder also manages the Feasibility Study Service by the Clinical team for all industry teams interested in conducting cancer trials in Ireland

Funding was used to protect the time of the Clinical Lead and Vice Clinical and to respond to the downward trend in overall accrual numbers.

Performance Metrics 7: Participation

Participation

Cooperative groups such as ours function best when they work together sharing expertise, experience and resources. This metric indicates participation with the wider community including:

- Number of scientific meetings held.
- Representation at International scientific meetings. (*We acknowledge the generous support from pharmaceutical companies that makes it possible to attend these important meetings.*)
- Trials introduced and developed by local Principal Investigators (PIs).

We held three scientific meetings, (Disease Specific Sub Group — DSSG) in 2016: February, June and October. Within these meetings there were disease specific meetings covering the following disease areas; Genitourinary, Lung, Gastrointestinal, Breast, Lymphoma/ Haematology, Translational, Gynaecology, Head and Neck, Central Nervous System, Paediatric and Melanoma.

The DSSG meetings also hosted meetings for Team Leaders from the cancer trials research units around the country, the Clinical Executive Committee and industry representatives. Some also include GCP training refreshers.

A Stakeholder Engagement and Patient Advocate Advisory Group (PAAG) became a permanent feature of these DSSG meetings during 2016. An average of 100 stakeholders and patients attended and topics discussed included Immunotherapy Trials, Translational Research, and Patient-led research.

Date:	Meeting:	Location:
Jan 7-9	ASCO- 2016 GU Cancers Symposium	San Francisco, US
Jan 21	NRG Oncology Group Meeting	Atlanta, US
Jan 21 – 23	ASCO- 2016 GI Cancers Symposium	San Francisco, US
Mar 9-11	European Breast Cancer Conference	Amsterdam, Netherlands
Mar 12	IBCSG	Amsterdam, Netherlands
Apr 13-16	6 th European Lung Cancer Conference (ELCC)	Geneva, Switzerland
Apr 21-22	2 nd John Fitzpatrick Irish Prostate Cancer Conference	Dublin, AVIVA stadium
29 Apr- 3 May	ESTRO 35	Turin, Italy
May 12- 14	ECOG-ACRIN Spring Meeting	Boston, MA, US
Jun 1-2	GCIG	Chicago, IL
Jun 3-7	2016 ASCO Annual Meeting	Chicago, IL
Jun 9-12	21st Congress of the European Haematology Association	Copenhagen
29 Jun-1 July	British Neuro-Oncology Society (BNOS) Annual Meeting	Leeds, UK
Jul 14-17	NRG Oncology Group Meeting	Dallas, TX, US
Sep 25-28	ASTRO Annual Meeting	Boston, MA
Oct 7-11	ESMO 2016 Congress	Copenhagen
Oct 20-21	Gathering around Cancer	Dublin, Croke Park
Nov 11-12	ETOP, annual meeting	Amsterdam
Nov 29 - 2 Dec	28 th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics	Munich, Germany
Nov 10-12	ECOG-ACRIN Group Meeting	Orlando, FL
Dec 3-6	2016 ASH Annual Meeting	San Diego, CA

Table 9: Cancer Trials Ireland participation at international scientific meetings during 2016.

Membership

This metric records the number of registered Members of Cancer Trials Ireland.

Cancer Trials Ireland total membership on 31st December 2016 exceeded 500 (50 new members joined during 2016).

During 2016 there were 136 new Stakeholder members (this number is broken down between Patient Advocates and Industry) bringing this group to over 850.

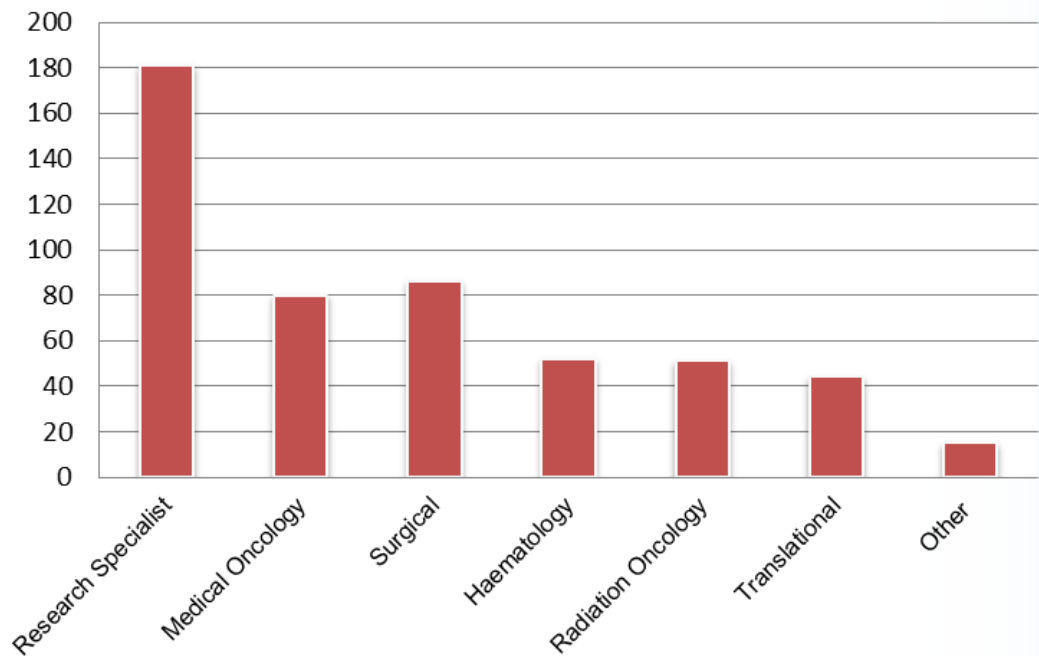


Fig. 4: Cancer Trials Ireland Membership

Performance Metrics 9: Publications

Publications

This metric records the publications in peer-reviewed journals and abstracts accepted at top level international meetings based on the findings of trials the Members of Cancer Trials are, or have been, involved in.

Sub Group	Peer Reviewed Journal Articles	Abstracts: Poster/Oral Presentations
Breast	6	10
Gastrointestinal	1	2
Genitourinary	2	9
Gynaecological	2	0
Lymphoma and Haematology	1	2
Lung	1	5
Melanoma	0	2
Other	0	0
Total	13	30

Table 10: Publications during 2016.

ARTICLES

Breast

Cancer Trials Ireland number: short name. 09-01: TRIO 018

Finn, R. S., J. P. Crown, J. Ettl, M. Schmidt, I. M. Bondarenko, I. Lang, T. Pinter, K. Boer, R. Patel, S. Randolph, S. T. Kim, X. Huang, P. Schnell, S. Nadanaciva, C. H. Bartlett and D. J. Slamon (2016). **"Efficacy and safety of palbociclib in combination with letrozole as first-line treatment of ER-positive, HER2-negative, advanced breast cancer: expanded analyses of subgroups from the randomized pivotal trial PALOMA-1/TRIO-18."** Breast Cancer Res 18(1): 67.

Cancer Trials Ireland number: short name. 12-43: TRIO 022

Finn, R. S., M. Martin, H. S. Rugo, S. Jones, S. A. Im, K. Gelmon, N. Harbeck, O. N. Lipatov, J. M. Walshe, S. Moulder, E. Gauthier, D. R. Lu, S. Randolph, V. Dieras and D. J. Slamon (2016). **"Palbociclib and Letrozole in Advanced Breast Cancer."** N Engl J Med 375(20): 1925-1936.

Cancer Trials Ireland number: short name. 05-09: IBIS-II

Forbes, J. F., I. Sestak, A. Howell, B. Bonanni, N. Bundred, C. Levy, G. von Minckwitz, W. Eiermann, P. Neven, M. Stierer, C. Holcombe, R. E. Coleman, L. Jones, I. Ellis, J. Cuzick and I.-I. investigators (2016). **"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."** Lancet 387(10021): 866-873.

Cancer Trials Ireland number: short name. 01-04: BCIRG 005

Press, M. F., G. Sauter, M. Buyse, H. Fourmanoir, E. Quinaux, D. D. Tsao-Wei, W. Eiermann, N. Robert, T. Pienkowski, J. Crown, M. Martin, V. Valero, J. R. Mackey, V. Bee, Y. Ma, I. Villalobos, A. Campeau, M. Mirlacher, M. A. Lindsay and D. J. Slamon (2016). **"HER2 Gene Amplification Testing by Fluorescent In Situ Hybridization (FISH): Comparison of the ASCO-College of American Pathologists Guidelines With FISH Scores Used for Enrollment in Breast Cancer International Research Group Clinical Trials."** J Clin Oncol 34(29): 3518-3528.

Cancer Trials Ireland number: short name. 06-02: SOFT

Regan, M. M., P. A. Francis, O. Pagani, G. F. Fleming, B. A. Walley, G. Viale, M. Colleoni, I. Lang, H. L. Gomez, C. Tondini, G. Pinotti, K. N. Price, A. S. Coates, A. Goldhirsch and R. D. Gelber (2016). **"Absolute Benefit of Adjuvant Endocrine Therapies for Premenopausal Women With Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Early Breast Cancer: TEXT and SOFT Trials."** J Clin Oncol 34(19): 2221-2231.

Cancer Trials Ireland number: short name. 10-05: TCHL

Toomey, S., A. J. Eustace, L. B. Pritzker, K. P. Pritzker, J. Fay, A. O'Grady, R. Cummins, L. Grogan, J. Kennedy, D. O'Connor, L. Young, E. W. Kay, N. O'Donovan, W. M. Gallagher, R. Kalachand, J. Crown and B. T. Hennessy (2016). **"RE: RNA Disruption Assay as a Biomarker of Pathological Complete Response in Neoadjuvant Trastuzumab-Treated Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer."** J Natl Cancer Inst 108(8).

Gastrointestinal

Cancer Trials Ireland number: short name.: 12-16: AC-ANGIOPREDICT

Betje, J., A. Barat, V. Murphy, T. Hielscher, N. C. Van Grieken, S. Belle, T. Zhan, N. Härtel, M. Kripp, O. Bacon, M. Cordes, E. W. Kay, H. M. Verheul, M. Neerincx, B. Hennessy, R. D. Hofheinz, T. Gaiser, B. Ylstra, J. H. Prehn, D. Lambrechts, A. T. Byrne, M. P. Ebert and N. Schulte (2016). **"Outcome of Colorectal Cancer Patients Treated with Combination Bevacizumab Therapy: A Pooled Retrospective Analysis of Three European Cohorts from the Angiopredict Initiative."** Digestion 94(3): 129-137.

Performance Metrics 9: Publications

Genitourinary

Cancer Trials Ireland number: short name. 02-04: EORTC Prostate

Bolla, M., P. Maingon, C. Carrie, S. Villa, P. Kitsios, P. M. Poortmans, S. Sundar, E. M. van der Steen-Banasik, J. Armstrong, J. F. Bosset, F. G. Herrera, B. Pieters, A. Slot, A. Bahl, R. Ben-Yosef, D. Boehmer, C. Scrase, L. Renard, E. Shash, C. Coens, A. C. van den Bergh and L. Collette (2016). **"Short Androgen Suppression and Radiation Dose Escalation for Intermediate- and High-Risk Localized Prostate Cancer: Results of EORTC Trial 22991."** *J Clin Oncol* 34(15): 1748-1756.

Cancer Trials Ireland number: short name. 08-18: CHHiP Study

Dearnaley, D., I. Syndikus, H. Mossop, V. Khoo, A. Birtle, D. Bloomfield, J. Graham, P. Kirkbride, J. Logue, Z. Malik, J. Money-Kyrle, J. M. O'Sullivan, M. Panades, C. Parker, H. Patterson, C. Scrase, J. Staffurth, A. Stockdale, J. Tremlett, M. Bidmead, H. Mayles, O. Naismith, C. South, A. Gao, C. Cruickshank, S. Hassan, J. Pugh, C. Griffin, E. Hall and C. H. Investigators (2016). **"Conventional versus hypofractionated high-dose intensity-modulated radiotherapy for prostate cancer: 5-year outcomes of the randomised, non-inferiority, phase 3 CHHiP trial."** *Lancet Oncol* 17(8): 1047-1060.

Gynaecological

Cancer Trials Ireland number: short name. 09-03: AGO OVAR 16 (GSK: VEG110655)

Harter, P., T. Johnson, D. Berton-Rigaud, S. Y. Park, M. Friedlander, J. M. Del Campo, M. Shimada, F. Forget, M. R. Mirza, N. Colombo, C. Zamagni, J. K. Chan, M. Imhof, T. J. Herzog, D. O'Donnell, F. Heitz, K. King, S. Stinnett, C. Barrett, M. Jobanputra, C. F. Xu and A. du Bois (2016). **"BRCA1/2 mutations associated with progression-free survival in ovarian cancer patients in the AGO-OVAR 16 study."** *Gynecol Oncol* 140(3): 443-449.

Cancer Trials Ireland number: short name. 09-03: AGO-OVA 16 (GSK: VEG110655)

Pulford, D. J., P. Harter, A. Floquet, C. Barrett, D. H. Suh, M. Friedlander, J. A. Arranz, K. Hasegawa, H. Tada, P. Vuylsteke, M. R. Mirza, N. Donadello, G. Scambia, T. Johnson, C. Cox, J. K. Chan, M. Imhof, T. J. Herzog, P. Calvert, P. Wimberger, D. Berton-Rigaud, M. C. Lim, G. Elser, C. F. Xu and A. du Bois (2016). **"Communicating BRCA research results to patients enrolled in international clinical trials: lessons learnt from the AGO-OVAR 16 study."** *BMC Med Ethics* 17(1): 63.

Lung

Cancer Trials Ireland number: short name. 14-13: MSD MK-3475-024 / KEYNOTE-024

Reck, M., D. Rodriguez-Abreu, A. G. Robinson, R. Hui, T. Csoszi, A. Fulop, M. Gottfried, N. Peled, A. Tafreshi, S. Cuffe, M. O'Brien, S. Rao, K. Hotta, M. A. Leiby, G. M. Lubiniecki, Y. Shentu, R. Rangwala, J. R. Brahmer and K.-. Investigators (2016). **"Pembrolizumab versus Chemotherapy for PD-L1-Positive Non-Small-Cell Lung Cancer."** *N Engl J Med* 375(19): 1823-1833.

Lymphoma and Haematological

Systematic Review

Scott, K., P. J. Hayden, A. Will, K. Wheatley and I. Coyne (2016). **"Bortezomib for the treatment of multiple myeloma."** *Cochrane Database Syst Rev* 4: CD010816.

Abstracts: Poster/Oral Presentations 2016**Breast**

Cancer Trials Ireland number: short name. 10-05: TCHL

Collins, D. M., S. F. Madden, N. Gaynor, W. M. Gallagher, N. O'Donovan and J. Crown (2016). **"Plasma chemokine profile of HER2+ patients treated with docetaxel (T) and carboplatin (C) in combination with trastuzumab (H) and/or lapatinib (L) in the neo-adjuvant setting."** Poster Presentation- SABCS.

Cancer Trials Ireland number: short name. 13-01: ABC Survey

Battley, J. E., C. Brady, M. O'Connor, C. G. Murphy, B. R. Bird, D. O'Mahony, J. R. Ismail, K. A. Duffy, J. M. Walshe, J. P. Crowne, C. M. Kelly, M. J. Martin, M. J. Kennedy, L. Coate, B. Hennessy, M. Keane, R. Feighery, M. Cunnane, V. Murphy, I. Parker and S. O'Reilly (2016). **"ICORG 13-01 ABC Survey: Are we meeting the needs of patients with advanced breast cancer (ABC) in Ireland? A nationwide survey."** Poster Presentation- 9th Annual World Cancer Congress.

Cancer Trials Ireland number: short name. 10-05: TCHL

Eustace, A. J., S. Toomey, J. Fay, A. Teiserkiene, M. Milewska, E. Kay, D. O'Connor, A. Fagan, L. S. Young, N. O'Donovan, J. M. Walshe, A. D. Hill, M. J. Kennedy, C. Power, D. Duke, N. Hambly, W. M. Gallagher, J. Crown and B. Hennessy (2016). **"The clinical impact of early immunological responses in human HER2-positive breast cancers on responsiveness to trastuzumab-based therapy."** Poster Presentation- ASCO Annual Meeting (J Clin Oncol 34, 2017 (suppl; Ab 587)).

Cancer Trials Ireland number: short name. 10-05: TCHL

Gaynor, N., A. Canonici, A. Eustace, M. McDermott, N. O'Donovan, J. Crown and D. M. Collins (2016). **"The effector capacity of peripheral blood mononuclear cells (PBMCs) from HER2+ breast cancer (BC) patients treated with chemotherapy and HER2-targeted therapies (ICORG 10-05)."** Poster Presentation- SABCS.

Cancer Trials Ireland number: short name. 12-45: SNAP

Gennari, A., Z. Sun, U. Hasler, M. Colleoni, J. Kennedy, R. Von Moos, M. J. Vidal, B. Hennessy, J. Walshe, K. A. Parraga, S. Morales Murillo, O. Pagani, A. Barbeaux, S. Borstnar, M. Rabaglio, R. Maibach, M. Regan and G. Jerusalem (2016). **"Randomized phase II study evaluating different schedules of nab-Paclitaxel in metastatic breast cancer (MBC): results of the SNAP study."** Poster Presentation- SABCS.

Cancer Trials Ireland number: short name. 15-34: Recurrence score

Keegan, N., M. Milewski, C. M. Kelly, V. Murphy, C. Chao, J. Walshe, M. J. Kennedy, M. O'Connor, C. Murphy, S. O'Reilly, M. Keane, K. Duffy, B. Hennessy and P. G. Morris (2016). **"The Impact of the 21 Gene Recurrence Score (RS) on Chemotherapy Prescribing in Estrogen Receptor (ER) Positive, Lymph Node (LN) Positive Early Stage Breast Cancer in Ireland."** Poster Presentation- SABCS.

Cancer Trials Ireland number: short name. 06-32: NSABP B-42

Mamounas, E. P., H. Bandos, B. C. Lembersky, C. E. Geyer, L. Fehrenbacher, M. L. Graham, S. L. Chia, A. M. Brufsky, B. T. Hennessy, G. S. Soori, S. R. Dakhil, T. E. Seay, J. L. Wade, E. C. McCarron, S. Paik, S. M. Swain, D. L. Wickerham and N. Wolmark (2016). **"A randomized, double-blinded, placebo-controlled clinical trial of extended adjuvant endocrine therapy (tx) with letrozole (L) in postmenopausal women with hormone-receptor (+) breast cancer (BC) who have completed previous adjuvant tx with an aromatase inhibitor (AI): Results from NRG Oncology/NSABP B-42."** Oral Presentation- SABCS.

Performance Metrics 9: Publications

Cancer Trials Ireland number: short name. 15-16: FLIPPER

Moreno, F., N. Martínez-Jáñez, I. Garau, J. A. Guerra, J. Alarcón, B. Bermejo, L. Gonzalez-Cortijo, C. Bueno, J. Lao, S. Bezares, L. Rosell, A. Blach, R. Caballero, E. Carrasco, F. Rojo, M. Martín, M. O'Connor, A. Hernando and J. Albanell (2016). **"A phase II study to compare fulvestrant (F) 500mg plus placebo versus (vs) F 500mg plus palbociclib (P) as first line treatment for postmenopausal women with hormone receptor (HR)-positive advanced breast cancer (BC) sensitive to endocrine therapy (ET). "The FLIPPER Study" (GEICAM/2014-12)." Poster Presentation- SABCS.**

Cancer Trials Ireland number: short name. 16-20: NL Ratio in BC

Rafee, S., D. J. McHugh, M. Greally, O. Ayodele, N. Keegan, M. Lim, A. Hassan, D. O'Mahony, B. Hennessy, C. Kelly, J. Kennedy, J. Walshe, M. O'Connor, G. Leonard, V. Murphy, V. Livingstone, M. Corrigan and S. O'Reilly (2016). **"Neutrophil-to-lymphocyte ratio (NLR) and platelet-to-lymphocyte ratio (PLR) as predictive biomarkers of pathologic complete response (pCR) in neoadjuvant breast cancer: an Irish Clinical Oncology Group study (ICORG 16-20)." Poster Presentation – ESMO (Ann Oncol 27 (suppl_6): 1538P).**

Cancer Trials Ireland number: short name. 10-05: TCHL

Toomey, S., A. J. Eustace, J. Fay, M. Milewska, A. Teiserkiene, E. Kay, D. O'Connor, L. S. Young, N. O'Donovan, W. Grogan, O. S. Breathnach, J. M. Walshe, M. J. Kennedy, A. D. Hill, C. Power, D. Duke, N. Hambly, W. M. Gallagher, J. Crown and B. Hennessy (2016). **"Impact of somatic PIK3CA and ERBB family mutations on pathological complete response (pCR) in HER2-positive breast cancer patients who received neoadjuvant HER2-targeted therapies." Poster Presentation- ASCO Annual Meeting (J Clin Oncol 34, 2017 (suppl; Ab 591)).**

Gastrointestinal

Cancer Trials Ireland number: short name. 12-07: LCCC 1029 (Regorafenib)

O'Neil, B., S. O'Reilly, S. Kasbari, R. Kim, R. McDermott, D. Moore, W. Grogan, A. Cohn, T. Bekaii-Saab, A. Ivanova, O. Olowokure, N. Fernando, J. McCaffrey, B. El-Rayes, A. Horgan, T. Ryan, G. Sherrill, G. Yacoub, R. M. Goldberg and H. Sanoff (2016). **"A multi-center, randomized, double-blind phase II trial of FOLFIRI + regorafenib or placebo for patients with metastatic colorectal cancer who failed one prior line of oxaliplatin-containing therapy." Poster Presentation- ESMO (Ann Oncol 27 (suppl_6): 464PD)**

Cancer Trials Ireland number: short name. 12-16: AC-ANGIOPREDICT

van Grieken, N. C., M. Cordes, H. M. Verheul, M. Neerincx, C. Punt, M. Koopman, G. A. Meijer, V. Murphy, A. Barat, J. Betge, M. Ebert, T. Gaiser, B. Fender, R. Klinger, S. Das, D. Smeets, D. O'Connor, D. Lambrechts, A. T. Byrne and B. Ylstra (2016). **"Copy number alterations as predictive biomarkers for response to bevacizumab in metastatic colorectal cancer." Poster Presentation-ESMO (Ann Oncol (2016) 27 (suppl_6): 53PD)**

Genitourinary

Cancer Trials Ireland number: short name. 02-04: EORTC Prostate

Bolla, M., A. C. M. Van Den Bergh, C. Carrie, S. Villà, P. Kitsios, P. M. Poortmans, S. Sundar, E. M. van der Steen-Banasik, J. Armstrong, J.-F. Bosset, F. Herrera, B. Pieters, A. Slot, A. Bahl, L. Collette and P. Maingon (2016). **"EORTC trial 22991: Results of a phase III study comparing 6 months of androgen suppression and irradiation versus irradiation alone for localized T1b-cT2aN0M0 prostate cancer." Poster Presentation- ASCO Genitourinary Cancers Symposium (J Clin Oncol 34, (suppl 2S, abstr 22)).**

Genitourinary

Cancer Trials Ireland number: short name. 15-21: The ExPeCT Trial

Brady, L., G. Sheill, T. Vlajnic, J. Greene, O. Casey, A.-M. Baird, E. Guinan, J. Hussey, B. Hayes and S. Finn (2016). **"The Impact of a Structured Exercise Programme on Adipokine Status in Metastatic Prostate Cancer Patients."** Poster Presentation- WCRF meeting.

Cancer Trials Ireland number: short name. 15-21: The ExPeCT Trial

Brady, L., G. Sheill, T. Vlajnic, J. Greene, O. Casey, A.-M. Baird, E. Guinan, J. Hussey, F. Cahill, M. Van Hemelrijck, N. Peat, S. Rudman, T. Lynch, R. P. Manecksha, B. Hayes, M. Cunningham, L. Grogan, J. McCaffrey, D. O'Donnell, R. Mc Dermott, J. O'Leary and S. Finn (2016). **"Adipokine Status Post-Exercise in a Cohort of Patients with Metastatic Prostate Cancer."** Poster Presentation- Trinity College 10th International Cancer Conference.

Cancer Trials Ireland number: short name. 15-21: The ExPeCT Trial

Sheill, G., L. Brady, E. Guinan, J. Hussey, D. Hevey, T. Vlajnic, O. Casey, A.-M. Baird, F. Cahill, M. Van Hemelrijck, N. Peat, S. Rudman, T. Lynch, R. P. Manecksha, B. Hayes, M. Cunningham, L. Grogan, J. McCaffrey, D. M O'Donnell, R. Mc Dermott, S. Finn (2016). **"Physical Activity and Quality of Life in Men living with Advanced Prostate Cancer"** Poster Presentation- Trinity College 10th International Cancer Conference.

Cancer Trials Ireland number: short name. 14-06: ANZUP ENZAMET study

Davis, I. D., M. R. Stockler, A. J. Martin, W. Hague, X. Coskinas, S. Yip, E. Tu, N. J. Lawrence, H. Chan, R. McDermott, S. Chowdhury, V. Marchesin, O. Deignan, F. Vera-Badillo, S. A. North, A. Montenegro and C. Sweeney (2016). **"Randomised phase 3 trial of enzalutamide in first-line androgen deprivation therapy for metastatic prostate cancer: The ANZUP ENZAMET Trial (ANZUP 1304)."** Poster Presentation- ASCO Annual Meeting (J Clin Oncol 34, (suppl; abstr TPS5090)).

Cancer Trials Ireland number: short name. 14-04: iPROSPECT Study

Greene, J. P., O. Casey, K. O'Leary, C. Fahey, S. Bracken, S. A. Glynn, A. Perry, W. Watson, S. Finn and R. McDermott (2016). **"The Irish Programme for Stratified Prostate Cancer Therapy (iPROSPECT)."** Poster Presentation- ASCO Genitourinary Cancers Symposium (J Clin Oncol 34, (suppl 2S, abstr 335)).

Cancer Trials Ireland number: short name. 05-03: Spinal Cord Compression

Lee, K., C. Small, P. Kelly, O. McArdle, J. O'Sullivan, D. Hacking, M. Pomeroy, M. Stevenson, J. Armstrong, M. Moriarty, M. Dunne, A. Clayton-Lea, I. Parker, C. Collins and P. Thirion (2016). **"(ICORG 05-03): Radiotherapy in malignant spinal cord compression; The quality of life analysis."** Poster Presentation- ESTRO (Radiother Oncol 119 (suppl_1): PV0281).

Cancer Trials Ireland number: short name. 15-21: The ExPeCT Trial

Sheill, G., L. Brady, E. Guinan, J. Hussey, D. Hevey, T. Vlajnic, O. Casey, A.-M. Baird, F. Cahill, M. Van Hemelrijck, N. Peat, S. Rudman, T. Lynch, R. P. Manecksha, B. Hayes, M. Cunningham, L. Grogan, J. McCaffrey, D. O'Donnell, R. Mc Dermott, J. O'Leary and S. Finn (2016). **"Physical Activity and Quality of Life in Men living with Advanced Prostate Cancer."** Poster Presentation- WCRF meeting.

Cancer Trials Ireland number: short name. 14-07: ANZUP ENZARAD study

Williams, S. G., I. D. Davis, C. Sweeney, M. R. Stockler, A. J. Martin, W. Hague, X. Coskinas, S. Yip, E. Tu, H. Chan, N. J. Lawrence, R. McDermott, S. Hughes, V. Marchesin, O. Deignan and P. L. Nguyen (2016). **"Randomised phase 3 trial of enzalutamide in androgen deprivation therapy (ADT) with radiation therapy for clinically localised high-risk or node-positive prostate cancer: ENZARAD (ANZUP 1303)."** Poster Presentation- ASCO Annual Meeting (J Clin Oncol 34, (suppl; abstr TPS5086)).

Performance Metrics 9: Publications

Lung

Cancer Trials Ireland number: short name. 14-13: MSD MK-3475-024 / KEYNOTE-024

Brahmer, J. R., D. Rodríguez-Abreu, A. G. Robinson, R. Hui, T. Csösz, A. Fülöp, M. Gottfried, N. Peled, A. Tafreshi, S. Cuffe, M. O'Brien, S. Rao, K. Hotta, A. C. Deitz, G. M. Lubiniecki, J. Zhang, R. Rangwala and M. Reck. **"Health-Related Quality of Life for Pembrolizumab vs Chemotherapy in Advanced NSCLC with PD-L1 TPS $\geq 50\%$: Data from Keynote-024."** Oral Presentation- WCLC (J Thorac Oncol (suppl: PL04A.01)).

Cancer Trials Ireland number: short name. 14-13: MSD MK-3475-024 / KEYNOTE-024

Garon, E., M. Reck, D. Rodríguez-Abreu, A. Robinson, R. Hui, C. Tibor, A. Fülöp, M. Gottfried, N. Peled, A. Tafreshi, S. Cuffe, M. O'Brien, S. Rao, K. Hotta, D. Turner, J. Stone, R. Rangwala and J. Brahmer (2016). **"Use of a 200-mg fixed dose of Pembrolizumab for the Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC)."** Poster Presentation- WCLC (J Thorac Oncol 12, suppl: P3.02C-030)).

Cancer Trials Ireland number: short name. 06-34: Palliative Lung

McDermott, R. L., P. G. Thirion, C. Small, D. Hacking, W. Sasiadek, M. Dunne and J. G. Armstrong (2016). **"(ICORG 06-34): A multicentre clinical trial using 3DCRT to reduce toxicity of palliative radiation for lung cancer."** Poster Presentation- ESTRO.

Cancer Trials Ireland number: short name. 14-13: MSD MK-3475-024 / KEYNOTE-024

Reck, M., D. Rodríguez-Abreu, A. G. Robinson, R. Hui, T. Csoszi, A. Fülöp, M. Gottfried, N. Peled, A. Tafreshi, S. Cuffe, M. O'Brien, S. Rao, K. Hotta, M. Leiby, G. M. Lubiniecki, Y. Shentu, R. Rangwala and J. R. Brahmer (2016). **"KEYNOTE-024: Pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) as first-line therapy for advanced NSCLC with a PD-L1 tumor proportion score (TPS) ≥ 50 ."** Oral Presentation- ESMO Congress Presidential Symposium session.

Cancer Trials Ireland number: short name. 06-36: ECOG 1505

Wakelee, H. A., S. E. Dahlberg, S. M. Keller, W. J. Tester, D. R. Gandara, S. L. Graziano, A. A. Adjei, N. B. Leighl, C. A. Butts, S. C. Aisner, J. M. Rothman, J. D. Patel, M. D. Sborov, R. S. McDermott, R. Perez-Soler, A. M. Traynor, T. L. Evans, L. Horn, S. S. Ramalingam and J. H. Schiller (2016). **"E1505: Adjuvant chemotherapy +/- bevacizumab for early stage NSCLC—Outcomes based on chemotherapy subsets."** Oral Presentation- ASCO (J Clin Oncol 34 (suppl; abstr 8507)).

Lymphoma and Haematological

Cancer Trials Ireland number: short name. 07-01: CLL-IRL

Appleby, N., F. M. Quinn, D. O'Brien, S. Liam, J. Kelly, I. Parker, K. Scott, M. R. Cahill, G. Crotty, H. Enright, B. Hennessy, A. Hodgson, M. Leahy, H. M. O'Leary, M. E. O'Dwyer, A. Hayat and E. A. Vandenberghe (2016). **"Minimal Residual Disease (MRD) Status in FCR-Treated CLL Patients at the End of Treatment Influences Progression Free Survival (PFS), Results of the Ctrial-IE (ICORG) 07-01/ CLL Ireland Study, with Mutational Analysis Providing Additional Insight."** Poster Presentation- ASH Annual Meeting and Exposition.

Cancer Trials Ireland number: short name. 13-17: RsqVD

O'Gorman, P., M. E. O'Dwyer, O. Gilligan, J. Quinn, M. Coyne, J. Krawczyk, P. T. Murphy, L. del Rosario McAlester, O. Harraghy, O. Cormican, E. Lenihan, K. Egan, M. R. Perera, G. Crotty, P. J. Hayden, B. Hennessy, H. M. O'Leary, K. Scott, I. Parker, M. Cunnane, J. Marron, A. Connell, E. Coghlan, J. P. Laubach and P. G. Richardson (2016). **"A Phase II Multi-Center Study of Lenalidomide, Subcutaneous Bortezomib and Dexamethasone (RsqVD) in Newly Diagnosed Multiple Myeloma – Ctrial-IE (ICORG) 13-17 Study."** Poster Presentation- ASH Annual Meeting and Exposition.

Melanoma

Cancer Trials Ireland number: short name. 13-22: SYS-ACT

Charles, E. M., C. Aura, J. Joseph, P. Dynoodt, O. Aslan, E. Hirschenhahn, J. Wouters, C. de Chaumont, A. Rahman, M. Rafferty, J. van den Oord, P. Regan, S. Curran, E. McDermott, G. Gullo, P. Donnellan, A. Fabre, R. Feighery, M. Warren, W. Gallagher and M. Rehm (2016).

“Protein quantification of apoptosis regulators in IHC-stained cell lines and melanoma tissue microarrays using digital image analysis and manual scoring.” Poster Presentation- 9th Swiss Apoptosis Meeting.

Cancer Trials Ireland number: short name. 13-02: BMS CA209-067

Sznol, M., P. F. Ferrucci, D. Hogg, M. Atkins, P. Wolter, M. Guidoboni, C. Lebbe, J. Kirkwood, J. Schachter, G. Daniels, J. Hassel, J. Cebon, W. Gerritsen, V. Atkinson, L. Thomas, J. McCaffrey, D. Power, J. Jiang, F. S. Hodi and J. Wolchok (2016). **“Safety profile of nivolumab (NIVO) and ipilimumab (IPI) combination therapy in patients (pts) with advanced melanoma (MEL).”** Poster Presentation- ESMO (Ann Oncol 27, (suppl_6): 1123P).

Other performance indicators

Standard Operating Procedures (SOPs)

During 2016 SOPs were implemented and/or updated in the following areas:

- Project Management
- Pharmacovigilance
- Data Management

SOP Number	SOP	Version Number/ Effective Date
18	Receipt and Processing of Safety Data	6/ 06-Jan-2016
21	Project Management	3/ 06-Jan-2016
28	Safety Reporting and Medical Evaluation of Safety Data	6/ 06-Jan-2016
35	CRF Development (Paper)	2/ 07-Mar-2016
54	RAVE eCRF Development	1/ 07-Mar-2016
55	NEW: RAVE Study Set-up	1/ 07-Mar-2016
56	NEW: Rave System Management	1/ 07-Mar-2016
57	NEW: RAVE User Administration	1/ 07-Mar-2016
58	NEW: RAVE Site Administration	1/ 07-Mar-2016
59	NEW: Data Management Study Maintenance	1/ 07-Mar-2016
60	NEW: Data Coding	1/ 07-Mar-2016
61	NEW: Data Transfers	1/ 07-Mar-2016
62	NEW: Rave Post Production Change	1/ 07-Mar-2016
63	NEW: Database Lock and Archiving	1/ 20-May-2016

Table 11: New and updated SOPs during 2016

Study Initiation Visits (SIVs)

A total of 82 Initiation Visits (compared to 69 SIVs during 2015) for 23 trials (compared to 16 trials in 2015) were performed during 2016.

Health Products Regulatory Authority (HPRA) and Ethics Submission Packages

During 2016 the following numbers of Regulatory and Ethics submissions were prepared for 87 trials:

- 122 Regulatory Submissions to the HPRA for 60 trials (81 submissions in 2015).
- 306 Submissions to the Ethics Committees for 87 trials in the Republic of Ireland (221 submissions in 2015).

Pharmacovigilance

The table below summarises our pharmacovigilance activities during 2016.

Pharmacovigilance Activity	Number
SAEs received and tracked by Cancer Trials Ireland (includes follow-ups)	389
SAEs received through Cancer Therapy Evaluation Program's Adverse Expedited Reporting System (CTEP AERS) (includes follow-ups)	63
SAEs received on Medwatch forms	16
SUSARs Entered onto Eudravigilance Database by Cancer Trials Ireland	102
PhV SOPs updated	2
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	11
Safety and clinical database reconciliations	17

Table 12: Pharmacovigilance Activities during 2016

Policies

Data Safety Monitoring Board (DSMB)

Cancer Trials Ireland has established a system for convening an independent Data Safety Monitoring Board (DSMB) that meets on an interim basis for In-house studies to review study progress and trial data. Ongoing study oversight is carried out by a Trial Steering Committee (TSC). Trials requiring a DSMB and a TSC are identified at protocol development / risk assessment stage, and formed according to standard operating procedures and a committee charter.

Currently one open study CTRIAL-IE 10-14, the Neo-AEGIS study, is reviewed by an independent DSMB that is composed of international member experts in the field of oesophageal cancer and clinical research. Recommendations are made by the DSMB to the Trial Steering Committee.

Trial Steering Committee (TSC)

For trials 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. To date, a TSC has been applicable to the CTRIAL-IE 10-14 Neo-AEGIS study only.

The TSC members comprise the Chief Investigator, Country Lead Investigators, Cancer Trials Ireland Clinical Lead and other members of the central office Operational Study Team. The meetings occur monthly and all aspects of the study are reviewed including any recommendations from the study DSMB and required actions discussed.

Safety Monitoring Committee (SMC)

Cancer Trials Ireland convened four regular Safety Monitoring Committee (SMC) meetings in 2016. The SMC's 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 its 2016 membership included the Clinical Lead, Vice Clinical Lead (both Consultant Medical Oncologists), one further Consultant Medical Oncologist, three Radiation Oncologists, two Haematologists, a Surgeon, a Pharmacist 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 (in accordance with the SMC Charter). A quorum must be present for the meeting to occur and following review of the information provided, the committee provides recommendations according to the categories defined in the Charter and based on the continuing benefit/risk assessment of the reviewed 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 and continued during 2016 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 central office 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 and are followed to resolution.

Publication Policy

An updated publication policy was drafted and finalised in October 2016. The policy specifies the requirements relating to the publication of any study where Cancer Trials Ireland has been involved. This includes recommendations about the writing and approval process for publications/ abstracts, the affiliation and study naming, and the authorship.

Accrual Monitoring System

Each research unit submits its accrual information to the NUI Clinical Research Facility, Galway (CRFG) on a monthly basis. This group ensures timely submission of data from the research units, cross checks the data submitted, collates the data across trials, disease areas and produces a variety of reports for different audiences internally and externally in conjunction with our central office team.

Communications

Communications

Cancer Trials Ireland was awarded a one-year HRB Knowledge Exchange and Dissemination Award (KEDS) in late 2015 to employ a part-time Communications Advisor to raise its profile among key stakeholders. This grant enabled the organisation expand considerably its communications capabilities during 2016.

International Clinical Trials Day

On International Clinical Trials Day 2016 – 19th May, the first Just Ask! campaign was launched to connect with patients and their families by encouraging them to ask their doctor about cancer trials. On that day the organisation's new name and brand was launched to make the organisation more accessible to the general public.



Also an independent report on the economic and health benefits of cancer trials prepared by DKM Economic Consultants was launched as the boiler plate argument for the contribution of cancer trials to the community.

Local events were supported and organised by the research teams in cancer trials research units in hospitals around the country. They included information initiatives within the hospital and through the media, with interviews with clinicians on local radio stations. The campaign was supported with a 10 day national and local radio advertising and media outreach programme.

Media

This launch of the Just Ask! campaign marked the start of the organisation's active media outreach programme which resulted in substantial national and local coverage of case studies of patients, the opening of trials and results announcements which have included local and national interviews with clinicians. This was the first-time cancer trials received this type of coverage and is leading to more enquiries from patients.

Key statistics: Total Campaign Reach - 2,122,056 opportunities to see key messages. Total Ad Value - €110,922.08. Total PR Value - €332,766.23 valuing earned editorial as three times more valuable than paid media. Message Cut Through – 89% and 100% based on the campaign call to action. This has included national coverage on RTE radio and TV, a full page 6 in The Irish Times main paper on cancer trials, features in The Irish Farmers Journal and The Sunday World and regular coverage in the medical press and regional press.

Short Films

During International Clinical Trials Day in May 2016 interviews were recorded with patients, their families and key stakeholders on the subject of cancer trials. These interviews were compiled into a 'news' report and posted on the website and publicised on Twitter. By way of follow up, in August a series of videos where patients and guardians talk about cancer trials was launched.

Communications

Twitter

We have been active on Twitter since April 2012. Our active communications programme has resulted in a 70% increase in followers and a 10 fold increase in daily impressions.

There was a significant spike in activity on the organisation's Twitter account and website on International Clinical Trials Day and similar set piece profile raising events.

DSSG Digest

The Digest provides the most up to date, news and listing of cancer trials in Ireland. During the year the organisation's regular magazine was revamped. Production was taken in-house which resulted in a considerable pre-production savings and reduced considerably the draw on internal staff resources.

It is distributed widely among members at the DSSG meetings. It is also distributed electronically and displayed on the internet. Hard copies are distributed to key stakeholder groups and cancer support groups across the country. Articles which feature in the Digest are regularly used and reprinted by specialist health publications.



The Just Ask! message features in the Irish Cancer Society's 12 Daffodil centres and the Society's Nurseline is taking the uplift in calls enquiring about trials.

Signs to raise the profile of cancer trials research units and recognise the work of the local teams have been installed in research units. Above is the Letterkenny Hospital research team with Dr Robert O'Connor, Head of Research at the Irish Cancer Society – which sponsored the signs and is one of Cancer Trials Ireland's key funders.



Eibhlin Mulroe, CEO, Cancer Trials Ireland, appeared on *The Business* on RTE 1 talking about the business of cancer trials in December 2016.



Dr Janice Walshe featured on RTE in November talking about the significant findings of the Cancer Trials Ireland trial Paloma 2.



Sports stars open renovated UHL cancer unit

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THE **CANCER trials** unit at University Hospital Limerick, which saw a major renovation in recent months, has been officially opened with the addition of new staff to support increased activity.

And to mark the occasion, sporting heroes from the region supported the work of the trials unit.

Eminent figures include Grand Slam and European Cup winner Marcus Horan, and All-Ireland-winning hurlers Richie Bennis, Patrickswell, and Noel McGrath, Tipperary.

The late Munster Rugby hero Anthony 'Axel' Foley was a proud supporter of cancer care at University Hospital Limerick, and was a board member of the Mid-Western Cancer Foundation. A spokesperson said that he was "aware of the importance of trials...and had been looking forward to attending this week's opening".

Launched by **Cancer Trials Ireland**, its CEO Eibhlín Mulroe said: "Patients who take part in trials

make a profound community contribution. What they do is really important. They are making a unique contribution to answering the really important cancer research questions which might help others in the future."

Consultant medical oncologist and director at UHL, Dr Linda Coate, welcoming the renovation, said that the **cancer trials** unit acts "as an Irish referral site for a number of exciting therapeutic trials", with 290 patients undergoing 35 different types of trials.

Galway role in cancer study

■ New research set to investigate pregnancy risks for women who have had breast cancer

A STUDY has got underway in Galway to investigate the risks of pregnancy for young women who have had breast cancer.

The Cancer Trials Research Unit in University Hospital Galway will be participating in the international cancer study.

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

Internationally, over 500 patients who had breast cancer will take part in the study.

Cancer Trials Ireland is co-ordinating the study in Ireland which has just opened at St Vincent's University Hospital, Dublin, and will eventually involve 30 patients from Dublin, Cork, Limerick, Waterford and Galway.

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

"About 15% of women are diagnosed with breast cancer

during their reproductive years.

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

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

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

Despite important progress in recent decades, the number of women diagnosed with breast cancer is on the rise. Today, a woman's chance of getting breast cancer is 1 in 8. Breast cancer still causes 52,000 deaths annually in the world.

Participants in the study have to be 42 years old or younger, have had early stage breast cancer, completed 18-30 months of hormone treatment and want to have a baby.

Participants will interrupt their treatment for a maximum of two years during which time they will try to get pregnant. Participants will be carefully fol-

News

Cancer trials call

Cancer Trials Ireland has called for a national health policy decision to mainstream **cancer trials** as a cancer treatment option for people with disease in its submission to the Oireachtas Committee on the Future of Healthcare. It also recommends the pending National Cancer Strategy sets a target of 5% for the number of people diagnosed with cancer who participate in drugs trial. The current rate of participation is 3%.

Health board

■ **Clinical trials:** Are patients on clinical trials guinea pigs? This is the provocative title of a public talk on Thursday, August 25th, at 6.30pm at the Mansion House, Dawson St, Dublin. Organised by the Irish Cancer Society and Cancer Trials Ireland, the panel of speakers will include cancer experts and patients. Admission free but booking essential by email to researchevents@irishcancer.ie

Cancer patients missing out on trials

■ More than two thirds of patients have no access to clinical trials

Swelyn Ring

There is no clinical trial available to two out of three cancer patients, it has emerged.

A study just published argues for a greater volume of trials and for "champion physicians" to increase participation.

It found there was no cancer trial option for 71% of patients because the trials that were open did not meet their particular cancer type, the stage of their disease, and line of treatment.

The authors said that low recruitment to cancer clinical trials is hampering continued progress in cancer care.

It is also important to establish why eligible patients turned down an opportunity to participate in a trial and to overcome this problem, clinical research needed to be embedded into the culture of hospitals.

The study by the Mater Hospital in Dublin, together with Cancer Trials Ireland, found one quarter of patients had no option to cancer trial but did not want.

The study, published in the Irish Medical Journal, involved a retrospective

analysis of 140 patients with cancer who attended the Mater.

There were 19 cancer trials available to patients when the four-month review began, in November last year. The range of treatments covered 16 different cancer types at different stages.

The treating doctor considered the cancer clinical trial option in most cases (92.9%) but only discussed the possibility of participation in just over half (54%) of them.

Among the reasons given for failing to consider the trial option included physician's discretion and patient ineligibility. Another reason was that patients had declined a previous trial option.

Consultant medical oncologist at the hospital, Dr Cathy Kelly, said the availability of trials was not unique to Ireland: "In the United States, studies show that between 46% and 77% of patients do not have a cancer trial option available to them."

Over the past 10 years, the number of patients participating in cancer trials in

Ireland has increased from 19 in 2006 to 115 in 2015.

Dr Kelly said the infrastructure developed by Cancer Trials Ireland has attracted international research groups and pharmaceutical companies to open trials in Ireland.

"While we found that 5% of patients enrolled in a cancer trial, which is in line with international figures, it is imperative to safeguard continued improvement in cancer outcomes that continue to recruit more patients to cancer trials," she said.

"The standard treatments for cancer that we use today were once examined in the setting of a cancer trial and the treatments of tomorrow only upon the completion of high quality trials.

A solution would be to open more trials, but the authors point out that the availability of funding is crucial. Cancer Trials Ireland, previously known as the All Ireland Co-operative Clinical Research Group, co-ordinates cancer clinical trials in Ireland. The study stressed that ongoing governmental and philanthropic support

Drug trial offers new hope to women suffering aggressive breast cancer

Lilish O'Regan
EMAIL

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SHARE



A group of women with an aggressive form of advanced breast cancer, which is no longer responding to standard treatment, are to undergo a new €750,000 drugs trial. Stock photo

A group of women with an aggressive form of advanced breast cancer, which is no longer responding to standard treatment, are to undergo a new €750,000 drugs trial.

Autumn 2016 Scientific Meeting

Our Autumn 2016 Scientific Meeting (Disease Specific Sub Group – DSSG), started with a mini conference on Translational Research: *Delivering on the promise 'from bench to bedside'*.



(l to r) Conference chair Prof. Bryan Hennessy, Clinical Lead, Cancer Trials Ireland, and conference speaker Professor Michael Kerin, Chair of Surgery and Vice Dean of Medicine at NUI Galway.



(l to r) Ruth McGinn, Data Manager, Tallaght Hospital, and Laura Corrigan, MSD.



(l to r) Michelle Gartland and Linda Tormey, Bayer.



(l to r) Q&A Session Chair Prof. William Watson, Translational Research DSSG Chair, Cancer Trials Ireland, conference speaker Dr. Antoinette Perry, Lecturer in Cancer Biology, UCD School of Biomedical Science, Conway Institute and Dr Robert O'Connor, Head of Research, Irish Cancer Society.



(l to r) Conference chair Prof. Bryan Hennessy, Clinical Lead, Cancer Trials Ireland, Kay Curtin, Patient Advocate, conference speaker Dr. Damir Vareslija, member of the BREAST-PREDICT project and Eibhlin Mulroe, CEO, Cancer Trials Ireland.



(l to r) Elaine McCarthy, Clinic Trials Co-ordinator, Maureen O'Grady, Team Leader and Lorraine O'Connell, Clinic Trials Co-ordinator all from the cancer trials research unit at University Hospital Limerick.



Conference delegates



Conference delegates



(l to r) Vivienne Martin and Kevin Hynes, Sanofi, and Suzanne Ennis, Astellas.

IRISH CLINICAL ONCOLOGY RESEARCH GROUP CLG

STATEMENT OF COMPREHENSIVE INCOME
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2016

	2016	2015
	€	€
		(Restated)
Income	3,482,205	2,846,731
Expenditure	(3,555,451)	(2,867,783)
Deficit on ordinary activities		
before interest	(73,246)	(21,052)
Interest receivable and similar income	30,433	11,657
Deficit for the financial year	(42,813)	(9,395)

BALANCE SHEET AS AT 31 DECEMBER 2016

	2016	2015
	€	€
		(Restated)
Fixed Assets		
Tangible assets	35,255	36,052
Current Assets		
Debtors	938,187	198,771
Cash and cash equivalents	4,570,572	5,360,326
	5,508,759	5,559,097
Creditors: Amounts falling due within one year	(4,882,088)	(4,890,410)
Net Current Assets	626,671	668,687
Net Assets	661,926	704,739
Reserves		
Retained earnings	661,926	704,739
Charity's Funds	661,926	704,739



Cancer Trials Ireland is supported by

