

Annual Review 2017



Together, we're finding answers to cancer.



In September 2017, the Group Central Office moved to a more affordable and suitable location from Fitzwilliam Square, Dublin 2 to an open plan office in Innovation House, DCU ALPHA, Dublin 11.



On International Women's Day we saluted and celebrated all women in research and gave a special shout out to all the heroic women on cancer trials around the country and around the world – thank you.

Cover Photo

Pictured at the launch of the 2017 **Just Ask Your Doctor!** public information campaign (L to R) Emily Hourican, journalist and cancer survivor and guest speaker at the launch and Evelyn O'Rourke, Member of the Board of Cancer Trials Ireland and RTÉ broadcaster.

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Dr Jonathan Westrup, Chairman

Cancer Trials Ireland has a unique network of cancer professionals both nationally and internationally actively engaged in finding new and better treatments to detect, stop and cure cancer.

Our work saves lives, extends lives and is proven to enhance the standard of care in our health service.

I would like to express our deep thanks to people who take part in cancer trials, and their families, for making such an enormous community contribution by helping us deliver hope and contribute to discoveries that will save and enhance the lives of millions of others around the world.

2017 was an important year for Cancer Trials Ireland and cancer care generally.

During the year we made great strides in consolidating the numerous governance and oversight structures we planned and introduced during the previous two years. While implementing and maintaining these changes require increased resources, they are critical to enable us to meet the increasing regulations and standards expected of an organisation like ours.

I want to take this opportunity to thank all my colleagues on the Board who give their time generously and voluntarily, our Membership, cancer trials units across the country, our CEO and staff for their commitment and diligence in getting these structures working at their optimum.

I believe we are now very well placed to take advantage of the opportunities to open more trials and studies and ultimately provide patients with more treatment options.

The publication of the National Cancer Strategy during 2017, and the NCCP being tasked with its implementation, was another major development. Of significance for us is the KPI that has been included in the strategy to double the number of patients participating in trials by 2020. This is a welcome commitment but will require support. Meeting this commitment will depend on hard budget commitments from the Department of Health and Health Service Executive.

From our Clinical Lead



Professor Bryan Hennessy, Clinical Lead

From a clinical perspective 2017 was a period of positive change and development. Despite the financial pressures, we expanded our portfolio with collaborative partners and Investigator Initiated Trials.

The Clinical Executive Committee (CEC) was reformed in 2017 with new clearly defined Terms of Reference developed and implemented. The CEC is the Clinical Leadership body of Cancer Trials Ireland. Its overarching aim is to advise and provide guidance to me as the Chair of the Committee and to the Board on equity of access for clinicians and patients to cancer research, access to novel therapeutics for Irish cancer patients, and to promote excellence in all types of cancer research in Ireland. In 2017, the CEC discussed and agreed new policies and strategies such as a policy for co-investigators working on combined drug and radiotherapy trials, new site performance metrics and changes to the credits system.

Under my leadership, the Translational Strategy Working Group (TSWG) was set up in early 2017 and is represented by 5 clinicians and 4 academic cancer researchers. The group recommended the introduction of translational Co-Chairs for each Disease Specific Sub Group (DSSG). This is now in place for Breast, Gastrointestinal, Genitourinary, Gynaecology, Lung, Lymphoma / Haematology and Paediatrics with full integration of the translational studies in the respective portfolios. Following this move we decided to dissolve the Translational DSSG and Dr Verena Murphy was appointed as Translational Research Leader in May 2017.

In the context of GDPR and new health regulations, our Biobanking Group, formed in 2017, will have an important role. This group is also tasked with development of a biosample access policy.

While there are still many important research questions we would like to pursue in our search for cancer cures, the limitation on the funding we receive from the Exchequer means that we have to say no to opening some worthy trials. This is clearly a very unsatisfactory situation in a developed economy.

In the context of the new National Cancer Strategy and its ambitious targets, we are ready, willing and very able to support the key agencies in delivering its targets for cancer research. However, translating these ambitions from aspiration to reality requires paired funding.



Eibhlin Mulroe, CEO

The publication of the National Cancer Strategy in 2017 brought huge excitement to the team at Cancer Trials Ireland. The strategy recognises the importance of our work and the need to do much more. While the research targets and recommendations are exciting, without an urgent injection of funding they cannot be met.

We have gone through a period of rapid change over the last three years. This change was informed by HRB International Panel Reviews, inspections, audits and contracting budgets due to the 20% cut in the last HRB grant cycle. We have, as a result, increased our focus on revenue-earning trials and reduced the number of academic In-house trials we can take on. Trials and their related costs do not correlate to the HRB's three year grant cycles; very often they can run for five years with many years of follow up (up to 20 years) during which costs are still incurred. So when our HRB grant was reduced we could not reduce our trial costs which was financially challenging for us.

An important change initiative during 2017 followed a technical review of our accounting policies. We now ensure all the costs for each trial are accounted for before they open and during their lifetime. Implementing this new policy has been a challenge but it means that we are keeping pace with the most up to date standards.

We met with our supportive colleagues at InterTrade Ireland during 2017 to strengthen our partnerships with the Northern Ireland Clinical Trials Network. This has led to 3 cross border trials under discussion and potential for more in the future.

While we continue to be very grateful to the HRB, Irish Cancer Society and St Luke's Institute of Cancer Research which have provided important and significant support to cancer trials, more is required. Cancer is on the increase and patients require more treatment options to save and extend their lives.

I would like to acknowledge the outstanding work and professionalism of our Group Central Office team. We have an outstanding team.

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.

ACHIEVEMENTS AND PERFORMANCE

- We ran a second successful externally funded **Just Ask Your Doctor!** public information campaign communicating with the public and members on radio and media interviews on the value of cancer trials. The 2017 campaign was supported by MSD, Bayer, Roche, Abbvie, Merck, Novartis and Janssen.
- Members had 18 internationally peer-reviewed articles and 22 international abstract presentations.
- In 2017, we implemented a more sophisticated analysis and reporting of the funding sources for the collaborative and industry-funded In-house Investigator Initiated Trials (IITs).
- The Scientific Management Group was re-structured in 2017 and all new studies are now considered for approval or adoption based on several criteria including research question and proposed budget.
- The HRB Grant is fully committed to ongoing academic In-house trials and Cancer Trials Ireland does not have the capacity to take on new In-house trials.
- Advocacy activities in 2017 included making representations to the Department of Health, National Cancer Control Programme and the Minister for Health's office.
- 2017 marked the beginning of a very important relationship with InterTradeIreland and clinicians on both sides of the border to develop an All-Ireland approach to cancer trials activity and to seek government support to enable this. This engagement followed on from commitments made in 1998 by the British, US and Irish governments in the Good Friday Agreement.
- In 2017, we established an internal working group to study the development of a Clinical Trial Management System which was supported by the Irish Cancer Society. The preliminary study identified requirements, opportunities, savings potential solutions and next steps for the second phase of implementation.
- We facilitated regular Stakeholder Engagement and Patient Advocate Advisory Group (PAAG) meetings in 2017; February, June and October. These meetings had an average of 100 stakeholders and patients in attendance. Topics included E-health, Crowdsourcing Biomarkers and the National Cancer Strategy. All took place at the regular scientific membership meetings where our Disease Specific Sub Groups met.

Cancer Trials Ireland undertakes translational and clinical cancer trials which investigate all cancer types; Central Nervous System, Head & Neck, Melanoma, Gynaecology, Lymphoma / Haematology, Lung, Gastrointestinal, Genitourinary, Breast and Paediatric, as well as Basket trials which include more than one cancer type.

Our work is critically important for people with cancer.

Our vision is focused on one primary purpose.

To provide every patient with cancer with access to potentially high-quality and life altering cancer trials, and make Ireland a highly attractive location to open cancer trials.

Our mission is:

To discover new diagnostics and treatments that will extend and enhance the lives of the millions of people who are diagnosed with cancer each year.

Following an organisational review completed in 2014, we embarked on an important strategic change programme to enable us to move from operating as a small organisation to a medium-sized clinical trials research group. This change programme was underpinned by 5 strategic pillars; Governance, Profile, Funding Model, Operational Capabilities and Clinical Capabilities.

Key organisational changes took place in 2016 and developed further during 2017. In response to obligations and recommendations made by the Health Products Regulatory Authority (HPRA) in 2015 and 2016, new functions and departments were established at the Group Central Office (GCO), including new medical oversight structures, Safety Monitoring Committee and processes. A new Finance Manager was appointed, and finance became an integral part of the decision-making process around new trials and studies presented for consideration.

Membership

Almost all cancer treating specialists in Ireland are members of Cancer Trials Ireland.

There are 590 members of Cancer Trials Ireland with an increase of almost 20% in members during 2017.

A list of Cancer Trials Ireland's stakeholders (which includes individuals, organisations and corporations) was created in 2016 and numbers have approximately doubled since 2016. While Patient Advocates, Collaborative Groups and Industry cannot be considered members of Cancer Trials Ireland they are engaging in our open meetings and we have approximately 35 members in our Patient Advocate Advisory Group. A recent meeting of our Leadership Team and Board of Directors decided that we should ask every staff member in Cancer Trials Ireland to dedicate a portion of their working time to patient engagement. It is hoped that this will enhance the richness of the group providing greater opportunities to seek patient expertise in the research decisions.

Activity

Cancer is a global health issue.

In 2012, there were 14.1 million new cancer cases and 8.2 million cancer-related deaths worldwide.

Incidences of cancer in Ireland reflect what is happening globally. The number of new cases of invasive cancer cases (including non-melanoma skin cancer) is expected to increase by between 86% and 125% for females and by between 126% and 133% for males between 2010 and 2040.

In Ireland the Department of Health's 2015-2017 Statement of Strategy notes that the incidences of cancer are projected to double by 2040. It states that *"a key task in the coming years will be to work to prevent cancer occurring in the first place as far as possible and to tackle cancer early when it does occur"*.

Since Cancer Trials Ireland was established in 1996, more than 15,000 patients have participated in over 350 of its trials.

As well as managing its own In-house clinical trials and research studies, Cancer Trials Ireland works with international research groups from around the world on Collaborative Trials which generates substantial inward investment and access to innovative treatments for cancer patients. It also works with the major pharmaceutical companies.

During the period of 2016-17, the 11 hospital-based cancer trials research units we fund directly (plus the 5 research units linked to these hospitals) were working on 173 clinical and translational trials in development, open to accrual or in follow-up 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.

Total number of trials and studies (In-house, Collaborative and Industry) in development, open to accrual and in follow-up by Type .

Status	In-house, Collaborative and Industry trials ⁽ⁱ⁾			Adopted Industry trials		
	No of trials	Clinical	Translational ⁽ⁱⁱ⁾	No of trials	Clinical	Translational ⁽ⁱⁱ⁾
In Development	35	26	9	21	20	1
Open to Accrual ⁽ⁱⁱⁱ⁾	63	36	27	44	43	1
In Follow up ^(iv)	75	66	9	35	35	0
Total	173	128	45	100	98	2

⁽ⁱ⁾ Industry trials with either pre-adoption or study management involvement. There were 5 Industry sponsored trials and we had limited Cancer Trials Ireland resource involved in these trials.

⁽ⁱⁱ⁾ Translational Study: This category included studies that are purely translational in nature (no involvement of investigational medicinal product) but do have Group Central Office involvement in the oversight and running of the study.

⁽ⁱⁱⁱ⁾ A number of trials closed to accrual during 2016 and 2017 and are not mentioned as open to accrual at the end of 2017.

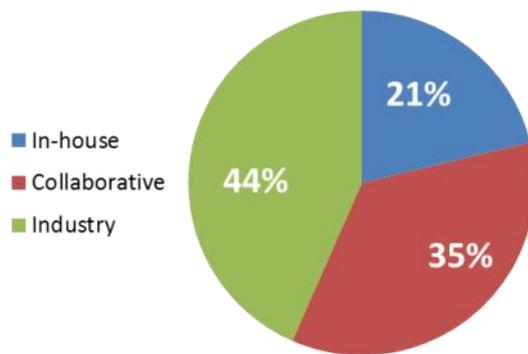
^(iv) Closed to accrual and including those in Close-Out.

Of the 122 trials that were open and recruiting patients during 2016/17 combined:

21% were **In-house** academic trials (which Cancer Trials Ireland initiates, sponsors, manages and monitors) and are generally funded by the grants received from the Health Research Board (HRB) and the Irish Cancer Society, or pharmaceutical companies.

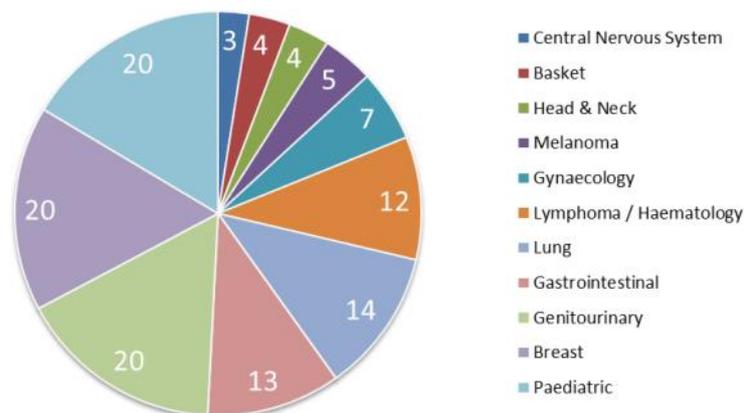
35% were **Collaborative** trials which involve us working closely with other cancer research groups around the world.

44% were **Industry** trials which were sponsored by pharmaceutical companies and adopted into our trials portfolio. Staff at the Group Central Office do limited work on these types of trials. While we do not receive support for this work, it is part of our commitment to sharing our industry expertise and supporting the clinical trial community.



Study Type	HRB Funded	Non HRB Funded	Total
In-house	23	3	26
Collaborative	31	12	43
Industry	0	53	53
Total	54	68	122

Overall trial activity at the end of 2017 including In-house, Collaborative and Industry Adopted Studies



Board Members during 2017



Darren Byrne, Chartered Accountant / CFO and Non-Executive Director.



Dr Jerome Coffey, Director of the National Cancer Control Programme (NCCP).



Dr Leisha Daly, Country Director of Janssen.



Dr Linda Coate, Vice Clinical Lead, Consultant Medical Oncologist, University Hospital Limerick.



Berchmans Gannon, Formerly Beauchamps Solicitors.



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



Dr Paul Kelly, Consultant Radiation Oncologist, Cork University Hospital.



Associate Prof Cathy Kelly, Consultant Medical Oncologist, Mater Misericordiae University Hospital, Dublin.



Prof Patrick Murray, Professor of Clinical Pharmacology, UCD.



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



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



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



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



Robert Cosgrave, Secretary

The governance structure at Cancer Trials Ireland has evolved in line with best practice standards and facilitates the growth of the organisation.

The Board rotates at the AGM every year in line with the organisation's Constitution.

The Board is chaired by Dr Jonathan Westrup, appointed in 2014. Dr Westrup is a strategy and governance specialist.

The Board meets a minimum of 5 times per year and permanent agenda items include reports from Clinical Executive Committee and Audit Committee, Governance, Strategy, Conflict of Interest Declarations and Finance. In 2017, the Board met 5 times as it did in 2016 .

The members of the Board are qualified to hold their position and represent a range of skills; governance, patient advocacy, clinical and radiation oncology, industry, finance and includes a National Cancer and Control Programme (NCCP) representative.

The Clinical Executive Committee (CEC), Scientific Management Group (SMG) and Disease Specific Sub Groups (DSSG) monitor progress of the ongoing clinical trials, make decisions on the approval or adoption of new trials to the portfolio and the CEC reports to the Board of Directors through its Chair; Prof Bryan Hennessy, Clinical Lead.

The Audit Committee is a subcommittee of the Board and was established in 2016. It met 4 times in 2017. Darren Byrne is the chair of the Audit Committee and member of the Board of Directors.



Pictured at the 2016 AGM (L to R) Professor Bryan Hennessy, Clinical Lead, Dr Jonathan Westrup, Chairman and Eibhlin Mulroe, CEO.

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.

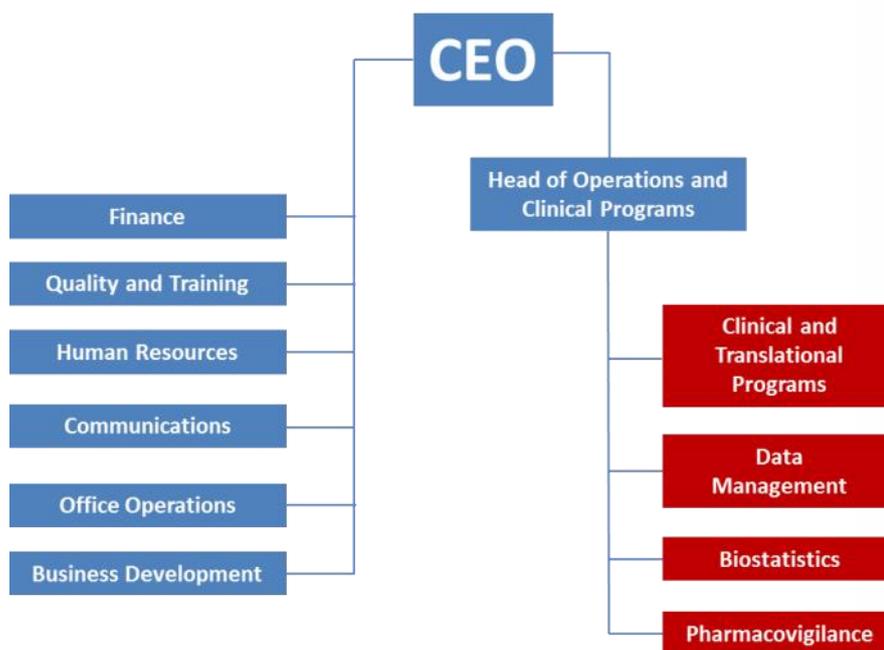
Location of hospital based Cancer Trials Research Units

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

There are approximately 50 (including interns) members of staff based in Cancer Trials Ireland's Group Central Office which, in addition to a range of corporate and governance duties, initiate, manage, and monitor trials across the country.

Reduced income leading to a decrease in staff numbers in certain functional areas since 2016 has been a challenge for the Leadership Team which has had to carefully manage staff costs and workload to meet existing contractual commitments and regulatory requirements.

The line management structures further evolved in 2017 with the appointment of a Head of Operations and Clinical Programs; this was a replacement post. The post holder oversees all activities relating to the clinical trials. The new structures were adopted in the GCO to enable a professional organisational structure and clear goals and targets for every member of staff. This has been further enabled by the continued use of the Project Management Timesheet System set up in 2016 and a revision of the Performance Management System during 2017.



The Cancer Trials Ireland office moved in September 2017 to the Innovation Hub on DCU Alpha campus located in Glasnevin, 3 miles outside of Dublin city centre. The building is shared with start-up tech companies, medical device developers and researchers. The office is open plan which is akin to our EU Academic Collaborative groups in Europe where their offices are often housed in University campuses and are open plan. This initiative was also designed to reduce overhead costs.

Financial Review

Cancer Trials Ireland is funded by grants from the Health Research Board, the Irish Cancer Society and St Luke's Institute of Cancer Research. The organisation also receives contributions towards costs for work done with international collaborative groups and from pharmaceutical companies for our own In house Investigator Initiated Trials. Cancer Trials Ireland does not fundraise but from time to time receives valuable and very welcome contributions from individuals and groups.

The Finance Team reporting to the Audit Committee continues to update where necessary, all relevant finance policies and procedures.

Plans for the future

A HRB International Scientific Panel Review took place in 2018 and the report has led to a 5-year commitment from the HRB to Cancer Trials Ireland. While the 20% funding cut has not been reversed in 2018 and 2019, there will be an overhead allocation for the Group Central Office in 2019 which is very welcome.

Implementing a successful cancer trials portfolio involves engaging and collaborating with numerous stakeholders at both a national and global level. As part of the change programme, Cancer Trials Ireland has strengthened and continues to strengthen its relationship with external organisations. The aim is to be even more connected with stakeholders such as the HRB, Irish Cancer Society, National Cancer Control Programme (NCCP) and Department of Health, Clinical Research Facilities, Clinical Research Development Ireland, international collaborative groups, pharmaceutical companies, and other stakeholders such as the wider cancer research community, cancer patients and the public where possible.

The organisation will continue to act as an advocate for cancer trials and highlight its contribution not only in terms of fighting the battle against cancer but also its economic contribution.

**CANCER TRIALS IRELAND CLG
(FORMERLY IRISH CLINICAL ONCOLOGY RESEARCH GROUP CLG)**

**STATEMENT OF INCOME AND RETAINED EARNINGS
FOR THE FINANCIAL YEAR ENDED 31 DECEMBER 2017**

	Notes	2017 €	2016 €
Income	4	3,570,106	3,482,205
Expenditure		(3,948,115)	(3,555,451)
Deficit on ordinary activities before interest		(378,009)	(73,246)
Interest receivable and similar income	5	9,815	30,433
DEFICIT FOR THE FINANCIAL YEAR	6	(368,194)	(42,813)
RETAINED EARNINGS AT THE BEGINNING OF THE FINANCIAL YEAR		661,926	704,739
RETAINED EARNINGS AT THE END OF THE FINANCIAL YEAR		293,732	661,926

BALANCE SHEET AS AT 31 DECEMBER 2017

	Notes	2017 €	2016 €
Fixed Assets			
Tangible assets	10	25,426	35,255
Current Assets			
Debtors	11	1,849,389	1,196,509
Cash and cash equivalents		2,917,040	4,570,572
		4,766,429	5,767,081
Creditors: Amounts falling due within one year	12	(4,498,123)	(5,140,410)
Net Current Assets		268,306	626,671
Net Assets		293,732	661,926
Reserves			
Retained earnings		293,732	661,926
Charity's Funds		293,732	661,926

The financial statements were approved and authorised for issue by the Board of Directors on 11/9/18 and signed on its behalf by:

Prof. Bryan Hennessey
Director

Dr. Jonathan Westrup
Director



Cancer Trials Ireland is supported by

