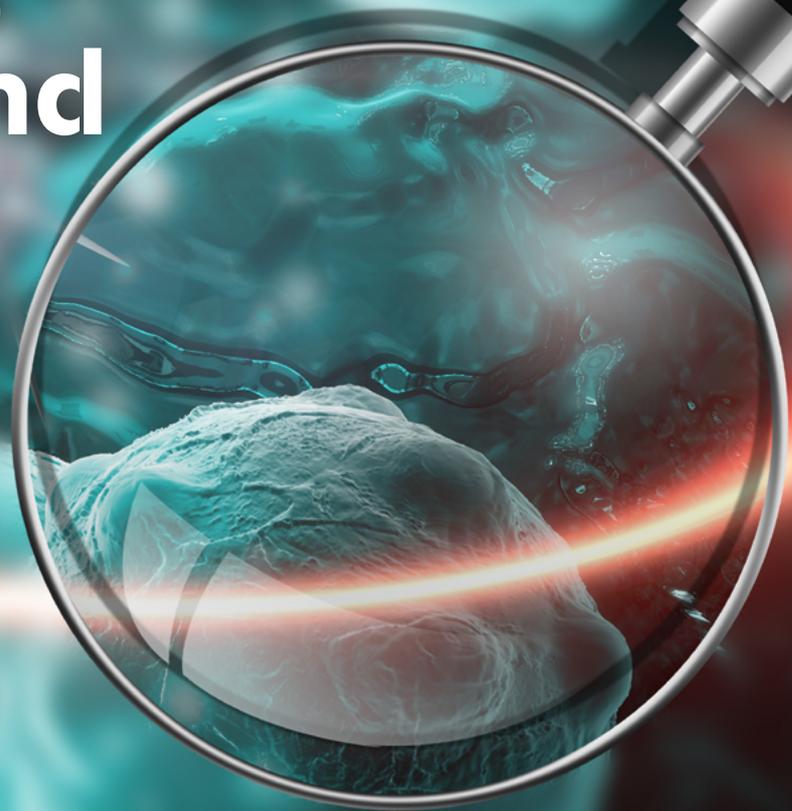




cancer
trials
ireland



STRATEGY

2022-2027

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

Supported by





HOPE

CHAIR MESSAGE



Deirdre Somers - Chair
Cancer Trials Ireland

Cancer Trials Ireland relentlessly pursues its vision to deliver access to leading and diverse cancer trials for patients on the island of Ireland and funding is critical.

In 2022, for the first time, the HRB provided core multi-annual funding. This allows CTI more autonomy in clinical decision-making, while keeping sight of the HRB's guiding principles to establish more Investigator-Led Trials. The Irish Cancer Society has increased its funding, from €500k to €1m, again over several years, putting CTI on a more secure and predicable financial footing and enabling us to support more trials. This crucial funding has been further augmented by some notable philanthropic donations which

has been crucial to enabling us to open trials in specific disease types. This new diversity and security of funding means that CTI can be confident in pursuing our vision.

Our funders, and all our stakeholders must have confidence in the governance, strategy, people and structures ensuring their funds are spent wisely, and that we continue to deliver for cancer patients in Ireland and we continue to progress in this regard. The Board has established an Audit & Risk Committee, a Governance & Nominations Committee, a Patient Consultants' Committee, and a Diversity Policy – all delivering to the statutory obligations we regularly fulfil with the Companies Registration Office and the Charity Regulator. We have refreshed and engaged Board of Directors with the appropriate balance of skills to support the 50+ experts on staff to do their jobs. We are in a strong position to move forward and achieve the Vision and strategic objectives set out in the pages of this document.

CLINICAL LEADERSHIP



Prof Ray McDermott



Prof Seamus O'Reilly

Almost 30 years ago, Irish doctors saw patients in the US availing of treatment options that simply were not available here.

To change that reality, a few oncologists formed Cancer Trials Ireland (formerly ICORG) in the 1990s with the specific intention of opening cancer trials so that they could get the latest potential lifesaving and life-extending treatments for their patients – treatments their patients could not access in any other way.

That was then, and is to this day, the fundamental reason for opening and conducting cancer trials in Ireland. They provide a way to give the newest, most innovative, most cutting-edge treatments to cancer patients that simply would not otherwise be available in this country – and all without cost to the patients themselves, or to the State.

Cancer clinical trials are a vital part of the *treatment* process for patients with cancer. That is an importance emphasis. Trials are treatment – they are not an elective extra only offered to people who happen to be in the right place in the right time. They are, or should be, for everyone.

CEO MESSAGE



Eibhlín Mulroe - CEO
Cancer Trials Ireland

The Cancer Trials Ireland strategy is very clear, we believe in collaborating with all stakeholders and represent the Island of Ireland as one cancer trials site where global clinical trials can operate

efficiently. In 5 years' time, we want to see every cancer patient in the country screened for potential clinical trials. We will work to build our early-phase capability and ensure patients have access to innovative treatments here in Ireland.

We have the building blocks to achieve success in cancer trials. The Health Research Board awarded Cancer Trials Ireland the National Network Grant in 2022, the Irish Cancer Society have increased their support and philanthropy in disease specific trials is growing. We are excited about the possibilities of core grant funding, and about working with our new host institution and academic partner, the Royal College of Surgeons, Ireland. We led renewed discussion between our government, Northern Irish colleagues and the National Cancer Institute, Washington, US. As a result, we continue to be in the unique position of being the only country in the EU that have a government-led/NCI MOU in place. The scene is set to achieve more and hit the targets set in the National Cancer Strategy to maximise the number of patients on trials in Ireland.

It is deeply encouraging to witness the clinical oncology community's commitment to cancer trials. Whether through investigators, sites, funders, patients, or our own staff – the sheer level of ambition that everyone shares to open as many trials as possible to provide more and better treatment options for patients in Ireland is inspiring.

Our doctors go above and beyond to open and operate trials without the proper, structural state support, and our strong results are ironically an Achilles heel. Having shown what we can do without the proper structural supports, the health system is not incentivised to 'fix a problem'. Yet structural supports are what we badly need to bring cancer trials in Ireland to the next level. We have too few staff at hospitals, and we will work to support the NCCP to build the team needed to deliver trials.

We are clear-eyed about what we can and cannot achieve without the structural investment mentioned above, in summary;

Health research must be embedded in health planning – so that the system values health research, and what it can do for patients and patient outcomes.

- More support staff are needed – with better defined career paths and training opportunities.
- Protected time needs to be offered to the surgical, radiation, and medical oncologists and haematologists who want to do research.
- Research governance must be resourced, so that hospitals, groups, and the system as a whole actually has the staff and frameworks to support embedding health research in health planning.
- Fulltime Data Protection staff must be employed, and given proper training and support, with research governance officers.
- We urgently need to streamline and harmonise the data protection documents hindering clinical trials in Ireland right now.

Finally, we need your help, if you are looking for a way to improve cancer trial access and options in Ireland, demand it. From your doctors, from your care teams – and from your elected representatives.

VISION, MISSION & VALUES

Vision:

An indispensable, all-Ireland, hub for cancer trials, globally recognised for excellence in governance, collaboration and innovation in clinical research.

Mission:

Maximise cancer trial access and outcome to prolong patient lives, and expand cancer research, in Ireland.

Values:

- **Trusted** by clinicians, patients, researchers and funders
- **Empathetic:** to our patients need and vulnerability
- **Collaborative:** with researchers, clinicians, patients, decision makers and our teams
- **Ambitious:** to find, sponsor and operate the highest quality cancer trials for Ireland
- **Accountable and transparent:** in everything that we do
- **Ethical and professional:** in achieving our goals
- **Determined:** in achieving our vision.

KEY TERMS:

ILT:

Investigator-Led Trial – A trial conceived of by a doctor or researcher (in this case a primary investigator) that seeks to ask a research question with a scientifically / potentially medically valuable answer without the need for a commercial imperative (see: page 6 for more).

Investigator:

The lead person (typically a medical/radiation/surgical oncologist or haematologist, when it comes to cancer trials) with clinical responsibility for a trial, from conception through design to execution.

Different kinds of studies:

- Within Cancer Trials Ireland, a **clinical trial** is one that features an ‘Interventional Medicinal Product’ or treatment intervention, typically a new medicine.
- **Translational Medicine (TM)** refers to observational studies that may use patient data / samples for research, but in these studies there is no intervention for the patient. They take no medicines / undergo no new treatments other than those received in the normal course of their care.
- **RT trial** – is a radiotherapy trial.

Collaborative Group:

This phrase describes various international academic organisations that may run international clinical trials, i.e., trials that are open in several different countries. Typically, these collaborative group studies are ILTs (see: above)

WHAT WE WILL ACHIEVE (Our Ambition)

Key Strategic Objectives 2022–2027

1. Maximise contribution to National Cancer Strategy

Meet & exceed peer, audit, and inspection requirements. Burnish our global reputation as a European trial sponsor. Increase trial diversity, access and patients recruited through an empowered clinical community that co-operates nationally to promptly speak internationally, and build world-recognised expertise in disease areas, like pancreatic. Maximise our quality, timelines, compliance & transparency through a well-trained, capable workforce that delivers and publishes results from cancer clinical trials that drive actionable conclusions and improved patient care.

2. Optimal, stable and scalable talent to serve growth

Maximise attractive features as an employer (science-led rather than profit-led research) to attract and retain passionate and ambitious candidates, and provide them with a well-defined path for development and opportunity.

3. Position clinical research as an integral part of cancer care through thought leadership, advocacy, and influence

Continue to maintain a sustained presence, and live discussion, about cancer clinical trials in the public sphere, and among key stakeholders like policy-makers, decision-makers and politicians. Continue to foster and build public support for clinical trials, which has never been higher. Keep building the hard-earned trust of people, patients and healthcare staff in Ireland.

4. Deliver a compelling “All-Island” cancer trial proposition

Strengthen the partnerships we have between the Island of Ireland and USA to pioneer successful co-operative models that prove the validity of the all-island approach and inspire similarly ambitious collaborations in trials, healthcare, and wider sectors.

5. Financially sustainable and funded for growth

Continue to grow a blended funding model that incorporates grant funding, commercial services, and philanthropy, while leveraging the partnerships and networks that put Cancer Trials Ireland on the world stage. Win a renewed HRB contract underpinned by consistent reporting, monitoring and delivery.

TARGETS

DISEASE AREA	TARGET NUMBER OF TRIALS	TARGET NUMBER OF PATIENTS
Breast	15-17 / year & 2-3 ILTs within 5 years	235 (80 Clinical; 5 RT; 150 TM)
CNS	1-2 (where trials become available)	5
Gastrointestinal (GI)	2, targeting oesophago-gastric, pancreas, Hepatocellular Cancer, Biliary Tract Cancer, Colorectal Cancer	20-30
Genitourinary (GU)	1-2 via Cancer Trials Ireland (ILT!?)	50
Gynae	3-4 Ovarian / 1 Endometrial / 1 Cervical	10-12
Head & Neck	2-3 studies, aim to cover most subsites: oral cavity, oropharynx, larynx, hypopharynx, salivary gland; preferably also in the post-op / adjuvant setting	10
Lymph & Haem	1 new study open and relapse each for Multiple myeloma, CLL 1 study per Lymphoid (high-grade NHL, low-grade NHL, Hodgkin's) and Myeloid (AML, MDS, MPN), New area: Cancer –associated thrombosis studies	150 (50 Clinical; 100 TM)
Lung	2-3 per year, total 10-12 open at any time	40-50
Melanoma	2	6

THE STORY OF CANCER CLINICAL TRIALS IN IRELAND

Patients, not profit

Investigator-Led Trials trials (i.e. non-commercial trials) are trials where the research questions are driven by patient need rather than commercial concerns.

The commercial model plays an essential role in modern medicines development, as the phenomenal response of the pharmaceutical and biotech industries to COVID has shown. But the academic-led approach allows for different kinds of scientific questions, like:

Could patients reap the same benefits of chemotherapy, or radiotherapy, if we used less treatment? Or: Which well-established, long-standing treatment(s) is, or are, best for treating a specific form of breast, or prostate, or lung cancer?

These important questions are mainly asked by the not-for-profit research sector. Through the support of the Health Research Board, the Irish Cancer Society – and other generous donors – doctors in Ireland can open trials that have the potential to change how cancer is treated.



What we do

Our team of 50+ staff work across an array of teams to support cancer treating doctors, surgeons, research nurses, data managers and other healthcare professionals at 18 cancer trial sites all over Ireland.

How?

We **sponsor** cancer trials – which is to say we take responsibility for ensuring that any trial we open in Ireland meets the legal requirements for conducting trials which in turn ensures continual medical oversight for the safety of the patients who participate in our trials.

We employ people dedicated to meeting **regulatory and research ethics standards**.

We **continually train** our staff and **audit our processes** against internationally recognised scientific and regulatory standards.

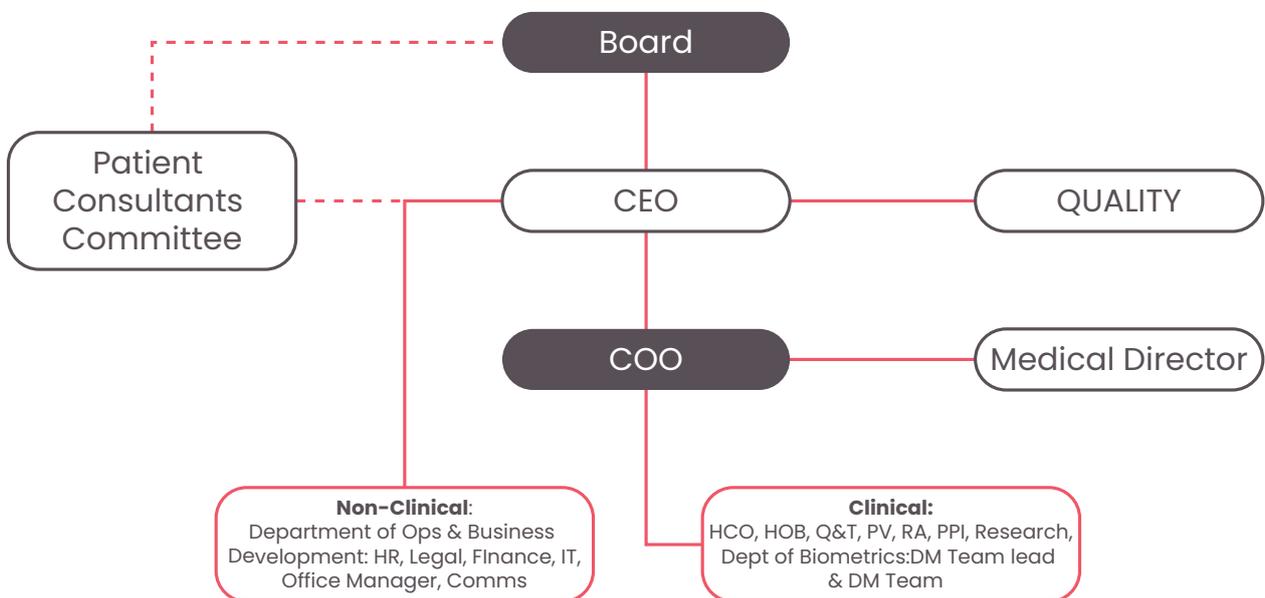
We have a **pharmacovigilance team** whose purpose is to track any side effects for patients on our trials – whether those events are trial-related or not – and ensure that relevant adverse effects are submitted to regulatory authorities as they occur, as well as providing periodic safety reports.

Our **clinical team** supports cancer-treating doctors and surgeons to develop research

‘protocols’ that will efficiently and effectively recruit patients and generate the data needed to answer the hypotheses (research questions) underpinning cancer trials. The same clinical team will shepherd the set-up of the trial, including obtaining the necessary regulatory authorisations and ethics committee approvals, before periodically visiting trial sites to ensure that a trial is operating precisely as directed in its protocol.

Meanwhile our **biometrics team** will work with the cancer-treating doctors and surgeons on the design and statistical methods used in the trial. They set up and manage the database that gathers and analyses the data about the patient on the trial and collaborate with the clinical team and the hospital sites to ensure the completeness and accuracy of the data collected. At the close of the trial, they analyse the final data to assess the outcome of the research questions of the trial and support the cancer-treating doctors and surgeons in the reporting of the results.

Our **leadership, finance and communications teams** work closely with our **Board** to ensure that the government, politicians, media – and people like you – understand the value of cancer trials, and see them not as diversions from patient care, but an essential part of it.



PATIENT CONSULTANTS COMMITTEE (PPI – Public & Patient Involvement)

For several years now, the Cancer Trials Ireland Patient Consultants Committee (PCC) has been bringing the voices of people affected by cancer into the heart of our work. The core avenue for PCC members to contribute their lived experience perspectives is through discussions at DSSG meetings on the development and delivery of cancer trials.

PCC members also review trial documents to make them more accessible to patients, plan PPI activities, raise awareness of trials, via media interviews and connecting with the wider cancer communities, among many other things. The objective is to improve cancer trials for all.

Through joint funding from the HRB and Irish Cancer Society, a Public Patient Involvement (PPI) Coordinator has recently been appointed to facilitate and support the PCC and PPI



Siobhan Gaynor



Patrick Kivlehan

within CTI. With the PPI Coordinator, the PCC have revised the Terms of Reference, developed a Strategic Plan and are developing new processes and tools to expand and further embed PPI in our work. At the time of writing, our first Patient-Led Research Project – which is a survey on the needs of patients with metastatic breast cancer – is underway.

Learn more about the Patient Consultants Committee, and its activity in Public & Patient Involvement on the Cancer Trials Ireland website:

www.cancertrials.ie



NETWORK

Inwardly, Cancer Trials Ireland is a CRO (Clinical Research Organisation) that can sponsor and operate cancer clinical trials with a specific focus on ILTs for prioritising scientifically valuable (as opposed to commercially valuable) outcomes.

Outwardly, when it comes to our members and stakeholders, Cancer Trials Ireland is principally a network through which

investigators and sites can open trials and recruit patients to them.

This network operates in a few dimensions. The first is geographic. Through HRB-funded regional groups, this aims to ensure equitable trial access around Ireland, and the capacity to run trials in the regions. In this respect, Cancer Trials Ireland facilitates co-operation and collective decision-making of these groups on issues of shared concern.



Prof Seamus O'Reilly

CLINICAL LEADERSHIP

Medical Oncologist in Cork University Hospital, Professor at University College Cork, co-National Director in Medical Oncology at the Royal College of Physicians in Ireland.



Prof Roisin Connolly

GROUP LEAD: Cork University Hospital (CUH), Bon Secours Hospital, Cork, University Hospital Waterford (UHW) and University College Cork (UCC).

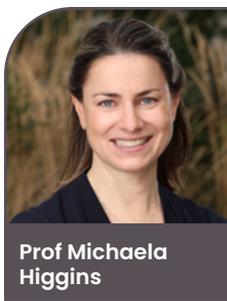
Professor Roisin Connolly is Director of Cancer Research at University College Cork, and a Medical Oncologist at Cork University Hospital.



Prof Ray McDermott

CLINICAL LEADERSHIP

Medical Oncologist at St Vincent's University Hospital, Tallaght University Hospital, and the Beacon Clinic.



Prof Michaela Higgins

GROUP LEAD: St Vincent's University Hospital (SVUH), Mater Misericordiae University Hospital (MMUH) and University College Dublin (UCD).

Professor Michaela Higgins is the President of the Irish Society for Medical Oncology, a clinical professor in UCD and a medical oncologist at St Vincent's Hospital.



Prof Sinead Brennan

GROUP LEAD: St Luke's Radiation Oncology Network (SLRON), UPMC Bon Secours, Beacon Hospital, University Hospital Galway (UHG) radiation oncology, Cork University Hospital (CUH) radiation oncology and Trinity College Dublin (TCD).

Professor Sinead Brennan (TCD) is a radiation oncologist at St James's Hospital, and the St Luke's Radiation Oncology network in Dublin. She is a Board member of the Irish Cancer Society, and chair of the Head & Neck DSSG in Cancer Trials Ireland.



Dr Janusz Krawczyk

GALWAY representative: Saolta Hospital Group (University Hospital Galway (UHG), Letterkenny University Hospital (LUH), Sligo University Hospital (SUH)).

Dr. Janusz Krawczyk is a Haematologist in Galway University Hospital and Senior Lecturer in Haematology at National University of Ireland – Galway.





GROUP LEAD: Tallaght University Hospital (TUH), St James’s Hospital (SJH), Midlands Regional Hospital, Tullamore (MRHT) and Trinity College Dublin (TCD).

Professor Maeve Lowery is Professor of Translational Cancer Medicine at Trinity College Dublin and Medical Oncologist at St James’s Hospital.



LIMERICK representative: University Hospital Limerick (UHL).

Dr Hilary O’Leary is a haematologist in University Hospital Limerick since 2009. She is currently clinical lead for the haematology service at University Hospital Limerick, and she represents the Department of Medicine on the Cancer Strategy Group at University of Limerick Hospitals.



GROUP LEAD: Beaumont Hospital (BH), Our Lady of Lourdes Hospital Drogheda (OLLHD), Connolly Hospital and Royal College of Surgeons of Ireland (RCSI).

Patrick Morris is Medical Director of the Cancer Clinical Trials and Research Unit, RCSI Hospital Group and a Medical Oncologist at Beaumont Hospital, Bon Secours Glasnevin and Our Lady of Lourdes Hospital in Drogheda.

However, the Cancer Trials Ireland network operates at a different level too – organised by disease area and disease specialty. In this regard, Cancer Trials Ireland facilitates ‘Disease Specific Sub-Group’ meetings that enable investigators and researchers with an interest in a given cancer (breast, GU, GI, lung) to share experiences, learning, and to horizon scan for future trials.

These two network functions support a unified discussion and decision-making capability that is very attractive to international collaborative groups and global pharma companies who can avail of a ‘one-stop shop’ when considering Ireland as a location for cancer clinical trials: Do we have the patient population? Can we

open multiple trial sites? Do we have the expertise? And the track record for accruing patients? Can we fulfil the myriad roles and responsibilities of a trial sponsor?

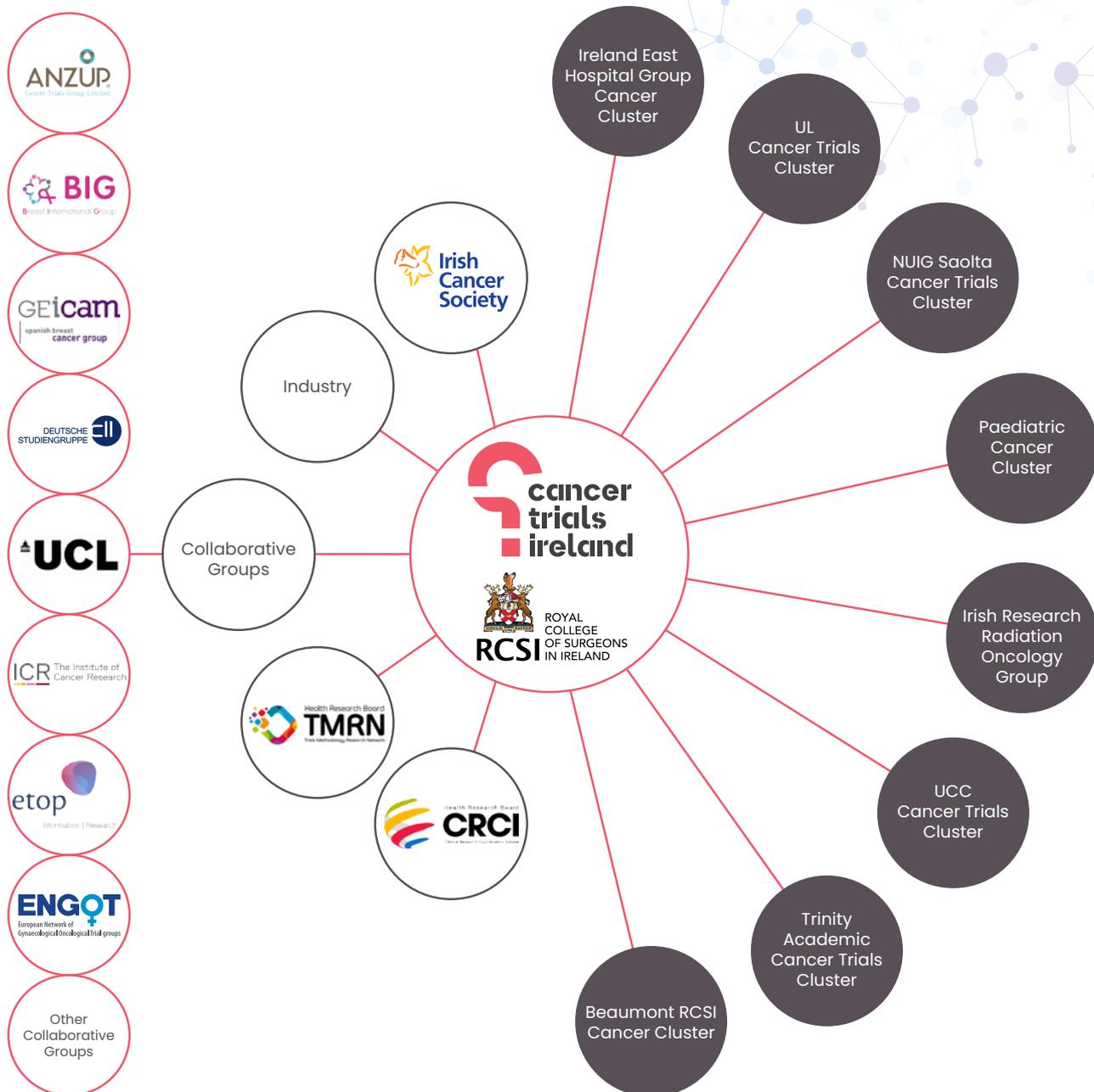
Recently our network was augmented by the Irish Research Radiation Oncology Group (IRROG, est. Jan 2022). This group unites all public radiotherapy departments and private collaborators across Ireland. IRROG’s main aim is to improve access to radiotherapy clinical trials across Ireland and develop national radiotherapy research infrastructure. It encompasses and represents all radiotherapy clinical trial research personnel nationally and is funded via the Health Research Board Cancer Trials Group scheme.



This overall network, with its different dimensions is bolstered by yet another network effect – created by our internationally respected, and internationally trained, principal investigators, who have developed their own global networks, and who use these networks – along with Cancer Trials Ireland’s – to bring cancer trials to Ireland. This is vital.

Ireland’s patient population is often too small for cancer trials outside of the bigger incidence cancers like breast, prostate and lung. Our proven ability to network and co-operate allows us to open pan-national and even pan-continental trials and bring treatment options that simply would not be otherwise available.

Stakeholder Map



OUR KEY STAKEHOLDERS:

Irish Cancer Society

The Irish Cancer Society is Ireland's leading patient organisation, and a significant funder of cancer clinical trials and clinical oncology research. They play a vital role in Ireland's cancer treatment and prevention ecosystem, that advocates for, and supports patients publicly and effectively, delivering a valuable, independent oversight of cancer care in Ireland.

Health Research Board

The Health Research Board (HRB) is a State Agency under the Department of Health that supports and funds health and social care research and provide evidence to inform policy and practice. It has 75 staff and an annual budget of €45 million, it manages an investment portfolio of approximately €200 million.

HSE NCCP

The National Cancer Control Programme (NCCP) was set up in 2007 to reorganize the way cancer care is delivered so that our cancer survival rates would compare more favourably with the best in Europe and the rest of the world. The NCCP aims to prevent cancer, treat cancer, and increase survival and quality of life for those who develop cancer, by converting the knowledge gained through research, surveillance and outcome evaluation into strategies and actions.

Royal College of Surgeons, Ireland

Founded as the national training body for surgery in Ireland, RCSI has been at the forefront of healthcare education and research since 1784. RCSI is the academic partner to Cancer Trials Ireland under the Network HRB grant, and now houses CTI on its Stephen's Green campus.

National Office for Research Ethics Committees (NREC)

NREC is responsible for establishing national RECs (NRECs) in specific areas of health research. These NRECs are tasked with delivering 'single national ethics opinions' which will help streamline the system of research ethics in Ireland – strengthening the national research infrastructure to protect patients and the public, while creating a more conducive environment for clinical trials and other regulated health research areas.

Health Products Regulatory Authority (HPRA)

The HPRA regulates medicines and devices for the benefit of people and animals. It's remit and regulatory functions include human and veterinary medicines, clinical trials, medical devices, controlled drugs, blood and blood components, tissues and cells, and cosmetic products. It is committed to excellence in health product regulation through science, collaboration and innovation.

HSE Research & Development

This HSE function was set up to develop a framework for governance, support and strategic direction for health research, to enable existing activity and to grow future research activity within the public health service. The ultimate aim is to foster the translation of research into policy and practice, to embed evidence-based practice within service delivery in order to improve the quality of health and social care services and the health and wellbeing of our patients and the population.

HRB-NCTO (National Clinical Trials Office)

The HRB National Clinical Trials Office is an independent, integrated, national clinical research network, providing centralised support in conducting multi-centre clinical trials and investigations, both commercial and academic, across Ireland.

CANCER & CANCER TRIALS IN IRELAND BY THE NUMBERS



€6.9M

In HRB funding over 5 years from Jan 2022



€6.5M

What Cancer Trials Ireland saves government annually in drug costs



40,000

Projected annual diagnoses by 2040



35,000

Patients on trials on the island of Ireland since 2000



24,000+*

Number of people diagnosed with cancer annually

*24,871 - 2019 stats from NCRI



650+

Members



623

Trials since 2000



194

CTI affiliated articles published in peer reviewed journals like NEJM since 2006



82

Practising Haematologists



71

Medical Oncs – 100 needed by 2028



50+

Staff in Cancer Trials Ireland



34

Radiation Oncologists



23

Collab group relationships studies



8

Cancer Trial Groups we work with in Ireland



5

Key Strategic Objectives



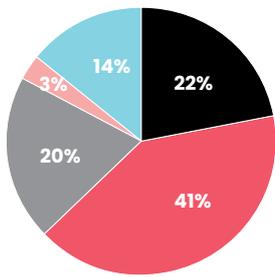
€3

What Cancer Trials can attract in investment for every €1 of gov funding**

Figures above current as of May 2023; 24,000 sourced from NCRI where latest figures available were for 2019.

** <https://www.cancertrials.ie/wp-content/uploads/2017/01/2016-05-18-DKM-Economic-Impact-of-Cancer-Research-Final-Report-Final.pdf> Page 7

FUNDING



Cancer Trials Ireland is funded by a blend of income streams all designed to maximise the number of Investigator-Led Trials that can be opened.

Irish Cancer Society	22%	Other grants	3%
Collab Groups* & pharma	41%	Philanthropy	14%
HRB	20%		

*Collaborative Groups are international academic organisations that are capable of running pan national cancer trials. In such instances, Cancer Trials Ireland might provide support as a European sponsor and/or as a provider of cancer clinical trials services in Ireland.

WHY DOES THE IRISH CANCER SOCIETY FUND CANCER TRIALS IRELAND?



Averil Power – CEO
Irish Cancer Society

The Irish Cancer Society funds Cancer Trials Ireland to support the development of new cancer treatments, increase the number of clinical trials available to Irish patients, and improve survival rates and the quality of life for

cancer patients in Ireland. Through this work we are building a strong international reputation for Irish cancer research.

In 2021, the Irish Cancer Society doubled funding to Cancer Trials Ireland from €500,000 to €1,000,000. In 2022, we did it again. From

here on we plan to do it every year – that is how important we see cancer trials as being for cancer patients and their family, friends and carers in Ireland.

None of this funding would be possible without the support of the public. Each year the Irish Cancer Society typically receives just 3% of our funding from the government, so we are reliant on the generosity of our wonderful donors, fundraisers and volunteers to continue our work.

The Irish Cancer Society is passionate about supporting cancer research and trials because research means new discoveries and new therapies. Better odds and lives saved. More birthdays, Christmases and other precious moments together.

PANCREATIC CANCER/THE POWER AND IMPORTANCE OF PHILANTHROPY

The remarkable fundraising success of Pat Smullen and the horse racing community has given pancreatic cancer patients in Ireland treatment options where previously there were none. These efforts, which continue to be augmented by other fundraisers for pancreatic cancer in and out of horse racing, led to the establishment of the Pat Smullen Pancreatic Cancer Fund, which aims to:

- Build lasting infrastructure in Ireland to aid with the diagnosis and treatment of pancreatic cancer.

- Fund research to improve the diagnosis, knowledge and treatment of pancreatic cancer in Ireland.

Already the Fund has driven successes under each objective – by helping to fund a Next Generation Sequencing machine in St Vincent’s Hospital (allowing for pancreatic cancer tumours to have their genomes sequenced) and by funding four trials (one already complete) and thus providing new treatment options for up to 195 patients in Ireland.

Our next objective is to co-fund the Pat Smullen Chair in Pancreatic Cancer Research, in UCD, with the agreement and participation of the HSE National Cancer Control Programme. Such a position could attract the

most eminent pancreatic cancer researchers in the world, and help to establish Ireland as a globally recognised centre of excellence for the research and treatment of this pernicious form of cancer.

About Pancreatic Cancer

Pancreas cancer is a disease which is often diagnosed at an advanced stage and is difficult to treat. There are just over 610 cases per year in Ireland which represents approximately 2.5% of all cancers and makes it the 9th most common cancer.

Unfortunately, there are over 530 deaths per year from pancreas cancer which represents 6% of all cancer deaths and makes pancreas cancer the 5th most common cause of cancer death after lung, colon, breast, and prostate cancers.

PAT SMULLEN PANCREATIC CANCER FUND



Prior to fund being established, no pancreatic cancer trials open in Ireland.

In 2019, Cancer Trials Ireland received a donation of €2.6 million, dedicated exclusively to supporting research in pancreatic cancer in Ireland. This led to the establishment of the Pat Smullen Pancreatic Cancer Fund.

Progress at a Glance

- Funding applications received, international peer review process makes its recommendations
- Funding Committee approves funding for 4 studies
- 15 patients recruited to Paricalcitol trial in 2020/2021
- Treatment options for 100+ patients in Ireland diagnosed with pancreatic cancer by 2023
- €100,000 infrastructure grant to St Vincent's University Hospital for NGS machine
- Fifth study in development in partnership with Australian collaborative group
- Investment ringfenced for academic research infrastructure in pancreatic cancer.



NGS Machine donation: Prof Ray McDermott, Dr Niall Swann, Eibhlin Mulroe, Pat Smullen, Prof Kieran Sheahan (2020)



Leading jockey Shane Foley finishing the first Coast to Curragh cycle with Pat's two brothers Brian and Ger Smullen (2021)



Paddy Smullen and Frances Crowley finishing the first Coast to Curragh cycle (2021)



NGS Machine in St Vincent's Hospital: Prof Kieran Sheahan and Frances Crowley take a look (2022)

PATIENT STORIES



In May 2020, diplomat Sarah McGrath was recovering from surgery for a badly broken ankle. Normally resident in Dublin 8, she was recuperating at home in Clarecastle, Co Clare when she found a lump in her breast.

Sarah made an appointment straight away to see her GP and she was referred for triple assessment. She subsequently received a diagnosis of stage 2 hormone positive breast cancer.

“When you look back in hindsight, you wonder if there anything you didn’t notice, but to be honest, I had no other symptoms,” says Sarah, who is now The Ambassador of Ireland to Singapore. *“I had no night sweats or tiredness, or any tiredness I had was because I’d just had major surgery on my ankle.”*

Her diagnosis came as a great shock. *“I wouldn’t say I was the best in the world for self-check – I’m a lot better at that now for obvious reasons – but I’d never had a breast lump before. Years ago, I’d had some lumps that turned out to be nothing, just swollen lymph nodes. I went to have the lump in my breast checked because it was the right thing to do but I was quite sure it wasn’t anything,”* she says. *“When I had my triple assessment, at the end of it, the consultant spoke to me. She said, ‘we won’t know for sure until the biopsy sample comes back but from the imaging, it is quite likely that it is something, and I just want to let you know that’. She was very reassuring and she said, ‘and if it is something, we’ll take care of it because that is what we do here’. I was very grateful for that because 10 days later when I went in to get my results, although it was still a big shock to hear the words, I felt that at least I was a small bit prepared for it.”*

Her treatment plan included two surgeries, chemotherapy and radiotherapy. Because the pandemic was ongoing, she attended her appointments by herself. *“In some ways, I can*

see how it would be nice to have someone to chat with when you’re doing your chemos,” she says. *“On the other hand, it’s not exactly a day out so in some ways it was easier to be there with my phone and my book and treat this like it was a flight or something like that. People are so kind and so good and it’s very hard on the people who love you. Sometimes you’re just better able to handle it if it’s just you, you do your treatment on your own and then go home. In some ways I wasn’t sorry that people couldn’t come with me, I think it could be very upsetting for them but then again, I’m quite a self-contained person so I could also appreciate for other people that would have been a very lonesome experience.”*

Having finished her active treatment, she will continue to take Tamoxifen for five more years and Zolodex for two years. Sarah is also taking part in an Irish Cancer Society-funded clinical trial, which is ongoing and is focused on studying non-recurrence. *“I don’t know if it’s said enough, when people are considering taking part in a clinical trial, but one of the positive things for me is the additional checks and monitoring that happen when you’re part of a trial, which I found very reassuring,”* she says. *“In my case, I was finished active treatment and I was in that kind of weird scenario where you go from talking to a medical professional almost every day to, well I’ll see you in six months. I found being on the trial and being seen every three months to be a gentler step down.”*

Sarah McGrath is now a member of the Cancer Trials Ireland Patient Consultants Committees, which takes part in and oversees cancer trial development from a patient perspective

STUDY STORY: CLL17

In 2016, Irish doctors, patients, and the Cancer Trials Ireland team were excited to learn about the development of a new trial to treat Chronic Lymphocytic Leukaemia (CLL) called CLL17. The objective of this trial was - and still is - to compare how certain treatments and combinations of treatments measure up, when treating patients with previously untreated CLL, regardless of age (once over 18) and fitness level.

We learned about the trials through one of our Investigators, Patrick Thornton, a medical oncologist based in Beaumont Hospital, who has strong ties to the University of Cologne / German CLL Study Group, which is the overall trial sponsor. Mr Thornton was involved in the trial's concept design and was well-placed to bring the trial to Ireland, with the support of Cancer Trials Ireland project management. Indeed, such was the anticipation around this trial that in some cases, CLL patients delayed receiving any treatment so that they might qualify for the trial (which only recruited previously untreated CLL patients).

That bears thinking about: imagine a patient with cancer foregoing any treatment so as to be able to get on a trial. It speaks to the excitement this opportunity generated, and that enthusiasm carried through emphatically when the trial opened in the Summer of 2021. CLL17 went on to be one of the best, and fastest recruiting trials in Cancer Trials Ireland's history. It opened in eight hospitals with an overall target recruitment of 40 - and went on to recruit 86 patients, with St James's Hospital being the joint highest recruiter of patients in the world with 19. Internationally, Ireland ranked fourth in the world for recruitment to this trial.

It is the kind of trial that perfectly exemplifies the successes Ireland can have in cancer trials - leveraging one of our world class investigator's networks to bring in an ILT that provides a much-needed treatment option for patients that wouldn't be accessible in any other way.

This is why Cancer Trials Ireland was formed almost 30 years ago, and it is why we are here today.

Trial details

CLL17 is an Investigator-Led Trial (ILT) sponsored by the University of Cologne and conducted by the German CLL Study Group (GCLLSG) in collaboration with several global cooperative groups. Cancer Trials Ireland is the collaborative group for Ireland, as it has been for previous, similar trials like CLL13.

CLL17 seeks to compare how certain treatments and combinations of treatments measure up when treating patients with previously untreated Chronic Lymphocytic Leukaemia, regardless of age (once over 18) and fitness level.



Patrick Thornton,
Beaumont



Elisabeth Vandenberghe,
St James's

There are three arms to the trial, which compare:

- 1. Ibrutinib (monotherapy)** - Ibrutinib is a tyrosine kinase inhibitor (TKI) that belongs to a group of targeted therapy drugs known as protein kinase inhibitors.
- 2. Venetoclax** (targeted therapy which helps destroy cancer cells) plus Obinutuzumab (a Type II humanised anti-CD20 monoclonal antibody)
- 3. Venetoclax plus Ibrutinib**

All three arms will be charted against Progression Free Survival for the patients taking part, with other survival and quality of life measures also being taken into account.





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