

Annual Review 2021



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

Supported by



What we do

Since Cancer Trials Ireland was established in 1996, more than 15,000 patients have participated in over 350 of its trials. Almost all cancer treating specialists in Ireland are members of Cancer Trials Ireland.

The organisation's trials are carried out in 14 hospital-based Cancer Trials Units (CTUs) across the country, supported by a central team of clinical researchers, project managers, data managers and other experts. As well as managing its own in-house academic trials, Cancer Trials Ireland also works with global pharmaceutical companies and international collaborative research groups, which generates substantial inward investment and access to innovative treatments for cancer patients.

Cancer is a global health issue. The World Health Organisation reports that cancer is the second leading cause of death globally and is responsible for an

estimated 9.6 million deaths in 2018. Globally, about 1 in 6 deaths is due to cancer.

According to the 2019 Annual Report from the National Cancer Registry of Ireland (NCRI), cancer is the most common cause of death in Ireland, accounting for almost 31% of deaths in 2016. The approximate annual average of deaths from invasive cancer occurred from 2014-2016 and was 9,020. It is estimated that about 35,440 invasive cancers were diagnosed annually in 2017, 2018 and 2019 in Ireland.

Taking the ageing population into account, NCRI projections (2019) show cancer rates have stabilised or even declined in recent years. Nevertheless, projected population growth and ageing in Ireland will result in a substantial increase in the number of cancer cases in the coming decades, potentially doubling from current levels by 2045.

Vision & Mission

The Board rotates at the AGM every year as per the Constitution. The Board is chaired by Dr. Jonathan Westrup, appointed in 2014 and he is a strategy and governance expert. The Board meets 5 times per year and permanent agenda items include reports from Clinical Executive Committee and Audit Committee

The vision at Cancer Trials Ireland is focused on one primary purpose. To provide every patient with cancer access to high-quality and potentially 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.

In order to achieve this vision, Cancer Trials Ireland must undertake translational and clinical cancer trials which investigate all disease areas and it must have in place the organisational capability to do so.

The 5 strategic pillars are the key to enable Cancer Trials Ireland to achieve this vision and mission:

1. Governance
2. Profile
3. Funding Model
4. Operational Capabilities
5. Clinical Capabilities

Published by Cancer Trials Ireland

Charity No. CHY12492

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2021 at a glance

In 2021, approximately 8% of the enrolling trials are Investigator-Led Trials (ILTs) (2020: 20%) funded by the grants received from the Health Research Board and the Irish Cancer Society. 29% (2020: 34%) of these open trials involved collaboration with cancer research groups and/or are Investigator-Led Studies which are funded through pharmaceutical companies. The 63% balance of open trials are run by international pharmaceutical companies in Irish hospitals (2020: 46%) where staff at the General Central Office do limited work and receive little or no support. However, to capture a complete picture of cancer clinical trials in Ireland, we adopt these trials into our portfolio.

During 2021, the 11 hospital based cancer trials research units we fund directly were working on 290 active cancer trials (including trials 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.

Of the 99 trials that were open and recruiting patients during 2021:

- 8% were **Investigator-Led 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.
- 29% were **Collaborative** trials which involve working closely with other cancer research groups around the world.
- 63% were **Industry** trials which were initiated and managed by pharmaceutical companies and adopted into our trials portfolio.

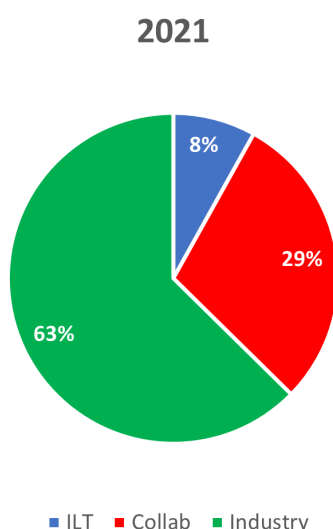


Fig 1: % of Enrolling trials which were ILTs, Collaborative and Industry trials.

There were 23 articles published in peer-reviewed journals and 6 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 91 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 was 567, with 64 new Members admitted during 2021. Membership includes all major universities and affiliated hospitals, which together treat more than 20,000 people with cancer annually in Ireland.

Chairperson's message



Deirdre Somers

Cancer Trials Ireland, 2021 will be remembered as the year we won multi-annual HRB grant funding to fund the core activities of Cancer Trials Ireland. This funding meant two critical changes in our HRB funding: 1) That we had the security of a five-year funding cycle, and 2) that the core funding would allow us more autonomy in making decisions about what trials, and types of trials to operate. 2021 was also the year that the Irish Cancer Society doubled our grant funding from €500,000 to €1m. This was another enormous vote of confidence, as was the partnership we cemented with the Royal College of Surgeons, Ireland, upon winning the HRB Cancer Clinical Trials Network Grant.

The staff at our central office worked tirelessly through a pandemic and ransomware attack to deliver some great trials. I would like to take the opportunity to thank the team for all the hard work and commitment to patients and research. I want to thank Eibhlín, the network of physicians and support staff who make cancer trials possible. I particularly wish to thank my colleagues on the Board of Cancer Trials Ireland. They have continually demonstrated a huge level of commitment, and have overseen a significant improvement in the organization's governance.

Our Board

The Board rotates at the AGM every year as per the Constitution. The Board is chaired by Deirdre Somers, appointed in 2021 and she is a strategy and governance expert. The Board meets 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 2021, the Board met five times. (2020: 5)

The members of the Board are qualified to hold their position and represent a range of skills; governance, patient advocate, clinical oncologists, radiation oncologists, industry representative, finance and National Cancer and Control Programme (NCCP) representative. In 2018 the Board appointed a new subgroup called the Patient Consultant's Committee (PCC) set up to integrate the patient voice and experience in the governance structure of the organization.

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

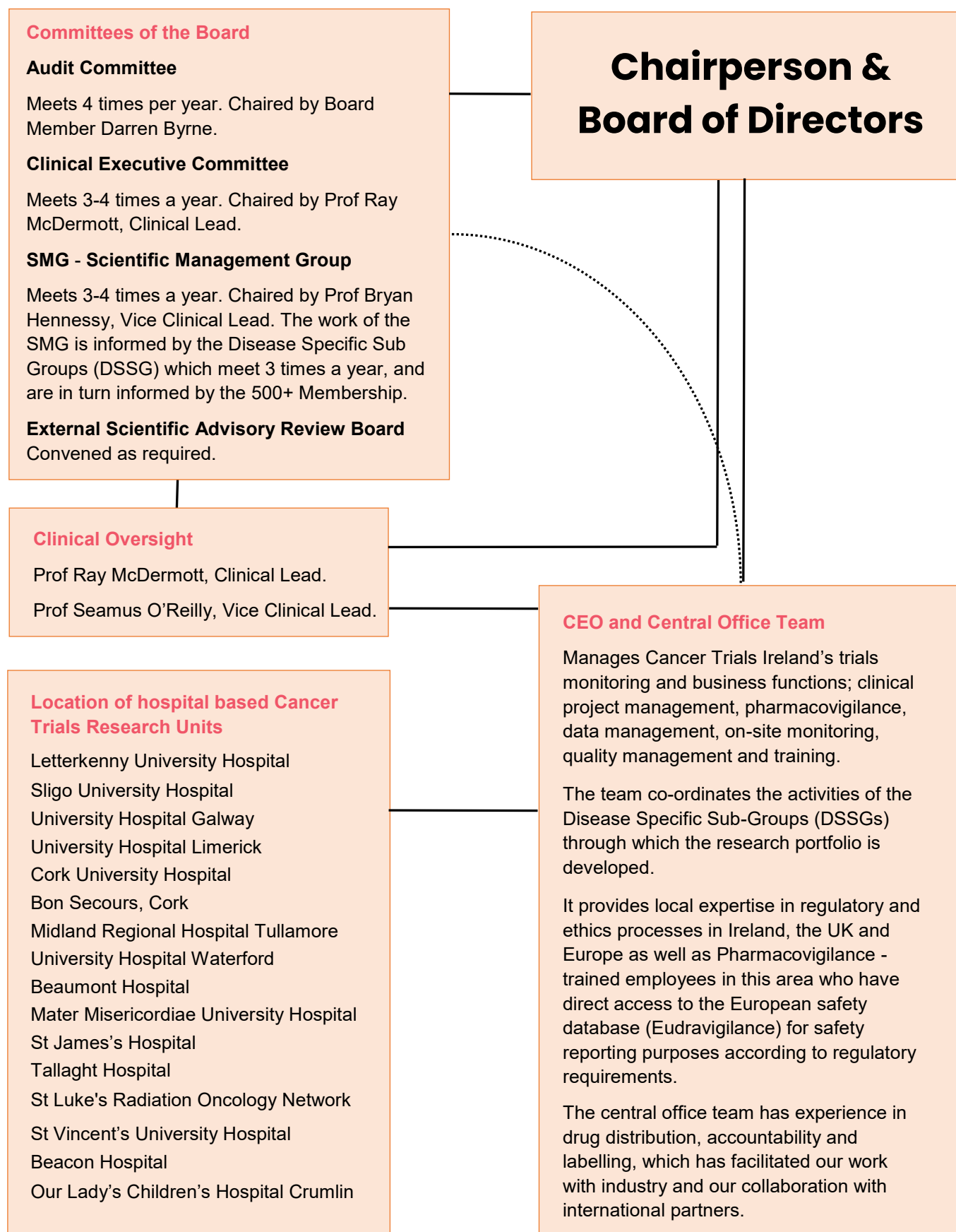
The Audit Committee is a subcommittee of the Board and was established in the summer of 2016 and met 7

times in 2020 (2019: 4) Darren Byrne is the chair of the Audit Committee and member of the Board of Directors.

- Deirdre Somers (Chair)
- Deirdre Somers
- Dr Ruth Barrington
- Darren Byrne
- Dr Jerome Coffey
- Prof Seamus O'Reilly
- Patrick Kivlehan (elected Nov 18th 2020)
- Rory Montgomery
- Paula Murphy
- Dr Robert O'Connor

Secretary: David Donovan

How we are organised



From our CEO



Eibhlín Mulroe

I am delighted to introduce our Annual Review for 2021.

2021 saw the challenges of the pandemic continue, and the further blow of the HSE Ransomware attack. These significant issues impacted revenue, trial monitoring, and plans to open new trials. Nevertheless, cancer trials Ireland delivered a strong and flexible performance, notably including the inaugural Cancer Retreat, a virtual event that rallied the community around International Clinical Trials Day. In spite of these challenges, CTI still managed to open and operate new trials, including an important trial, CLL17, which was much anticipated by the relevant patient community. This trial has been a wonderful exemplar of an Investigator-Led Trial that delivers life changing benefits to Irish patients. Elsewhere, the clinical oncology community was more broadly galvanized by the Cancer Retreat, which gave a platform to the key leaders for cancer research, including the head of the HRB, the Irish Cancer Society, the chair of an international collaborative group (ANZUP) and An Taoiseach, Micheál Martin, TD.

In spite of having no formal fundraising department, we continue to be the recipient of incredible, sustained generosity from all over Ireland, most obviously – but by no means exclusively – from the horse racing community, and friends of Pat Smullen. I am delighted to report that the faith shown in Cancer Trials Ireland in 2019 yielded new trial and treatment options for pancreatic cancer patients in 2021, notably through the Paricalcitol study, and also through the development of the FEED and PATCH studies.

I want to thank our amazing Chair and Board for their expertise, support and guidance through a very difficult wider environment, and I look forward to leveraging their energy and abilities in the coming year. In closing I must thank the team at our office and at sites, their intelligence and commitment to cancer research make this place the best working environment. We have a great purpose, bringing hope to our cancer patients.

From our Clinical Lead



Prof Ray McDermott

In 2021 we have had unprecedented levels of consultation with sites members and stakeholders. The primary driver of this has been the new HRB Cancer Trials Network and Cluster funding model, and the complex and significant applications we all have made for funding under this scheme. Those applications were certainly onerous, but one of the benefits is the clear picture we have of what you, as members want:

- More collaborative group trials
- More Investigator-Led Trials

And beyond that, more clarity and communication around feasibilities, and more protected time for research. These results are not surprising, we have shared the same goals, and obstacles, for many years – but they are useful, as is the knowledge that (as of last year) public support for trials has never been higher. But we still face major challenges. One lasting effect of the pandemic is the impact on employers and employees at every level of society. While we have always seen a degree of staff turnover throughout our history, it was heightened by a job market that heavily favours employees. We must acknowledge that staff capacity is a key limiting factor for opening and running new trials, and developing a scalable talent strategy will be one of our strategic pillars for the future.

Finally I want to congratulate our colleague Prof Seamus O'Reilly for spearheading Ireland's first Cancer Retreat back May.

Achievements & Performance 2020

- In 2020 and early 2021, Cancer Trials Ireland applied for the Health Research Board Cancer Trials Network Call with the Royal College of Surgeons as the Host Institution. The submission was made in January 2021, later in the year the HRB communicated that the application was successful and will award €6.9m over 5 years from Jan 2022.
- Despite the Covid Pandemic, Cancer Trials Ireland ran the 6th successful externally funded Just Ask Your Team public information campaign communicating with the public and members on radio and media interviews on the value of cancer trials. This included a new podcast.
- In 2021, there are increases in numbers of patients on trials through increased collaborations with international trial consortia. 101 trials were open to patient accrual. Of these 8% were Investigator Led Studies (2020: 20%) and 31% (2020: 34%) were collaborative group trials, which involve collaboration with other collaborative groups in EU and global. The 61% (2020: 46%) balance of open trials are run by international pharmaceutical companies in Irish hospitals.
- As part of Just Ask 2021, Cancer Trials Ireland hosted Ireland's inaugural Cancer Retreat, a virtual event that was opened by An Taoiseach, and featured contributions from the NCCP Director, CEO of the HRB, and CEO of the Irish Cancer Society. The event also involved more than 20 oncologist/haematologist contributors and was attended by more than 250 members of the cancer trials community in Ireland.
- Cancer Trials Ireland hosted two stakeholders' events on DSSG meeting days, addressing 1) Public & Patient Involvement and 2) Protected Time for health researchers.
- Cancer Trials Ireland CEO addressed the Joint Oireachtas Committee for the Implementation of the Good Friday Agreement (October) as part of the All-Island Cancer Research Institute delegation.
- In March 2021, Cancer Trials Ireland facilitated the reinstatement of an MOU between the National Cancer Institute in America, the Irish Government, and the Northern Irish Government. The signatories were NCI's director (Dr Ned Sharpless), Minister for Health, Stephen Donnelly, and NI Minister for Health Minister Robin Swann, and the event featured messages of support from An Taoiseach, First Minister Arlene Foster, and deputy First Minister Michelle O'Neill, and Norris Cochran, Acting Secretary of the US Department of Health & Human Services.
- Prof Seamus O'Reilly, of Cancer Trials Ireland's Clinical Leadership, published a peer-reviewed paper about the impact of COVID on cancer trials in Ireland.
- Cancer Trials Ireland facilitated regular Stakeholder Engagement and Patient Consultants Committee (PCC) meetings in 2021.
- The Pat Smullen Fund met in 2021 through the Coast for Curragh cycle to raise funds for pancreatic trials. The Cancer Trials Ireland Pat Smullen committee continue to meet in 2021 to oversee the spending of funds once in April and again in September.



Frances Crowley, Eibhlin Mulroe, Mrs & Mr Lync (Coast to Curragh)



Pictured signing a new memorandum of understanding to 'reinvigorate' the Ireland - Northern Ireland - NCI Cancer Consortium is Minister for Health Stephen Donnelly; Northern Ireland Minister for Health Robin Swann; and Dr Norman E Sharpless on behalf of the National Cancer Institute (NCI), US

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 9 to 23.**

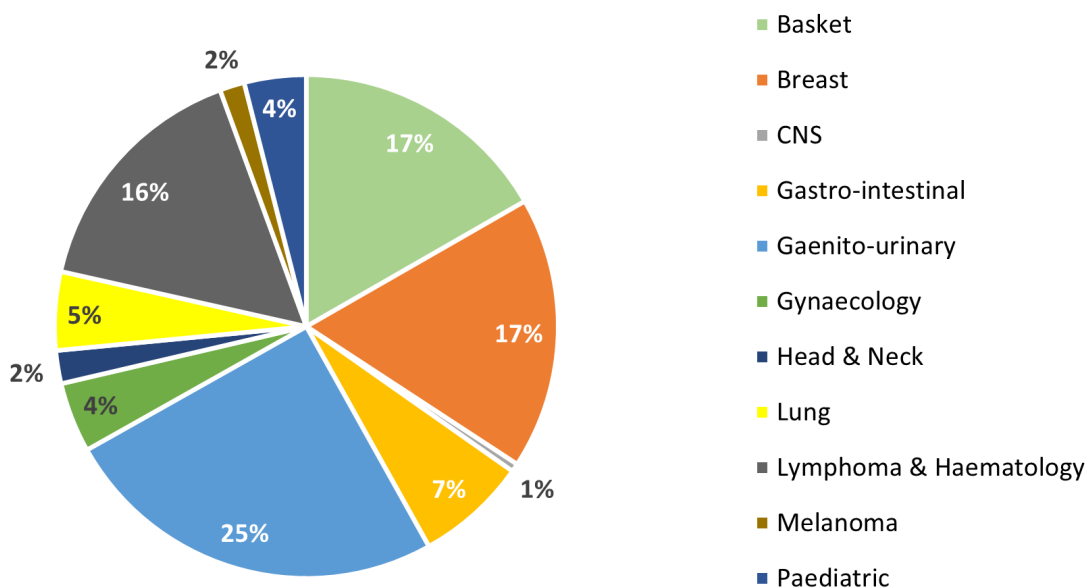
No	Performance Metric	Explanation
1	Accrual	Refers to the number of patients recruited to a trial.
2	Trials portfolio	The number and type of trials in our portfolio.
3	Cancer trials research unit monitoring	Monitoring activity of cancer trials research units includes a broad range of activities conducted 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	Membership	The number of Members of Cancer Trials Ireland.
7	Participation	Attendances at scientific meetings, International Meetings, and trials introduced and developed by local Principal Investigators (PIs).
8	Publications	The number of publications in peer-reviewed journals and abstracts accepted at top level international.
9	Plans for future period	How Cancer Trials Ireland will adapt to funding changes.

Accruals: IMP/RT/Medical Device

- This metric records the number of patients recruited, or accrued, to all type of trials by disease area.

By disease area (percentage)

IMP/RT/Med Dev By Disease Area (2021)



By disease area (accrual numbers)

NOTE: There were also 3 accruals to Non-CTRIAL studies (not included in this chart)

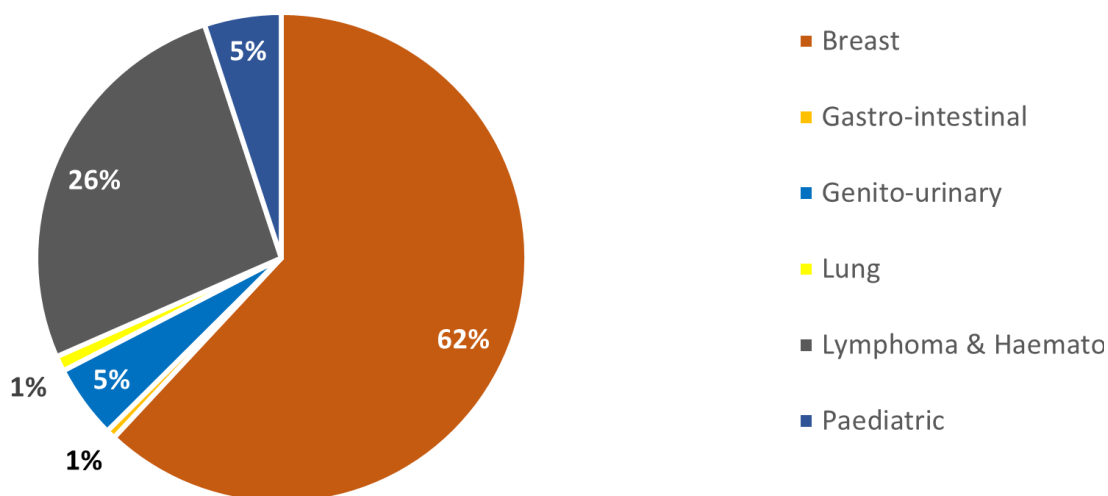
Disease area	2021
Basket	63
Breast	66
CNS	2
Gastro-intestinal	27
Genito-urinary	94
Gynaecology	17
Head & Neck	8
Lung	19
Lymphoma & Haematology	60
Melanoma	6
Paediatric	15
Total	377

Accruals: Biobank/Registry/Translational

- This metric records the number of patients recruited, or accrued, to all type of studies by disease area.

By disease area (percentage)

Biobank/Registry/Translational by Disease Area



By disease area (accrual numbers)

NOTE: There were also 448 accruals to Non-CTRIAL studies (not included in this chart)

Disease Area	2021
Breast	306
Gastro-intestinal	3
Genito-urinary	24
Lung	5
Lymphoma & Haematology	131
Paediatric	25
Total	494

Trials portfolio

This metric records the number and type of trials open and in development during 2021. In-house trials and Collaborative trials (which involve research organisations in other countries) were an important area of focus during 2021. 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.

Table 1

Disease Area	2017	2018	2019	2020	2021
Basket	6	6	5	9	9
Breast	68	54	57	45	47
CNS	5	5	5	5	5
Gastro-intestinal	33	43	40	31	31
Genito-urinary	44	44	46	42	46
Gynaecology	8	13	16	14	15
Head & Neck	8	9	11	11	10
Lung	45	36	34	30	32
Lymphoma & Haematology	31	27	31	30	45
Melanoma	11	10	12	8	8
Paediatric	29	40	38	43	42
Total No of active trials*	288	287	295	268	290

Table 1 shows the total number of trials active in a particular disease group. 'Active' means trials in development, open, in treatment, in follow-up.

Table 2

Disease Area	2017	2018	2019	2020	2021
Basket	3	4	4	7	4
Breast	21	14	13	13	13
CNS	2	1	2	2	5
Gastro-intestinal	14	8	10	14	12
Genito-urinary	18	16	12	13	17
Gynaecology	7	5	7	8	6
Head & Neck	3	4	0	2	3
Lung	15	13	10	5	9
Lymphoma & Haematology	12	7	6	7	14
Melanoma	5	3	0	2	3
Paediatric	20	26	26	22	19
Total No of active trials*	120	101	90	95	105

Table 2 shows the total number of trials open to accrual only.

Collaborations with international research groups

A large part of the 2021 portfolio of studies in development, open and in follow up studies originate from successful collaborations with international groups.

- **ABCSG** - Austrian Breast and Colorectal Cancer Study Group
- **AIEOP** (Italy) - Associazione Italiana di Ematologia e Oncologia
- **ANZUP** - The Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group
- **BC Cancer** - British Columbia cancer
- **BIG** - Breast International Group
- **Bristol Royal Hospital**
- **CCTG** - Canadian Cancer Trials Group
- **CRUK** - Cancer Research UK
- **CCRI** (Austria) – St Anna Children’s Cancer research Institute
- **Children’s Cancer Research Institute Vienna** (Austria)
- **COG** – Children’s Oncology Group
- **DCOG** – Dutch Childhood Oncology Group
- **DSCLL** – Deutsche Studiengruppe CLL
- **Dutch Collaborative Group**
- **EBMT** – European Society for Blood and Marrow Transplantation
- **ECOG** - ACRIN (Eastern Cooperative Oncology) and ACRIN (American College of Radiology Imaging Network) Research Group
- **EMN** – European Myeloma Network
- **ENGOT / NOGGOG** - The European Network for Gynaecological Oncological Trial groups
- **EORTC** - European Organisation for Research and Treatment of Cancer
- **Erasmus Medical Centre**
- **ETOP** - European Thoracic Oncology Platform
- **European Rhabdoid Registry**
- **Fondazione IRCCS Istituto Nazionale Tumori, Milano**
- **Fondazione Michelangelo**
- **Fundacion Para la Investigacion Hospital Universitario La Fe**
- **GBG** - German Breast Group
- **GCIG** – Gynaecologic Cancer intergroup
- **GEICAM** - Grupo Español de Investigación en Cáncer de Mama
- **GERCOR** - Groupe Coopérateur Multidisciplinaire en Oncologie
- **GOSH (UK)** – Great Ormond Street Hospital
- **Gustave Roussy Cancer Campus Paris**
- **HOPP** Children’s Cancer Centre (Heidelberg)
- **HOVON** - Hemato-Oncologie voor Volwassenen Nederland
- **IBCSG**—International Breast Cancer Study Group
- **ICR** - Institute of Cancer Research
- **Institut Jules Bordet**
- **ITCC** - Innovative Therapies for Children with Cancer

- **Karolinska University Hospital**
- **Lawson Health Research Institute (Canada)**
- **LLR** – Leukemia & Lymphoma Research
- **MASC** – Melanoma and Skin Cancer Trials
- **Movember**
- **NCRN**—National Cancer Research Network UK (incorporating Cancer Research UK (CRUK), Clinical Trials Research Unit (CTRU) & Medical Research Council (MRC))
- **NRG Oncology** – incorporating National Surgical Adjuvant Breast and Bowel Project (NSABP); the Radiation Therapy Oncology Group (RTOG); the Gynecologic Oncology Group (GOG).PrECOG—Sister Foundation of ECOG
- **PCCTC** - The prostate Cancer Clinical Trials Consortium
- **Royal Marsden NHS Foundation Trust**
- **Scandinavian Prostate Cancer Group**
- **SIOPE** - European Society for Paediatric Oncology
- **St Anna Kinderkrebsforschung**
- **SWOG** - Southwest Oncology Group
- **TRIO** - Translational Research in Oncology
- **TROG** - Trans-Tasman Radiation Oncology Group
- **UNICANCER (France)**
- **UCL** - University College London
- **University Hospital Freiburg**
- **University Hospital Muenster**
- **University of Birmingham**
- **University of Edinburgh**
- **University of Florence**
- **University of Leeds**
- **University of Liverpool**
- **UPCI** – University of Pittsburgh Cancer Institute
- **Walton Centre NHS Foundation**

Specific collaborations during 2021

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

We continued our strong collaboration with ANZUP. We are the EU sponsor on two large international phase III prostate trials (ENZAMET and ENZARAD). Both trials were open to accrual in research units in Ireland, the UK and selected sites in Europe through our partnership with the EORTC. Both studies are in follow up. In addition, a new large prostate cancer trial, DASL, is now open in Irish and UK hospitals with Cancer Trials Ireland being the EU sponsor.

DSCLL – Deutsche Studiengruppe

CLL is an important collaboration enacted in 2020 and resulting in the CLL17 study opening in 2021, a phase 3 randomized trial for the treatment of previously untreated chronic Lymphocytic Leukaemia. Accrual to this trial immediately took off and a steady enrolment over the entire year was seen.

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 2021 the NSABP B-51 and the NSABP B47 trials in breast cancer were still in follow up. Also the NRG GU005 (prostate cancer) and NRG HN002 (head and Neck Cancer) were in follow up.

(collaborations continued)

HOVON – In 2019 we were successful to form a collaboration with the Hemato-Oncologie voor Volwassenen Nederland (HOVON) group and subsequently the HOVON studies 150 and 156, both large phase 3 randomized trials for the treatment of acute myeloid leukemia or myelodysplastic syndrome were opened for accrual in 2021.

ENGOT – Since 2018 we have an active collaboration with the ENGOT, the European Network for Gynaecological Oncological Trial groups, which resulted in the opening of ENGOT-cx8 (stage V recurrent cervical cancer) in 2020, these are now in follow up; ENGOT cx12 (metastatic and recurrent cervical cancer) and ENGOT cx11 (high-risk, locally advanced cervical cancer) studies were open to accrual in 2021.

ETOP

ETOP specialises in European lung cancer research collaboration, and we had already several trials available for Irish patients. In 2019, the ETOP ALERT study, a single arm phase 2 study for advanced non-small lung cancer was open for accrual in Ireland.

Industry collaborations

Since the inception of ICORG, now Cancer Trials Ireland, we have established clinical research partnerships with many global pharmaceutical and biotechnology companies. In 2021 the study portfolio included studies from AbbVie, Artios, Astellas, Astra Zeneca, Basilea, Bayer, Beigene, BioProtect, Blueprint, Boehringer Ingelheim, Boston Scientific, Bristol Myers Squibb, Celgene, Chimerix, Clovis Oncology, Daicchi Sankyo, Eisai, Exelixis, Glycomimetics, Glaxo Smith Kline, Immunogen, Immunomedics, Incyte, Karyopharm, LOXO, MEI Pharma, Medivation, Merck-Serono, Millennium, Mirati, MSD, Nordiv, Novartis, Oncanova, PDS Biotechnology, Pfizer, Prothena, Puma Biotechnology, Radius Pharma, Regeneron, Roche, Sanofi, Syneos Health, Takeda, Unicancer and Zymeowrks. 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.

Research Unit staff around Ireland



Erica Bennett
Bons Cork



Fausta Barizaite
SVUH



Debra O'Hare
CUH



Cian Ronayne
CUH



Amy Mahon
SVUH

Cancer trials research unit monitoring

The conduct of a clinical trial should be adequately monitored in order to ensure the reliability and robustness of the results. Monitoring of clinical trials is a requirement of ICH GCP, EU and national regulations. Monitoring activity is carried out on a study by study basis both in the individual cancer research unit and remotely. Each study undergoes a risk analysis, prior to the study being open to patients, which determines the level of monitoring activity and rationale for the chosen monitoring strategy. The risk-based monitoring plan contains detailed information on how the study will be monitored from the time of study initiation to study closure. The COVID pandemic required to develop adaptive strategies to facilitate continued trial conduct and develop resilience for clinical trial conduct in a pandemic reality. It can include the possibility of remote monitoring and close out which, with the support of the hospital, allows for the clinical trial to be monitored without the need to have staff visit the hospital.

The monitoring level can be a combination of on-site or remote 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 or remote 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.

Audits

Number of days spent in 2021 preparing for and conducting audits and follow-up activity as well as active participation in external sponsor and third party audits at our central office and at cancer trials research units around the country.

Audit Type	Preparation (days)	Audit (days)	Follow-up (days)
External Third Party Audit of Cancer Trials Ireland Central Office	0.5	1.25	1
External Sponsor audit of Cancer Trials Ireland (central office)	13	0	4
Cancer Trials Ireland internal audit	8	11	48.5
Cancer Trials Ireland Audit of Research Units	15	9	90
Audit strategy/planning and audit/inspection readiness	2	-	-
Total	38.5	21.25	143.5

Staff training (internal)

Training courses conducted by the central office training team along with attendance by central office staff and investigators/ investigational staff at research units.

Type of Training	Number of Sessions	Number of attendees (Central Office Staff)	Number of attendees (Research Unit Staff)
Bridge Learn (LMS) - Demonstration	2	52	0
Chief Investigator Training	5	14	22
Clinical Trial Regulation - PMs	1	17	0
Clinical Trials for Medical Trainees	1	0	27
Data Management Induction	2	12	0
Data Protection (DP)	4	50	0
Essential Document Training	3	9	0
Ethics and Regulatory Induction	3	23	0
GCP: Basic/ Refresher Training (Investigator only)	2	0	27
GCP: Basic/ Refresher Training (Sponsor and Investigator)	4	38	0
GCP: Essentials	4	7	0
Introduction to Clinical Trials	1	6	0
IT Security Guidance	1	45	0
Monitor Training (multiple topics): SIV, Pharmacy,	8	39	0
Pharmacovigilance Training	12	26	0
Quality and Training induction	13	26	0
RECIST 1.1 Trainig	1	6	0
Therapeutic Area training: Breast Cancer	1	27	0
TMF Induction Training	7	28	0

Pharmacovigilance

Pharmacovigilance activity	Number
SAEs received and processed by Cancer Trials Ireland * from MOM reviewed studies	83
Collaborative Irish SAEs received and processed (non inhouse studies) SAEs received through Cancer Therapy Evaluation Program's Adverse Expedited Reporting System (CTEP AERS) (includes follow-ups) / MedWatch studies	21
SUSARs Entered onto Eudravigilance Database by Cancer Trials Ireland	6
PhV SOPs updated	0
Annual Development Safety Update Reports (produced in-house) distributed to relevant Ethics Committees and Competent Authorities by Cancer Trials Ireland	9
Annual Development Safety Update Reports (received from another sponsor) distributed to relevant Ethics Committees and Competent Authorities by Cancer Trials Ireland	7
6 Monthly SUSAR line listings produced	23
Safety and clinical database reconciliations	30

Staff training (external)

Significant external training courses attended by staff.

Date	Course	Attendees
22/02/2021	CTIS for SME and Academia (Part 1)	Ethics and Regulatory Coordinator Quality and Training Associate II Project Managers
25/02/2021	MSSO MedDRA v24.0 training	Clinical Data Manager Head of Biometrics
04/03/2021	CTIS for SME and Academia (Part 2)	Ethics and Regulatory Coordinator Quality and Training Associate II Project Managers
23/03/2021	RQA: Data Integrity & Quality Tolerance Limits	Quality Assurance Auditor
20/04/2021	MedDRA European Webinar	Pharmacovigilance Manager Clinical Data Manager
28/04/2021	Trinity Masterclass: Amendments to Health Research Regulations – Exploring Consent	Quality Training Manager Ethics Regulatory Coordinator
12/05/2021	Irish Health Research Forum: Genomics	Project Manager
25/05/2021	CTMS Study Management	Project Managers Quality and Training Associate II Head of Business Development
27/08/2021	Cybersecurity Focus	Quality Assurance Auditor
16/09/2021	Clinical Trials and Health Research Confidentiality	Ethics and Regulatory Coordinator
20/09/2021	Eudravigilance training	Pharmacovigilance Manager
09/11/2021	EFGCP: Audit & CSV Training	Quality Training Manager
29/11/2021	EMA: Clinical Trial Regulation and CTIS	Pharmacovigilance Manager Quality Training Manager
03/12/2021	EMA & ECRIN: Live Demonstration of CTIS and Q&A	Ethics and Regulatory Coordinator
Throughout 2021	EFGCP Webinars on a variety of topics related to COVID-19 and Clinical Trials: vaccinations, what worked, what did not work, trial design.	Quality Assurance Auditor Quality Training Manager

Participation in conferences & meetings

Date	Meeting
19/01/2021	Health Research Board (HRB) Clinical Research Coordination Ireland (CRCI) Quality Working Group
28/01/2021	Health Research Board (HRB) Clinical Research Coordination Ireland (CRCI) Annual Working Groups Meeting
04/02/2021	World Cancer Day: Queen's University Belfast 'Time for an All-Island Cancer Moonshot'; European Parliament and Public Hearing on COVID-19 impact on cancer
15/02/2021	European Forum for Good Clinical Practice (EFGCP) webinar: COVID-19 Vaccinations in Trial Participants: Should this happen or not?
17/02/2021	European Thoracic Oncology Platform (ETOP) Live Webinar: Highlights of the World Conference on Lung Cancer (WCLC) Virtual Congress 2020
23/02/2021	Queen's University, Belfast: 'Leading Through a Pandemic' - Michael Dowling, Northwell Health
08/03/2021	European Forum for Good Clinical Practice (EFGCP) Webinar "Back to the Future Part I: CT Methodology. What worked under Covid-19 and should stay?"
11/03/2021	A National System of Research Ethics Review - Transition to National RECs for Regulated Health Research
16/03/2021	Ireland-Northern Ireland-National Cancer Institute (NCI) Cancer Consortium webinar
18/03/2021	17th St. Gallen International Breast Cancer Conference
21/03/2021	44th International Breast Cancer Study Group (IBCSG) Annual Meeting
23/03/2021	Health Research Board (HRB) Clinical Research Coordination Ireland (CRCI) Quality Working Group
26/03/2021	Irish Association for Cancer Research (IACR) Annual Conference 2021
31/03/2021	European Association of Neuro-Oncology (EANO) webinar on glioblastoma
21/04/2021	Irish Prostate Cancer Outcomes Research Programme (IPCOR) study funded by Movember and the Irish Cancer Society "What Men Want"
23/04/2021	John Fitzpatrick Irish Genitourinary Cancer Conference 2021
23/04/2021	European Network of Gynaecological Oncological Trial Groups (ENGOT) - General Assembly
27/04/2021	St James' Hospital Cancer Symposium (GastroIntestinal Cancer)
08/05/2021	World Ovarian Cancer Day 2021: Ovarian Cancer - PARP inhibitors and beyond
10/05/2021	European Forum for Good Clinical Practice (EFGCP) Webinar: Back to the Future Part II: CT Methodology. What was acceptable during the Covid-19 pandemic but should NOT stay?
12/05/2021	Irish Health Research Forum Webinar (IHRF): Advancing Genomics in Ireland: Part 2
19/05/2021	Gynecological Cancer InterGroup (GCIg) Harmonisation Meeting
21/05/2021	Cancer Trials Ireland: Cancer Retreat
25/05/2021	European Network of Gynaecological Oncological Trial Groups (ENGOT): Masterclass in Gynaecological Oncology
26/05/2021	Patient Voice in Cancer Research - Diet and Nutrition
28/05/2021	Blood Cancer Network Ireland (BCNI) Annual Symposium
04/06/2021	American Society of Clinical Oncology (ASCO): Annual Meeting
11/06/2021	Breast International Group (BIG) General Assembly
16/06/2021	Webinar: Cancer Care after Covid
21/06/2021	American Association for Cancer Research (AACR): CANCER DISCOVERY 10TH ANNIVERSARY SYMPOSIUM: THE NEXT DECADE OF DISCOVERIES
28/06/2021	Irish Society of Medical Oncology (ISMO): 18th Post ASCO Review Meeting
12/07/2021	European Forum for Good Clinical Practice (EFGCP) Webinar - Confidentiality, COVID-19 and consequences for future research design in and beyond the pandemic
17/08/2021	IQVIA webinar
18/08/2021	CTI Cancer Retreat Vimeo

19/08/2021	Webinar 1: 'Sequencing treatments in metastatic Castration Resistant Prostate Cancer' Dr Daniel J George, Professor of Medicine and Surgery, Member of the Duke Cancer Institute, US
06/09/2021	Irish Lung Cancer Community (ILCC) meeting
09/09/2021	Launch of the HSE National Framework for Governance, Management and Support of Health Research
16/09/2021	Clinical Trials & Health Research Conference 2021
21/09/2021	Health Research Board (HRB) National Clinical Trials Office (NCTO) Quality Working Group meeting
27/09/2021	Webinar on Wellbeing at the workplace
29/09/2021	Breast International Group (BIG) Scientific Meeting
30/09/2021	European Network of Gynaecological Oncological Trial Groups (ENGOT): Operational Representative Meeting
30/09/2021	Irish Platform for Patients' Organisations, Science & Industry (IPPOSI) Digital Discussion Outcome Report: LEARNING FROM THE PANDEMIC RESPONSE: IMPLICATIONS FOR HEALTH INFORMATION IN IRELAND
01/10/2021	European Network of Gynaecological Oncological Trial Groups (ENGOT): General Assembly
08/10/2021	European Association of Neuro-Oncology (EANO) AGM
13/10/2021	Webinar 2 - Interpreting the Real World Evidence for Xofigo (Radium223)
15/10/2021	Webinar Terry McVeigh
26/10/2021	European Organisation for Research and Treatment of Cancer (EORTC) and Breast International Group (BIG): Early Breast Cancer
26/10/2021	European Organisation for Research and Treatment of Cancer (EORTC) and Breast International Group (BIG): Early Breast Cancer
26/10/2021	Webinar: Early Breast Cancer: new strategies to optimise adjuvant endocrine treatments in breast cancer.
26/10/2021	European Patients' Forum (EPF) CONGRESS 2021: THE DIGITAL TRANSFORMATION OF HEALTHCARE
02/11/2021	EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY (ESMO) Guidelines: Real World Cases Webinar - Ovarian Cancer
02/11/2021	Gynecological Cancer InterGroup (GCIg) pre meeting
03/11/2021	National HSE R&D: ROADMAP FOR THE REFORM OF THE HSE RESEARCH ETHICS COMMITTEES
04/11/2021	An Oncology Fellowship During the Pandemic; Adapting to a New Normal Dr Geoffrey Watson, Princess Margaret Cancer Center, Toronto
04/11/2021	The Gathering Around Cancer Conference 2021
08/11/2021	World Cancer Series Europe
09/11/2021	SpR Oncology Study Sessions Evening Series 2021-2022 Osteosarcoma and Ewings sarcoma
10/11/2021	World Cancer Series Europe
12/11/2021	Irish Society for Gynaecological Oncology (ISGO) Annual Conference
12/11/2021	The Gathering (playback)
17/11/2021	Gynecological Cancer InterGroup (GCIg) Autumn 2021 Meeting
17/11/2021	Irish Health Research Forum Webinar (IHRF): Health research – how to be responsive and resilient in the face of crises
24/11/2021	Health Products Regulatory Authority (HPRA) Clinical Trial Regulation webinar
24/11/2021	EU Webinar: The EU Mission on Cancer and the Europe's Beating Cancer Plan
25/11/2021	Health Products Regulatory Authority (HPRA) Clinical Trial Regulation webinar
30/11/2021	Breast Cancer PPI Study Presentation, Dr Sarah McGarrigle, TCD
02/12/2021	HSE webinar: THE VISION FOR THE IMPLEMENTATION OF THE HSE RESEARCH GOVERNANCE, MANAGEMENT AND SUPPORT FUNCTION
07/12/2021	EU Webinar: Approach to precision medicine
17/12/2021	Breast International Group (BIG) Extraordinary General Assembly

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.

Area	Peer Reviewed Journal Articles 2021	Abstracts: Poster/Oral Presentations 2021
Basket	0	0
Breast	11	1
Gastrointestinal	0	1
Genitourinary	7	0
Gynaecological	3	2
Head and Neck	0	0
Lung	2	1
Lymphoma and Haematological	0	1
Melanoma	0	0
Other	0	0
Total	23	6

*Compiled from approval for/notification of abstracts received by Cancer Trials Ireland from Investigators. Potentially additional abstracts have been presented.

Peer reviewed journal publications

Breast

Cancer Trials Ireland Study Number: short name. 06-31: TAILORx Study

Albain, K. S., R. J. Gray, D. F. Makower, A. Faghih, D. F. Hayes, C. E. Geyer, E. C. Dees, M. P. Goetz, J. A. Olson, T. Lively, S. S. Badve, T. J. Saphner, L. I. Wagner, T. J. Whelan, M. J. Ellis, W. C. Wood, M. M. Keane, H. L. Gomez, P. S. Reddy, T. F. Goggins, I. A. Mayer, A. M. Brufsky, D. L. Toppmeyer, V. G. Kaklamani, J. L. Berenberg, J. Abrams, G. W. Sledge & J. A. Sparano (2021). "Race, Ethnicity, and Clinical Outcomes in Hormone Receptor-Positive, HER2-Negative, Node-Negative Breast Cancer in the Randomized TAILORx Trial." J Natl Cancer Inst 113(4): 390-399.

Cancer Trials Ireland Study Number: short name. 10-05: TCHL

Eustace, A. J., S. F. Madden, J. Fay, D. M. Collins, E. W. Kay, K. M. Sheehan, S. Furney, B. Moran, A. Fagan, P. G. Morris, A. Teiserskiene, A. D. Hill, L. Grogan, J. M. Walshe, O. Breathnach, C. Power, D. Duke, K. Egan, W. M. Gallagher, N. O'Donovan, J. Crown, S. Toomey & B. T. Hennessy (2021). "The role of infiltrating lymphocytes in the neo-adjuvant treatment of women with HER2-positive breast cancer." Breast Cancer Res Treat 187(3): 635-645.

Cancer Trials Ireland Study Number: short name. 11-24: NSABP B47

Ganz, P. A., R. S. Cecchini, L. Fehrenbacher, C. E. Geyer, P. Rastogi, J. P. Crown, M. P. Thirlwell, D. M. Ellison, J. F. Boileau, P. J. Flynn, J. H. Jeong, E. P. Mamounas & N. Wolmark (2021). "NRG Oncology/NSABP B-47 menstrual history study: impact of adjuvant chemotherapy with and without trastuzumab." NPJ Breast Cancer 7 (1): 55.

Cancer Trials Ireland Study Number: short name. 12-43: TRIO 022/ PALOMA-2

Gelmon, K., J. M. Walshe, R. Mahtani, A. A. Joy, M. Karuturi, P. Neven, D. R. Lu, S. Kim, P. Schnell, E. Bananis & L. Schwartzberg (2021) "Efficacy and safety of palbociclib in patients with estrogen receptor-positive/human

epidermal growth factor receptor 2-negative advanced breast cancer with preexisting conditions: A post hoc analysis of PALOMA-2" Breast 59: 321-326

Cancer Trials Ireland Study Number: short name. 11-03: SOLE

Guerini-Rocco, E., K. P. Gray, C. Fumagalli, M. R. Reforgiato, I. Leone, P. Rafaniello Raviele, E. Munzone, R. Kammler, P. Neven, E. Hitre, G. Jerusalem, E. Simoncini, A. Gombos, I. Deleu, P. Karlsson, S. Aebi, J. Chirgwin, V. Di Lauro, A. Thompson, M. P. Graas, M. Barber, C. Fontaine, S. Loibl, J. Gavilá, K. Kuroi, B. Müller, S. O'Reilly, A. Di Leo, A. Goldhirsch, G. Viale, M. Barberis, M. M. Regan & M. Colleoni (2021). "Genomic Aberrations and Late Recurrence in Postmenopausal Women with Hormone Receptor-positive Early Breast Cancer: Results from the SOLE Trial." Clin Cancer Res 27(2): 504-512.

Cancer Trials Ireland Study Number: short name. 11-03: SOLE

Jerusalem, G., S. Farah, A. Courtois, J. Chirgwin, S. Aebi, P. Karlsson, P. Neven, E. Hitre, M. P. Graas, E. Simoncini, E. Abdi, C. Kamby, A. Thompson, S. Loibl, J. Gavilá, K. Kuroi, C. Marth, B. Müller, S. O'Reilly, A. Gombos, T. Ruhstaller, H. J. Burstein, M. Rabaglio, B. Ruepp, K. Ribi, G. Viale, R. D. Gelber, A. S. Coates, S. Loi, A. Goldhirsch, M. M. Regan, M. Colleoni & SOLE Investigators (2021) "Continuous versus intermittent extended adjuvant letrozole for breast cancer: final results of randomized phase III SOLE (Study of Letrozole Extension) and SOLE Estrogen Substudy." Ann Oncol 32(10): 1256-1266.

Cancer Trials Ireland Study Number: short name. 15-02: PanHER

Keegan, N. M., S. J. Furney, J. M. Walshe, G. Gullo, M. J. Kennedy, D. Smith, J. McCaffrey, C. M. Kelly, K. Egan, J. Kerr, M. Given, P. O'Donovan, A. Hernando, A. Teiserskiene, I. Parker, E. Kay, A. Farrelly, A. Carr, G. Calzaferri, R. McDermott, M. M. Keane, L. Grogan, O. Breathnach, P. G. Morris, S. Toomey & B. T. Hennessy (2021). "Phase Ib Trial of Copanlisib, A Phosphoinositide-3 Kinase (PI3K) Inhibitor, with Trastuzumab in Advanced Pre-Treated HER2-Positive Breast Cancer "PanHER"" Cancers (Basel) 13(6): 1225.

Cancer Trials Ireland Study Number: short name. 14-11: PENELOPE-B

Loibl, S., F. Marmé, M. Martin, M. Untch, H. Bonnefoi, S. B. Kim, H. Bear, N. McCarthy, M. Melé Olivé, K. Gelmon, J. García-Sáenz, C. M. Kelly, T. Reimer, M. Toi, H. S. Rugo, C. Denkert, M. Gnant, A. Makris, M. Koehler, C. Huang-Bartelett, M. J. Lechuga Frea, M. Colleoni, G. Werutsky, S. Seiler, N. Burchardi, V. Nekljudova & G. von Minckwitz (2021). "Palbociclib for Residual High-Risk Invasive HR-Positive and HER2-Negative Early Breast Cancer-The Penelope-B Trial." J Clin Oncol 39(14): 1518-1530.

Cancer Trials Ireland Study Number: short name. 12-30: TailorX Tissue Bank

Lynch, S. M., N. M. Russell, S. Barron, C. A. Wang, T. Loughman, P. Dynoddt, B. Fender, C. Lopez-Ruiz, A. O'Grady, K. M. Sheehan, J. Fay, V. Amberger-Murphy, A. Saha, R. Klinger, C. A. Gonzalez, N. Al-Attar, A. Rahman, D. O'Leary, F. T. Lanigan, A. P. Bracken, J. Crown, C. M. Kelly, D. P. O'Connor & W. M. Gallagher (2021). "Prognostic value of the 6-gene OncoMasTR test in hormone receptor-positive HER2-negative early-stage breast cancer: Comparative analysis with standard clinicopathological factors." Eur J Cancer 152: 78-89.

Cancer Trials Ireland Study Number: short name. 15-17: PALLAS

Mayer, E. L., A. C. Dueck, M. Martin, G. Rubovszky, H. J. Burstein, M. Bellet-Ezquerria, K. D. Miller, N. Zdenkowski, E. P. Winer, G. Pfeiler, M. Goetz, M. Ruiz-Borrego, D. Anderson, Z. Nowecki, S. Loibl, S. Moulder, A. Ring, F. Fitzal, T. Traina, A. Chan, H. S. Rugo, J. Lemieux, F. Henao, A. Lyss, S. Antolin Novoa, A. C. Wolff, M. Vetter, D. Egle, P. G. Morris, E. P. Mamounas, M. J. Gil-Gil, A. Prat, H. Fohler, O. Metzger Filho, M. Schwarz, C. DuFrane, D. Fumagalli, K. P. Theall, D. R. Lu, C. H. Bartlett, M. Koehler, C. Fesl, A. DeMichele & M. Gnant (2021) "Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multicentre, open-label, randomised, phase 3 study." Lancet Oncol 22(2): 212-222.

Cancer Trials Ireland Study Number: short name. 16-20: IBCSG 48-14 POSITIVE

Partridge, A. H., S. M. Niman, M. Ruggeri, F. A. Peccatori, H. A. Azim Jr, M. Colleoni, C. Saura, C. Shimizu, A. B. Sætersdal, J.R. Kroep, A. Mailliez, E. Warner, V. F. Borges, F. Amant, A. Gombos, A. Kataoka, C. Rousset-Jablonski, S. Borstnar, J. Takei, J. E. Lee, J. M. Walshe, M. R. Borrego, H. C. Moore, C. Saunders, F. Cardoso, S. Sunjar, V. Bjelic-Radisic, K. L. Smith, M. Piccart, L. A. Korde, A. Goldhirsch, R. D. Gelber & O. Pagani (2021) "Who

Peer reviewed journal publications

are the women who enrolled in the POSITIVE trial: A global study to support young hormone receptor positive breast cancer survivors desiring pregnancy" *Breast* 59: 327-338.

Genitourinary

Cancer Trials Ireland Study Number: short name. 16-70: BMS CA209-274/ CheckMate 274

Bajorin, D. F., J. A. Witjes, J. E. Gschwend, M. Schenker, B. P. Valderrama, Y. Tomita, A. Bamias, T. Lebre, S. F. Shariat, S. H. Park, D. Ye, M. Agerbaek, D. Enting, R. McDermott, P. Gajate, A. Peer, M. I. Milowsky, A. Nosov, J. N. Antonio Jr, K. Tupikowski, L. Toms, B. S. Fischer, A. Qureshi, S. Collette, K. Unsal-Kacmaz, E. Broughton, D. Zardavas, H. B. Koon & M. D. Galsky "Adjuvant Nivolumab versus Placebo in Muscle-Invasive Urothelial Carcinoma." *N Engl J Med* 384(22): 2102-2114.

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

Hayes, B., L. Brady, G. Sheill, A. M. Baird, E. Guinan, B. Stanfill, J. Dunne, D. Holden, T. Vlajnic, O. Casey, V. Murphy, J. Greene, E. H. Allott, J. Hussey, F. Cahill, M. Van Hemelrijck, N. Peat, L. A. Mucci, M. Cunningham, L. Grogan, T. Lynch, R. P. Manecksha, J. McCaffrey, D. O'Donnell, O. Sheils, J. J. O'Leary, S. Rudman, R. McDermott & S. Finn (2021) "Circulating Tumour Cell Numbers Correlate with Platelet Count and Circulating Lymphocyte Subsets in Men with Advanced Prostate Cancer: Data from the ExPeCT Clinical Trial (CTRIAL-IE 15-21)." *Cancers (Basel)* 13(18): 4690.

Cancer Trials Ireland Study Number: short name. 08-17: IMRT Prostate

Howe, O., L. White, D. Cullen, G. O'Brien, L. Shields, J. Bryant, E. Noone, S. Bradshaw, M. Finn, M. Dunne, A. M. Shannon, J. Armstrong, B. McClean, A. Meade, C. Badie & F. M. Lyng (2021) "A 4-Gene Signature of CDKN1, FDXR, SESN1 and PCNA Radiation Biomarkers for Prediction of Patient Radiosensitivity." *Int J Mol Sci.* 22(19): 10607.

Cancer Trials Ireland Study Number: short name. 13-21: Radium-223 & Enzalutamide mCRPC study

McDermott, R. S., J. Greene, J. McCaffrey, I. Parker, S. Helanova, A. M. Baird, A. Teiserskiene, M. Lim, H. Matthews, O. Deignan, J. Feeney, P. G. Thirion, S. P. Finn & P. J. Kelly (2021) "Radium-223 in combination with enzalutamide in metastatic castration-resistant prostate cancer: a multi-centre, phase II open-label study." *Ther Adv Med Oncol* 13: 17588359211042691.

Cancer Trials Ireland Study Number: short name. 11-05: GSK VEG113387 adjuvant pazopanib RCC study

Motzer, R. J., P. Russo, N. Haas, C. Doehn, F. Donskov, M. Gross-Goupil, S. Varlamov, E. Kopyltsov, J. L. Lee, H. Y. Lim, B. Melichar, M. Zemanova, B. Rini, T. K. Choueiri, L. Wood, M. N. Reaume, A. Stenzl, S. Chowdhury, R. McDermott, A. Michael, M. Izquierdo, P. Aimone, H. Zhang, C. N. Sternberg & PROTECT study investigators (2021) "Adjuvant Pazopanib Versus Placebo After Nephrectomy in Patients With Localized or Locally Advanced Renal Cell Carcinoma: Final Overall Survival Analysis of the Phase 3 PROTECT Trial." *Eur Urol* 79(3): 334-338

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

Silva, R., B. Moran, A. M. Baird, C. J. O'Rourke, S. P. Finn, R. McDermott, W. Watson, W. M. Gallagher, D. J. Brennan & A. S. Perry (2021) "Longitudinal analysis of individual cfDNA methylome patterns in metastatic prostate cancer." *Clin Epigenetics* 13(1): 168.

Cancer Trials Ireland Study Number: short name. 14-06: ENZAMET

Sweeney, C. J., A. J. Martin, M. R. Stockler, S. Begbie, K. N. Chi, S. Chowdhury, X. Coskinas, M. Frydenberg, W. E. Hague, L. G. Horvath, A. M. Joshua, N. J. Lawrence, G. M. Marx, J. McCaffrey, R. McDermott, M. McJannett, S. A. North, F. Parnis, W. Parulekar, D. W. Pook, M. N. Reaume, S. K. Sandhu, A. Tan, T. H. Tan, A. Thomson, E. Tu, F. Vera-Badillo, S. G. Williams, S. Yip, A. Y. Zhang, R. R. Zielinski & I. D. Davis (2021) "Overall Survival of Men with Metachronous Metastatic Hormone-sensitive Prostate Cancer Treated with Enzalutamide and Androgen Deprivation Therapy." *Eur Urol* 80(3): 275-279.

Gynaecological

Cancer Trials Ireland Study Number: short name. 16-68: FORWARD 1

Moore, K. N., A. M. Oza, N. Colombo, A. Oaknin, G. Scambia, D. Lorusso, G. E. Konecny, S. Banerjee, C. G. Murphy, J. L. Tanyi, H. Hirte, J. A. Konner, P. C. Lim, M. Prasad-Hayes, B. J. Monk, P. Pautier, J. Wang, A. Berkenblit, I. Vergot & M. J. Birrer (2021) "Phase III, randomized trial of mirvetuximab soravtansine versus chemotherapy in patients with platinum-resistant ovarian cancer: primary analysis of FORWARD I." *Ann Oncol* 32 (6): 757-765.

Cancer Trials Ireland Study Number: short name. 11-29: ICON8/8B

Morgan, R. D., I. A. McNeish, A. D. Cook, E. C. James, R. Lord, G. Dark, R. M. Glasspool, J. Krell, C. Parkinson, C. J. Poole, M. Hall, D. Gallardo-Rincón, M. Lockley, S. Essapen, J. Summers, A. Anand, A. Zachariah, S. Williams, R. Jones, K. Scatchard, A. Walther, J. W. Kim, S. Sundar, G. C. Jayson, J. A. Ledermann & A. R. Clamp (2021). "Objective responses to first-line neoadjuvant carboplatin-paclitaxel regimens for ovarian, fallopian tube, or primary peritoneal carcinoma (ICON8): post-hoc exploratory analysis of a randomised, phase 3 trial." *Lancet Oncol* 22(2): 277-288.

Cancer Trials Ireland Study Number: short name. 18-27: PORTEC 4a

Wortman, B. G., E. Astreinidou, M. S. Laman, E. M. van der Steen-Banasik, L. C. H. W. Lutgens, H. Westerveld, F. Koppe, A. Slot, H. A. van den Berg, M. E. Nowee, S. Bijmolt, T. C. Stam, A. G. Zwanenburg, J. W. M. Mens, I. M. Jürgenliemk-Schulz, A. Snyers, C. M. Gillham, N. Weidner, S. Kommoss, K. Vandecasteele, V. Tomancova, C. L. Creutzberg, R. A. Nout & P. S. Group (2021). "Brachytherapy quality assurance in the PORTEC-4a trial for molecular-integrated risk profile guided adjuvant treatment of endometrial cancer." *Radiother Oncol* 155: 160-166.

Lung

Cancer Trials Ireland Study Number: Short Name. 12-53: ETOP SPLENDOUR

Peters, S., S. Danson, D. Ejedepang, U. Dafni, B. Hasan, H. S. Radcliffe, F. Bustin, J. Crequit, L. Coate, M. Guillot, V. Surmont, D. Rauch, J. Rudski, D. O'Mahony, I. B. Aranda, A. Scherz, Z. Tsourti, H. Roschitzki-Voser, A. Pochesci, G. Demonty, R. A. Stahel & M. O'Brien (2021) "Combined, patient-level, analysis of two randomised trials evaluating the addition of denosumab to standard first-line chemotherapy in advanced NSCLC - The ETOP/EORTC SPLENDOUR and AMGEN-249 trials." *Lung Cancer* 161: 76-85.

Cancer Trials Ireland Study Number: short name. 14-13: MK3475-024/ KEYNOTE-024

Reck, M., D. Rodríguez-Abreu, A. G. Robinson R. Hui, T. Csősz, A. Fülöp, M. Gottfried, N. Peled, A. Tafreshi, S. Cuffe, M. O'Brien, S. Rao, K. Hotta, T. A. Leal, J. W. Riess, E. Jensen, B. Zhao, M. C. Pietanza & J. R. Brahmer (2021) "Five-Year Outcomes With Pembrolizumab Versus Chemotherapy for Metastatic Non-Small-Cell Lung Cancer With PD-L1 Tumor Proportion Score ≥ 50 " *J Clin Oncol* 39(21): 2339-2349.

Plans for future period

In 2021 we will begin scoping and planning for the new Cancer Trials Ireland strategy (2022-2027). This will coincide with the HRB Cancer Trials Network grant period, which will allow Cancer Trials Ireland more flexibility via infrastructure funding.

The new strategy will be built around our existing pillars of Governance, Funding Model, Operational Capability, Clinical Capability, and Profile. These pillars will be underpinned by well-defined programmes of activity and an updated Vision and Mission for the organisation.

We are excited for the future.

Peer reviewed journal publications

Abstracts: Oral and Poster Presentations

Breast

Cancer Trials Ireland Study Number: short name. 15-02: PanHER

Prior L., N. M. Keegan, S. J. Furney, J. M. Walshe, G. Gullo, J. Crown, M. J. Kennedy, D. Smith, J. McCaffrey, C. M. Kelly, K. Egan, J. Kerr, M. Given, N. Sheehy, P. O'Donovan, A. Hernando, A. Teiserskiene, I. Parker, E. Kay, R. McDermott, M. M. Keane, S. O'Reilly, L. Grogan, O. Breathnach, P. G. Morris, S. Toomey & B. T. Hennessy (2021) "Phase Ib/II trial evaluating safety and efficacy of copanlisib (PI3K inhibitor) and trastuzumab in pre-treated advanced HER2-positive breast cancer: Results from the PanHER study" Poster Presentation – SABCS (abstr P5-16-08).

Gastrointestinal

Cancer Trials Ireland Study Number: short name. 10-14: Neo-AEGIS

Reynolds, J. V., S. R. Preston, B. O'Neill, M. A. Lowery, L. Baeksgaard, T. Crosby, M. Cunningham, S. Cuffe, G. O. Griffiths, R. Roy, S. Falk, G. Hanna, F. R. Bartlett, I. Parker, A. Alvarez-Iglesias, M. Nilsson, G. Piessen, S. Risum, N. Ravi & R. S. McDermott (2021). "Neo-AEGIS (Neoadjuvant trial in Adenocarcinoma of the Esophagus and Esophago-Gastric Junction International Study): Preliminary results of phase III RCT of CROSS versus perioperative chemotherapy (Modified MAGIC or FLOT protocol). (NCT01726452)." Oral Presentation – ASCO Annual Meeting (J Clin Oncol 39: 2021 (no. 15 suppl; abstr 4004)).

Gynaecological

Cancer Trials Ireland Study Number: short name. 16-04: PRIMA

O'Cearbhaill, R., J. A. Pérez-Fidalgo, B. Monk, I. Tusquets, C. McCormick, J. Fuentes, R. Moore, C. Vulsteke, M. Shahin, F. Forget, W. Bradley, S. Hietanen, D. O'Malley, A. Dørum, B. Slomovitz, K. Baumann, F. Selle, P. Calvert, G. Artioli, T. Levy, A. Kumar, I. Malinowska, Y. Li, D. Gupta & A. González-Martín (2021). "Efficacy of niraparib by timing of surgery and residual disease: a post-hoc analysis of patients in the PRIMA/ENGOT-OV26/GOG-3012 study." Poster Presentation – SGO Meeting (Gynecologic Oncology 162, S65).

Cancer Trials Ireland Study Number: short name. 19-02: ENGOT cx12/GCT1015-07

Vergote, I., B. J. Monk, R. L. Coleman, L. M. Randall, K. Fujiwara, C. Marth, L. L. Woelber, E. Van Nieuwenhuysen, D. Cibula, P. Calvert, I. Boere, A. González-Martín, E. Kalbacher, N. Colombo, D. Lorusso, S. N. Banerjee, F. C. Maluf, I. Soumaoro & B. M. Slomovitz (2021). "Tisotumab vedotin versus investigator's choice chemotherapy in second- or third-line recurrent or metastatic cervical cancer (innovaTV 301/ENGOT-cx12/GOG 3057, trial in progress)." Poster Presentation – ASCO Annual Meeting (J Clin Oncol 39: 2021 (no. 15 suppl; abstr TPS5596)).

Lung

Cancer Trials Ireland Study Number: short name. 16-61: ETOP Booster

Soo, R., J-Y. Han, G. Dimopoulou, B. C. Cho, C. M. Yeo, E. Nadal, E. Carcereny, J. de Castro, M. A. Sala, R. Bernabe, L. Coate, M. Provencio, R. Garcia Campelo, S. Cuffe, S. Hashemi, M. Früh, B. Ruepp, H. Roschitzki-Voser, R. Stahel & S. Peters (2021). "A randomized phase II study of second-line osimertinib (Osi) and bevacizumab (Bev) versus Osi in advanced non-small-cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) and T790M mutations (mt): Results from the ETOP BOOSTER trial." Oral Presentation - ESMO Virtual Plenary (Ann Oncol 32, no 7 suppl; abstr VP3-2021).

Lymphoma and Haematological

Cancer Trials Ireland Study Number: short name. 16-02: CyBorD-DARA

Swan, D., M. E. O'Dwyer, M. Cahill, J. Krawczyk, V. Mykytiv, J. Quinn, R. Henderson, C. McEllistim, A. Hernando, I. Parker, M. Nolan, E. Lenihan, E. Szegezdi, S. D. Naicker, K. Lynch, A. Natoni, A. Ryan & P. Murphy (2021). "Cybord-Dara in Newly Diagnosed Transplant-Eligible Multiple Myeloma: Follow up Results from the 16-Bcni-001/Ctrial-IE 16-02 Study Show High Rates of MRD Negativity at End of Treatment." Poster Presentation – ASH (Blood 138 (Supplement 1): 2756)

Communications

Increasing awareness of Cancer Trials Ireland

A number of activities are undertaken during the year to increase the awareness of cancer trials and showcase the work that is being done across the country. These opportunities will continue to be pursued during the coming years. They include the following:

- **International Clinical Trials Day:** This is the organisation's annual set piece publicity event which results in a boost to the organisation's profile, the work of its members and contribution of patients. In 2021, we hosted Ireland's inaugural Cancer Retreat, which was virtually attended by 250+ members of the Irish clinical oncology research community. This was supported by significant digital and media communications leveraging patient stories, where possible on Investigator-Led Trials, to maximise the reach of our message to "Just Ask".
- **Mainstream media relations:** We are placing stories in local and national media on the opening of trials and announcing trial results. Features are also placed in national newspapers such as The Irish Independent, Irish Times, Irish Examiner, and Irish Tabloids and magazines.
- **Specialist media relations:** Details of trials are featured regularly in specialist medical press such as the Medical Independent, Cancer Professional and UPDATE Oncology and Haematology Journal.
- **Online:** In 2021 we continued to augment our upgraded website with video content created for and around the Cancer Retreat. Regular updates on topical news and cancer trials listing are provided on our website (www.cancertrials.ie) and regular posting on our Twitter and LinkedIn accounts, with the numbers of followers continuing to grow steadily. Our Vimeo account hosts our videos.
- **DSSG Digest:** The DSSG Digest newsletter lists the latest news and up to date listing of open cancer trials. It is widely distributed within the community (including the media) both electronically and in hard copy.
- **Annual Review:** The publication of the organisation's Annual Review is another opportunity used to profile the organisation's successes and progress.
- **Conferences:** Attendances at conferences are used regularly to raise the profile of the organisation's work
- **Quarterly accruals published:** We established a process for publishing the accruals figures for each quarter, broken down by study type and disease area. members on study news and updates.

Implementing public and patient involvement (PPI)

- Several of the Disease Specific Sub-Groups (DSSGs) have patient consultants in attendance at closed meetings.
- The Patient Consultant's Committee (PCC) was set up as a sub-group of the Board in 2018. The Chair of the PCC now sits on the Board of Cancer Trials Ireland and a new Chair was appointed in 2020.
- In 2021, the PCC appointed a new chair (Patrick Kivlehan) and welcomed a new member (Peter MacNamara)
- The PCC held several meetings with its counterpart council in the Canadian Clinical Trials Group (CCTG) and its chair, Judy Needham, on best practices for involving clinicians in PPI
- Patrick Kivlehan (PCC chair) was a plenary speaker at the inaugural Cancer Retreat
- The CTI Autumn DSSG stakeholder meeting focused on PPI, and welcomed Clinician & Patient speakers from the Canadian Clinical Trials Group
- The new Cancer Trials Ireland podcast featured an episode dedicated to PPI, featuring Prof Sean Dinneen (NUIG)

Fundraising:

Irish Cancer Society

After an incredible public response to the 2021 Daffodil Day in March 2021, the Irish Cancer Society doubled funding for the year to Cancer Trials Ireland, from €500,000 to €1m. This in remarkable generosity showed confidence in Cancer Trials Ireland and opened the door to more funding for investigator-led trials.

Pancreatic

The work of Pat Smullen and his family, friends, and the horse racing community in 2019 truly put Cancer Trials Ireland on the fundraising map, particularly in the area of pancreatic trials research. In 2021, three other very significant donors and donor groups came through in this area, namely:

- The Friends of Brian Lenihan – who raised €100,000 to fund the first phase of the Paricalcitol Trial. This wasn't the only benefit to accrue to Cancer Trials Ireland, as a member of this group, former EU Ambassador Rory Montgomery, went on to become a member of the Cancer Trials Ireland Board, and even spoke to media about his dear friend Brian Lenihan, and the Paricalcitol Trial.
- Ray Fenton – who lost his wife to pancreatic cancer, organised a walking event named 'Deirdre's Way' in honour of his wife which went on to raise €63,700.
- Coast to Curragh – Gavin Lynch, yet another member of the horse racing community, and someone who lost his mother to pancreatic cancer, organised a charity cycle that took in several race tracks between Bettystown and the Curragh, managing to raise an incredible €185,000 along the way.
- These marquee events aside, the horse racing community continued to make smaller, personal donations amounting to €3,773 over 2021. Later in the year, a young jockey winning a student horse race in the Curragh asked that the Curragh donate €500 to Cancer Trials Ireland.

Breast

The O'Flaherty Foundation, an Irish-based organisation which supports causes that promote health, generously elected to donate a total of €60,000 for breast cancer research over two years (2021 & 2022; €30,000 per annum). Cancer Trials Ireland is extremely grateful for the donations and we will keep our membership informed on decisions about how this money is allocated to breast cancer trials research.

Gastrointestinal

As in previous years, the Oesophageal Cancer Fund organised a charity walk to raise money to support the NeoAEGIS trial. Their target was €50,000, which they more than met. Thanks also to the CTI staff members who took part themselves.

Gynae & Ovarian

- In spring, Patricia Redmond and her colleagues in AIG, and her friends outside it, organised and took part in a 'virtual walk' from Dublin to Paris. In so doing they raised nearly €30,000 for Cancer Trials Ireland. This money has been added to the Friends of Cancer Trials Ireland fund, through whom Patricia made contact.
- While the pandemic halted plans to host the third annual gala lunch of the Friends of Cancer Trials Ireland in 2020, and in 2021, the group has been busy on our behalf. The Committee contacted previous gala attendees to ask if they might continue their support of Cancer Trials Ireland in the absence of an event. Their community responded well, raising almost €12,000 (€11,976).

Other

- **Colorectal** - Thanks to Beth Dowling and her friends, who raised €10,000 to support the Lithium study (11-32). Beth and her friends were inspired to organise their charity walk in memory of her friend's father, Derek. Nine participants each walked 300km in a single month.
- **Louise Creevy: Mini-marathon** - Louise was a cancer patient who took part in the LOXO trial in recent years. Following her passing, her friends banded together to organise a mini-marathon in her memory, and to raise money for Cancer Trials Ireland. Together they raised an incredible €30,000+ for which we are grateful and humbled
- **Lung** – Donegal Shines a light, €1,000

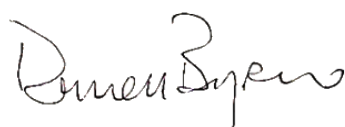
Statement of income & retained earnings for the financial year ended 31 December 2021

	Notes	2021 €	2020 €
Income	5	3,955,641	3,955,939
Expenditure		(4,030,826)	(3,532,466)
Deficit on ordinary activities before interest		(75,185)	423,473
Interest receivable and similar income	6	342	2,288
DEFICIT FOR THE FINANCIAL YEAR	7	(74,843)	425,761
RETAINED EARNINGS AT THE BEGINNING OF THE FINANCIAL YEAR		959,675	533,914
RETAINED EARNINGS AT THE END OF THE FINANCIAL YEAR		884,832	959,675

Balance Sheet as at 31 December 2021

	Notes	2021 €	2020 €
Fixed Assets			
Tangible assets	11	127,157	37,283
Current Assets			
Debtors	12	1,840,174	2,708,930
Cash and cash equivalents		6,243,973	5,116,863
		8,084,147	7,825,793
Creditors: Amounts falling due within one year	13	(7,326,472)	(6,903,401)
Net Current Assets		757,675	922,392
Net Assets		884,832	959,675
Reserves			
Retained earnings		884,832	959,675
		884,832	959,675

The financial statements were approved and authorised for issue by the Board of Directors on 18th October 2022 and signed on its behalf by:



Darren Byrne
Director



Deirdre Somers
Director & Chairperson

*Full copy of financial statements for 2021 at www.cancertrials.ie