

HRB NCTO INTERNATIONAL CLINICAL TRIALS DAY 2024

"Advancing Healthcare
in Ireland through
Clinical Research"

2024

Date: May 9, 2024
Venue: O'Reilly Hall, UCD

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Session 1: Key State Stakeholders

AGENDA

9:30–10:30 Registration & Welcome

Session Chair: Dr. Robert O'Connor

10:30 Dr. Robert O'Connor, HRB NCTO Director
Welcome & Introduction to NCTO

10:35 Prof. Fai Ng, CRF UCC & NCTO Chairperson
A Vision for Clinical Research

10:45 Dr. Muiris O'Connor, Assistant Secretary, Department of Health
Improving access to clinical trials for people in Ireland

10:55 Dr. Mairéad O'Driscoll, Chief Executive, Health Research Board
Fostering Clinical Research in Ireland

11:05 Dr. Cepta Duffy, Manager High Potential Start-Ups, Enterprise Ireland
Growing Indigenous Innovation

11:15 Dr. Ana Terrés, Head of Research and Evidence, HSE R&D
Addressing Roadblocks to Enable Clinical Trials in Ireland

11:25 Aileen Sheehy, Programme Manager, National Office–NREC
Clinical Trials in Ireland: Creating a Sustainable Environment for Ethics Assessment

11:35 Dr. Donal O'Connor, Clinical Manager Medical Devices, HPRA
Clinical Trials Landscape For Medicines And Devices In Ireland: The Regulators Perspective

Chair: Prof. Peter Doran, UCD School of Medicine

11:45 Keynote Speaker: Lord James O'Shaughnessy
Learnings from Review of the UK Clinical Trial Sector

12:15 PANEL SESSION: INTERNATIONAL LEARNINGS
How can we apply international learnings to augment clinical research activity in Ireland

12:35 LUNCH BREAK & NETWORKING OPPORTUNITY

Session 2: Innovation AGENDA

Session Chair: Prof. Paul McNally, CHI



13:40 **Simone Walsh**, Chair & Programme Manager, IRNM
Building Research Capacity in Ireland: The Role of the Research Nurses/Midwife



13:50 **Prof. Susan Smith**, Prof. of General Practice, Trinity College Dublin
Balancing Innovation and Impact: Pragmatic Trials in Primary Care



14:00 **Prof. Jarushka Naidoo**, Consultant Medical Oncologist, Beaumont
Clinical Trials for Lung Cancer in Ireland: Building & Sustaining a Program



14:10 **Prof. Fidelma Dunne**, Director, Institute for Clinical Trials, University of Galway
The Emerge Trial



14:20 **Prof. Alistair Nichol**, Director, Irish Critical Care-CTN
Innovating in an Emergency Clinical Research Response to a Pandemic



14:30 **Prof. Ger Curley**, Professor of Anaesthetics and Critical Care, RCSI
Perioperative and Surgical Clinical Trials

14:40 **COFFEE BREAK & NETWORKING OPPORTUNITY**

Session 3: Innovators

AGENDA

Session Chair: Michèle Cunnane, HRB NCTO



15:00 **Alison Liddy**, Senior VP, Patient & Site Centric Solutions, IQVIA
Reducing Site and Patient Burden in Clinical Research



15:10 **Prof. Martina Hennessy**, Director Wellcome–HRB CRF–SJH
Pioneering Advanced Therapy Medicinal Product (ATMP) trials in Ireland



15:20 **Prof. Austin Duffy**, Director of Research, START Dublin
START Dublin – Ireland's Phase I Cancer Centre



15:30 **Dr. Bárbara Oliveira**, Co-Founder & CCO, Luminate Medical
Developing Innovative Solutions for Chemo Side Effects



15:40 **Richelle Flanagan**, Registered Dietitian, My Moves Matter
Advancing Healthcare through Patients as Innovators



15:50 **PANEL SESSION**
Overcoming the Hurdles



16:20 **Dr. Robert O'Connor**, HRB NCTO
Wrap Up & Conclusion

16:30 **FINISH**

Foreward

Dear Delegate,

On behalf of the HRB-National Clinical Trials Office, University College Cork and all our partner institutions, researchers and collaborators, we would sincerely like to welcome you to this year's annual national conference in celebration of International Clinical Trials Day 2024. These are busy times in clinical research, and we are very grateful for your time and support of the meeting.

Clinical research provides the evidence with which we can improve care and health outcome and the research community in Ireland has a proud history of contributing to that effort over the decades. There is a national and global tide of new knowledge and innovation potentially feeding further improvement but advancing with that tide and reaping the benefits will need a collective effort from us all. Hence, the title of our programme this year: **"Advancing Healthcare in Ireland through Clinical Research"**

In weaving the programme, we have tried to connect with as many key areas and stakeholders as possible.

- Over the morning sessions we will hear from key state and regulatory stakeholder who oversee the landscape that supports our sector.
- We are truly honoured that Lord James O'Shaughnessy, Chair of the recent UK Clinical Trial sector review, is travelling to share his insight on our nearest neighbour's plans for advancing clinical trials and we hope that his observations and recommendations will seed thoughts of improvement for Ireland.
- The afternoon sessions seek to showcase the energy, vitality and impact of clinical research activity across our country through Medicines and MedTech and from primary care right through to the most cutting-edge cell and gene therapies. We also hope to showcase the people driving these innovations, not least people affected by ill health who are ever more vital partners in driving innovation.

At its core our programme has two key aims:

1. To help connect and network the whole community and thereby assist in overcoming challenges and growing the amount and impact of clinical research in Ireland.
2. And to show off, with pride, what our community is already achieving.

So, we hope you will enjoy your day, connect with new colleagues to advance research and ponder where our collective efforts could and should take us on that mission to Advance Healthcare in Ireland through Clinical Research.

Finally, this event would not be possible without the support of so many people.

- We're very grateful to the HRB NCTO and Cork CRF colleagues who did so much work in the background to make this event possible.
- Thanks to the organisations whose financial support made the meeting possible in the first place.
- Thanks to our speakers, panellists and chairs who have provided such a rich tapestry of research insights for us, complemented by those with stands on show.
- The colleagues in the event, catering and AV teams looking after the practical side of the meeting.
- And a special thanks to you for joining us and the work that you do in whatever capacity to advance and improve health in Ireland.

Dr Robert O'Connor &
Prof Wan-Fai Ng

Introduction & Objectives

International Clinical Trials Day (ICTD) celebrates the ongoing contributions of Clinical Trials and Investigations to medical science, highlighting their role in advancing healthcare and improving patient outcomes.

Clinical Trials and Investigations are a cornerstone of healthcare advancement and **each May** we celebrate the start of the first modern Clinical Trial by James Lind which ultimately identified a cure for scurvy.

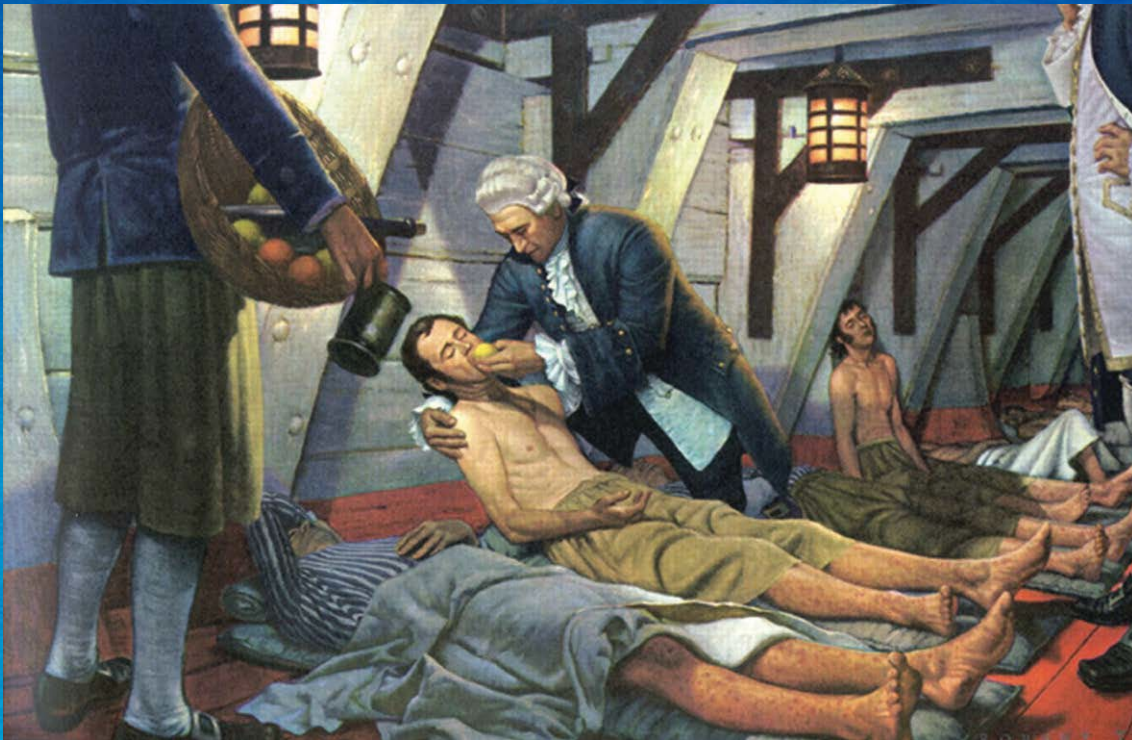
The programme looks set to bring a dynamic and insightful conference celebrating ICTD and the role and contribution of clinical research to the Irish Health Sector. Designed to bring together **key national stakeholders** from **Government, HSE, National Regulatory & Ethics Agencies, Clinical Research Facilities/Centres, National Clinical Trial Networks, Pharmaceutical Companies, Clinical Research Organisations, Medtech Companies & Medical Device Innovators** and **Clinical Trial Researchers** amongst others. This event will showcase advancement in clinical research and trials in Ireland.

Objectives

Building on the success of previous events, Our conference aims to foster learning, networking and collaboration within the clinical trial sector in Ireland. Attendees will have the opportunity to:

- Gain insights into the latest innovations and trends shaping the clinical trial landscape in Ireland.
- Network and connect with key stakeholders, fostering collaborations and partnerships.
- Learn from industry experts and innovators about ongoing evolutions in regulation and practice in clinical trials.
- Explore the industry experience of trials in Ireland, including success stories and challenges.
- Discover national innovators and their groundbreaking innovations in providing high-quality clinical trials.

About International Clinical Trials Day



International Clinical Trials Day (ICTD) was launched in 2005 to celebrate the day when Scottish naval surgeon James Lind started his famous clinical trial on scurvy in 1747 and laid the foundation for modern clinical research.


While serving as a surgeon on the HMS Salisbury (a ship of the British Royal Navy), Lind carried out experiments on 12 sailors suffering from scurvy.

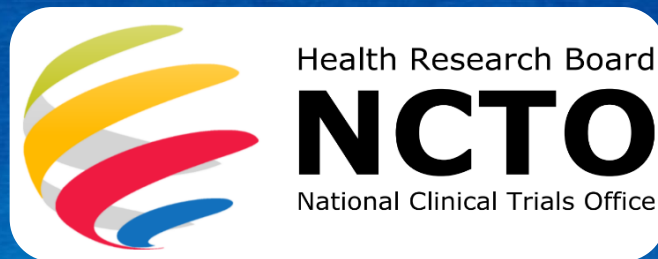
The men, grouped into pairs, were given a variety of dietary supplements (e.g., cider, vinegar, seawater, garlic, mustard, oranges and lemons) over six days.

Those who consumed citrus fruits noticeably improved, providing evidence of the superiority of this treatment over others (two centuries before the discovery of vitamin C, the active substance). Clinical trials have come a long way since Lind's discovery.

Each year, ICTD, celebrated on or around 20th of May, provides the opportunity for organisations, clinical research professionals, and the public to acknowledge the achievements that result from clinical research and to discuss various trial topics.

You can learn more about James Lind's trial at www.ecrin.org

Keep the conversation going online – on  using the hashtag
#ICTD2024
@HRB_NCTO



HRB NCTO is the “one-stop-shop” for connecting into all aspects of Clinical Trials and Clinical Investigations for the Medicines and MedTech sector in Ireland.

With the support of the Health Research Board, host institution– University College Cork, Enterprise Ireland and the seven University-based Clinical Research Facilities/Centres (CRFs/Cs) in the Republic of Ireland the Health Research Board National Clinical Trials Office (HRB NCTO), is delivering on the aims of the National Clinical Trials Coordination Programme 2021 over the 4 year term of its funding award.

This programme was developed to build on the positive achievements of previous investments in clinical trials coordination and future investments in national clinical trials infrastructures.

The overall aim of this investment is to ensure that Ireland has the capacity to conduct innovative high quality clinical research for the benefit of people’s health and the economy. HRB NCTO, as an integrated Clinical Trial network, will be aligned to the local supports of the existing clinical trials infrastructures to ensure a harmonised strategic national approach to the conduct of high-quality clinical trials in Ireland.

The HRB NCTO central office provides overarching support and expertise, through a range of services and activities to academia and industry. The partner CRF/Cs provide the infrastructure, physical space and facilities, experienced research and specialist support staff and the necessary quality and oversight programs that are critical for the successful conduct of world-class patient-focused research.

Our seven partner CRF/Cs have world-class research expertise

- **HRB CRF–University College Cork at Cork University Hospital, Mercy University Hospital & University Hospital Waterford**
- **HRB CRF Galway at University Hospital Galway**
- **Royal College of Surgeons Ireland CRC at Beaumont Hospital**
- **University College Dublin CRCs at Mater Misericordiae University Hospital and St. Vincent’s University Hospital**
- **Wellcome Trust – HRB CRF at St. James’s Hospital**
- **HRI-CRSU – Health Research Institute Clinical Research Support Unit at University Hospital Limerick, Co Limerick**
- **Children’s Health Ireland (CHI)–CRC at Children’s Health Ireland**

Session 1: Key State Stakeholders Biographies



Dr. Robert O'Connor
NCTO Director

Dr. Robert O'Connor has 25+ years of experience spanning Research, Management, Education, Health, Advocacy, Governance, and Communication sectors. With expertise in research strategy and communications, clinical trials, oncology, pharmacology, translational health research, and life sciences.

Robert serves on the boards of several national health organisations and has provided extensive strategic support and consultancy to a wide array of health sector stakeholders.

Robert's role is to direct the NCTO to help foster further growth in impactful clinical research and align its work with patient need and the ambitions of health researchers, indigenous start-ups and other European and international organisations, companies and partners.



Prof. Fai Ng
Director, CRF UCC &
Head of NCTO

Prof. Ng is the newly appointed Director of the Cork Clinical Research Facility. He is a consultant rheumatologist with globally recognized expertise and is a key opinion leader in Sjögren's syndrome and fatigue research. He has led numerous early-phase clinical trials and experimental medicine studies. Prof. Ng has published extensively in his field, with over 170 peer-reviewed articles, seven book chapters, and other notable contributions to the literature on Sjögren's syndrome, as well as securing >£60m in recent grant income.

Prof. Ng was previously the Director of the NIHR Clinical Research Facility in Newcastle. He qualified from Cambridge University, completed his rheumatology training in London, and obtained a PhD in Immunology at Imperial College London.



Muiris O'Connor
Assistant Secretary,
Research & Development
and Health Analytics
Division, Department of
Health

Muiris O'Connor is Assistant Secretary in the Dept. of Health, heading the R&D and Health Analytics Division, where his responsibilities include:

- The development of policy and legislation in the area of health information and the implementation of Slaintecare reforms.
- International engagement to ensure Ireland's participation in the growing regional and global health agenda, including enhancement of All-Island cooperation in health, social care and health research..
- A new unit focused on Health Research Policy and Innovation. This team will work to strengthen health research in Ireland and ensure that research and innovation are embedded in our health and social care system.

Before his current position, Muiris held roles in academia and government entities including the Higher Education Authority, the Department of Education and Skills, and the Economic and Social Research Institute.

Session 1: Key State Stakeholders Biographies



Dr. Mairéad O'Driscoll
Chief Executive, HRB

Dr Mairéad O'Driscoll is the Chief Executive Officer of the HRB the key funder and supporter of clinical research nationally. As CEO she oversees an annual investment of €45m in health research activity, an awards portfolio of approximately €200m and leads a staff of 75 people.

Before being appointed CEO, Mairéad held a number of different roles in the HRB, including Director of Funding, as well as Head of Policy, Evaluation and External Relations. Prior to joining the HRB, Mairéad worked as a researcher in both academia and industry before moving into policy research, initially with the Royal Society in London, and later with the Wellcome Trust.

She is a member of several national and international groups, including the Executive Committee of International Consortium for Personalised Medicine (ICPerMed), which she chaired for two years.



Dr. Cepta Duffy
Manager High Potential
Start-Ups (Industrial &
Life Sciences), Enterprise
Ireland

Dr. Cepta Duffy manages the High Potential Start-Ups (Industrial & Life sciences) Division in Enterprise Ireland, providing support and advice to emerging Bio, Pharma and Medical Device Companies in Ireland. She graduated from NUI Galway with an honours degree and PhD in Biochemistry. Cepta then worked with various Biotechnology and Pharmaceutical companies mainly in the area of Research & Development and Business Development in the US, Brazil and Ireland. Cepta joined the Research & Innovation Division in Enterprise Ireland in 2007 and has worked with the Technology Transfer team and the Lifesciences team before joining the High Potential Start-up Division.



Dr. Ana Terrés
Head of Research and
Evidence, Assistant
National Director, HSE

Dr. Ana Terrés brings over twenty-five years of experience in research, research administration, and strategic development to her work. She has played a key role in shaping the landscape of health research, notably as the Assistant National Director at the Health Service Executive, where she established the HSE National Research and Development office and developed the HSE Action Plan for Health Research, 2019-2020. Her earlier post-doctoral career commenced with a Marie Curie fellowship and continued as a biomedical researcher at Trinity College Dublin. Her entrepreneurial spirit led her to co-found Innovadis, a pioneering biotechnology startup affiliated with TCD.

Session 1: Key State Stakeholders Biographies



Aileen Sheehy
Programme Manager,
National Office for
Research Ethics
Committees

Aileen Sheehy is the Programme Manager for the National Office for Research Ethics Committees in Ireland, with primary responsibility for clinical trials. As a senior member of the National Office team, Aileen manages the processes and procedures that underpin the national system of research ethics review and is an expert in the regulatory aspects of research ethics review for clinical trials. She also sits on the Board of the MedEthics EU group.

Aileen brings a wealth of experience to the National Office in research policy, advocacy and project management across academia and government agencies in Cambridge, Oxford and Dublin. Before joining the National Office team in early 2020, Aileen worked on Data Policy in the HRB Research Funding and Strategy division.



Dr. Donal O'Connor
Clinical Manager Medical
Devices, HPRA

Dr. Donal O'Connor is the Clinical Manager for Medical Devices in the Health Products Regulatory Authority (HPRA) and is a member of the Clinical Investigation and Evaluation working group and the Orphan Device task force at the European Commission. Dr. O'Connor has previously worked in clinical trial assessment for medicines and also regulated medicines and vaccines with the HPRA and European Medicines Agency.

Before working in regulation, Donal trained in General Surgery and is a fellow of the European Board of Surgery. Donal remains involved in surgical education and clinical research as an adjunct lecturer in Surgery with Trinity College Dublin.



**Lord James
O'Shaughnessy**
UK Member of House
of Lords

A former Health Minister, Lord O'Shaughnessy chaired a review of the UK clinical trial sector, authored the influential 2023 report on Commercial Clinical Trials in the UK, and brings a wealth of insight on the key ingredients of a high performance national clinical trial ecosystem.

Lord O'Shaughnessy has operated at the highest levels of government, including as a Minister at the Department for Health & Social Care, as Director of the No.10 Policy Unit, and as an advisor to DHSC Ministers during the COVID-19 crisis. As Minister his responsibilities included implementing the Life Science Industrial Strategy, delivering a new pricing scheme with the pharmaceutical industry, chairing the National Genomics Board, and driving the digital transformation of the NHS.

Session 2: Innovation Biographies



Simone Walsh
Chair & Programme
Manager, IRNM

Simone Walsh is Chair and Programme Manager of the Irish Research Nurses and Midwives Network (IRNM). She is a Registered General Nurse, Certified Project Management Professional, and holds an MSc in Public Health.

Simone was a Nurse Researcher on the National Drug-Related Deaths Index, a national epidemiological surveillance system, housed at the Health Research Board. Simone has 17 years' experience in research project management; working as a senior leader for the last 8 years. She specialises in research governance and medical technology regulatory affairs. Simone is committed to championing and advancing the roles of research nurses/midwives on the Island of Ireland.



Prof. Susan Smith
Professor of General
Practice, Trinity College
Dublin

Susan Smith is Professor of General Practice at Trinity College Dublin and works as a General Practitioner at Inchicore Family Doctors in Dublin 8. Her research interests include improving outcomes for patients with multimorbidity and related clinical issues such as medicines management. She has been the PI or Co-PI on eight RCTs of interventions for chronic disease management in Irish primary care settings and has just commenced a large national poly pharmacy study. She is an editor and author with the Cochrane Collaboration and is Clinical Lead for the HRB Evidence Synthesis for Clinical Guidelines programme, which supports production of Ireland's Clinical Guidelines. She also has an interest in health equity and coordinates the Deep End Ireland Group, which advocates for needs-based resource allocation for primary care services for socioeconomically disadvantaged groups.



Prof. Jarushka Naidoo
Consultant Medical
Oncologist, Beaumont RCSI
Cancer Centre

Jarushka Naidoo is a Full Professor of Medical Oncology and a Consultant Medical Oncologist at Beaumont RCSI Cancer Centre in Dublin, Ireland and an Adjunct Professor of Oncology at Johns Hopkins University.

Prof. Naidoo serves as the Chair of the Lung Cancer Disease-specific subgroup (DSSG) of Cancer Trials Ireland, is the Founder and Chair of the Irish national lung cancer research group, the 'Irish Lung Cancer Alliance,' and a national immunotherapy toxicity network through the RCPI. She is currently a part of the ETOP, EORTC, ECOG-ACRIN and NRG Cooperative clinical trial groups, and the clinical trials portfolio in lung cancer has tripled since her return. Prof Naidoo was named the Irish Cancer Society's Clinician Research Leader Award 2021.

Session 2: Innovation Biographies



Fidelma Dunne is a Professor of Medicine at University of Galway Ireland, Consultant Endocrinologist at Galway University Hospitals. Director of the Institute of Clinical Trials at the University of Galway and Lead for the All-Ireland Clinical Trial Network in Diabetes. She is past President of the IADPSG (2016–2022), President of the Irish Endocrine Society (2021–2024) and National Specialty Director for Endocrinology training (2023–2026).

Her research interest in diabetes and pregnancy spans 30 years with >250 peer review publications. She has received the Jorgen Pedersen award (DPSG 2021) and Norbert Freinkel award (ADA 2024). She initiated the ATLANTIC DIP network which established key metrics for Diabetes in pregnancy nationally and shaped clinical and research practice. She has completed the EMERGE trial of Metformin in pregnancies complicated by GDM (JAMA 2023) and is currently conducting the longitudinal follow-up of EMERGE women and their children.

Prof. Fidelma Dunne
Director, Institute for
Clinical Trials, University
of Galway



Professor Nichol is the Chair of Critical Care Medicine in University College Dublin and the Director of the Irish Critical Care– Clinical Trails Network and Consultant Intensivist in St Vincent’s University Hospital, Dublin. He has been an investigator on peer reviewed grants worth over 65 million euros from Ireland, Europe, Australia, New Zealand and Canada. He has published over 250 manuscripts with over 30 in the highest ranked medical journals– in NEJM, Lancet, Nature and JAMA. Currently he is completing trials in the critically ill which will randomize over 20,000 patients in the next 5 years. He has academic interests in Pandemic Preparedness, Cardiac Arrest, Trauma and Mechanical Ventilation.

Prof. Alistair Nichol
Director of the Irish
Critical Care–CTN &
Consultant, St Vincent’s
University Hospital



Gerard Curley is Professor of Anaesthesia and Critical Care at the Royal College of Surgeons in Ireland and Consultant in Anaesthesia and Intensive Care in Beaumont Hospital. He completed clinical and research training in Ireland and Toronto, under the supervision of Professor John Laffey and Professor Brian Kavanagh. His translational research focuses on the role of inflammatory pathways, resolution mediators and innate immune dysfunction in the pathogenesis of critical illness. The group’s aim is to develop novel immunomodulatory therapies to promote the resolution of inflammation.

Prof. Ger Curley
Professor of
Anaesthesia and
Critical Care, RCSI

Session 3: Innovators Biographies



Alison Liddy
Senior Vice
President, Patient
and Site Centric
Solutions, IQVIA

Alison Liddy, Senior Vice President at IQVIA for Patient and Site Centric Solutions, thrives on variety and challenge. With a career spanning over 20 years in the healthcare and life sciences industry, she excels in overseeing large global teams, P&L management, revenue growth, and C-Suite Relationship Management. Alison's expertise extends to Digital & Change Transformation projects in the data and patient space within the Life Science industry. Passionate about creating efficient ways of working and utilizing technology to drive outcomes, she has held executive positions at ICON plc. and Accenture contributing significantly to their patient, site, and data strategy implementation that helped aide in accelerating drug delivery.



**Prof. Martina
Hennessy**
Director Wellcome-HRB
Clinical Research Facility,
St James's Hospital

Professor Martina Hennessy, a clinical pharmacologist and consultant physician at St James's Hospital Dublin, specialising in hypertension, cardiovascular risk, and medication safety, with research interests spanning advanced therapies, antiretroviral pharmacology, and medical education. She directs the Wellcome-HRB Clinical Research Facility at St James's Hospital, a collaboration with Trinity College. Additionally, she serves as Associate Professor of Medical Education and Director of Internship at Trinity College's School of Medicine. Since January 2023, Prof Hennessy holds the position of Chief Academic Officer (CAO) for the Dublin Midlands Hospital Group (DMHG), overseeing research, innovation, education, and training across seven hospitals.



Prof. Austin Duffy
Director of Research,
START Dublin

Dr. Austin Duffy is a consultant medical oncologist at The Mater Hospital and associate Professor of Translational Oncology at UCD. In 2023 he became Director of Research for START Dublin, a tripartite partnership between The Mater, UCD and The START Center for Cancer Research to establish Ireland's first dedicated site for phase 1 clinical trials in oncology. Between 2008 and 2017 Professor Duffy developed and led over 25 early-phase clinical trials including the first-in-human combination of immune checkpoint inhibition with loco-regional treatment for hepatocellular carcinoma. In 2016 Professor Duffy was awarded a National Cancer Institute Director's Award for Innovation in cancer research before returning to Ireland as a medical oncologist at the Mater Hospital. In October 2021 the National University of Ireland conferred the higher doctorate degree, Doctor of Medicine (DMed), on Professor Duffy in recognition of his internationally recognised research.

Session 3: Innovators Biographies



Dr. Bárbara Oliveira

Co-Founder & Chief
Clinical Officer, Luminare
Medical

Dr. Bárbara Oliveira is the Chief Clinical Officer and Co-Founder of Luminare Medical, an Irish start-up developing medical devices to reduce the side effects of chemotherapy. Bárbara earned her PhD from the University of Galway, Ireland, where she explored a new pain-free modality for breast cancer diagnosis. Her passion to understand the needs of patients drives her vision to radically shift the status quo of medical device development and bring quality of life to the forefront of innovation, by giving patients access to affordable and effective devices for chemotherapy side effects. Bárbara was recently recognised with the MIT Innovators Under 35 Europe award in 2023, and the European Prize for Women Innovators award in 2024.



Richelle Flanagan

Registered Dietitian
Co-Founder & CEO
MyMovesMatter

Richelle is a registered dietitian for 20 years and a past president and CEO of the Irish Nutrition and Dietetic Institute. Her diagnosis of Parkinson's Disease (PD) 7 years ago led her to advocate for more personalised care and research based upon sex and gender and to set up My Moves Matter www.mymovesmatter.com, a digital self-care companion to empower people with PD. My Moves Matter is currently collaborating on three pilot trials with University College Cork, France Parkinson and NICHE Ulster University, Coleraine. She is a World Parkinson Ambassador, a member of the Dublin Committee of the Parkinson's Ireland, a EUPATI fellow and co-founder of the Women's Parkinson's Project.

Session & Panel Chairs

Biographies

Session / Panel 1 Chair



Prof. Doran is the Director of the UCD Clinical Research Centre, Director of Research at St Vincent's Healthcare Group and Prof of Clinical Trials at the UCD School of Medicine. He was previously Associate Dean for Research at the UCD School of Medicine, Vice Principal for Research, Innovation & Impact at the UCD College of Health and Agricultural Science and Director of the Institute for Clinical Trials at the University of Galway

Peter established and previously led the graduate taught programme in clinical and translational research at UCD and Chaired the Biomedical research Degrees Committee of the School of Medicine.

He leads a major research programme in trial methodology including novel trial designs, predictive modelling and better trial outcomes. Prof Doran also leads the UCD-Abbott Biomarker programme, which is contributing to major national and international end organ damage biomarker studies, reflecting his research interests in the molecular drivers of organ damage, biomarker discovery and translation to practice.

Prof. Peter Doran
Director of the UCD
Clinical Research Centre &
Prof. of Clinical Trials at
the UCD School of
Medicine

Session 2 Chair



Prof. Paul McNally is Director of Research and Innovation and the Director of the Clinical Research Centre at Children's Health Ireland, Crumlin.

Paul is a consultant in respiratory medicine and Associate professor of paediatrics at RCSI. He led the development of the model of care for cystic fibrosis in Ireland, and the model of care for respiratory medicine for children. Paul's main areas of research interest are in clinical trials, early cystic fibrosis (CF) lung disease and the real-world effects of the new generation of CF treatments (CFTR modulators). He is a board member of the CF registry of Ireland.

He graduated from UCD School of Medicine in 1998 completing his paediatric fellowship in the Children's hospital of Philadelphia. He has an extensive publication record in paediatric respiratory disease and treatment.

Prof. Paul McNally
Director of the Clinical
Research Centre at
Children's Health Ireland

Session 3 Chair



Michèle Cunnane has over 25+ years' experience in Clinical Research, having previously worked in HRB CRCI, Cancer Trials Ireland (formerly ICORG), INEOS Healthcare, SRG Interresource Satellite Operations and IQVIA (formerly Quintiles) in various Data Management and Leadership positions. Within her role, Michèle acts as the primary contact for the HRB NCTO Feasibility programme and is the co-ordinator for the HRB NCTO Study Feasibility & Start-Up and Budget Costing Working Groups.

Michèle Cunnane
Trial Platform Lead, HRB
NCTO

Partner CRF/Cs

HRB CRF – University College Cork at Cork University Hospital, Mercy University Hospital & University Hospital Waterford



The HRB Clinical Research Facility University College Cork (HRB CRF-UCC) was established in 2011 to promote excellence in the design, safe-conduct, analysis and reporting of patient-focused research. The facility provides the dedicated infrastructure, experienced research and support staff and the necessary quality and oversight programs that are critical from the successful conduct of world class patient-focused research.

HRB CRF-UCC is funded by the Health Research Board and University College Cork and is operated jointly with the University and its affiliated medical centres, which cover the south and south-western regions of the Republic of Ireland with a population of over 1 million.

It supports a wide range of Academic and commercially funded research, including both interventional trials and observation studies, across pharmaceutical, nutraceuticals, medical device and care pathway themes.

It can provide access to local clinical researchers and networks, clinical research facilities and staff as well as other supports such as biostatistical and methodological support, data management, quality management, study monitoring.

Email: crfc@ucc.ie

crfc.ucc.ie



Wellcome - HRB
Clinical Research Facility
at St. James's Hospital

Wellcome Trust HRB Clinical Research Facility at St. James's Hospital

The Wellcome HRB CRF (CRF) is a clinical research partnership between St. James's Hospital and Trinity College Dublin.

Located in the heart of Ireland's largest teaching hospital it supports a wide range of studies from observational studies to complex clinical trials.

Currently the CRF employs approximately 20 staff with the mix of skills and experience needed to conduct high quality clinical research. This specialised team-work under a rigorous quality system that meets international standards (ICH-GCP) and has successfully completed Health Product Regulatory Authority Inspections.

The CRF includes a research pharmacy and aseptic compounding suite capable of supporting trials of advanced therapies. It also contains neurophysiology and exercise physiology suites and is adjacent to the Centre for Advanced Medical Imaging (3T MRI).

The CRF supports the conduct of Phase I (including inpatient) to Phase III clinical trials, medical device studies and non-regulated clinical studies.

Email: crfsjh@tcd.ie

www.sjhcrf.ie

Partner CRF/Cs

University College Dublin Clinical Research Centre



UCD School of Medicine
Scoil an Leighis UCD

The University College Dublin Clinical Research Centre (UCD CRC) is an academic led, multi-site, patient-focused resource supporting clinical and translational research. It operates under a single integrated governance structure within the UCD School of Medicine and has been created to deliver one of the University's strategic objectives of advancing high quality, impactful clinical and translational research. The centre is also responsible for delivering high quality education programmes to serve future academic and industry staffing needs.

The UCD CRC has two modern purpose-built facilities, at the Mater Misericordiae University Hospital and at St Vincent's University Hospital. Together, these two hospitals serve the healthcare needs of approximately 1 million people in the Dublin area and act as local, regional and national referral centres for a host of clinical specialties.

The UCD CRC is at the core of the UCD Academic Health Sciences research and innovation strategy and will provide a focal point for collaborative, multidisciplinary patient-focused research.

The centre links the clinical community to core university research institutes including the UCD Conway Institute, Systems Biology Ireland, the UCD Charles Institute of Dermatology and Applied Research for Connected Health (ARCH).

Our reputation for implementing complex clinical research programmes across multiple sites to the highest ethical, regulatory and scientific standards positions the UCD CRC ideally to enable and drive a wider academic health sciences collaboration.

Email: crc@ucd.ie

www.ucd.ie/medicine/research/ucdclinicalresearchcentre



HRB Clinical Research Facility Galway

The HRB Clinical Research Facility, Galway (HRB CRFG) is a joint venture between Galway University Hospitals (GUH) and National University of Ireland, Galway (NUIG) and has been in operation since March 2008.

It provides the infrastructure, physical space, facilities, expertise and culture needed to optimally support patient focused research studies and clinical studies aimed at understanding a range of diseases and translating the knowledge obtained through this research work into reimbursed, regulatory approved advances in patient care as speedily as possible.

The objective of HRB CRFG is to improve human health through the generation of new medical knowledge from patient-based research and speedily translate the knowledge obtained through this research into reimbursed, regulatory approved advances in patient care.

The guiding philosophy of this CRF is to stimulate, engage and support health care professionals from diverse areas of expertise to undertake high quality clinical research.

Email: crfg@nuigalway.ie

www.nuigalway.ie/hrbcfrg

Partner CRF/Cs

Royal College of Surgeons in Ireland Clinical Research Centre at Beaumont Hospital



The RCSI CRC provides state of the art facilities and expertise to enable investigators to conduct clinical research to the highest standards. The first academic research centre in Ireland, the Centre opened in September 2000.

The Centre is located on the Beaumont Hospital campus, one of RCSI's principal teaching hospitals in Dublin. This location supports the Centre's translational focus and provides ready opportunities for clinician-based research studies. Since opening in September 2000, the Centre has had more than 19,700 patient visits.

During this time, the activities of the Centre have developed a cohort of highly skilled and trained research nurses with the attendant expertise to enable clinical research.

The aim of the RCSI Clinical Research Centre is to advance medical knowledge of illness and improve patients' care.

By working in partnership with academia, funding agencies and the commercial sector, we are contributing to the development of life-enhancing therapies through basic research and clinical trials. The Centre achieves this by providing a physical infrastructure and support, primarily through study management, and research nurse expertise.

Email: crcapplications@rcsi.ie www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/clinical-research-centre



Children's Health Ireland Clinical Research Centre (CHI-CRC)

Children's Health Ireland (CHI) was established in 2019 and governs and operates local paediatric services for the Greater Dublin Area as well as all national paediatric specialist services, some of which are on an all-island basis.

This encompasses the existing Dublin children's hospitals, Crumlin, Temple Street and Tallaght Hospital, as well as the new paediatric outpatients and urgent care centres at Connolly and Tallaght. Excellence in research and innovation are key strategic objectives of CHI. The new children's hospital is planned to open in 2024 on a campus shared with St James's Hospital and will include a purpose built clinical research facility (CRF).

The CHI-CRC, a HRB funded clinical research centre, was established in 2021 on foot of the move of the Children's Clinical Research Unit (CCRU) from the National Children's Research Centre (NCRC) to CHI, and now incorporates clinical research and trials activity across all CHI sites. The CHI-CRC provides dedicated staff, infrastructure and resources to clinical teams and study sponsors to enable them conduct paediatric clinical trials, clinical investigations of medical devices and other complex research

studies. The CHI-CRC is led by Paul McNally, Director of Research and Innovation at CHI. The CRC has been heavily supported over many years by the Children's Health Foundation (CHF) – the fundraising partner of CHI.

Email: rio@nchgi.ie www.childrenshealthireland.ie/research-innovation-index/

Partner CRF/Cs



UNIVERSITY OF
LIMERICK
OLLSCOIL LUIMNIGH

Health
Research
Institute

Health Research Institute Clinical Research Support Unit Limerick

The Health Research Institute Clinical Research Support Unit (HRI CRSU) was established in 2014 as an integral part of the HRI to support HRI members in the conduct of clinical research projects.

The CRSU maximises the impact of the research activities of the HRI by establishing partnerships with other institutions locally, nationally and internationally. Such partnerships include industry, philanthropic trusts, other academic institutions and healthcare providers, whether hospital or primary community care based.

The CRSU serves as the coordinating unit for University of Limerick (UL) led studies, single site or multi-site. In cases where UL is part of a multi-site project but is not the lead site, the CRSU acts as the link for the lead site, to engage with UL researchers and clinicians.

The CRSU facilitates researchers in the conduct and successful delivery of high quality impactful clinical research through the support of a highly experienced nursing team. All our nurses have the relevant training and experience to support PI's in the conduct of their research, ensuring compliance with ICH GCP E6 R2 and relevant legislation.

HRI CRSU activities involving University of Limerick Hospitals staff is conducted through a sub-unit, the University of Limerick/UL Hospitals Clinical Research Unit (CRU). The UL/ UL Hospitals CRU is a jointly governed and resourced unit established to promote clinical research among UL academic staff and UL Hospitals staff based in the CERC building.

Email: Siobhan.M.Egan@ul.ie

www.ul.ie/hri/clinical-research-support-unit

HRB Funded Clinical Trial Networks

HRB Primary Care Clinical Trials Network Ireland

Led by Professor Andrew Murphy, National University of Ireland, Galway



HEALTH RESEARCH BOARD
Primary Care CTNI
CLINICAL TRIALS NETWORK IRELAND

Primary care plays a crucial role in healthcare delivery. Building on the success of a previous HRB funding award, this CTN will advance its role by supporting national, international, and industry trials, developing early career researchers in the area, addressing chronic disease and involving patients in the development of research programmes.

Email: info@primarycaretrials.ie

www.primarycaretrials.ie



HRB Dementia Trials Ireland

Led by Professor Iracema Leroi, Trinity College Dublin

Clinical trials for dementia are low compared to other health conditions, which is one of the main reasons why our ability to manage/slow the condition is lacking. This CTN aims to tackle this problem and triple the number of clinical trials available for people living with dementia in Ireland by 2026.

Email: info@dementrials.ie

www.dementrials.ie

HRB Diabetes Collaborative Clinical Trial–Network– Ireland

Led by Professor Andrew Murphy, National University of Ireland, Galway



Health Research Board
DIABETES COLLABORATIVE
CLINICAL TRIAL NETWORK

Diabetes is one of the most common chronic diseases in Ireland, and numbers affected are increasing alongside the increase in obesity rates.

This CTN will focus initially on clinical trials for diabetes in pregnancy, technologies in diabetes, diabetes and foot disease, diabetes and advanced therapies, and diabetes and behavioural change, with the aims of improving the control and treatment of diabetes and delivering a better quality of life to people living with it.

Email: info@diabetestrialsctn.ie

www.diabetestrialsctn.ie

HRB Funded Clinical Trial Networks



HRB Irish Network for Children's Clinical Trials (in4kids)

Led by Professor Geraldine Boylan, University College Cork

Clinical trials of new therapies in children have been extremely limited in Ireland. In4kids will allow more children in Ireland to access leading therapies and medicines through well governed trials, to improve their health and wellbeing. This CTN will also develop educational and training resources for healthcare staff involved in paediatric trials and harness a young persons' advisory group to ensure they have a voice in determining research priorities.

Email: info@in4kids.ie

www.in4kids.ie

HRB Irish Critical Care Clinical Trials Network

Led by Professor Alistair Nichol, University College Dublin



Irish
Critical Care
Clinical Trials
Network

Following a successful five years of a previous HRB funding award, this CTN will continue improving the outcomes (survival and recovery) for patients requiring Intensive Care Unit (ICU) treatment in Ireland and building capacity for the conduct of clinical trials in ICU.

Having already established itself as an Irish hub for clinical trials in ICU, this Network is now setting its sights on becoming a world-leading coordination centre for the same.

Email: iccctn@ucd.ie

www.iccctn.org



HRB Infectious Diseases Clinical Trials Network Ireland

Led by Professor Patrick Mallon, University College Dublin

This CTN unites leading clinicians and researchers with extensive, collective expertise in specific areas of infectious diseases, and aims to enhance the quality of clinical trial design in the area nationally, solve common health problems for people in Ireland, and lead any future national pandemic response.

Email: polina.smolovyk@ucd.ie

<https://www.ucd.ie/medicine/research/researchcentres/ucdcentreforexperimentalpathology/hostresearch/idctni/>

HRB Funded Clinical Trial Networks

HRB Rare Disease Clinical Trial Network

Led by Dr Rachel Crowley and Dr Cormac McCarthy at University College Dublin



This CTN aims to enhance rare disease care and outcomes, with the following objectives:

- Act as a collaborative hub for trials in rare diseases
- Facilitate and support the conduct of trials in rare diseases
- Increase the opportunities for rare disease patients to access high-quality clinical trials.

This will result in increased in patient engagement; more trial opportunities for rare disease patients; increased opportunity for investigator-initiated trials; significant industry investment into Irish healthcare; enhanced knowledge of rare disease through patient focused research and parallel translation scientific studies.

Email: suzanne.mccormack@ucd.ie

www.rarediseaseresearch.ie



HRB PPI Ignite Network

Led by Prof. Sean Dinneen and Edel Murphy

The new Network grows and consolidates the work of its predecessor, PPI Ignite. The PPI Ignite Network promotes excellence and inspires innovation in public and patient involvement (PPI) in health and social care research in Ireland.

Public and patient involvement in research means that the public and patients are involved in planning and doing research from start to finish and help tell the public about the results of research.

The Network is based at seven Universities in Ireland, with a National Programme Office at NUI Galway. There are ten national partners and fifty-three local partners.

Email: hello@ppinetwork.ie

www.ppinetwork.ie

HRB Funded Clinical Trial Networks

Cancer Trials Ireland



As the leading cancer research trials organisation in Ireland, Cancer Trials Ireland's (CTI) aim is to be an indispensable all-Ireland hub for cancer trials, globally recognised for excellence in governance, collaboration and innovation in clinical research. The network supports trials by the foremost Medical, Surgical and Radiation Oncologists, as well as Haematologists and Research Specialists (Oncology Research Nurses, Translational Scientists, Data Managers, Pharmacists and staff) in Ireland. 98% of all cancer treating specialists in Ireland are members of Cancer Trials Ireland.

CTI enables, supports and oversees the running of over 100 trials involving thousands of patients. Everyday functions include planning, opening, co-ordinating, supporting, monitoring and auditing cancer trials in Ireland. CTI provide training, facilitate co-operation between all professionals working in the area, support the development of cancer trials research units around the country, set policy and champion the opening of more cancer trials in Ireland through engagements with key stakeholders both in Ireland and internationally.

Email: info@cancertrials.ie

<https://www.cancertrials.ie/>

Other national Clinical Trial Networks (CTNs)

There are over a dozen other specialised networks focussing on delivering quality disease-specific clinical trials in Ireland.

If you would like to see a more comprehensive listing of the established Clinical Trial Networks in Ireland please visit.

<https://ncto.ie/clinical-trial-networks/>

ICTD Calendar of Events 2024

Thursday May 9th	Title	Advancing Healthcare in Ireland through Clinical Research 2024	Host	HRB NCTO
	Website	www.ncto.ie/ictd-2024	Location	O'Reilly Hall, UCD, Belfield, Dublin
Thursday May 2nd	Title	Deliberating Ethics in Trials: Scope and Necessity of Ethical Oversight	Host	HRB TRMN
	Website	See www.hrb-tmrn.ie/training-education/upcoming-events for further details	Location	Study day, online
Thursday May 9th	Title	The role of AI in clinical trials	Host	HRB TRMN
	Website	See www.hrb-tmrn.ie/training-education/upcoming-events for further details	Location	Webinar
Friday May 10th	Title	Cancer Retreat	Host	CTI
	Website	https://www.cancertrials.ie/2024/04/cancer-retreat-2024-registrations-open/	Location	RCSI, Dublin 2 (09:00-13:00)
Friday May 17th	Title	UCD CRC International Clinical Trials Day	Host	UCD CRC
	Location	Information Stands at the following locations: * St. Vincent's University Hospital - Centrepoint (09:00-14:00) * Mater Misericordiae University Hospital - Ground Floor Concourse (09:00-14:00) * National Maternity Hospital (Holles Street) - Front Entrance (10:00-12:00) * National Rehabilitation Hospital - Main Reception Area (09:00-14:00) * Wexford General Hospital (09:00-14:00) * St. Luke's Hospital Kilkenny - The Foyer (09:00-14:00)		
Friday May 17th	Title	START Competition Awards Ceremony	Host	HRB TRMN
	Website	www.startcompetition.com	Location	[Closed event]
Monday May 20th	Title	Public Webinar on Cancer Trials	Host	CTI
	Website	www.cancertrials.ie/justask	Location	Online (13:00)
Monday May 20th	Title	ICTD Stand - Meet the Clinical Research Support Unit	Host	HRI - Clinical Research Support Unit
	Location	Main Hospital Hallway [Close to Costa], University Hospital Limerick (09:00-13:00)		
Monday May 20th	Title	ICTD Clinical Trials Information Stand	Host	CRF-SJH
	Location	St James's Hospital Concourse		
Monday May 20th	Title	ICTD Clinical Trials Information Stand & Launch of new RCSI CRC Brochure	Host	RCSI CRC
	Location	Beaumont Hospital		
Tuesday May 21st	Title	ICH GCP Training	Host	HRI - CRSU
	Location	Boardroom, 3rd Floor, CERC Building, University Hospital Limerick (13:00-16:30)		
Tuesday May 21st	Title	ICTD Clinical Trials Information Stand	Host	CRF-UCC
	Location	CUH Entrance Lobby (10:00-16:00)		
Thursday May 23rd	Title	ICTD 2024: Data Centric Clinical Research	Host	ECRIN
	Location	https://ecrin.org/ictd-2024	Location	Hybrid Event: CERTH, Thessaloniki, Greece
Friday May 24th	Title	Rapid Research Methods Applicable in Clinical Trials	Host	HRB TRMN
	Website	See www.hrb-tmrn.ie/training-education/upcoming-events for further details	Location	Study day, in person
Friday May 24th	Title	CHI's Annual Research & Audit Day	Host	CHI
	Location	The Royal College Of Surgeons, St Stephens Green, Dublin 2 [In-Person event]		

Meeting Support

HRB NCTO would like to sincerely thank the following organisations for their support for this conference



University College Dublin
Ireland's Global University



Health Research Board

NCTO

National Clinical Trials Office

email: ncto@ucc.ie

website: ncto.ie



[HRB National Clinical Trials Office \(NCTO\)](#)



Keep the Conversation going online on  using the hashtag [#ICTD2024](#)
[@HRB_NCTO](#)