

Newsletter Autumn, 2024



Dear Colleagues,

A warm welcome to the Autumn edition of our newsletter. As the season turns, we hope you had the chance to enjoy some well-deserved rest over the summer months. With cooler days now upon us, it's the perfect time to reflect on the vibrant activity across the Irish Clinical Research sector over recent months.

In this edition, we're highlighting some of the most exciting news from across the ecosystem of Clinical Research in Ireland, while also taking a look at some of the fantastic events being held in the coming months. In particular, we are excited to share some of the details surrounding our upcoming event 'Medtech Advance: Transforming Clinical Investigations in Ireland'. Taking place in Medtronic's customer innovation centre in Galway, it will bring together many of the leading figures in Ireland's Medtech sector for an enlightening workshop and rare networking opportunity.

As always, we encourage you to stay connected and continue sharing your stories, achievements, and innovations with us. Follow us on LinkedIn and X/Twitter (both linked below), and don't hesitate to reach out with any material you'd like to see featured in future editions.

Sincerely, NCTO Team



MedTech Advance Event

News From Across the Network

Upcoming Events

Ecosystem Updates















MedTech Advance: Transforming Clinical Investigations in Ireland

We're delighted to share the details of our upcoming workshop and networking event, "MedTech Advance: Transforming Clinical Investigations in Ireland", taking place on Thursday, 3rd October 2024, facilitated by our dedicated Medtech Expert and Clinical Industry Liaison Officer, Fiona Ryan (pictured above).

This event will bring together a unique mix of Irish regulatory agencies, including Health Products Regulatory Authority (HPRA) and the National Office for Research Ethics Committees, along with experts offering guidance on conducting clinical investigations in Ireland and insights into current EU developments. The event will also feature case studies from individuals who have conducted clinical investigations both in Ireland and internationally.



Medtronic Customer Innovation Centre, Galway



Medtronic Customer Innovation Centre, Galway

Galway's significant presence in the medical device industry and MedTech sector holds global importance, and we are delighted that Medtronic will be hosting this event at their Customer Innovation Centre in Galway city.

This event is also supported by Enterprise Ireland, Health Products Regulatory Authority (HPRA), IDA Ireland, Irish Medtech and the National Office for Research Ethics Committees.

With unprecedented demand for tickets, the workshop is currently over-subscribed for this year, but this event will be held yearly, so keep an eye on our social channels for ticket releases for next year's event.

New easier access to information about clinical trials taking place in Europe

Search for clinical trials - EMA (euclinicaltrials.eu)

The launch of a new version of the Clinical Trials Information System (CTIS) allows more efficient access to information about clinical trials in the European Union (EU) for patients, healthcare professionals and other stakeholders.

Since 20 September 2024, additional features have been be implemented on the CTIS public portal. The new features allow users to carry out advanced searches and download their search results. Updated **search tips** are also available.

This makes it easier than ever for patients in Ireland to find relevant clinical trials, and for researchers to get an overview of the number of trials currently approved in Ireland, the types of trials, trial sponsors, number of patients recruited.

Snapshot of number of CT trials authorised in Ireland on 24 Sept 2024 by sponsor type:

• Commercial Sponsor: 199

• Academic / not for profit Sponsor: 39

• Total: 238

Nominations open for the HRB Impact Award 2025

Applications are now open for the fourth HRB Impact Award. The award aims to showcase the achievements and practices of individuals - and their teams - so they might serve as a role model and inspiration for the wider HRB community and the public at large.

With a prize fund of €50,000, the winner will be announced at the HRB Grant Holders Conference in February 2025. Nominations close 1.00 pm, 10 October 2024.

For more informaion and to apply, click **here**.

Dates for your Diary

International
Clinical Trials
Methodology
Conference
30 Sep – 3 Oct 2024
Edinburgh

'Advancing the Workforce and Future Trialists' 17 Oct 2024 Institute of Clinical Trials, Galway

16th Annual IRNM Conference 28 Nov 2024 RCSI

Limerick

HRB-TMRN Winter School 29 Nov 2024 University of

If you would like your event featured here in future newsletters, email ncto@ucc.ie and we will be happy to accommodate.











Wellcome-HRB Clinical Research Facility at St James's Hospital Celebrate their 10 Year Anniversary

The CRF was established as a joint entity between Trinity College Dublin and St James's Hospital. After a decade they have much to celebrate with over **350 studies** and **100 regulated clinical trials**.

Since then, the CRF has facilitated some **22,000** adult and paediatric engagements with clinical research and/or gain access to innovative and experimental treatments.

They are having a ten-year celebration event here at the John Durkan Lecture Theatre on Thursday 3rd October (invitation only). Their aim is to spotlight on the value of public participation in high quality and well-regulated clinical research and clinical trials.

We at the NCTO would like to send them our heartfelt congratulations on a very successful decade of work. Here's to many decades more!



Professor Fidelma Dunne named 2024 Norbert Freinkel Award recipient by the American Diabetes Association

The American Diabetes Association, the foremost global organisation dedicated to diabetes research and education, has selected Professor Fidelma Dunne (interim director of the Institute for Clinical Trials at University of Galway) as the esteemed Norbert Freinkel Award recipient for 2024. This prestigious award, recognising outstanding scientific achievement in the understanding and treatment of diabetes and pregnancy, is a ground-breaking honour for Professor Dunne and is the first award by the Association to an Irish recipient.

Our sincere congratulations to Professor Dunne on this richly deserved award!









New HRB Board appointments







Minister for Health, Stephen Donnelly, has appointed **Dr. Tracy Cunningham** as Chairperson Designate of the Health Research Board (HRB) and welcomed two new Board members, **Professor Mark Lawler** and **Professor Peter Doran**.

Dr. Cunningham, previously Chief Medical Officer at Amryt Pharma, brings extensive experience in clinical development, research, and medical affairs within the pharmaceutical industry

Professor Doran, Director of the UCD Clinical Research Centre, specializes in multisite-clinical research and patient-focused programs.

Professor Lawler, from Queen's University Belfast, is an expert in digital health, precision medicine, and health inequalities research.

NCTO would like to extend our utmost congratulations to Dr. Cunningham and Professors Doran and Lawler on their appointments and thoroughly look forward to working with them going forward.

RCSI opens doors to new €32 million Education and Research Centre at Connolly Hospital





The Royal College of Surgeons in Ireland (RCSI) has officially opened a new €32 million Education and Research Centre (ERC) at Connolly Hospital, Blanchardstown. The three-story facility includes a lecture theatre, mock operating room, practical skills spaces, and a communal atrium, enhancing the student experience for RCSI's Graduate Entry Medicine students and those on clinical rotations.

The centre also features a new HSE pathology laboratory, increasing diagnostic capacity for the surrounding communities.

Funded by the HSE, the building will support medical education, clinical research, and patient care, embodying sustainability with energy-efficient designs like solar panels and green roofs.



PPI Ignite Network Launch National PPI Festival 2024

The launch, taking place on Tuesday, October $1\cdot 10$ am - 12pm, will include a number of speakers including a dynamic panel discussion on Connect. Collaborate. Celebrate: Exploring the key Ingredients of Successful PPI Partnerships. There will also be a showcase of some of the fantastic events happening across Ireland as part of the festival and an official launch of the new National PPI Ignite Network- 5 ECTS Introduction to PPI Module for Postgraduate Students.

To attend in-person, register here: https://shorturl.at/cDL0G and to attend online, register here: https://shorturl.at/cDL0G

HSE, in partnership with the Irish Pharmaceutical Healthcare Association (<u>IPHA</u>), announce updated Bipartite Model Clinical Trial Agreement (CTA) for Clinical Trials





The Health Service Executive (HSE) has partnered with the Irish Pharmaceutical Healthcare Association (IPHA) and leading commercial contract research organizations to create two pre-approved clinical trial agreement templates. These templates will improve clinical trial timelines and decrease cost and effort for all parties involved. Their use is mandatory for all HSE hospitals and highly recommended for all other hospitals, whether public or private.

The updated Bipartite Agreement became effective on 23rd August 2024 and supersedes all previous versions of the agreement. This launch follows our recent release of the Tripartite CTA in May 2024, which was created to streamline agreements among multiple stakeholders, making it easier for patients to participate in innovative clinical trials.

Find out more here.

IPPOSI and HSE Launch Online Research Ethics Course for the Public and Patients





<u>IPPOSI</u>, together with <u>HSE Research and Development</u>, the <u>National Office for Research Ethics Committees</u>, a number of patient partners and a wider partnership collaborative, is proud to announce the launch of a new online course on Research Ethics for the public and patients.

The course, the first of its kind, aims to enhance the public's understanding of ethical considerations in health research, including informed consent, data protection and privacy and the ethical review process. Additional lessons on topics such as Artificial Intelligence, Research with Children and Biobanking will also be a feature of this course.

Find out more here.

Brokerage event for IHI's 2025 calls



IHI will hold a brokerage event in Brussels, Belgium on 12-13 November 2024.

The aim of the event is to provide people interested in IHI's 2025 calls for proposals with the opportunity to network face-to-face and start forming consortia. There will also be pitching sessions and poster sessions to give research organisations, patient groups and companies the chance to showcase their capabilities.

Medical Workforce Intelligence Report 2023



The Medical Council has published its <u>2023 Medical Workforce</u> <u>Intelligence Report</u> spotlighting the reliance on international doctors and the changing demographics of GPs in Ireland.

The report presents an analysis of data on doctors who have retained their place on the Medical Council's medical register in 2023. It focuses on the clinically active medical workforce in Ireland, presenting quantitative analysis of demographics and divisional status, and details on employment and practice such as self-reported role, medical discipline and specialty, and working hours.

Further Publications & Reports



Frontiers in Pharamacology have compied some interesting publications under the topic: 'Building the Clinical Research Workforce: Challenges, Capacities and Competencies'

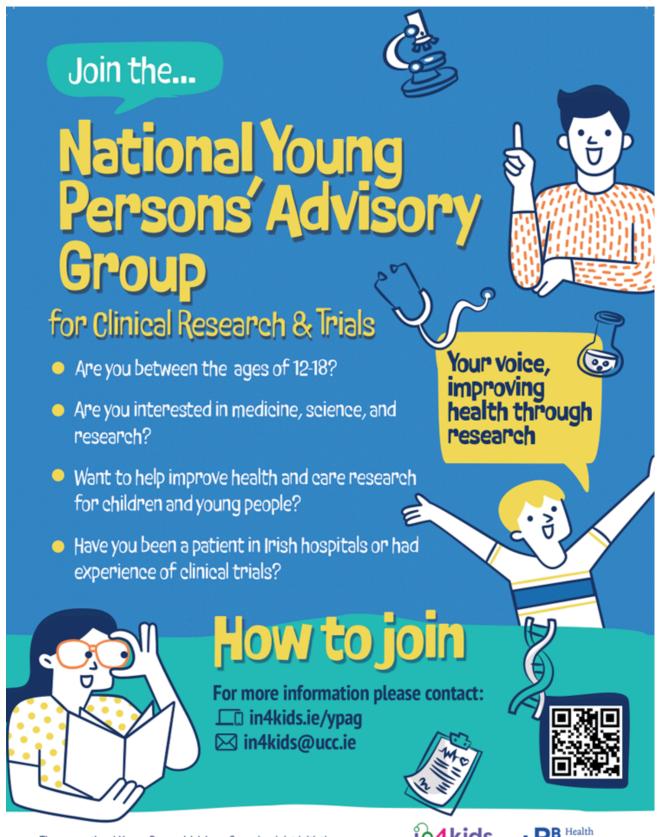
Find them collected on their website.



Some interesting global reports from IQVIA institute:

- Rethinking Clinical Trial Country Prioritization: Enabling agility through global diversification.
- Global Trends in R&D 2024: Activity, productivity, and enablers: Annual trend report from the IQVIA Institute for Human Data Science.

In4Kids Launch the National Young Persons' Advisory group for Clinical Research and Trials



The new national Young Persons' Advisory Group is a joint initiative between the Children's Health Ireland Clinical Research Centre and In4Kids, the national paediatric clinical trials network. CHI-CRC and In4Kids are supported by the Health Research Board.











Events



IRNM 16th Annual Conference 2024

The Irish Research Nurses and Midwives Annual Conference is a significant event that brings together professionals from across Ireland who are involved in research within the fields of nursing and midwifery. This conference serves as a platform for research nurses, midwives, and allied healthcare professionals to share their work, discuss new developments, and explore the challenges and opportunities in their respective fields.

The conference will feature a series of presentations, workshops, and poster sessions where attendees can present their research findings, exchange ideas, and engage in professional development. Keynote speakers, leaders in healthcare research provide insights into emerging trends and the future direction of nursing and midwifery research.

Register Today Abstract Submissions



ICTMC is the leading international platform for researchers and practitioners to present the very latest in trials methodology research and we are excited to provide further details about our keynote speakers for this year's conference.

Visit the conference website to find out more about the speakers and their presentations. Don't miss out on the conversation, make sure you register for ICTMC 2024 today: <u>register</u> here.

The Health Research Board – Trials Methodology Research Network (HRB-TMRN) has launched a **Travel Bursary for Irish Researchers**, including PhD students, who wish to attend ICTMC 2024. Find out more **here**.

TMRN Winter School: Innovations in Cancer Methodology, November 29th

WINTER SCHOOL

Innovations in Cancer Trials Methodology SAVE THE DATE: 29th November 2024 Location: Limerick

Dr Frances Shiely

Director of Education, HRB Clinical Research Facility Senior Lecturer, Epidemiology, School of Public Health University College Cork

Trials methodology - Building a work program for impact







For more information, visit www.hrb-tmrn.ie X @hrbtmrn



The HRB-TMRN are hosting their annual Winter School on Nov 29th in University of Limerick.

This and many other of their other events are conveniently listed on their **events page**.

You can register for this event **here.**

WINTER SCHOOL

Innovations in Cancer Trials Methodology
SAVE THE DATE: 29th November 2024

Dr Mohamad Saab

Senior Lecturer, Vice Dean of Graduate Studies, School of Nursing and Midwifery, University College Cork Enhancing Men's Awareness of Testicular Diseases (E-MAT) using Virtual Reality: Lessons Learned from a Feasibility Trial and Study Within A Trial (SWAT)







For more information, visit www.hrb-tmrn.ie 🗶 @hrbtmrn

WINTER SCHOOL

Innovations in Cancer Trials Methodology
SAVE THE DATE: 29th November 2024
Location: Limerick

Professor Sarah Brown

Cancer Clinical Trials Methodology, University of Leeds Director, Leeds Institute of Clinical trials Research Director, Cancer Research UK Clinical Trials Unit







For more information, visit www.hrb-tmrn.ie X @hrbtmrn



WINTER SCHOOL

Innovations in Cancer Trials Methodology
SAVE THE DATE: 29th November 2024

Assistant Professor Sarah Dillon

Advanced Healthcare Practice, University of Limerick

Dr Patrick O'Donnell

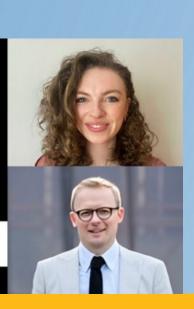
Associate Professor of General Practice, University of Limerick Advancing Equitable Representation of Minority Populations







For more information, visit www.hrb-tmrn.ie 🗶 @hrbtmrn





An Instituid do Thrialacha Cliniciúla Institute for Clinical Trials

"Advancing the Workforce and Future Trialists" TRIALIST PROGRAMME 17.10.2024

The upcoming event hosted by the Institute for Clinical Trials will offer a comprehensive dive into various aspects of clinical research, bringing together experts from different fields. The day will begin with a welcome from Prof. Fidelma Dunne.

Attendees will gain valuable knowledge on feasibility assessments, financial planning, and the intricacies of approvals, contracts, and site initiation. Covering topics such as ethics, regulatory processes, study documentation, and data management.

In the afternoon, sessions will explore safety reporting, clinical trial monitoring, inspections, and close-out reporting.

For the full programme and details of how to register, visit their website.

Ecosystem Updates



Our colleagues at the National Office for Research Ethics Committees have a rolling call for expressions of interest for new members of our Committees that review:

- Clinical trials for investigational medicinal products for human use (NREC-CT A, B, C & D)
- Clinical investigations of medical devices (NREC-MD)
- Performance studies of in vitro diagnostics (NREC-MD)

Being a member of NREC is an exciting opportunity to support Irish health research at a national level, to gain insight into forefront health developments, and to ensure that Irish research is strengthened by the highest ethics standards.

Find out more on their website: https://www.nrecoffice.ie/committees/become-a-member/

canSERV relaunches Open Call for applications for complimentary access to cancer research services



<u>The EU-funded canSERV initiative offers over 400 advanced cancer research technologies and services to both European and international researchers at any career stage, supporting the entire oncology research process.</u>

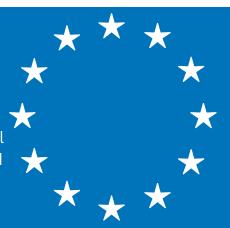
These services, aligned with Europe's Cancer Mission and Beating Cancer Plan, include tailored training and aim to accelerate the transition of pioneering research from lab to clinical practice. Researchers from academia, industry, and SMEs are invited to apply for the latest Open Call, which supports projects spanning cancer understanding, prevention, diagnosis, treatment, and quality of life.

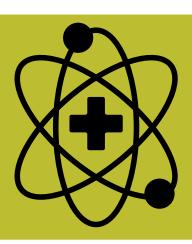
Available services include disease models, personalised oncology technologies, biomarker research, clinical trials, and ethical guidance, with applications due by 28 November 2024. The budget for this call is 1 million euros, potentially increasing based on demand, and proposals will be reviewed by an independent panel.

For more information and the text of the Call, visit the **canSERV website**.

ECRIN

ECRIN will host the 4th CTU Day online from 10AM TO 13h (CET) on 13 December 2024. The event is open to members of ECRIN national partner networks. This year they have built a program that includes information on ECRIN activities, a focus on a couple of ECRIN's national CTU Networks, and more information on how we can work together and support the advancement of clinical research. The agenda will be released shortly. **Register Today**.





MEDTECH

Irish Medtech is hosting 'Global Access 2024' on the 23 & 24 October with an impressive line up of speakers discussing a diverse range of topics including: EU Medtech future regulatory system, global regulatory trends, talent, impact of horizontal legislation, clinical investigations landscape and innovations in quality management systems. **Register Today**.

REG & ETHICS

The National Office for Research Ethics Committees has announced that they're closing the COVID-19 sub committee. This group was incredibly important in helping ensure COVID-19 research was enabled during a time of significant challenge in the pandemic noting that as "the emergency circumstances under which the NREC COVID-19 and subsequent standing COVID-19 Subcommittee was set up to respond to, are no longer applicable, the COVID-19 Subcommittee is no longer in service as of 31 August 2024".





CRF MANAGER SOFTWARE

CRF Manager is a web-based resource management system, currently being used in many of our clinical research facilities, which facilitates the administration of clinical research studies and research facility management. NCTO provides a service that supervises and supports the administration of CRF Manager.

Contact crf-manager@ucc.ie for more.