



Health Research Board
NCTO
National Clinical Trials Office

Newsletter Highlights

Newsletter Summer, 2023

ICTD 2023

in4kids Spotlight

Medtech Round-up

Education

Ecosystem Updates



Dr. Robert O'Connor, Director NCTO

Dear Reader,

A very warm welcome to the Summer edition of our newsletter. It has been a exciting and busy time for the NCTO. Our recent International Clinical Trials Day (ICTD) event, kindly hosted by RCSI, was a great success, bringing together stakeholders from across the landscape of Clinical Trials in Ireland. In this issue, we share some of the details of the conference and we would like to extend our sincere gratitude to all of you who attended and made it such a great event.

We are also very excited to introduce to you our new Director, Dr. Robert O'Connor (pictured above). Well known to many in the sector, Dr. O'Connor has a wealth of experience in the field of clinical research and brings a passion and energy to the role that will complement the existing track record of achievement by the NCTO, as we seek to grow Ireland's reputation as a leading country in which to conduct clinical research.

In this issue, we will also update you on the exciting and growing Medtech sector and the activities of our Clinical Industry Liaison Officer, Olive O'Driscoll. Moreover, as part of our ongoing series of highlights from our partner Clinical Trials Networks, we will highlight the fantastic work of the **in4kids** network, whose recent launch has been a source of great excitement in the field of children's research in Ireland.

Sincerely,
The NCTO Team

HR^B Health
Research
Board

 **UCC**
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

 Enterprise
Ireland



ncto.ie



[@HRB_NCTO](https://twitter.com/HRB_NCTO)



ncto@ucc.ie

International Clinical Trials Day (ICTD) 2023 Conference



The HRB NCTO International Clinical Trials Day event took place on May 10th, 2023 in RCSI, Dublin. The theme for this year's event was "Advancing Clinical Research in Ireland 2023" and was supported by the Health Research Board with contributions from IQVIA and Sanofi. It was a huge success with more than 140 delegates attending, our first in-person event since 2019, with feedback questionnaires rating the conference very highly - 95% rated the conference as excellent or very good.

The conference consisted of a speaker session in the morning followed by presentations from each of the Irish Clinical Research Facilities/Centres in the afternoon. Speakers included representatives from the different stakeholders in Ireland such as HRB, Enterprise Ireland, HRB NCTO, HSE Research & Development, Health Products Regulatory Authority and National Research Ethics Committee. The keynote speaker was Dr Marianne Pilgaard [CEO Trial Nation, Denmark] on the Clinical Research landscape in Denmark and what we in Ireland can learn from their successes.

A full recording of the event, selected photographs and copies of all presentations are available on the HRB NCTO website via this link: www.ncto.ie/ictd/.



L-R: Michèle Cunnane (NCTO), Jane Bryant (NREC), Clare Foley (HPRA), Prof. Ivan Perry (CRF-UCC), Dr. Marianne Pilgaard (Trial Nation), Dr Sarah Craig (HRB), Garrett Murray (Enterprise Ireland), Cllr Racheal Batten (HSE), Dr. Oonagh Ward (HRB)

Dates for your Diary

UKCRFN 18th Annual Conference, 6 & 7 July '23



Health Innovation Hub Awards, 12 July '23



IRNM Summer School, 20 July '23



HRB-TRMN's 8th Trials Methodology Symposium, Galway, 20 Oct '23



IRNM Conference, Limerick, 16 Nov '23



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

Children possess unique physiological, developmental, and psychological characteristics that set them apart from adults. It is crucial to ensure that they receive equitable access to high-quality healthcare based on evidence from paediatric studies, rather than treating them as miniature adults.

More than a decade ago, the idea of establishing a national network for Children's Clinical Trials, known as "**in4kids**," was born with two core objectives that remain relevant today:

- Enhancing the quality and quantity of children's research in Ireland.
- Prioritizing the perspectives and experiences of children and their families in research design.

Recognising the significance of this network, the consortium were awarded core funding by the **Health Research Board** in 2021.



Pictured at the in4kids Launch is in4kids Lead, **Prof. Geraldine Boylan**; in4kids Co-lead, **Prof Eleanor Molloy** with **Mandy Daly**, Parent Advocate and member of in4kids Executive Management Committee & **Cameron Keighron**, D1 Now Member



Still from the Gael Scoil Dara film.

in4kids also serves as the central hub for the pan-European Clinical Trial Network, **conect4Children (c4c)**. The official launch of the in4kids network took place in January 2023, marking a momentous milestone for children's research in Ireland.

To celebrate this occasion, a short film featuring Irish school children from Gael Scoil Dara, winners of 2022 START competition was commissioned. These children not only demonstrate their understanding of clinical trials but also conduct their own randomized control trials (RCTs).

Their Dedicated Team

University College Cork serves as the host institution for **in4kids**. Leading the network is **Professor Geraldine Boylan**, an expert in Neonatal Physiology, and co-leader **Professor Eleanor Molloy**, a distinguished figure in Paediatric Medicine from Trinity College Dublin. Overseeing the day-to-day operations of the network are **Teresa Berkery**, the in4kids Network Manager, and **Melissa Walsh**, the conect4children Programme Manager.

Additionally, in4kids benefits from the expertise of two PPI coordinators: **Sonia Lenehan**, based in the INFANT Centre, and **Shane Comer**, based in Children's Health Ireland (CHI) in Dublin. **Claire O'Donohoe**, the Clinical Trial Start-up Manager, holds a joint appointment between in4kids and CHI, responsible for managing feasibility assessments across the network. Lastly, based in Galway, **Petek Eylul Taneri** is a post-doctoral researcher specializing in Core Outcome Sets.

Join the in4kids Network

in4kids extends an invitation to all members of the paediatric research community in Ireland to join them and become part of the network. By doing so, members gain access to a dedicated platform that provides tailored support and tools for conducting paediatric research. They also have increased opportunities for collaboration on national clinical research projects and receive updates on the latest advancements in both national and international paediatric research.



As emphasised by their expert panel during their launch event, there are challenges, but more importantly, significant opportunities for clinical trials in Ireland.

in4kids is committed to seizing these opportunities as they strive to ensure that children have equitable access to evidence-based healthcare, like adults.

University of Galway Launches Institute for Clinical Trials



Noreen Doyle with Professor Peter Doran at University of Galway for the launch of the Institute for Clinical Trials.
Credit: Andrew Downes/Xposure.

Congratulations to the newly founded Institute for Clinical Trials at University of Galway on their highly successful launch during the FutureTrials event, held on 30th & 31st of May.

Professor Martin O'Donnell, Dean of the College of Medicine, Nursing and Health Sciences at University of Galway and Consultant, said: "This institute will consolidate our areas of considerable strength in clinical trials, ensure the rapid translation of medical discoveries to clinical evaluation and ultimately improve the lives of patients and health of our population, leveraging the academic strengths of our University and its healthcare partner Saolta University Healthcare Group. The Institute will also focus on developing sustained, mutually advantageous partnerships with industry and academic partners, positioning our region as a leader in health and med tech research."

Medtech Round-up



Olive O'Driscoll, CILO for NCTO

Part of our International Clinical Trials Day, included a lively and interactive MedTech Session entitled: "A whistle stop tour of conducting clinical investigations in Ireland".

This parallel session was Chaired by Prof Martina Hennessey, Director SJH CRF with three expert panel speakers. Olive provided an overview of the Clinical Investigation ecosystem in Ireland and here forthcoming Toolkit, which helps Sponsors to navigate that system. Dr Donal O'Connor, Clinical Manager at HPRA provided an insightful presentation of case studies on med tech Clinical investigations (CI) applications and their assessment of CIs based on risk of the device. Ms Emma Meade, Director of Clinical Research, Neuromod Devices provided a real world industry perspective on carrying out CIs in Ireland, which ultimately led to CE mark and *De Novo* approval of their Lenire device by the FDA.

It has been a busy and exciting time for Med Tech in Ireland and especially at the NCTO.

Olive O'Driscoll, our CILO (Clinical Industry Liaison Officer) attended the Enterprise Ireland Start-Up Showcase which took place at the RDS, Dublin 28th April. The Showcase is the largest High Potential Start-Up event in the year bringing together the many new companies that Enterprise Ireland has invested in during 2022, along with key start-up ecosystem players including investors, accelerators, and national and regional providers of start-up ecosystem supports. There were a number of fascinating med tech panel discussions including Róna Ní Ghriallais, CTO & Co-Founder, ProVerum and Brian Shields, CEO & Co-Founder, Neurent Medical with both companies recently/currently undergoing clinical investigations of their products.

NCTO also attended the MedTech Strategist Innovation Summit, Dublin April 2023. The conference brought together some of the leading voices in today's MedTech world to provide both insight and opportunity. Olive met with established and start-up Irish med tech companies who are planning clinical investigations in Ireland, as well as Enterprise Ireland, who were a platinum sponsor of the event.



Last but by no means least, Olive was invited to present to the Irish Medtech Association RDI Working Group, which aims to help sustain and evolve Irish Medtech as a globally competitive innovation cluster that differentiates itself through the delivery of high-quality products and services. The group's three keys areas of focus are (1) Clinical Innovation (2) Talent/People & Resources and (3) Funding.



Educational Opportunities

In this section, we will highlight two fantastic programmes.

The **MSc in Clinical Research, University of Galway.**

The course aims to "provide training for the next generation of healthcare workers in the clinical research arena and a platform for achieving greater efficiencies in applying medical discoveries to clinical practice".

The course overview, key facts, outline and much more can be found [here](#).

N.B. The 2023 course is now full, but is accepting submissions for the wait-list.



Top L-R: Colm McElwain, Thomas S., Niamh Hurney.
Middle L-R: Nathan Devaney, Josie Carroll, Chloe Ryan.
Bottom L-Rt: Dr Sonja Khan (Lecturer), Dr Elaine Loughlin, Dr Sarah Gorey and Professor Andrew Smyth (Course Director)

UCC | School of Public Health
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

**PG Cert
CLINICAL
TRIALS
PART TIME
(ONLINE)**

This course is designed to give a competitive advantage for those wishing to pursue a career in clinical trials. The course begins in September and is paced for the working professional. Physicians, pharmacists, nurses, managers, scientists, health scientists, and workers in the allied health professions are encouraged to apply.

**www.ucc.ie/en/cku17
clinicaltrials@ucc.ie**

CRF-UCC
HRB Clinical Research Facility University College Cork

TMRN
Health Research Board
Trials Methodology Research Network

HRB CRF-UCC Certificate in Clinical Trials (online)

Currently accepting applications for part-time students, until the 30th June 2023 (Non-EU) and the 3rd of July 2023 (EU). The programme will commence on the 18th of September 2023.

Students have the option of progressing to the MSc in a step-wise manner with the option of graduating after year 1 with a Cert, year 2 with a Dip or completing the full programme and graduating with an MSc in year 3.

Find out more [here](#)

REG & ETHICS

NREC's annual report for 2022 is available to view online now! It gives an overview of the breadth of work achieved by the National Office last year, reflecting the vibrant health research landscape in Ireland.

Read it here: <https://tinyurl.com/yefy5dkz>



TRAINING & CONSULATION

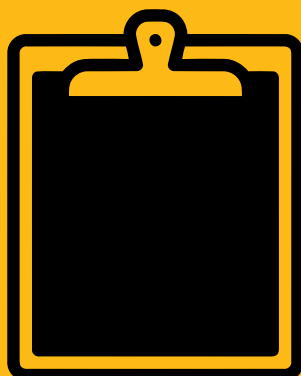
ICH-GCP (E6) Revision 3:

Public consultation on the draft is open until September 26 September 2023

<https://www.ema.europa.eu/en/news-events/open-consultations>

ECRIN

Both Switzerland (**Swiss Clinical Trial Organisation (SCTO)**) and Greece (**GreCRIN**) have joined ECRIN-ERIC as member countries. NCTO welcomes the further expansion of this important European network.



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.

Feel free to forward to a colleague and if you wish to subscribe to this newsletter or opt-out, please email ncto@ucc.ie