



HRB NCTO Newsletter



As we are now well and truly into Autumn, we can see that “Conference Season” is upon us. It is fantastic to be back meeting face to face again and we all certainly appreciate the opportunity to do so, more than ever. This Autumn NCTO Newsletter highlights many upcoming events, some in person and some virtual. Please let us know if you would like us to promote your events on our website and/or in our Winter Newsletter, we are very happy to do so!

Congratulations to the HRB Dementia Trials Ireland Network on their formal launch this week, you can read more about the fabulous event which took place on the 27th of September, later in this Newsletter.

September was a very busy month for NCTO as we hosted many of our Autumn Working Group and Stakeholder meetings during the month. I am delighted to let you know that the NCTO MedTech working group met for the first time on Sept 8th and working with our Enterprise Ireland Colleagues, work plans were forged for the group for the year ahead.

We are delighted to put the Spotlight on the Diabetes Collaborative Clinical Trial Network led by Director Professor Fidelma Dunne in this newsletter where you can learn more about the ambitious plans of this network.

Wishing all a happy and safe Autumn.

Best wishes,

Fionnuala

Dr Fionnuala Keane, Manager NCTO

SAY HELLO TO NEW HRB NCTO TEAM MEMBER

We are delighted to welcome Eoghan Cooke, Communications Officer to the NCTO Team

Eoghan is a communications expert who began his career with a BA (Hons) in English and Philosophy



from UCC, subsequently traveling to Scotland to study Philosophy of Science for his PhD in the University of Edinburgh. Having developed a deep affinity and respect for the scientific method, he went on to begin studying and researching the effectiveness of Virtual Reality as a communications tool in the medical space. This culminated in the development of the 'E-MAT' VR simulation, a tool for enhancing men's awareness of testicular disorders and developed this simulation during the course of an MSc in

Interactive Media in UCC's Computer Science Department. Eoghan also founded Cervindi Ltd., a business that helped SMEs in Cork to develop and publish their online presences.

In a HRB-funded trial designed to study E-MAT, it was Eoghan's responsibility to engage various stakeholders through the use of social media outreach and to study the effectiveness of various recruitment channels in this clinical trial. Furthermore, Eoghan was responsible for the technical delivery of the VR simulation to participants from GAA clubs across Munster. This granted Eoghan a unique insight into the relationship between clinical trials, branding, and communications that he will bring to his new role as Comms Officer for the NCTO.

Eoghan will become the NCTO's first dedicated Communications Officer and will play a key role in delivering the NCTO's message to a broad audience of stakeholders from across the spectrum of the clinical trials community.

Email: ECooke@ucc.ie

WHERE
DO I
START



REMINDER

The "Practical Guide on Data Protection for Health Researchers" created by the Irish Health Research Data Protection Network (HRDPN) in consultation with the DPC is available on our website.

Check out: <https://bit.ly/3UyLuzY>

MEDICAL TECHNOLOGY WORKING GROUP



The inaugural meeting of the NCTO Medical Technology Working Group (MTWG) took place at the Trinity Biomedical Sciences Institute, on Thursday 8th September 2022.

It was a hybrid meeting, with many of the attendees attending in person. The meeting was co-chaired by Prof Martina Hennessy Director, Clinical Research Facility, St James Hospital and Olive O'Driscoll Clinical Industry Liaison Officer, NCTO. The meeting was well attended by members of the Clinical Trial Facilities/Centres, Enterprise Ireland, and Irish Medtech Association, IBEC.

The meeting focused on establishing new Terms of Reference for the MTWG. All agreed that the group will continue to focus efforts on supporting companies to conduct an increased number of high-quality clinical investigations in Ireland. To do this, the CILO has already had a number of engagements with companies to signpost them to supports and services available in Ireland and to help them engage with the HPR. The group plan to help Sponsors navigate the Irish clinical investigation ecosystem, identify barriers in the system and continue to support companies to conduct clinical investigations in Ireland. The Med Tech Toolkit, which is a series of med tech resources available to companies, was reviewed and the group agreed which documents to update. The CILO also provided an update on the number and type of company engagements which have taken place since the role started in April 2022. The next meeting of the MTWG will take place at the end of 2022.



ATTENTION CLINICAL RESEARCHERS

The **Health Research Data Protection Network (HRDPN)** training subgroup will hold a free practical workshop on DPIA completion on 20 October 2022 (10.30 - 13.30) at the Pilar Centre, Mater Hospital, Dublin. Led by Data Protection Officers from hospitals and universities, this workshop aims to provide practical assistance to clinical researchers, project managers etc. who struggle to complete DPIAs for their studies/trials. The workshop will provide researchers an opportunity to discuss challenges encountered with experienced DPOs. The output from the workshop will inform the development of future training and documentation to be developed by the HRDPN.

Places are limited. To register, click here: <https://bit.ly/3E7JEjx>

SPOTLIGHT ON

DIABETES COLLABORATIVE CLINICAL TRIAL NETWORK



The Diabetes Collaborative Clinical Trial Network (DC-CTN) was an idea started in 2014 to bring together experts from diabetes in the clinical research and patient areas, from all over the island of Ireland to improve outcomes and wellbeing for patients with diabetes through research and collaboration.

The network was funded by the HRB in 2021 and is led by Director Professor Fidelma Dunne who holds an MD (University College Cork), PhD (University of Birmingham UK), Masters in Medical Education (University of Dundee Scotland), and Masters in Clinical Research (NUI Galway). The Network Program Manager Dr Peadar Rooney was appointed in May 2022 and alongside Professor Dunne manages the day-to-day activities of the network. They are developing the structures for prioritising research areas, embedding education and training in clinical research, clinical trials and facilitating patient and

public involvement. They are also growing relationships with the wider team of diabetic clinicians' and researchers who make up the network.

Diabetes is one of the most common chronic diseases in Ireland and the number affected by diabetes is increasing at an alarming rate alongside the increase in obesity rates. Good diabetes control and treatment avoids diabetes complications, and quality of life is sustained. Patients with diabetes throughout the course of their disease receive treatment from multiple disciplines including pharmacotherapy, surgery, medical nutritional interventions, psychology, and physiotherapy. In addition, they are exposed to new and evolving technologies to measure glucose and deliver insulin. To further advance treatments and technologies for patients with diabetes a multi-disciplinary collaborative approach is required with representation from all the departments patients will encounter.

The HRB Diabetes Collaborative Clinical Trial Network is an all-island collaborative network, the aim is to bring together key stakeholders from different disciplines to design and work on a range of ambitious multi-centre diabetes clinical trials. These trials will have the aim of improving health and wellbeing for all patients with diabetes on the island of Ireland.

The Network Activities for the first year will focus on the following:

- 1) Establishing a transparent and sustainable governance structure
- 2) Establishing a patient and public panel, that will ensure the patient voice is at the heart of the network

- 3) Create a sustainability plan with a focus on national and international grant applications, alongside industry/SME financial and in-kind contributions.
- 4) Create and catalogue educational resources for early career researchers
- 5) Network with industry partners, diabetes charities and patient advocate groups
- 6) Attract other researchers, so the researcher trial base will expand to cover other key areas e.g. diabetes in the Paediatric and Elderly populations
- 7) Create a five-year research strategy that will focus on areas of established expertise including Diabetes in Pregnancy, Technologies, Behavioural change interventions, Diabetes and foot disease, Diabetes and Advanced therapies, all underpinned by Epidemiology and Health Economic Assessments.

It is foremost in the minds of the Network members, that all Network activities have patient and public involvement and are complimentary to the priorities of the National HSE Diabetes clinical care programme. While it is early days for the Diabetes Collaborative CTN, the core working group is working hard to increase the collaboration between members, and access for patients to clinical trials.

Dementia Trials Ireland Network Launch 27th September 2022

DTI officially launched their Clinical Trial Network with a very well attended event in Naughton Institute Trinity College Dublin.

The event was opened by 'The Forget-Me-Nots Choir', followed by an introduction to DTI by Prof Iracema Leroi (co-lead) with the event concluding with a panel discussion that included PPI and Steering Group members chaired by Prof Sean Kennelly.

Congratulations to all involved on such a great event.

Follow DTI on....

Twitter @DementiaTrials

Online @ www.dementrials.ie



EMA UPDATES

ACCELERATING CLINICAL TRIALS IN THE EU

The EMA have published a 2022 – 2026 workplan aimed at Accelerating Clinical Trials in the EU (**ACT EU**). It seeks to transform how clinical trials are initiated, designed and run and to further develop the EU as a focal point for clinical research, promote the development of high-quality, safe and effective medicines, and to better integrate clinical research in the European health system. For more information, click here <https://bit.ly/3f7p9nv>

ARE YOUR SITES REGISTERED AS CLINICAL SITES ON EMA ORGANISATION MANAGEMENT SYSTEM?

All sites who want to take part in **Clinical Trials of IMP (CTIMP)** under the **Clinical Trial Regulation (CTR)** must be registered on the **EMA Organisation Management System (OMS)**.

Pharma Sponsors and CROs must choose from list of registered sites when competing their clinical trial applications via the Clinical Trial Information System (CTIS) under the CTR.

NCTO encourages HRB-Clinical Research Facilities/ Centres to assist their local hospitals and other clinical sites to register on the OMS to make site selection and set up easier and faster for potential sponsors.

You can check what site(s) are registered at [OMS Web UI \(europa.eu\)](https://european-commission.eu/oms-web-ui). The CTR transition period ends on 30 January 2023. From that date onwards, all new Clinical Trial applications will be via CTIS and if your site is not registered on OMS it may cause unnecessary delays in setting up trials at your site(s).

If you need advice/assistance on registering your sites, contact the NCTO QRM @ ruben.keane@ucc.ie

WATCH THIS SPACE

We are launching a new version of the NCTO website in October...date to be confirmed

www.ncto.ie



MEET HRB NCTO @

IRNM Annual Conference

9-10 November 2022, Limerick Strand Hotel, Limerick

More information: <https://bit.ly/3BsU4HC>

Irish Health Research Forum

10 November 2022; 09:30 - 13:00

The Ashling Hotel, Dublin

Registration: <https://bit.ly/3S954AS>

Enterprise Ireland's 'Venture Build' Training Day

30 November 2022; Guinness Enterprise Centre, Dublin



Medtech Rising 2022

Ireland's Business Leaders Conference & Medtech Awards Ceremony

1 December 2022; Galmont Hotel, Galway

Registration: <https://bit.ly/3UyqfxY>

DATES FOR YOUR DIARY

NREC - National Office Webinar [Online]

27 October 2022; 10:00 - 13:00

Registration: <https://bit.ly/3DWjr7w>



Health Research Board 2022 National Conference

30 November 2022; 9.00 - 16.00

Radisson Blu Royal, Dublin

Registration: <https://bit.ly/3f6Hfep>

