

# HRB NCTO Winter 2022 Newsletter



Health Research Board  
**NCTO**  
National Clinical Trials Office

As with each Newsletter this year, we have been profiling the HRB funded Clinical Trial Networks and in this edition, we are profiling the Dementia Trials Network who held their formal launch on the 27<sup>th</sup> of September 2022! Congrats to all on what was a fantastic event.

In this edition of our Newsletter, Niall Hore, NCTO ECRIN European Correspondent (EUCCO), shares with us details of the ECRIN summer school which was held in Rome in late September. This was the first opportunity for the ECRIN EUCCO's from the different member countries to meet face to face in 3 years!

The IRNM held their annual conference in Limerick on the 10<sup>th</sup> of November 2022, this was also the first face to face meeting of the group in 3 years and was a highly successful event, well done to all involved.

The annual NCTO/HPRA compliance meeting took place on the 24<sup>th</sup> of November 2022 at the HPRA offices in Dublin. This is one of the most important meetings in our NCTO calendar and we are very grateful to the HPRA for their availability, guidance and hospitality. You can read more details of this meeting in this newsletter.

## Dates for your Diary 2023

- ✳ **NCTO ICTD Day** 11<sup>th</sup> May '23
- ✳ **ECRIN ICTD Day** 23<sup>rd</sup> May '23

## New NCTO website launched

- ✳ Check out [www.ncto.ie](http://www.ncto.ie)

## General Information

**General Enquiries:** [ncto@ucc.ie](mailto:ncto@ucc.ie)

**Feasibility Programme:** [trials-feasibility@ucc.ie](mailto:trials-feasibility@ucc.ie)

- To promote an event or advertise a post/job, email [ncto@ucc.ie](mailto:ncto@ucc.ie) and we will post on our website
- Sign up to our mailing list by emailing [ncto@ucc.ie](mailto:ncto@ucc.ie)
- Opt out on receiving this newsletter by emailing [ncto@ucc.ie](mailto:ncto@ucc.ie)



MedTech Rising 2022 – Ireland's Business Leaders' Conference took place in Galway on 1st December and Olive O'Driscoll, NCTO Clinical Industry Liaison Officer, was invited to Chair the panel session 'How to leverage Ireland's clinical research ecosystem'. This was a great opportunity for MedTech Research and the supporting infrastructure to be in the spotlight and we could clearly see increased interest in this area at this event.

Thanks to all who attended and participated in the NCTO End of Year meeting on the 7<sup>th</sup> of December 2022, see more details here also!

Finally, I would like to thank you for your continued participation in and support of the work of the NCTO and the wider Network, we look forward to 2023 positively and to meeting at more face-to-face events in the coming months!

Wishing you all a happy and safe Christmas

Best wishes,

*Fionnuala*

Fionnuala Keane, NCTO Manager

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### **Model Clinical Trial Agreement**

Standard (model) CTA now available for use between the Site and the Sponsor – [link to access](#)

## **HRB NCTO End of Year Meeting Dec 2022**

The NCTO End of Year Meeting was held online on the 7<sup>th</sup> of December 2022 and was a huge success, many thanks to all who attended and participated in the event.

The 1<sup>st</sup> session on the day involved presentations from the NCTO Team on the work of the Network and of each of the NCTO Working Groups. In the 2<sup>nd</sup> session an Investigator/Researcher/Coordinator from each of the 7 CRF/C's from across the country presented on a study which was run through and supported by their local CRF/C. This was a great opportunity to showcase the excellent ongoing world class research happening in our CRF/C's on a daily basis.

Both sessions were recorded.

You can view Session 1 on the following link:  
<https://youtu.be/LByT6zviyRE>

Session 2 will be available soon on our [website](#)



## **NCTO Quality Working Group Annual Compliance Meeting with HPRA**

The annual NCTO/HPRA compliance meeting took place on 24<sup>th</sup> of November 2022 at the HPRA offices in Dublin. This was our first 'Hybrid' meeting with eleven NCTO network members attending in person and a further seven people joining virtually. NCTO network attendees comprised members of both the Quality and Pharmacovigilance working groups. Representatives from NCTO office, CRC-UCD, CRF-UCC, CRF- RCSI, CHI, CRF-Galway, R & D NUIG, Welcome Trust/ St-James-CRF, CRSU-UL, Cancer Trials Ireland, and the INFANT Centre-UCC were present.

NCTO network members submitted 12 questions in advance, which were addressed in detail by experts from the HPRA GCP/PV inspectorate and assessors. The questions were on a broad range of topics including nurse consenting, low interventional clinical trials, and systems validation.

NCTO were delighted that HPRA invited representatives from NREC including head of office Dr Emily Vereker., who attended in person and other members of NREC who attended virtually. NREC input on questions regarding consenting was particularly valuable.

HPRA was represented in person by Anne Hayes (Inspection Manager), Lorcan Gregorian (GCP/GVP Head of Inspections) and Christine Prendergast (GCP/GVP Inspector) with several other HPRA staff attending virtually.

This is one of the most important meetings in our NCTO calendar and we are very grateful to the HPRA for their availability and guidance and their hospitality. Special thanks to Christine who facilitated the setup of the meeting and liaised with NCTO for many months in advance of the meeting.

NCTO hope to publish the questions submitted and the HPRA replies on our website in due course.

We are looking forward to next year's meeting already!

# Med Tech Round-Up

There has been a lot of exciting news on the MedTech front.

Our Clinical Industry Liaison Officer, Olive O'Driscoll, was an invited speaker at **Enterprise Ireland's Venture Build** event at the Guinness Enterprise Centre on 30<sup>th</sup> of November. There were over forty attendees present, many of whom were commercialisation fund holders for life science projects. Attendees received updates on MDR and IVDR as well as the role of the NCTO and CILO.

**MedTech Rising 2022** – Irelands Business Leaders' Conference took place in Galway on 1<sup>st</sup> of December and Olive was invited to Chair the panel session 'How to leverage Ireland's clinical research ecosystem'. The session was attended by over two hundred people and there was a lively debate amongst the panel members (pictured below), Emma Meade (Director of Clinical Research, Neuromod Devices), Lucia Prihodova (Programme Manager, National Office for Research Ethics Committees) and Andrea Sauerland (Vice President, Clinical Operations, Endotronix) regarding conducting clinical investigations in Ireland and the EU for both CE mark and FDA clearance/approval. There were some extremely interesting questions from the audience also, covering DPIA's, CRO's and top tips for conducting clinical investigations in Ireland. A short clip of the panel session can be found [here](#).

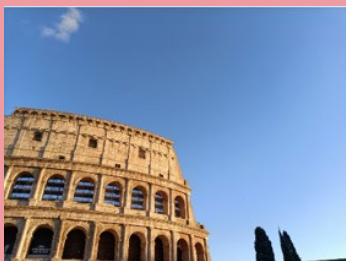


The **HRB NCTO MedTech Working Group** met on 12<sup>th</sup> of December and agreed the Terms of Reference for the group as well as the work plan for 2023. A busy and exciting year is planned for MedTech in 2023 and the working group are focused on increasing the number and quality of clinical investigations in Ireland and ensuring that Sponsors are aware of the MedTech supports and resources available to them through the NCTO and CRFs/CRCs.



## ECRIN SUMMER SCHOOL 2022

After three years, the ECRIN (European Clinical Research Infrastructure Network) Summer School finally returned for the 2022 edition, held on September 26<sup>th</sup> to 28<sup>th</sup> in Rome with Niall Hore, the European Correspondent for Ireland and his ECRIN colleagues joining together from all over Europe. Although Niall may have brought with him some Irish spring rain to the Eternal city, it did little to dampen the group's mood who were excited to step away from their computers and meet with colleagues for three days of workshops and learning in the heart of the beautiful Villa Borghese.



With a group of 30 colleagues spanning 18 nationalities, a main focus was to address working in multicultural teams and the unforeseen barriers of language, which was addressed through cross-cultural team building workshops. Learning about how different cultures play a role in a working environment was a great exercise and the workshops gave people an opportunity to share their experiences leading to fascinating insights.



Invited speakers engaged in dialogue with the ECRIN on staff on telemedicine, clinical trial distribution, patient advocacy and perspectives on patient engagement in clinical trials in Europe. The school also provided a great chance for the team to give feedback on the organisation as a whole, with sessions dedicated to induction for new staff, training materials available, suggestions for updates to the Quality Management System, and consultations on what are the next steps for ECRIN in the future.



The Summer School itself was hosted by ECRIN's Italian partner, ItaCRIN, who shared with us their unique insights to Roman life, providing suggestions on lesser-known sites to see, tips for visiting busy attractions, and of course, the best kept secrets of where to find the tastiest gelato and pizza in town. The hosts also delighted the group with activities after the days' sessions with a visit to the Galleria Borghese and a walking tour of the city at night on route to a restaurant of delicious Roman cuisine.

# Dementia Trials Ireland Launch 2022



27<sup>th</sup> of September 2022 saw the long-awaited launch of **Dementia Trials Ireland (DTI)**.

Taking place in the Naughton Institute, TCD, the launch began with a riveting performance by the Forget-Me-Nots choir directed by Norah Walsh. Mike Hanrahan, current GBHI fellow, singer with Stockton's Wing and member of the DTI Patient and Public Involvement (PPI) panel joined the choir for 'A River Rolls On' a song recorded for his mum Mary who had Vascular dementia. This moving performance was followed by Professor Iracema Leroi lead of DTI and Provost Dr Linda Doyle introducing DTI and setting the importance of DTI in context. Visiting Professor Martin Rossor joined them to wish DTI well with all its endeavours setting up clinical trials in Ireland. Professor Sean Kennelly, co-lead DTI chaired a panel discussion, before the event drew to a close. Panel discussion members included Professor Brian Lawlor, Professor Mary McCarron, caregiver Simon Murphy and politician Deirdre Heney who are both members of the DTI PPI panel and Bronagh Hayden from Biogen. The launch was organised by Karen Meenan, PPI and Comms lead for DTI, supported by Lara Gibney Network Coordinator for DTI. Dr Anne-Marie Miller, the newly appointed Senior Network Manager who started working with the Dementia Trials Ireland team in November was also present at the launch.

DTI has received funding for five years from the Health Research Board (HRB) to develop and expand dementia clinical trials in Ireland. The trials that are currently in place are small and DTI intends to not only expand but also include diverse types of studies, both pharmacological and non-pharmacological, suitable for all stages and sub-types of dementia. Imaging, biomarkers and neuropsychological methods will be used to assess healthy volunteers, carers, and people with dementia who take part in a trial. The aim of DTI is to improve the lives of those at risk of, or living with, dementia and that everyone has the opportunity to access clinical trials.

For further information please visit: [dementriatrials.ie](https://dementriatrials.ie)

# Dementia Trials Ireland Launch 2022

