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Health Research Board
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh
Enterprise Ireland

Health Research Board
NCTO
National Clinical Trials Office

Newsletter Christmas, 2023

Dear Reader,

A very warm welcome to the Christmas/Winter edition of our newsletter. It has been an exciting, busy and, at times, challenging year for us all but we're looking forward with optimism to bringing new health innovation to our community in 2024.

Our recent End of Year Meeting and Networking Event, 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 day and we would like to extend our sincere gratitude to all of you who attended and made it such a great event.

In this issue, we will also be spotlighting our Feasibility Programme and Michèle Cunnane, our Trial Platform Lead, who will be well known to many of you. We are very grateful to all of you who contribute to making it such a success and enabling us to connect Academic and Industry Sponsors with potential Investigators.

Moreover, our European Correspondent, Niall Hore, shares with us some of his recent work with our European counterparts via ECRIN (European Clinical Research Infrastructure Network).

Last, but by no means least, we will update you on some of the latest changes in the regulatory landscape of clinical trials in Ireland, with some crucial information for those involved in conducting clinical trials.

And, of course from all of us here at the NCTO team, Nollaig Shona Dhuit!

ncto.ie @HRB_NCTO ncto@ucc.ie

NCTO End of Year Meeting & Networking Event 2023

Dr Ana Terrés, of the HSE Research Office, provides updates on the ongoing commitment of the HSE to clinical research in Ireland

The NCTO was pleased to welcome collaborators and key national regulators from across the Irish Clinical Trials Landscape to our End Of Year annual networking meeting.

Our aim with this meeting was to bring together representatives and key regulatory stakeholders in the space to enable information sharing, networking and to increase awareness of all the great work being done by so many of the key organisations to deliver and enable high quality trials in Ireland.

Session 1:

Our first session of the afternoon consisted of presentations from each of the NCTO Team members regarding their various activities and on behalf of the key working groups that form the backbone of the NCTO national collaboration.

We heard from Dr. Robert O'Connor (Director, NCTO), Dr. Ruben Keane (Quality and Regulatory Affairs Manager), Evelyn Crowley (Data Analyst, NCTO), Niall Hoare (European Correspondent, NCTO & ECRIN), Olive O'Driscoll (Clinical Industry Liaison Officer, NCTO), Michèle Cunnane (Trial Platform Lead, NCTO) & Eoghan Cooke (Communications Officer, NCTO).

Session 2:

Our second session focused on 'The Evolving Governance & Regulatory Landscape' in Ireland. Important updates were provided by:

Dr Emily Vereker of the **National Office for Research Ethics Committees** (NREC), about their ongoing critical role in the Ethical oversight of trials.

Dates for your Diary

Rare Disease Clinical Trials Conference, 29 Feb - 1 Mar 2024

HSRPP Conference 2024, 25 – 26 April, UCC

HRB NCTO ICTD Conference, 9 May 2024

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

NCTO End of Year Meeting & Networking Event 2023

Dr. Ruben Keane, NCTO, delivers the latest on the regulatory landscape for Clinical Trials and Investigations.

Dr. Donal O'Connor, Barry O'Hea and Philip Kelly of the **Health Products Regulatory Authority** (HPRA) spoke in detail about Medicines & Medical Devices and the need for those involved in Clinical Investigations of these products to be in communication with the HPRA to ensure their products are meeting the necessary standards. The impending deadline for transitioning clinical trials approved under the older Clinical Trial Directive to the current Clinical Trial Regulations was also highlighted, to ensure that submissions are made sufficiently in advance.

Dr. Ana Terrés of **HSE Research and Development** lead the group through the details of the **HSE Action Plan** for Health Research that aims to embed research as part of health service delivery (among many other aims!).

To close out the session, Prof. Ivan Perry of CRF-UCC & NCTO, then delivered the latest on the Development of the IRG Governance Framework in the South/Southwest Hospital Group which is acting as a pilot for wider national health research governance changes.

Session 3:

Our third session was focused on Innovation & Evolution in Clinical Trials. With our first speaker, joining us from **HRB Clinical Research Facility - University College Cork** and **Irish Data Stewardship Network (Sonraí)**, Brendan Palmer, both entertaining and informing with his presentation entitled: "The Hitchhiker's Guide to Reproducible Research", which highlighted the crucial need for good data governance in clinical trials.

Jeremy Towns and Emer Guinan of CRF-SJH, then spoke about the ongoing efforts at **HRB Clinical Research Facility at St. James's Hospital**, Dublin to support Patient Engagement and PPI at every stage of the clinical trials process.

Faye Regan of **University College Dublin Clinical Research Centre**, shared her insights and wealth of experience regarding Trial Sponsorship.

NCTO End of Year Meeting & Networking Event 2023

Prof. Fidelma Dunne of the **HRB Clinical Research Facility at University of Galway** then delivered a fantastic case study entitled: "Supporting an Academic Research Study (EMERGE)". EMERGE is a key study, led by Galway examining therapeutic options for management of diabetes during pregnancy.

To close out this session, Siobhan Egan of the **Health Research Institute (HRI), University of Limerick** informed the group of their the HRI's ongoing efforts to build the Clinical Research Support Unit community.

Session 4:

Our fourth and final session was a panel discussion, chaired by our Director, Dr. Robert O'Connor entitled "The Ingredients that make Clinical Trial Networks work" with Panellists - Prof. Ray McDermott (**Cancer Trials Ireland**), Dr. Iracema Leroi (**Dementia Trials Ireland**) and Prof. Alistair Nichol (**Irish Critical Care Clinical Trials Network**) (all pictured bellow):

With such a wealth of experience and knowledge, the panel had a lively and interesting discussion covering everything from successes in the process of creating and managing a CTN to hurdles and roadblock that might face new and existing CTNs.

With Thanks:

We would like to sincerely thank every organisation and individual who contributed to the success of the day, we hope to see many of you again at our International Clinical Trials Day taking place on the 9th of May 2024 and look forward to continuing to create connections and foster the growth of the Irish Clinical Research Ecosystem.

Feasibility Spotlight

Michèle Cunnane, Trial Platform Lead

The **HRB NCTO National Study Feasibility Programme** connects Academic and Industry Sponsors with potential investigators in Ireland. Our study feasibility service is free of charge and aims to streamline the clinical trial investigator site identification and study feasibility process nationally, delivering consistency and efficiency in the process.

All therapeutic areas are covered by this Programme. For Non-Oncology, we connect with our partner CRF/Cs (**https://ncto.ie/clinical-research-facilities-centres/**) through dedicated feasibility co-ordinators who are based there. They offer these opportunities to research active investigators within their local networks/affiliated hospitals.

Where the indication of a proposed study falls under the remit of one of the HRB funded Clinical Trial Networks **https://ncto.ie/clinical-trial-networks/** HRB NCTO also contacts the relevant CTN to ascertain their interest.
For Oncology Studies, we collaborate with Cancer Trials Ireland and Cancer Clinical Trials Units across Ireland on those feasibility assessments.

Michèle Cunnane, Trial Platform Lead in HRB NCTO (pictured left), actively manages the National Study Feasibility Programme. She has over 25+ years' experience in Clinical Research, having previously worked in HRB CRCI, Cancer Trials Ireland (formerly ICORG), INEOS Healthcare, SRG Interesource Satellite Operations and IQVIA (formerly Quintiles) in various Data Management and Leadership positions.

To place a study feasibility service, email **trials-feasibility@ucc.ie** with supporting study supporting information/documents – see **https://ncto.ie/services/study-feasibility/** for further details.

The tradition of the **ECRIN (European Clinical Research Infrastructure Network) Summer School** continued this year with a twist with the first ECRIN 'AUTUMN' School taking place from November 27th to 29th. This year's event was extra special as note only did it take place in the new ECRIN offices on the beautiful Saint-Jacques Street, it also coincided with ECRIN celebrating 10 years since it was attributed the European Research Infrastructure Consortium (ERIC) legal status by the European Commission which enables Member country contributions which sustain the organisation's core.

ECRIN Autumn School 2023

The Autumn School was attended by **NCTO's Niall Hore, the European Correspondent for Ireland**, along with 14 other European Correspondents from the ECRIN National Scientific Partners and members from the core team based in Paris, the City of Lights.

Day 1 of the Workshop allowed the team to reconnect with their colleagues in person after countless hours of communication through emails and team meetings. Presentations were then provided by the core team giving insights on the importance of the EU Cross-border Trials Initiative (EU-X-CT), advancements in Platform Trial Methodologies & Designs and the role they play in multinational clinical trials, and an in-depth information/training session on the new EU funding, Lump Sum Model that will have a large impact in the sector moving forward.

Day 2 of the workshop focused on team building and learning to work with a diverse group on complex project. By listening to others' real-life experiences and concerns in the workplace, it highlighted the need to be considerate, and also to ensure that everyone has a voice and is entitled to share their opinions in a safe environment. These lessons can be brought forth in all aspects of life but can be the key ingredients to forming a thriving team and carrying out successful projects, especially when working with others in a distributed research infrastructure.

Day 3 of the Autumn school provided each member the opportunity to give feedback on how operations take place within the organisation, but also a chance to contribute to ECRIN ‘s goals moving forward and how they may be achieved. Though the workshop soon came to an end after three days of fruitful work, the trip to Paris that coincided with the Network Meeting (attended by NCTO Director Robert O’Connor), allowed a gathering of those who hold ECRIN close to their heart to attend a celebration of 10 years since obtaining ECRIN ERIC status, at the aptly named venue, Le Grand Coeur. Here we heard from ECRIN’s director, but also from those who were with ECRIN from the very beginning, contributed to its growth, and of course played its role in obtaining its ERIC status.

ECRIN CTU Day 2023

The ECRIN online CTU Day 2023 took place on December 4th, 2023. The annual event is open to Clinical Research Facilities and Centres from ECRIN member’s national partner networks. The programme this year provided updates on ECRIN activities such as new project involvement and data centre certification, updates on the latest developments with the Clinical Trials Information System from a CTIS Sponsor Product Owner, and a presentation on Data Fairness principles and how to apply them. There was also added Irish interest at the event this year as NCTO’s Niall Hore, (pictured right) the European Correspondent for Ireland, was invited to speak on the structure and work carried out by the National Clinical Trials Office.


Niall Hore, NCTO European Correspondent for Ireland

Transitioning trials to CTR/CTIS - Beat the last minute rush!

Both the **European Medicines Agency (EMA)** and **Irish Regulator (HPRA)** have issued reminders to clinical trial sponsors re transitioning clinical trials to the **Clinical Trials Regulation (CTR)** via **Clinical Trial Information System (CTIS)**.

Your trial needs to be transitioned if:

- It was authorised under the Clinical TrialsDirective (CTD)
  AND
- Is likely to be ongoing beyond **30 January 2025**

HPRA advise Sponsors to transition their trials by October 2024 to allow for review and assessment time. Only approx. 390 transitional trials had been submitted to CTIS by October 2023, out of an estimated 4,000 - 6,000 trials.
Guidance to Sponsors is available le on the **CTIS website** (under the section “Transitioning Trials”)

Annual HPRA/NCTO Compliance Meeting

Meeting took place at HPRA offices on 23 November 2023. This hybrid meeting was attended by members of the **NCTO Quality working Group and Pharmacovigilance working group** and by several **HPRA** and **NREC** staff.
NCTO working group attendees included representatives from CRF-UCC, CRF/SJH-TCD, CRF- RCSI, CRC-UCD, CRSU- UL, CRF- NUI Galway, R+D NUI Galway, Childrens Health Ireland, Cancer Trials Ireland, Infant Centre UCC, Dementia Trials Network.
This annual meeting is a regulatory highlight of the HRB-NCTO calendar. It gives CRF/C staff (and associated members of the QWG and PvWG) the opportunity to meet the regulators face to face and get advice/ guidance on compliance issues. Many thanks to Anne Hayes - Inspection Manager, Lorcan Gregorian GCP/PV Inspection Manager and Christine Prendergast GCP/PV Inspector at HPRA for hosting the event and for the time and preparation given to the answers to the compliance questions.
We hope to include the Questions and Answers on NCTO website in the New Year by kind permission of the HPRA.

HPRA publish their Annual Report for 2022

HPRA’s key activities included:

- 529 new human medicines were authorised
- 64 applications were issued for clinical trials of human medicines
- The HPRA received 10,918 suspected adverse reaction reports for human medicines
- 199 medical device economic operators registered by the HPRA on the national database

See the full report for more details: **HPRA publishes 2022 Annual Report**

Ecosystem Updates

CRF MANAGER

CRF Manager: From 01 January to 30 November 2023, 333 CRF Manager queries were addressed. During this same time period, 6,059 visits were recorded, reflecting a 26% growth compared to the corresponding period in 2022. Additionally, recruitment was recorded at 1,615 participants, marking a 48% increase from the same period in 2022.

MEDTECH

The Clinical Industry Liaison Officer and NCTO team launched a new Website in September **(Medtech Support - HRB NCTO | Health Research Board - National Clinical Trials Office**) and now the Medtech Toolkit is also available for download here**: Medtech Toolkit - HRB NCTO** | Health Research Board - National Clinical Trials Office

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