HRB NCTO Newsletter

It's hard to believe we are already midway through 2022! It has been a busy 6 months for the NCTO with many developments some of which are reported on here. All NCTO services are operational with our full team now in place.

In this newsletter we are delighted to introduce you to our latest team members - Olive O'Driscoll as Clinical Industry Liaison Officer supporting MedTech research and Niall Hore as ECRIN European Correspondent for Ireland (read more about Olive and Niall's roles later in this newsletter). The HRB NCTO International Clinical Trials Day event on May 12th was a huge success with a report of the day and links to all presentations included in this newsletter. Irish representatives attended the EU Stars meeting in May (see summary report of the event by Dr Ruben Keane, NCTO QRAM). We are looking forward to joining the UK CRF Network at their upcoming annual conference in Bournemouth on July 14th and 15th; details on how to register are also included here.

In our series on promoting the Clinical Trial Networks we showcase the Irish Critical Care Clinical Trials Network in this Newsletter. The ICC-CTN has delivered an impressive portfolio of important clinical research since it was established in 2015 – see here a summary report on their important work to date.

Wishing all a happy and safe summer break and looking forward to catching up again in our Autumn Newsletter.

Best Wishes,
Fionnuala

Dr Fionnuala Keane, Manager NCTO

HRB NCTO INTERNATIONAL CLINICAL TRIALS DAY EVENT MAY 12TH 2022

The **HRB NCTO International Clinical Trials Day event** was hosted on May 12th, 2022, on-line via Zoom. The theme for this year's event was "Clinical Research in Ireland 2022", supported by the HRB with contributions from Bayer, GSK, IQVIA and Sanofi.

The event consisted of a speaker session in the morning followed by a panel discussion in the afternoon. The event also launched a Calendar of Events from around the country which showcased the activities that were ongoing around the country to celebrate International Clinical Trials Day 2022. (HRB NCTO ICTD Calendar of Events 2022)

Approximately 230 people attended the on-line conference with feedback questionnaires extremely positive - 91% rating the conference as excellent or very good!

Prof Joe Eustace, Director of NCTO chaired the event with Dr Mairead O Driscoll, Chief Executive, Health Research Board and Garrett Murray, Head of Life Sciences, Enterprise Ireland delivering the opening addresses of the day. Mairead focused her presentation on the significant investments made by the HRB in Ireland's clinical trial capacity – over €100 million since 2010 and Gareth focusing on the opportunities for success that exit at the intersection between Irish Industry and the Irish Clinical Research System.

Dr Fionnuala Keane, Manager, HRB NCTO provided an update on HRB NCTO and ECRIN activities, with the HRB Clinical Trial Networks and PPI Ignite showcased in the mid-morning session.

There was also a panel session in the afternoon titled, "Opportunities to improve the Irish Research Ecosystem" with representatives from the Health Research Board (HRB), Health Service Executive (HSE), National Research Ethics Committee (NREC), Health Products Regulatory Authority (HPRA), Health Research Data Protection Network (HRDPN), National Clinical Trials Office Clinical Industry Liaison Officer, industry, patients and investigators. This session included discussions on how we can increase patient involvement across the whole process of clinical research, the impacts of the

varying requirement for Data Protection Impact Assessments (DPIA's) and their institutional review and the challenges facing Clinical Investigation for medical devices in Ireland at present among other topics.

Of significant interest on the day was the Keynote addresses by Dr Eoghan De Barra, Beaumont hospital/RCSI, Consultant in Infectious Diseases and Senior Lecturer at Beaumont Hospital / RCSI, who spoke about COVID 19 Clinical Research and Irelands experience and by Dr Ruben Keane, NCTO Quality and Regulatory Affairs Manager who discussed the changing landscape of Clinical Research in Ireland.

The purpose and importance of the event was to promote Ireland as a potential leader in clinical research internationally and to showcase ongoing trials led by Irish Investigators and Researchers, in many cases, funded by the HRB with national and international collaborations.

The event was recorded live, all of the recordings from the event are available through this link: HRB NCTO International Clinical Trials Day Event 12th May 2022 Playlist

SAY HELLO TO NEW HRB NCTO TEAM MEMBERS

We are delighted to welcome Ms Olive O'Driscoll, Clinical Industry Liaison Officer (CILO) to the NCTO team.

Olive is a biomedical engineer who trained in the NHS and then moved on to work in the UK and Ireland in medical device clinical research and regulatory affairs both in industry (e.g. Medtronic Cryocath, Crescent Diagnostics) and academia (e.g. University College London).

She held senior management positions in medical device and pharmaceutical regulated clinical trials in Ireland, Europe and USA across multiple therapeutic areas including oncology, ENT, diagnostics, cardiovascular and rheumatology. She founded Irish medical device start-up AventaMed in 2013 and led the company as CEO, raising over €5m in investment and growing the company from prototype/concept stage to commercialisation. This involved conducting multiple clinical investigations (in EU and USA), FDA pre-submission meetings and IDEs in USA, and regulatory approval of the device, which is now commercial in Europe.

She joined NCTO in April 2022 and will work with medical device companies in Ireland to help them navigate the clinical research landscape and supports available. Olive is very

much looking forward to meeting with medical device companies that are interested in conducting clinical investigations in Ireland, now or in the future.

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We are also delighted to welcome Niall Hore, European Correspondent (EuCO) to the NCTO team.

With a background in research, Niall holds a Bachelor of Science Degree in Energy from the University of Limerick and a Higher Diploma in Biopharmaceutical and Medical Device Manufacturing from the Technological University of Dublin. After spending four years working in Canada and New Zealand in the finance industry, Niall returned to Ireland and joined MaREI, a centre for Energy, Climate and Marine research where, as a Research Support Officer, he was responsible for the co-ordination of cross-institutional programme plans, building close working relationships with industry partners and implementing effective project management standards.

HRB NCTO is the scientific partner for Ireland to ECRIN and Niall, having just joined NCTO in June, as the European Correspondent for Ireland, will play a pivotal role in the coordination of the activities and strengthen the interaction between ECRIN, the HRB NCTO and the partner CRF/C's, in order to facilitate and support participation in European multinational collaborations. Niall will act as the key contact point in Ireland for ECRIN and the network of European Correspondents in other ECRIN countries while also providing advice to national investigators and sponsors wishing to develop multinational studies in Europe and support to foreign investigators and sponsors wishing to undertake clinical research studies in Ireland.

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EU STARS
STRENGTHENING TRAINING OF ACADEMIA IN REGULATORY SCIENCE

STARS is a collaboration of 21 partners from 18 countries including the majority of the European National Competent Authorities (NCA) and the EMA which focuses on strengthening training of academia in Regulatory Science. NCTO CRF/Cs have been involved in the project since its inception and several members of the NCTO-Quality working group attended the STARS meeting in Brussels on 19th May 2022 to hear about the achievements and recommendations of the project.

Some of the major outcomes of the project are:

- A comprehensive inventory of existing support activities for academic investigators/ trial staff Comprehensive Inventory - Stars (csa-stars.eu)
- Three Pilot projects which demonstrated that regulatory support activities can be implemented efficiently Pilot Projects - Stars (csa-stars.eu)
- A white paper listing STARS recommendations to the various stakeholder groups: NCAs, Academic researchers and institutions, EU ministries and funders, Industry. STARS_Common_Strategy.pdf (csa-stars.eu)
- Core and Comprehensive Curricula for development of basic and more in-depth training courses in Regulatory training for Clinical trials, by academic institutions STARS Curricula - Stars (csa-stars.eu)

Rabia Hussain, Head of Trial Operations and Associate Director UCD Clinical Research Centre, delivered an excellent presentation on 'The needs of academic medicine developers' and Laurance O'Dwyer, Scientific Affairs Manager, HPRA co-chaired the panel session on 'Facilitating the Translation of Academic Research into Clinical Practice – How to Move Forward'

Image 1: Rabia Hussain, Head of Trial Operations & Associate Director at UCD Clinical Research centre
Image 2: Members of HRB_NCTO Quality Working Group: Shane Feeney, Emma Deenihan, Ruben Keane, Mandy Jackson & Kevin Keohane

Investigator Led/Academic trials play an essential role in the development of medicines, vaccines and medical devices, however there is a large translational gap between academic research and reaching the patient. The STARS project aims to help reduce this gap and enable the academic research to pass the scrutiny of the regulators and to reach the patient population.

In order to bridge the 'valley of death' between academic research and getting the finished medicine/device to the patient what is needed is:

- early engagement by researchers with the regulatory authorities – pre grant application
- awareness by researchers of the many **existing** regulatory supports available -e.g scientific advice
- education of researchers and support staff on regulatory affairs and pathways to EU approvals of medicines and devices
- engagement with funders and inclusion of costs of regulatory support in grant applications

Further information on EU STARS can be found at: Welcome to STARS! - Stars (csa-stars.eu)

CLINICAL TRIAL INFORMATION SYSTEM (CTIS) AND PLATFORM TRIALS

Clare Foley, Assessor at HPRA kindly provides some background and clarification to a point raised by NCTO QRM, Ruben E. Keane, in Spring NCTO Newsletter.

Broadly speaking there is not a functional issue in terms of the CTIS database's ability to support platform trials. In order to increase flexibility for the conduct and governance of complex/platform trials, sponsors can consider the submission of a single, shared master protocol in the primarily submitted 'reference' trial, for which the submitted protocol would contain the common master protocol part and at least one of the sub-protocols. The sponsor can then make the submission of the different sub-protocols as separate clinical trial applications (CTAs) under different EU-CT numbers once the "reference trial" with the Master Protocol has been authorised. The biggest advantage of such submission strategy would be that any change to the master protocol part could be implemented through the submission of a single substantial modification application to the reference trial dossier and sub-protocol specific substantial modifications could be submitted without undue delays.

See recently published Q&A on Complex clinical trials Q 1.3 for further information.

SPOTLIGHT ON

HRB IRISH CRITICAL CARE-CLINICAL TRIALS NETWORK

Irish Critical Care Clinical Trials Network

The ICC-CTN established in 2015, led by Professor Alistair Nichol, has developed a pipeline of high-quality intensive Care Unit (ICU) research within Ireland.

Beginning with just two staff members, the team has grown to over nine members, which have been involved in the coordination of over 17 ICU clinical trials to date, with a further 8 preparing to begin in ICUs across the country (as of June 2022).

The expansion of the ICC-CTN has seen global trials roll out in ICUs throughout Ireland and has put Irish patients at the forefront of global COVID-19 research. This research has led to a variety of high-impact publications and findings that have improved the survival and recovery of ICU patients across Ireland. Our recent Thought Leadership Film captures our journey to date.

ICC-CTN thematic research priorities

Supported by the Health Research Board (HRB), the ICC-CTN reacted to the COVID-19 pandemic in real time by conducting trials nationally which helped to discover the most effective way to treat critically ill patients in the ICU, collect crucial data on patients admitted to the ICU due to the COVID-19 virus and sequence the genomes of those who had a critical reaction to the virus. These trials included GenOMICC, SPRINT-SARI and REMAP-CAP. The ICC-CTN's coordination of these trials in Ireland and beyond resulted in the award of the 2022 Research Impact award from UCD, with the results of these trials being incorporated into treatment guidelines issued by the HSE and WHO and changing clinical practice globally.

Other HRB ICC-CTN thematic research priorities include out of hospital cardiac arrest, trauma, and respiratory failure, as well studies currently being carried out on ICU nutrition,

which is a novel area of research that is yet to be reported on and often overlooked within the research space.

Our Objectives

After receiving a renewal of funding from the HRB CTN-2021 award scheme, the network has begun the implementation and expansion of projects and activities including PPI, Training, Education & more. They have defined their goals for the future of the network as to:

- **Continue to conduct world-leading studies**. Following on from previous high quality clinical trials conducted in Ireland and worldwide, that have helped to guide patient treatment and improve outcomes in the critically ill.
- **Build on the ICC-CTN reputation as a world leading ICU trial co-ordination centre**. Having successfully established itself as a national hub for Irish ICU research co-ordination, it will continue to develop our network of collaborating European ICU's to allow us to deliver our trials on time and on budget.
- **Expand the ICU network infrastructure and research portfolio**. The ICC-CTN has received both national and international research funding that have allowed it to expand its collaborations in Ireland and internationally. This momentum will be used to increase geographical scope, broaden the types of research being carried out and grow the network team.
- **Support the next generation of clinicians/scientists**. Training and educational opportunities will continue to be provided to clinicians and researchers throughout Ireland to support their professional development and develop a pipeline for future research leaders.
- **Deliver novel research methodologies at the bedside and learn about how research is conducted.** Carrying out research on how clinical trials are currently being conducted, with an aim to improve both the quality and methods used.
- **Put a focus on the patient's voice.** By involving patients and their families in research activities to ensure its relevance to the population, by reflecting their experiences and by making research both accessible and easy to understand for all. We have national (Irish Critical Care-Public and Patient Involvement; ICC-PPI) and international PPI groups and a program of public engagement research

The **HRB ICC-CTN** will continue to co-ordinate high quality and high impact trials to improve the outcomes of our patients and reduce the burden of critical illness on these patients, their families and Irish society as a whole.

UK CLINICAL RESEARCH FACILITY NETWORK

16TH ANNUAL CONFERENCE - COLLABORATING FOR SUCCESS
14TH & 15TH JULY 2022

The conference is expected to attract over 400 delegates from across the UK's experimental medicine infrastructure and will take place at the Bournemouth International Centre; a perfect venue to host a thriving exhibition area, showcase fascinating national speakers, networking, and knowledge sharing.

The theme highlights the importance of collaboration between our healthcare system, universities, and partner organisations, which is key to both clinical research delivery and access to experimental medicine and early phase studies. The conference will explore how we can use collaboration to improve research outcomes that links BRCs, ECMC, Hospitals, Universities, and all of our partners, while also providing opportunities for extended interactive learning sessions on a variety of important topics and activities such as wellbeing and mindfulness.

Please visit the UKCRF Network conference page for more information, including the conference programme and registration. Deadline registration is Friday 24th June.

GENERAL INFORMATION

General Enquiries: ncto@ucc.ie **Feasibility Programme**: trials-feasibility@ucc.ie

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