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**HRB** Health Research Board



**UCC**

University College Cork, Ireland  
Coláiste na hOllscoile Corcaigh



**Enterprise Ireland**



Health Research Board

**NCTO**

National Clinical Trials Office

## Newsletter Summer, 2024



Dear Reader,

A very warm welcome to the Summer edition of our newsletter. It has been a busy time in the Irish Clinical Trials Sector. We held our flagship International Clinical Trials Day conference in May, where we were delighted to see many of you in attendance.

In this issue, we will share with you some of the highlights, images and insights from the conference, which was held in the spectacular O'Reilly Hall, UCD.

The focus on 'Advancing Healthcare in Ireland through Clinical Research' was underscored by the rich interactions and networking opportunities that only an in-person event can provide. A highlight was the keynote address by Lord James O'Shaughnessy, whose insights from the UK Clinical Trials ecosystem provided valuable lessons applicable to the Irish sector.

Moreover, as part of our ongoing series highlighting our various supports and offerings, this edition we focus on Clinical Industry Liaison Officer (CILO), Fiona Ryan, with over 20 years' experience in the sector, she has been a fantastic addition to our team and as a dedicated Medtech expert, she is key to the NCTO and Enterprise Ireland's ongoing commitment to support the booming Irish Medtech sector.

Sincerely,  
The NCTO Team



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# HRB NCTO ICTD 2024

Each May, we celebrate the inception of modern clinical trials by James Lind, and this year was no exception, with several hundred stakeholders, researchers and triallists from across the Irish health sector and beyond joining us at O'Reilly Hall, UCD.

With a focus this year on 'Advancing Healthcare in Ireland through Clinical Research' we decided on an in-person event to maximize the networking potential of this keystone event.

With almost 300 attendees registered, this event was our largest ICTD conference to date.



A Full House at O'Reilly Hall, UCD



Lord James O'Shaughnessy, Keynote Speaker

A highlight was the keynote address by Lord James O'Shaughnessy, who shared many of his learnings and insights from his detailed knowledge of the Clinical Trials ecosystem in the United Kingdom, with many of the lessons learned being applicable to the Irish sector.

The subsequent panel session chaired by Professor Peter Doran, UCD CRC, on international learnings underscored the importance of global perspectives in enhancing our research activities.

Our sessions on 'Innovation' and 'Innovators,' chaired by Professor Paul McNally, CHI CRC and our own Michèle Cunnane, respectively, highlighted the groundbreaking work being done in clinical research. The presence of national stakeholders from various sectors (HSE, HRB and many more) reinforced the collaborative spirit on display.



Dr. Mairéad O'Driscoll, Chief Executive, Health Research Board





(L-R) Lord James O'Shaughnessy, Keynote. Prof. Wan Fai Ng, CRF-UCC, Dr. Muiris O'Connor, Department of Health. Prof. Peter Doran, UCD CRC.

This event was more than just a conference; it was a celebration of our many fantastic network partners and the fruits of collaboration. A heartfelt thank you to all speakers, panelists, attendees, and various partners. Together, we showcased the immense potential of clinical trials in transforming healthcare.

Thank you all for making this day a resounding success.

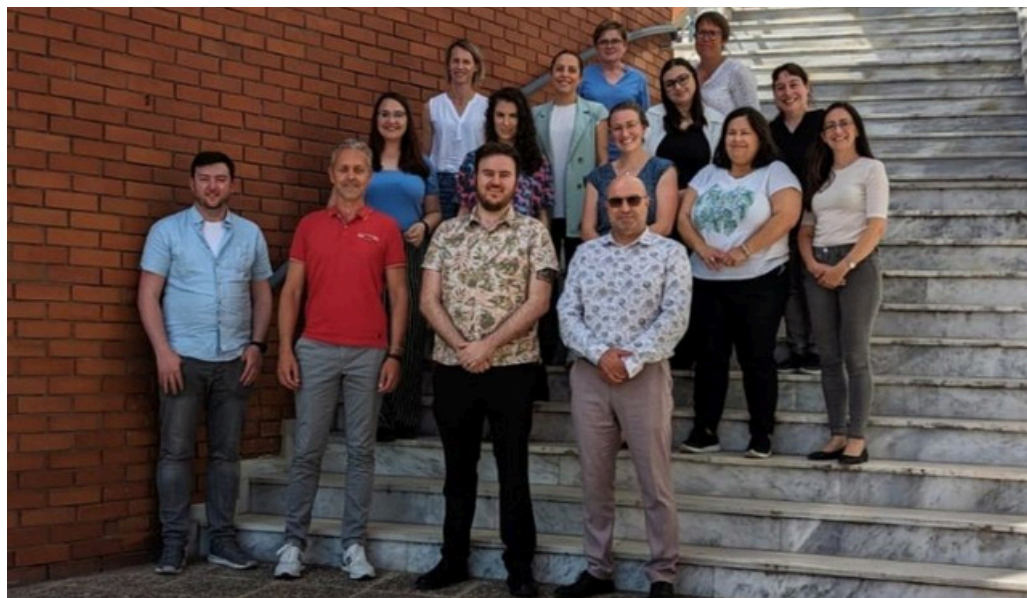


To celebrate International Clinical Trials Day (ICTD) 2024, ECRIN co-hosted with its Greek scientific partner, GRECRIN, a number of events in Thessaloniki, Greece over May 22nd-24th, including the ICTD conference.

Launched in 2005, the event provides the opportunity for organisations, clinical research professionals, and the public to acknowledge the achievements that result from clinical research and allows representatives from across Europe to discuss novel ideas and issues relating to multinational clinical trials.

This year, the discussions and presentations focused on Data Centric Clinical Research, with the event attended by two of NCTO's representatives, Niall Hore the ECRIN European Correspondent for Ireland, and Eoghan Cooke, Communications Officer for NCTO.

To kick off, Eoghan and Niall attended the first in-person meeting of the Communications Working Group, where insights were shared by each member country, with a vast variety of experiences and perspectives, it was a fantastic opportunity to learn and discuss.



**Communications Working Group.**

Over the course of the day, delegates from all over Europe listened to presentations from a wide array of speakers, covering topics such as the use of real-world data VS real-world evidence, the challenges and complexities of implementing novel approaches, and also the uses and potential capabilities of using AI tools as digital solutions in clinical trials.

## Dates for your Diary

**UKCRF Network  
Annual Conference**  
**4 - 5 July 2024**  
**Leicester**



**3rd BioBANC  
Symposium**  
**6 Sep 2024**  
**University of  
Galway**



**International Clinical  
Trials Methodology  
Conference**  
**30 Sep – 3 Oct 2024**  
**Edinburgh**



**16th Annual IRNM  
Conference**  
**28 Nov 2024**  
**RCSI**



**If you would like your  
event featured here in  
future newsletters, email  
[ncto@ucc.ie](mailto:ncto@ucc.ie) and we will be  
happy to accommodate.**



With a variety of delegates from different sectors relating to clinical trials, an emphasis was made this year on opening dialogues where discussions were encouraged after each presentation through panel discussions and the use of interactive tools like SLIDO to give everyone in attendance a voice, leading to interesting debates and discussions on differing viewpoints.



Director General, Prof. Jacques Demotes Opens the Conference.

Overall, it was a lively, informative and highly productive event and a fantastic showcase of what is possible when we co-operate openly and enthusiastically with our European partners.

Next year's event will be held in Madrid, on May 20th, co-hosted Spanish national partner SCReN. It promises to be a truly special edition as well, as it celebrates ICTD's 20th anniversary! Save the date and see you there!



## ACT EU

The **Accelerating Clinical Trials in the EU** (ACT EU) initiative is launching two advice pilots aimed at improving the quality of applications for clinical trials, the foundation for the development of safe and effective medicines in Europe.

The first pilot offers developers of medicinal products advice on clinical trials and requirements for marketing authorisation applications (MAA). This pilot consolidates the views of EMA's **Scientific Advice Working Party** (SAWP) and HMA's Clinical Trials Coordination Group (CTCG) to minimise avoidable divergences. It is the first time that both entities are providing joint scientific advice on clinical trials.

The second pilot provides technical and regulatory support on the dossier of a clinical trial application (CTA) prior to its submission through the **Clinical Trials Information System**. The pre-CTA pilot will provide consolidated views between different member states on pre-submission topics.

More details and information on how to apply are available in the **news announcement** and the **ACT EU website**.

# Events



## UK Clinical Research Facility Network 19th Annual Conference

“Making the invisible, visible:  
addressing equal access to clinical research”

**Thursday 4th to Friday 5th July 2024**

Hosted by NIHR Leicester CRF

Registration is now open!

For more, see the [Full Programme](#) & [Conference Website](#)

## Start-Up day 2024



The CILO and Director attended the Enterprise Ireland Start-Up Day 2024 at the Printworks, Dublin Castle on 14th May demonstrating the strong pipeline of promising, innovative and export-focused entrepreneurs located throughout the country. In 2023, 26 companies were spun out of third level institutions, 16 of which were supported through the Enterprise Ireland

Commercialisation Fund Programme. This very successful event showcased pioneering entrepreneurs who have benefited from a range of support programs, including High Potential Start-Up, Pre-Seed Start Fund, and New Frontiers. Featuring a conference format, 10 teams spinning out from research, pitched their “Big Idea”, with the best pitch awarded to LaNua Medical for their GateKeeper Embolization Device. NCTO staffed an information stand detailing its support services, which attracted a large number of attendees.



# ICTMC 2024

7th International Clinical  
Trials Methodology  
Conference.  
Edinburgh. UK  
30 Sep - 3 Oct

ICTMC is the leading international platform for researchers and practitioners to present the very latest in trials methodology research and we are excited to provide further details about our keynote speakers for this year's conference.

Visit the conference website to find out more about the speakers and their presentations. Don't miss out on the conversation, make sure you register for ICTMC 2024 today: [register here](#).

Submit an Abstract:

Prospective authors are invited to submit a title and maximum 400 word abstract in electronic form, according to the [guidelines](#). The deadline for submission is Tuesday 30th April, with notification to authors being sent out during the week beginning Monday 1st July.

The Health Research Board – Trials Methodology Research Network (HRB-TMRN) has launched a **Travel Bursary for Irish Researchers**, including PhD students, who wish to attend ICTMC 2024. Find out more [here](#).

The poster for the BioBANC Symposium III is primarily maroon with white text. It features a QR code on the left and a photograph of a person in a lab coat and gloves working with a sample on the right. The text includes the event title, date, location, time, and a free registration link. Logos for the University of Galway, BBMRI-ERIC, and the National Breast Cancer Research Institute are at the bottom.

**BioBANC Symposium III**  
*SAVE THE DATE!*

 **6<sup>th</sup> September 2024**

University of Galway | 10am-4.30pm

Free Registration <https://forms.office.com/e/2L6Tbdw3L3>

 OLLSCOIL NA GAILLIMHE  
UNIVERSITY OF GALWAY

 BBMRI-ERIC

 NATIONAL BREAST CANCER  
RESEARCH INSTITUTE

 Ollscoil na Gaillimhe  
University of Galway

 An Institiúid de Thriailaíocht Cliniciúil  
Institute for Clinical Trials

**3rd BioBANC Symposium “BioBANC na Gaillimhe  
6th of September 2024 (10:00 a.m. – 4:30 p.m.)  
University of Galway**

This year's event will consist of workshop to jointly discussing the Roadmap for Biobanking in Ireland together with the Irish community. Following an introduction to BBMRI-ERIC, the European research infrastructure for biobanking. This will be followed by an afternoon session on Quality Matters.

Please use [this link](#) to register for this event.

# CILO Spotlight



Fiona Ryan, Clinical Industry Liaison Officer (CILO)

The NCTO has a dedicated Medtech expert, Ms. Fiona Ryan, funded by **Enterprise Ireland** – the **Clinical Industry Liaison Officer (CILO)**.

Fiona brings over 20 years of industry expertise, backed by a Master of Business Studies (MBS) in Strategic Management and Marketing, and a Bachelor of Arts (B.A.) in European Studies from UCC. She embarked on her career at the European Parliament before managing the European Commission's European Information Centres at Enterprise Ireland's Dublin and Waterford offices. In this capacity, she facilitated industry stakeholders' access to pertinent EU information. Transitioning to IDA Ireland's South West office, Fiona assumed the role of Regional Executive, developing and leveraging strong relationships across clients, service providers and stakeholders at a local level to support the continued growth and economic development of the South West region through FDI.



In her private sector tenure, Fiona has specialised in Quality Assurance and Regulatory compliance, initially within the FMCG sector and later transitioning to the healthcare and medical technology industries with her most recent position at Stryker Corporation.

As Clinical Industry Liaison Officer, Fiona supports Medtech companies and entrepreneurs to navigate the clinical research landscape and the many supports available in Ireland. The CILO supports include education, outreach services, such as the Medical Device Toolkit, and advice and support on regulatory requirements, including the Medical Device Regulations (MDR) and In Vitro Diagnostic Regulation (IVDR) changes.

If you are developing a Medtech or diagnostic device and would like to network with others in the sector or have any questions about conducting clinical investigations in Ireland, please get in touch with Fiona at [ncto@ucc.ie](mailto:ncto@ucc.ie).



## CILO Supports:

- Clinical Research Infrastructure Capabilities
- Comprehensive **Medtech Toolkit**
- Medical Device Regulations (MDR)
- InVitro Device Regulations (IVDR)
- Networking Support and Connecting with State Supports
- Education and Outreach services
- Benchmarking Advice



# News From Across the Network



Tallaght University Hospital (TUH) has just launched its first ever - five year, Research & Innovation strategy. It includes plans for a new state of the art **Innovation Centre** and **Clinical Research Facility**, on their main campus.

Find the full document [here](#).



Congratulations to **Professor Fidelma Dunne**, Director of the **Diabetes Collaborative Clinical Trial Network**.

Professor Dunne was induced into the Royal Irish Academy alongside 27 other members, these newly elected Members were officially admitted to the Academy, for their exceptional contributions to the sciences, humanities and social sciences, as well as to public service.

# Announcing the Launch of the Tripartite Model Clinical Trial Agreement (CTA): A Message from the HSE



We are delighted to announce that the HSE in partnership with the Irish Pharmaceutical Healthcare Association (IPHA) has officially launched the standardised site contract—the Model Clinical Trial Agreement (CTA)—for tripartite clinical trials involving Contract Research Organisations (CROs).

This significant development, marking International Clinical Trials Day, aims to improve the clinical trial landscape in Ireland, further enabling patients to participate in cutting-edge health research.

The Model CTA, agreed upon by both the HSE and the IPHA, is designed for use between the Site, the CROs, and the Sponsor. Following extensive review by CROs, IPHA member companies, the HSE, and other dedicated stakeholders, this standardised document ensures fairness and balance. The introduction of a single standard clinical trial agreement for Ireland will reduce delays and costs for hospitals and companies, increase efficiencies, and enable more timely setup of trials in Ireland, thereby significantly improving patient health outcomes.

The Model CTA is standardised and therefore changes to the standard text in the document are not permissible. It must be used for any Model CTA contract negotiations with CROs commenced after 20.05.24. However, if discussions have already commenced on a CTA before 20.05.24 then the Model CTA will not be mandatory.

We would like to thank all of the contributors who helped in developing this agreement in particular Comyn Kelleher Tobin Solicitors, the State Claims Agency, and the Department of Health, who all share in our dedication to improving the clinical trial infrastructure and improving health outcomes in Ireland

The Tripartite Model CTA is **[available to view on our website](#)** or to **[download here](#)**.

We would sincerely appreciate it if you could share the announcement with any of your interested colleagues.

Kind Regards,  
National Office, HSE Research and Development Department  
Please send queries to  
**[researchanddevelopment@hse.ie](mailto:researchanddevelopment@hse.ie)**

## HPRA Publish IVDR Transitional Provisions

To support the supply of IVDs to the EU market, Articles 110 and 113 of the IVDR set out a number of transitional provisions (TPs). Full details can be found **[here](#)**.





SUPPORTED  
BY THE  
HEALTH  
RESEARCH  
BOARD



**JOIN  
NOW**

## **JOIN THE IRISH RESEARCH NURSES AND MIDWIVES NETWORK TODAY!**

Did you know the IRNM offers peer support, education and professional development resources to research nurses and midwives, and to research assistants and allied health professionals?

12 months full membership is only €40 and €25 for undergraduate nurse or midwife students.

Members enjoy access to free education resources and reduced conference, together with reduced masterclass and summer school entry fee!

SCAN ME TO  
JOIN TODAY



## **SAVE THE DATE !**

**IRISH RESEARCH NURSE AND MIDWIVES NETWORK  
16TH ANNUAL CONFERENCE**

**BUILDING RESEARCH CAPACITY IN IRELAND:  
THE ROLE OF THE RESEARCH NURSE/MIDWIFE**

**Thursday 28th November 2024  
RCSI University of Medicine and Health Sciences**

[www.irnm.ie](http://www.irnm.ie)





## Interested in becoming an NREC member?

Our colleagues at the National Office for Research Ethics Committees have just launched a rolling call for expressions of interest for new members of our Committees that review:

- Clinical trials for investigational medicinal products for human use (NREC-CT A, B, C & D)
- Clinical investigations of medical devices (NREC-MD)
- Performance studies of in vitro diagnostics (NREC-MD)

Being a member of NREC is an exciting opportunity to support Irish health research at a national level, to gain insight into forefront health developments, and to ensure that Irish research is strengthened by the highest ethics standards.

Find out more on their website: <https://www.nrecoffice.ie/committees/become-a-member/>

## Minister for Health publishes 'Digital for Care: A Digital Health Framework for Ireland 2024-2030'

Minister for Health Stephen Donnelly has launched 'Digital for Care: A Digital Health Framework for Ireland 2024-2030'. This framework sets out a roadmap to digitally transform health services in Ireland and improve access for patients.

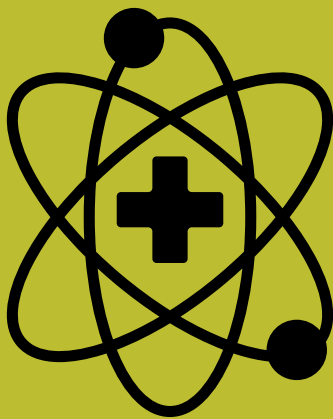
This year will see the roll-out of a patient app that will provide people with important medical history and records. Next year will see the rollout of a 'Shared Care Record' to integrate patient records no matter what part of the health service they engage with. A longer-term deployment of Electronic Health Records (EHR) is also included.

Find out more [here](#).



## REG & ETHICS

HSE Research & Development are establishing and supporting a Community of Practice for Research Ethics Committees (RECs) and are inviting REC Managers to join. Find out more [here](#).



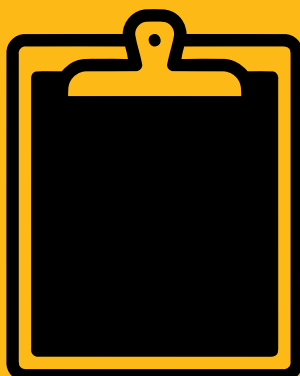
## MEDTECH

The HPRA public consultation on a draft guide for health institutions who manufacture and use in-house in vitro diagnostic medical devices in Ireland was finalized on 26 January 2024. Find out about the outcome [here](#).

## CONNECT WITH US

We have recently been publishing several series of articles that might be of interest to our Newsletter readers. They cover much of the work in with NCTO engages, including out various supports.

[Read more](#)



## 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](mailto: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](mailto:ncto@ucc.ie)