

Newsletter Highlights

NCTO ICTD Event

ECRIN ICTD Event

EMA Publications

Rare Disease CTN

Ecosystem Updates



Health Research Board

NCTO

National Clinical Trials Office

Newsletter Spring, 2023



It has been a busy first few months for the NCTO with planning for our first in-person International Clinical Trials Day (ICTD) Conference in recent times well underway amongst many other activities.

ICTD 2023 Conference will be held in the Royal College of Surgeons, St Stephen's Green, Dublin 2 on Wednesday May 10th. Registration for this event will open in April and we are delighted to reveal that our Key-Note speaker will be Dr Marianne Pilgaard (CEO Trial Nation, Denmark).

Continuing our series of promoting HRB funded Clinical Trial Networks, in this newsletter, we showcase the Rare Disease Clinical Trial Network, Ireland. In their article, you will learn of this CTN's objectives and details of upcoming training and conference events.

The team at NCTO are very much looking forward to seeing you in person at our ICTD Conference in May.

With Best Wishes,

Michèle

Michèle Cunnane, Interim Manager, HRB NCTO



ncto.ie



[@HRB_NCTO](https://twitter.com/HRB_NCTO)



ncto@ucc.ie

International Clinical Trials Day (ICTD) 2023 Conference



RCSI - Dublin

We here at the HRB NCTO are delighted to announce our upcoming hybrid International Clinical Trials Day (ICTD) event on May the 10th. This will be a fantastic opportunity to stay abreast of the latest updates and developments in the Irish Research Landscape.

Speakers will be representative of the various stakeholders and organisations active in clinical research in Ireland. The Key-Note address will be from Dr. Marianne Pilgaard (CEO Trial Nation, Denmark) on the Clinical Research landscape in Denmark and what we in Ireland can learn from their successes.

The event will be held in the heart of Dublin City Centre at the RCSI, St. Stephen's Green. We encourage in-person attendance to maximize this unique opportunity to network with your colleagues from the Irish research ecosystem and ask questions directly of our speakers.

Registration will open in April – date to be confirmed, we will inform you of this via a separate communication. This event always books up very quickly, so we advise you to register as soon as this becomes available.



RCSI - Dublin

Dates for your Diary

**NCTO ICTD Event:
Dublin, 10 May '23**

**ECRIN ICTD Event:
Warsaw, 23 May '23**

**Institute for Clinical
Trials Launch: Galway,
30 & 31 May '23**

**Diabetes CTN Launch:
Galway, End of May
'23**

**ICCTN Summer
Meeting: Belfast, 13
June '23**

**UKCRFN 18th Annual
Conference,
Nottingham, 6 & 7 July
'23**

HRB-TRMN:

- **Spring School, Dublin
30 & 31 March '23**
- **8th Trials
Methodology
Symposium, Galway
20 Oct '23**

ECRIN ICTD 2023

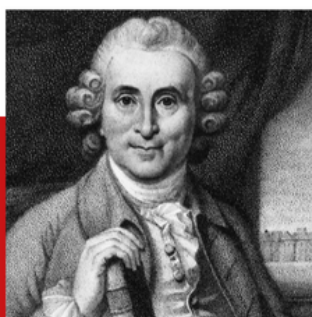
ECRIN together with their Polish National Partner, PolCRIN (Agencja Badań Medycznych) look forward to welcoming you to ICTD 2023 in Warsaw on May 23rd. This year, the discussions will focus on Decentralised Clinical Trials: challenges and opportunities. They have an outstanding lineup of experts joining to share their perspectives and experiences with decentralised clinical trials. Please see their save the date below and stay tuned to their website (<https://ecrin.org/ictd>) to get the latest information on this exciting event!



ICTD International
Clinical Trials Day
23 May 2023

Decentralised Clinical Trials

Challenges & opportunities



SAVE THE DATE 23 May 2023

Join us in Warsaw or online

www.ecrin.org

#ICTD2023

European Medicines Agency Publications

Guide on Computerised Systems and Electronic Data in Clinical Trials was published on 9 March 2023. It covers requirements and expectations for computerised systems, including validation, user management, security, and electronic data for the data life cycle.

Recommendation Paper on Decentralised Elements in Clinical Trials" was published on 13 December 2022). It will be updated on an ongoing basis.

Rare Disease CTN Spotlight



Members of the RDCTN, RAIN, HCRI and IPPOSI at RD Day in Stormont

The Rare Disease Clinical Trial Network is an initiative designed to attract and support rare disease clinical trials to Ireland. The network was funded by the HRB in 2022 and is led by Professor Rachel Crowley and Prof Cormac McCarthy at University College Dublin and St Vincent's University Hospital. The Network Manager Brendan Molloy was appointed in October 2022 and alongside Professor Crowley and Prof McCarthy manages the day-to-day activities of the network.

A rare disease is defined as a disease or condition which affects fewer than 1 in 2000 people. It has been estimated that up to 300,000 adults and children in Ireland are affected by rare diseases, more than 6000 rare diseases have been documented to date. Rare disease clinical trials are complex by their nature, specialised trial designs are required because of the very low numbers of participants and limited knowledge of these rare and ultra rare conditions.



Rare Disease Clinical Trial Network Objectives:

- Facilitate and support the conduct of trials in rare diseases
- Involve patients in the design of rare disease clinical trials
- Educate early career researchers in the design of rare disease clinical trials
- Increase the opportunities for rare disease patients to access high-quality

Accomplishing these objectives will result in increased patient engagement, more trial opportunities for rare disease patients, increased opportunities for investigator-initiated trials, significant industry investment into Irish healthcare, enhanced knowledge of rare disease through patient focused research.



RARE DISEASE CLINICAL TRIAL METHODOLOGY – ONLINE TRAINING EVENT:

The objectives of the event are:

- Broaden the network of rare disease methodology researchers;
- Develop the skills of researchers through workshops using practical scenarios in rare disease research;
- Explore potential new collaborations in rare disease methodology research;
- Raise awareness of rare disease research methods.

Attendees have the opportunity to:

- Meet key leaders in rare diseases research;
- Engage in formal and informal networking and idea generation with other trainees and investigators;
- Discuss career development and strategic planning for academic success;
- Explore research collaborations.

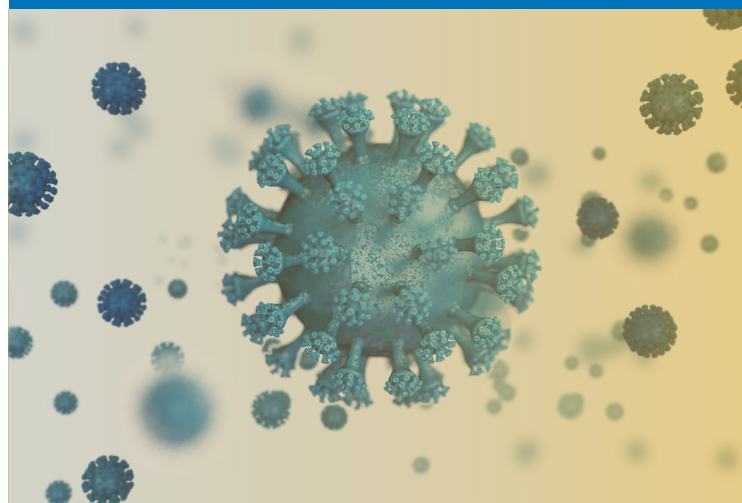
The event will be held in July 2023.

INTERNATIONAL RARE DISEASE CONFERENCE:

An International Rare Disease Conference is currently being planned for the 29th of Feb and 1st of March 2024. The conference will involve patients, patient advocacy groups, clinicians and leading pharmaceutical companies.

The following topics will be discussed:

- Challenges and solutions to setting up and running rare disease clinical trials in Ireland
- Rare Disease clinical trial methodology
- The drug development process (bench to bedside)
- Outcome measures that are important to individuals affected by Rare Diseases
- The patient perspective on rare disease clinical trial design
- Training for early career researchers in clinical trial methodology



MONTHLY ONLINE JOURNAL CLUB

- Early career researchers will have the opportunity to discuss a recent article in their own field
- led by Dr Adam James and will feature a distinguished guest speaker at each event.
- Twitter: https://twitter.com/rare_trial
- To participate or find out more contact Brendan at: brendan.molloy1@ucd.ie

REG & ETHICS

NREC have established a National Irish Covid-19 Biobank (NICB) REC. NNICB-REC does not assess/approve studies using data/samples from NICB. Investigators must get local REC approval before approaching NICB to access samples/data. **National Irish Covid Biobank REC - NREC** (nrecoffice.ie)

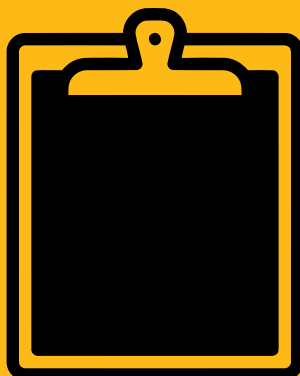


MEDTECH

Innovation Summit Dublin 2023, Europe's largest MedTech partnering and investment conference, will be held April 25th-27th. This conference will offer a broader and deeper take on the issues and concerns driving the medical device industry today.

ECRIN

To promote each of ECRIN's 12 National Partners across Europe, ECRIN will be highlighting a Partner during each month in 2023. To find out more about our European Partners, follow ECRIN on **Twitter** and **LinkedIn**.



TRIALS & FEASIBILITY

The HRB NCTO National Study Feasibility Programme connects Academic and Industry Sponsors with potential investigators. It aims to provide feedback within two weeks of initial receipt of a feasibility request. Contact trials-feasibility@ucc.ie for more information.

If you wish to unsubscribe/opt-out, email ncto@ucc.ie