Newsletter Highlights

Health Research Board
NCTO
National Clinical Trials Office

Newsletter Spring, 2025

Dear Colleagues,

Unfortunately, this will be the last newsletter from the team and HRB-NCTO.
Regretfully, our funding agencies have indicated that they are not in a position to renew supporting our organisation. As a result, with one important exception, we will be winding down our operations this coming Easter.

We understand that this news may have significant implications for our clinical, industry, and research partners in medicines and medtech. We are committed to ensuring as smooth a wind down as we can and are currently compiling a comprehensive list of relevant connection points to support the networking needs of our stakeholders during this process.

Importantly, with the support of ECRIN, Niall Hore will be staying on as part of the UCC CRF in his role as the European Correspondent to continue the bidirectional connectedness for Medicines and Medtech trials into and from our European clinical research partners.

We are grateful for the collaborative relationships we have built over the years and the critical work we have undertaken together in advancing clinical research. We are also touched by the many kind words we have received from colleagues outlining the myriad ways we have helped support and secure clinical trials in this country.

Personally, I also want to acknowledge the huge contribution of each team member (Eoghan, Ruben, Fiona, Evelyn, Niall and Michèle) in enabling that mission and the support of our hosting university, UCC and PIs (over four years) Profs Joe Eustace, Ivan Perry and Wan-Fai Ng.

Sincerely,
Robert O'Connor, Ph.D
Director, HRB-National Clinical Trials Office

HRB Health Research Board

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Enterprise Ireland

ICH-GCP Revision 3 – Groundhog Day or Brave New World?

By Dr Ruben E. Keane

ICH GCP Revision 1 (R1) came into being in 1996 and those of us working in Clinical Research collaborated comfortably with it for 20 years.

However major changes in trial design and methodology (e.g. Basket trials, Umbrella trials, Platform trials), huge advances in the technology used in trials (including electronic data capture, e-consenting, reporting of patient data via portable devices), plus the advent of decentralised trials during those 20 years made it necessary to revise the guideline.

When Revision 2 (R2) was published in 2016 there was an initial panic among us in the clinical researcher community- what changes would this revision bring, how would we implement it, update all our SOPs, and train Investigators and site staff? In the event the transition to R2 went very smoothly.

R2 was published as an' integrated addendum,' thus clinical researchers could concentrate on the new parts only, no changes were made to the old R1 text, but new parts were added. R2 kept the thirteen principles from R1, with which we were familiar, and while it introduced concepts like 'risk proportionate approaches' and gave a nod to use of data from electronic sources, it was not hugely different to what we were used to. It was a bit like putting a lean-to extension on your house, while knowing that this was a short-term fix at best.

Having waited 20 years for the first update, only five years later we began to hear about another revision coming, R3. This was not surprising given the very rapid development of innovative technologies and advances in trial design and methodologies.

ICH
harmonisation for better health

R3 includes much more thoughtful and extensive changes than the last revision, really bringing ICH-GCP up to date with the latest in clinical research evolutions. Adopted in January 2025, after extensive public consultation, R3 has a strong focus on proportionate, risk-based approach to both the design and conduct of clinical trials. It reduces the thirteen principles to eleven and includes a new (much overdue) section on Data governance for both Sponsor and Investigator.

While keeping its original focus on the rights, safety, and welfare of 'participants '(the term 'subject' has, been replaced by 'participant' in R3, acknowledging the importance of those who choose to 'participate' in clinical trials). R3 gives much clearer direction on that other pillar of ICH, Data Integrity. R3 is designed to be applied to different trial types and allows for the use of emerging technologies and methodologies (as long as you take a risk proportionate approach!), thus future proofing it for several years.

R3 will come into force in the EU on the **23rd of July 2025**. Work is already underway in our Clinical Trial Facilities/ Centres across Ireland to ensure that Clinical Researchers, Investigators and site staff are ready to implement this important revision.

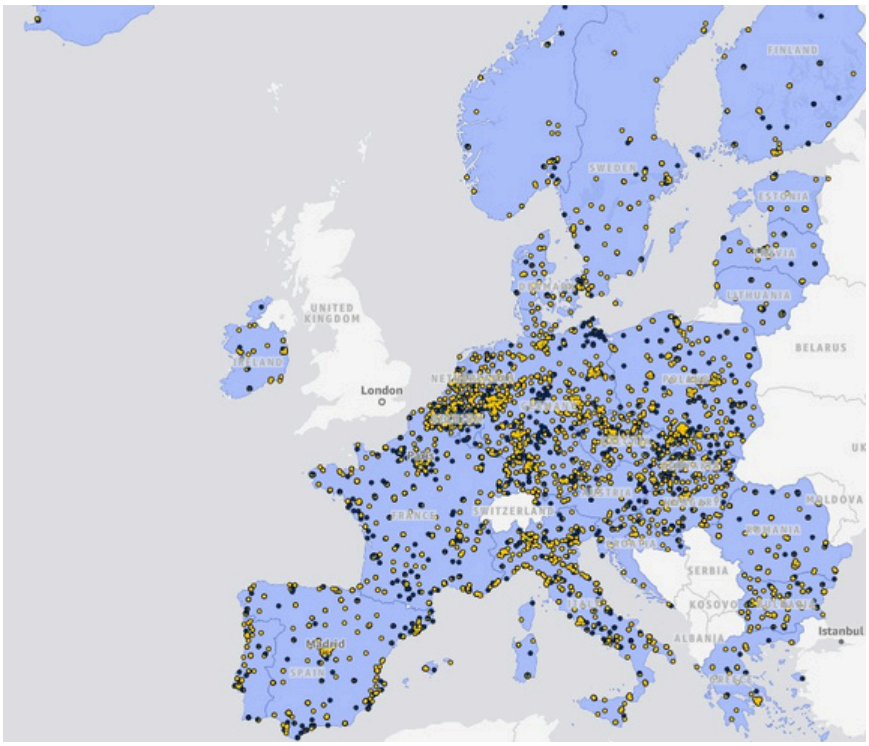
The full text of R3 can be found here: ICH Official **web site**.

News From Across the Network

EU Clinical Trials Information System Launches Map
The European Medicines Agency (EMA) has just introduced a new EU clinical trial map, offering real-time data from the EU Clinical Trials Information System (CTIS).

This user-friendly tool makes it easier than ever for patients and healthcare professionals to find and explore clinical trials across Europe.

With a simple search users can access clear, lay-friendly Trials information: **https://euclinicaltrials.eu/search-for-clinical-trials/trial-map/**



Rare Disease Research Conference 2025

The Rare Disease CTN are holding their yearly conference 10th April 2025, O'Reilly Hall UCD.

It will bring together world leading researchers, patient advocates, regulatory experts, industry representatives and other stakeholders to share knowledge and experience across topics such as rare disease research methodology, translation, European Reference Network Patient Registries and rare disease clinical trial partner perspectives.

For more and to register:
https://rarediseaseresearch.ie/conferences/

Dates for your Diary

Rare Disease Research Conference 2025, UCD O'Reilly Hall, Dublin
10 April 2025

ECRIN's ICTD 2025, Madrid, Spain
20 May 2025

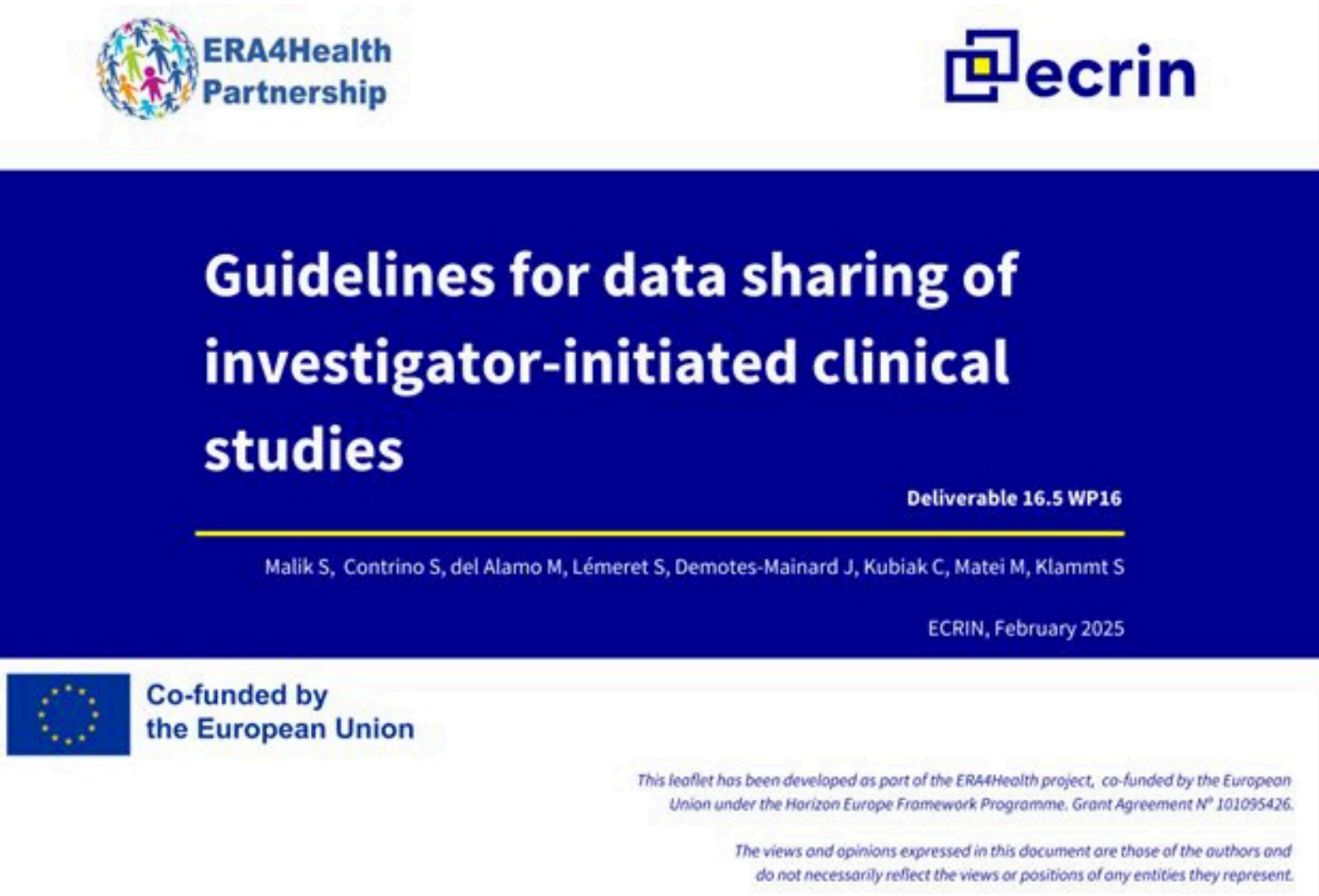
HRB Network for Children's Clinical Trials (in4kids) General Assembly

06 June 2025

HRB-TMRN Trials Methodology Summer School 2025, University of Galway
09 June 2025

FUTURE TRIALS II Institute for Clinical Trials, Galway
17 - 18 June 2025

News From Across the Network



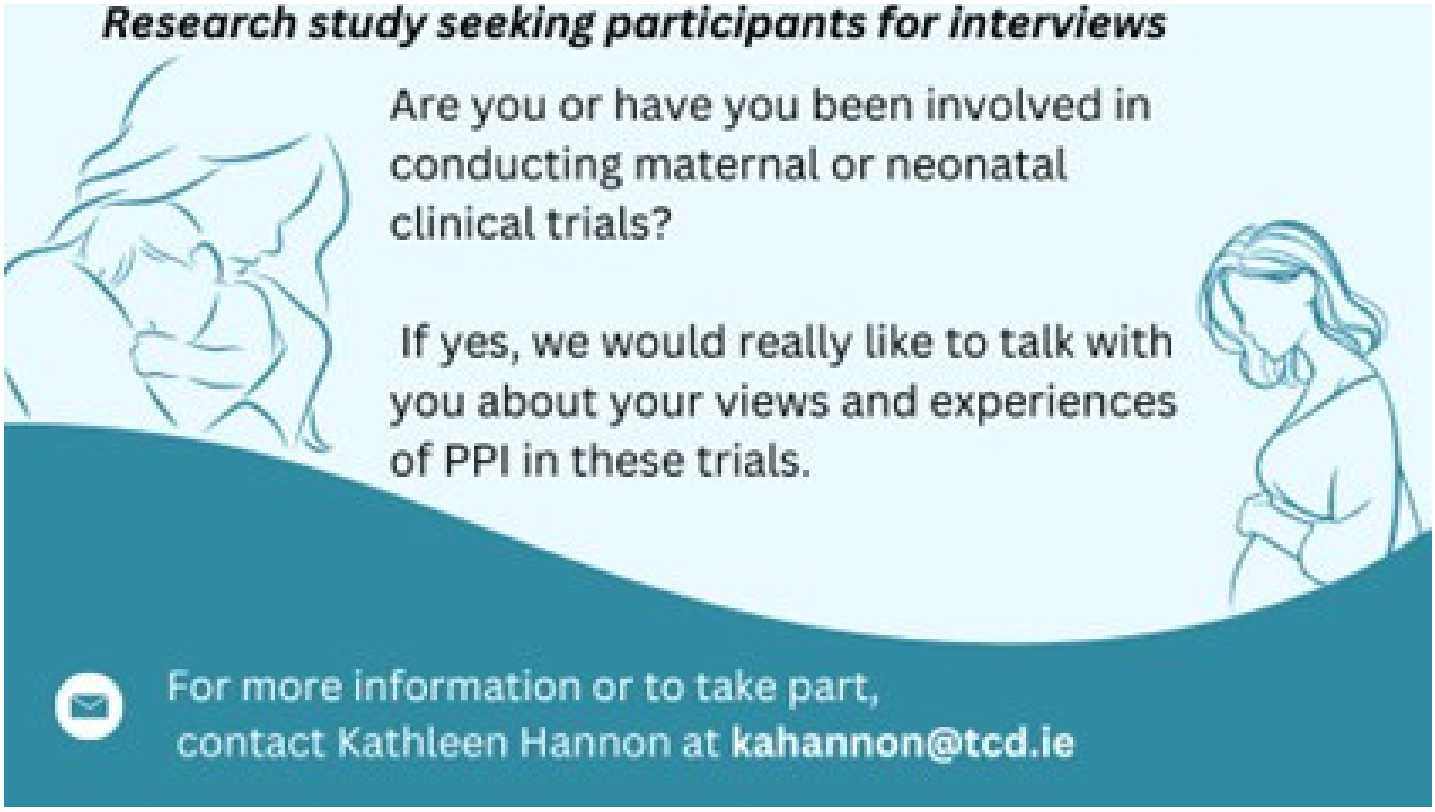
New Leaflet on the Guidelines for Data Sharing of Investigator-initiated Clinical Studies

The team at **ECRIN (European Clinical Research Infrastructure Network)** has completed deliverable 16.5 within WP16, producing a revised leaflet to summarise guidelines for data sharing of investigator-initiated clinical studies.

Many funding bodies require a data sharing plan, or statements about data sharing for secondary use by the grant applicants, in order to make their data available.
Using these guidelines will foster compliance with funder policies and encourage the expectation to share data more widely.

Download document (PDF) **https://lnkd.in/dZiPnpf5**

News From Across the Network



Call for Stakeholders in Maternal and Neonatal Clinical Trials to take part in Research Study

HRB-TMRN are inviting stakeholders in maternal and neonatal clinical trials to take part in one-to-one interviews with me to share their views and experiences of Patient and Public Involvement (PPI).

The interviews can be conducted via Microsoft Teams or by phone. Participants based in Ireland can choose to have the interview in person.

Stakeholders include:

- Health promotion and prevention of noncommunicable and communicable diseases, including vaccine-preventable and other cancers caused by infections and smoke- and aerosol-free environments (€5M)
- Personalised Cancer Medicine (€3M)
- Radiation safety and quality of computed tomography imaging of children and young adults (€1M)
- Support the establishment of new networks of expertise on cancer and cancer conditions (€1M)

If you might be interested in taking part email Kathleen Hannon, PhD Candidate School of Nursing & Midwifery, Trinity College Dublin at **kahannon@tcd.ie**

News From Across the Network

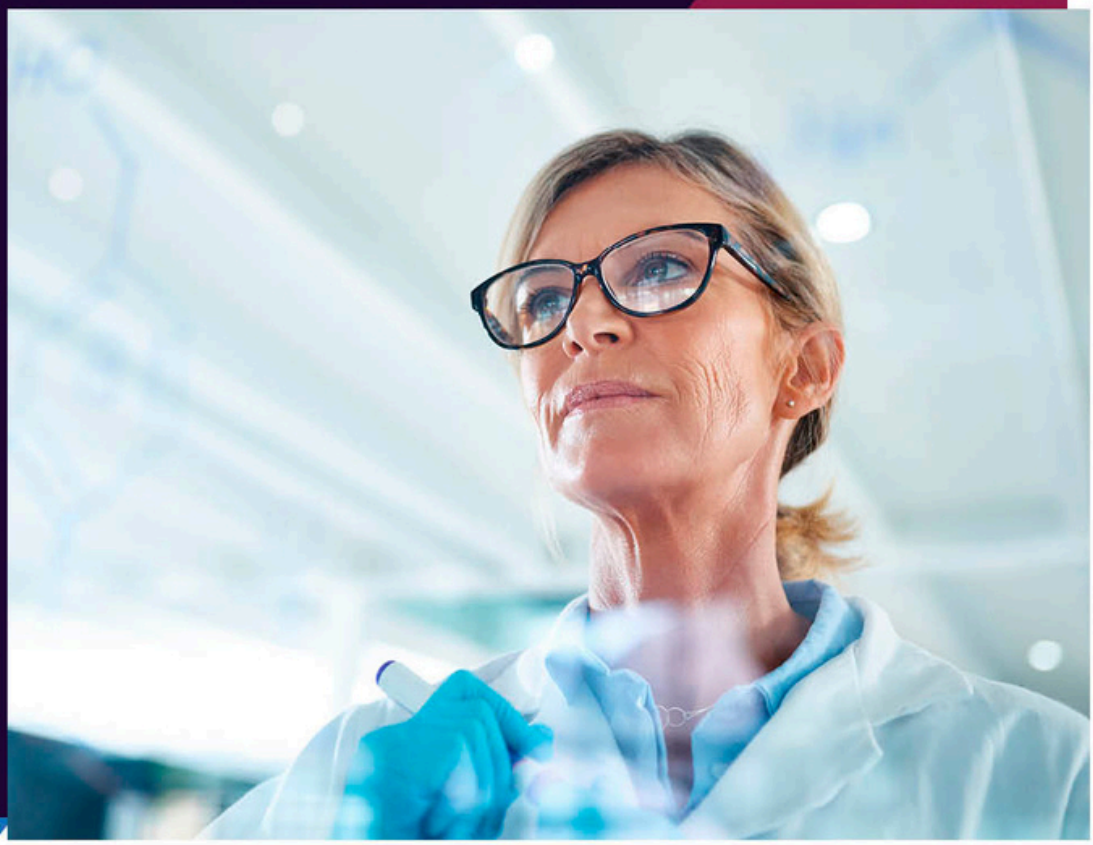
ACT-EU webinar

The HRB-NCTO team were delighted to facilitate a national network meeting between colleagues across the academic clinical research landscape in Ireland and the ACT-EU team in the EMA. The meeting aimed to outline ACT-EU initiatives and supports for those undertaking non-commercial trials.
With >70 attendees, the meeting:

- Provided a detailed overview of the ACT EU Programme
- Outlined ACT EU's activities aimed at assisting non-commercial sponsors
- Presented more information on the CTR/CTIS regulatory helpdesk, including statistics and insight
- Offered an overview of available training resources and materials for CTIS to support non-commercial
- sponsors.

More details on the various activities and supports available from the ACT EU team can be found on **this link**.

Clinical Trials



NCTO Contribute to Clinical Trials Campaign:

Read the Article Here

How clinical trials improve health in Ireland

Eoghan Cooke
Communications Officer, NCTO

Events

ICTD 2025: Rethinking Clinical Trials: Inclusivity in Practice

International Clinical Trials Day 2025 will focus on 'Rethinking Clinical Trials: Inclusivity in Practice'. It will be co-hosted by **ECRIN** (European Clinical Research Infrastructure Network) and its Spanish scientific partner **SCReN** (Spanish Clinical Research Infrastructure Network) on **May 20th, 2025.**

- **Join the Wait list for Onsite tickets.**
- **Register For Online Attendance**

ICTD brings together patients, health policy actors, health authorities, clinical researchers, health professionals and citizens from Europe and beyond to discuss issues related to multinational clinical studies, with Irish representatives including **Professor Fidelma Dunne**, Director of the Institute for Clinical Trials at the University of Galway, and **Professor Frances Shiely**, Professor of Clinical Trials University College Cork.

Why inclusivity?
The need for greater inclusivity in clinical studies is clear in Europe and there is an increasing obligation to progress from discussion to concrete implementation. By uniting different stakeholders from the community, ICTD will shed light not only on why diversity, equity and inclusion should be embraced in clinical research but will give concrete examples of what has been done so far, where there are still hurdles to overcome, and what is underway to work to resolve these difficulties.

Events

HRB Network for Children's Clinical Trials (in4kids)
General Assembly

In4kids, the HRB Network for Children's Clinical Trials will host a General Assembly Meeting on **Friday, 6th June in Dublin**. Please save the date for this event which will bring together leading voices to discuss "**Shaping the Future of Children's Clinical Trials in Ireland".**

The meeting promises to be an engaging and insightful day, with a range of discussions, presentations, and opportunities for networking.
Further details, including the venue, agenda, and speakers, will be shared with you in the coming weeks. In the meantime, please **save the date** in your calendar.