



WELCOME

Dear colleagues and friends of the Network, welcome to the Winter edition of the HRB-TMRN Network Newsletter. This issue brings together highlights from a busy few months across our partner institutions: a look at our featured methodology project, a round-up of news from the community, and dates for your diary as we head into 2027.

IN BRIEF

- PRECIS-3-C - HRB funds a pragmatic design tool for cluster trials
- Oversight, upskilled - new online training on IDMCs and TSCs
- Winter webinars - platform trials, SPIRIT and CONSORT 2025, and estimands
- Doctor, Doctor! - congratulations to Dr. Emer Gunne and Dr. Simone Lepage
- Apples with apples - NutriGrow sets a reporting standard for preterm nutrition
- HRB-TMRN in Birmingham - 28 Irish talks, posters and PPIE at ICTMC 2026
- Have your say - EDI workshop, a remote delivery Delphi study and the GUIDE-COS survey
- Clearer leaflets, fairer trials - the new MAPLE toolkit for accessible PILs
- Research methodology - SPIRIT-ROUTINE: routine data, reported right

If you have news, publications or events to share in the next issue, we would love to hear from you:

hrb-tmrn@universityofgalway.ie - The HRB-TMRN Team

RESEARCH SPOTLIGHT

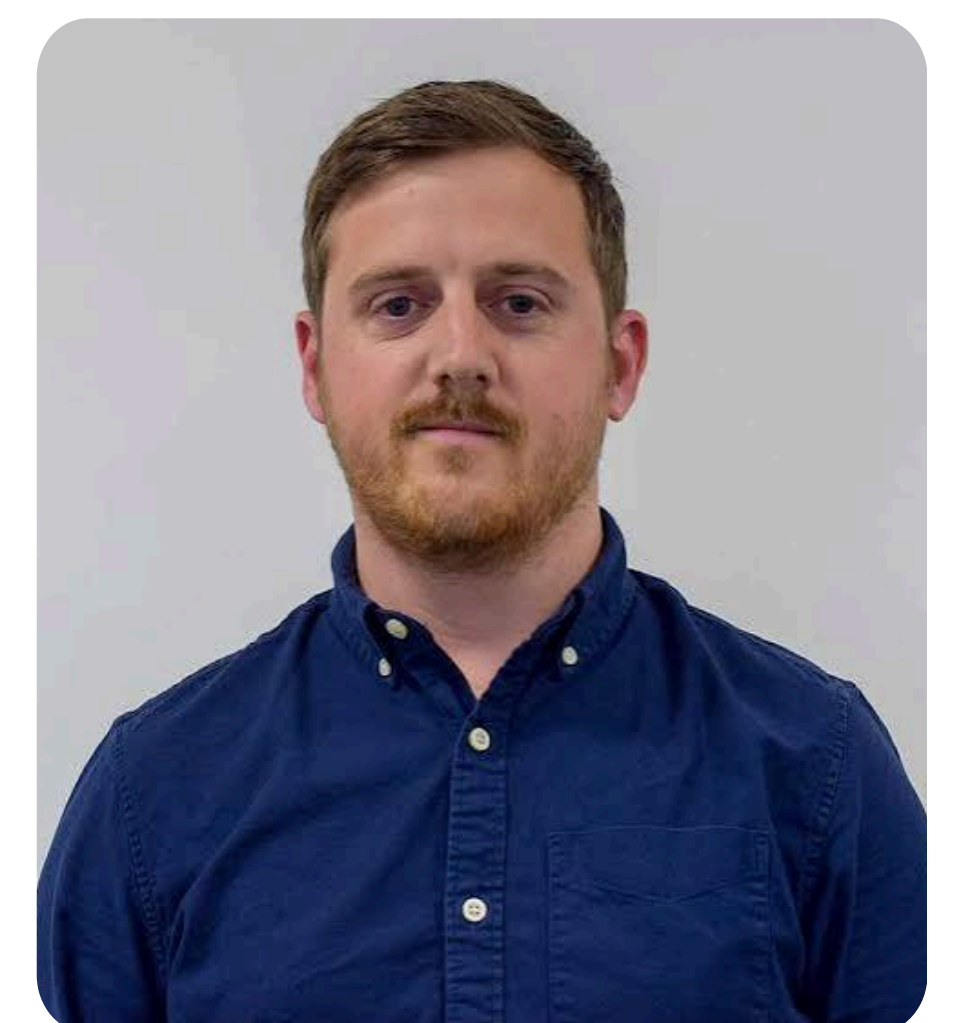


Designing trials for the real world: HRB funds PRECIS-3-C to extend the PRECIS-3 tool to cluster randomised trials

HRB-TMRN congratulates Network research associate Dr. Andrew Willis (pictured), whose project PRECIS-3-C is one of 29 new projects funded under the Health Research Board's Investigator-Led Projects (ILP) 2026 scheme.

The PRECIS tools help researchers design trials on a continuum from pragmatic to explanatory, that is, by how closely a trial reflects everyday healthcare. The latest version, PRECIS-3, is led by HRB-TMRN partner Prof. Frances Shiely, University College Cork. PRECIS-3-C will extend it to cluster randomised trials, where groups such as GP practices, hospitals or schools are randomly allocated rather than individuals. The goal is cluster trials that better reflect the settings where their results will be used.

"Clinical trials should give us evidence that is relevant to the real world, not just evidence that health treatments work under ideal conditions. By extending PRECIS-3 to cluster randomised trials, this project will promote better trial design that more closely reflects everyday healthcare. Ultimately, this will help us produce evidence that is more useful to patients, healthcare professionals and decision-makers leading to real improvements in the way healthcare is delivered," said Dr. Willis. We look forward to following the project as it develops.



[Read the HRB announcement here →](#)

[Read more on PRECIS-3 here →](#)

INDEPENDENT DATA MONITORING COMMITTEES - ONLINE TRAINING SERIES

This online series gives insight into how Independent Data Monitoring Committees (IDMCs) work, who should sit on them, how to present to them and the decisions they make - open to clinicians, statisticians and trial coordinators/managers. Led by Assoc. Profs. Sharon Love and Elizabeth George, University College London.

The IDMC training series is hosted by HRB-TMRN in collaboration with the Irish Critical Care Clinical Trials Network and in association with University College London.

Session 1: Setting up an IDMC

When independent oversight adds value, what independence means, and how to find the right members - balancing clinical, statistical and regulatory expertise.

18 Nov 2026 · 10:00-12:00

Apply now →

Session 2: The IDMC meeting

Key requirements of an IDMC charter, what IDMC reports should include for robust closed-session discussion, and when stopping guidelines apply.

16 Dec 2026 · 10:00-12:00

Apply now →

Session 3: IDMC decision making

Who makes key trial decisions, what makes a meeting quorate, and how IDMC recommendations shape a trial - with real-world case studies.

20 Jan 2027 · 10:00-12:00

Apply now →

HRB-TMRN WINTER WEBINAR SERIES

Delivered in collaboration with the Trials Methodology Research Partnership.



Platform trials: only suitable for a pandemic?

Prof. Thomas Jaki, MRC Biostatistics Unit, University of Cambridge · 12 November 2026 · 13:00-14:00 · [Register here →](#)



Updated SPIRIT and CONSORT 2025 guidelines: enhancing trial transparency and reporting

Prof. Sally Hopewell, University of Oxford · 03 December 2026 · 13:00-14:00 · [Register here →](#)



Which estimand should we use? Guidance on balancing clinical relevance and statistical reliability

Dr. Brennan Kahan, UCL Innovative Clinical Trials Unit · 28 January 2027 · 13:00-14:00 · [Register here →](#)

TRIAL STEERING COMMITTEES - ONLINE TRAINING SERIES

This online series introduces **Trial Steering Committees (TSCs)**: their role, remit and responsibilities, and how they work with sponsors, investigators, PPI contributors and Data Monitoring Committees. It combines expert talks with real-world scenarios to build confidence to serve as a TSC member or chair. It's open to anyone involved in trial oversight across Ireland and the UK.

Workshop 1: TSC roles, remit and responsibilities

Understand the core oversight role of the TSC; specific responsibilities of TSC members and the Chair; and the essential contribution of PPI to TSC deliberations.

10 NOVEMBER 2026 · 10:00-12:00

Apply now →

Workshop 2: TSCs in practice: real-world scenarios

Apply TSC guidance to challenging real-world situations through facilitated groupwork and reflect on your own readiness to serve as a TSC member or chair.

01 DECEMBER 2026 · 10:00-12:00

Apply now →

■ TWO NEW DOCTORS FOR THE NETWORK

Congratulations, Dr. Emer Gunne and Dr. Simone Lepage

HRB-TMRN warmly congratulates two of our 2021 - 2026 cohort of Scholars on completing their PhDs in 2026. Dr. Simone Lepage (University of Galway) was supervised by Prof Declan Devane and Dr. Laura Flight (NICE). Her PhD, The Kid’s Trial, taught children how trials work by building one with them: 224 children from 15 countries took part online. Her work has produced five papers (most recent listed below), and she is now a Lecturer in Midwifery at University of Galway.



Dr. Emer Gunne (University College Dublin) was supervised by Prof. Peter Doran, Prof. Michael Keane and Dr. Sinéad Holden. Her PhD explored digital technologies in clinical trials. Through the PRODIGY-ILD study, she examined how ePROMs and smartwatches can support research with people living with interstitial lung disease (BMJ Open, 2025; JMIR Human Factors, 2026 (listed below)).



Simone and Emer (top and bottom picture respectively) bring to twelve the number of Network PhD Scholars who have completed since 2014, across five partner universities. Through our PhD peer support programme, Scholars gain a community, mentorship and a sense of belonging that a single PhD rarely provides. Congratulations, Emer and Simone!

■ NETWORK PHD / EARLY CAREER RESEARCH



Patient Experiences of Digital Technology Use in Interstitial Lung Disease (PRODIGY-ILD Study): Qualitative Study Using Reflexive Thematic Analysis

Gunne, E. et al. (2026) JMIR Hum Factors · [Read the paper →](#)



Does resistance training make a difference to the quality of life or heart health for older adults compared to aerobic exercise? A systematic review protocol from The People’s Review

Quinn, É. et al. (2026) PLOS One · [Read the paper →](#)



Feasibility and Methodological Reflections From the Co-Creation of a Randomized Controlled Trial (The Kid’s Trial): Decentralized, Child-Led Citizen-Science Study.

Lepage, S. et al. (2026) J Med Internet Res · [Read the paper →](#)

■ METHODS IN FOCUS



Comparing Apples with Apples: A New Standard for Reporting Preterm Nutrition Research

How much should preterm babies be fed, and how fast should they grow? Decades of research have not settled this, partly because studies measure and report nutrition and growth so differently that their findings are hard to

compare or combine. The NutriGrow scientific study tackles this problem (Meiliana, M. et al., 2026). Building on a scoping review and following the COMET handbook approach, the team ran two real-time Delphi surveys: the first on which measures to report, the second on how to report them. In all, 313 participants from 32 countries took part in the first survey and 121 from 26 countries in the second, spanning parents and consumers, healthcare professionals and researchers. Three online consensus meetings then finalised the framework. The result is a minimum reporting set of eight measures, each with guidance on how and when to measure it. They cover what babies receive (the type of milk, any supplements, and the nutrition they actually get) and how they grow (including weight and length). This is the first multidisciplinary international consensus in the field. Widespread adoption would make studies comparable, strengthen evidence synthesis and could inform evidence-based feeding guidelines. The lesson holds for trialists everywhere: agree what to measure and how to report it, and better answers follow.

[Read more here →](#)



Ireland in Birmingham: HRB-TMRN at ICTMC 2026

In September, the trials methodology community gathered at the ICC Birmingham for the MRC-NIHR Trials Methodology Research Partnership’s 8th International Clinical Trials Methodology Conference (ICTMC), held from 14 to 17 September. HRB-TMRN travelled as a national group, bringing together 9 bursary awardees, PhD and Summer Scholars, public partners, network executive members and colleagues from five universities and two HRB clinical trial networks. Between them they contributed 28 talks, posters and chaired sessions, Ireland’s strongest showing at ICTMC to date.

A programme full of Irish work

Irish contributions spanned the breadth of the field. Kathleen Durkin of Dementia Trials Ireland compared study start-up delays with national recommendations, and JP Connelly (TCD) shared practical lessons on involving people living with dementia in long-term care. Almas Khan (UCC) presented her work on reaching people with complex physical and mental health needs. Simone Lepage (UoG) brought the final results of The Kid’s Trial, a decentralised trial co-created with children. Dimity Dutch (UCC) showed how caregivers can shape outcome measurement in infant feeding research, and Teena Thomas (UoG) introduced the QASSIST study on inclusive trial design. Caitríona Ryan (TCD) presented a Bayesian n-of-1 trial, and Summer Scholar Alexandra Dudka (TCD) travelled to present her simulation study on vitamin D and sample size. In a joint poster, HRB-TMRN PhD Scholars reflected on what a structured doctoral network gives early-career methodologists: community, mentorship, visibility and a sense of belonging.



Putting PPIE centre stage

Public and patient involvement was a strong thread throughout the conference. A spotlight session co-ordinated by HRB-TMRN, on building shared learning and capacity for PPIE in trials methodology, was co-delivered with TMRP colleagues from the Universities of Newcastle, Liverpool, Glasgow and Leicester and their public partners. Separately, Cassandra Dinius of the Rare Diseases Clinical Trials Network spoke about onboarding PPI partners. Our public partner, Prof. Derek Stewart, who presented at the meeting, described travelling with the Irish delegation as “a genuine and heartfelt sense of belonging, shared endeavour and collaboration”.

Moments that stayed with us

Attendees came home with plenty to think about. Prof. Peter Sasieni’s opening keynote showed how sustained research and public education can transform population health. The Doug Altman Memorial Lecture introduced the “Altman Number”, a playful measure of how closely connected the trials methodology community is. Others singled out sessions on decentralised trials, response-adaptive randomisation and AI in trials methodology.

Back home, already making a difference

Within weeks, the conference was paying off. Marci Kay Livingston (UL) used her talk to launch and recruit for her GUIDE-COS survey. Teena Thomas invited delegates at her poster to join an upcoming QASSIST consensus meeting. Conversations at Almas Khan’s poster led her to design a new study with trial recruiters. As Kathleen Durkin put it, she “came away with more knowledge, connections, ideas, and plans than can be summed up in any report.”

■ PPIE AT ICTMC - Prof. Derek Stewart

Better Research Together: A Public Partner Looks Back, and Ahead



Prof. Derek Stewart, HRB-TMRN public partner (centre left), with members of the HRB-TMRN ICTMC 2026 delegation and friends and colleagues from Ireland’s wider trials methodology community.

Public and patient involvement and engagement (PPIE) is a growing part of HRB-TMRN’s presence at ICTMC, through its PPIE in Trials Methodology Roadmap work. Prof. Derek Stewart, HRB-TMRN public partner, has presented in a spotlight session at all three ICTMCs since 2022. In Harrogate, he recalls, patients and research participants went unmentioned. By Birmingham, PPIE had a spotlight session and three parallel sessions of its own. Yet, Derek feels, too many researchers still present their PPIE work with only a passing reference to their partners rather than alongside them, and he argues that involvement is “a process, not a method”. His advice to first-time public partners is to find each other quickly, treat the conference as a stepping stone, and not try to attend everything: “take time out and go for a coffee”. For ICTMC 2028, he would like a Shared Community Spotlight on Better Research Together, with public partners and researchers presenting jointly on inclusion, innovative design and partnership. Asked to sum up how researchers and public partners work together, the former teacher offers a school report: ‘Well done, could do better!’

FUNDING & OPEN CALLS

Open - closing 01 December 2026

MRC-NIHR Better Methods, Better Research (BMBR)

Two commissioned calls open: use of synthetic data in health and social care research; and novel evaluative methodologies to overcome systemic barriers in social care research.

[Details →](#)

Open - closing 14 January 2027

ERA4Health IICS4all 2027

Funds large multi-country clinical studies comparing how well existing treatments work, or testing whether off-patent drugs can be repurposed. Online information session for applicants on 10 November 2026.

[Details →](#)

Open - closing 12 November 2026

HRB Summer Student Scholarships 2027.

Undergraduates on a Level 8 degree can undertake a health or social care research project over the summer (6 - 8 weeks).

[Details →](#)

DATES FOR YOUR DIARY



16-19 MAY 2027

Society for Clinical Trials 2027

Chicago, USA

[Call for Abstracts →](#)



2-4 NOV 2027

Cochrane Colloquium 2027

Kyoto, Japan

[Further Info →](#)



23-25 SEP 2027

ISCTM Autumn Conference 2027

Barcelona, Spain

[Details →](#)

PARTICIPATION OPPORTUNITIES

Designing Trials for Everyone: COB-MS EDI Workshop

Who takes part in a trial shapes what its results can tell us. Embedding Equality, Diversity and Inclusion in Clinical Trials: Spotlight on Multiple Sclerosis Research is a free, 1-day workshop that treats evidence-informed EDI as a core part of good trial design. Hosted by the COB-MS team at the University of Galway, the workshop (Nov 30th) is now open for registration. Researchers and PWLE will explore how inclusive design, recruitment and patient and public involvement can make trials more representative and their findings more relevant. The workshop will also build trust between practitioners, researchers, people with MS and the public. The workshop is open to all!

[Further Information and Registration →](#)

Modified Delphi: Help Shape Guidance on Remote Intervention Delivery in Trials

Have you worked on a clinical trial in which a complex intervention was delivered remotely? A PhD researcher at the University of Leeds, working with the Trials Methodology Research Partnership (TMRP), is looking for trialists to take part in a modified Delphi study. The study will refine a set of considerations for delivering interventions remotely within trials. Taking part involves two short online surveys of 20 to 30 minutes each. Everyone who completes both rounds will receive a £20 voucher as a thank you. The study has ethical approval from the University of Leeds School of Medicine Research Ethics Committee.

[Submit an Expression of Interest →](#)

Core Outcome Set Development: PWLE and professional perspectives needed

How can we better incorporate the perspectives of people with lived experience into Core Outcome Set (COS) development? This is the focus of **GUIDE-COS**, a PhD project by HRB-TMRN scholar Marci Kay Livingston at the University of Limerick.

A brief 10-minute survey is now open to gather perspectives on incorporating lived experience into the long-list stage of COS development. The findings will help shape practical guidance for COS developers.

The survey is open to people with lived experience who have participated in COS research, COS developers, trial methodologists, PPI researchers and others interested in ensuring the lived-experience perspectives are included in future COS. Closing 04 December 2026.

[Access survey here →](#)

Study Recruitment!

Core Outcome Set Development

- We are inviting people with lived experience who have participated in COS research, COS developers, trial methodologists, or anyone else with an interest in ensuring PWLE are meaningfully included in COS development to complete an online survey about proposed guidance for including lived-experience perspectives in COS development.

Estimated at 10-15 minute

SURVEY HERE:

[HTTPS://A-QR.CO/000621VF](https://a-qr.co/000621vf)

This project has been approved by the EHSREC (Ref No: 2026_05_12_EHS(EK))

To learn more about the study please contact Livingston.Marci@ul.ie

■ NEW METHODOLOGY RESOURCE

Clearer Leaflets, Fairer Trials:

Introducing the MAPLE Framework and Toolkit

Long, complex patient information leaflets (PILs) can stop people with lower English language literacy from taking part in clinical trials. The MAPLE project, led by the University of Bristol in collaboration with [National Voices](#), set out to tackle this barrier. It promotes accessible PILs as part of the layered approach to information provision recommended by the Health Research Authority.

The team had already co-developed [a framework of recommendations for accessible PILs](#). Knowing that guidance alone rarely changes practice, they have now turned it into practical tools. These were co-developed through 19 workshops with more than 150 people, including members of racially marginalised communities, adults with learning disabilities and/or autism, adults with physical and mental health conditions, and the LGBTQIA+ community.

The **free resources** include:

- A modifiable accessible PIL that trial teams can download and adapt offline for their own trial
- A collection of guides to support adapting the PIL
- Example images and image guidance for each section of the PIL

For trialists, MAPLE offers a ready-made route to more inclusive recruitment, starting with the very first document a potential participant reads. [Read more on MAPLE here →](#)



■ RESEARCH METHODS & REPORTING

SPIRIT-ROUTINE: Routine Data, Reported Right

More and more randomised controlled trials use cohorts or routinely collected health and care data, such as electronic health records, registries or administrative claims. These trials can streamline recruitment, intervention delivery and follow-up, both during the trial and in the long term, and can lower costs.

Using routinely collected data in trials also brings challenges. Information governance pathways are often unclear, data quality varies, recording and access to data can be delayed, and regulatory or ethical requirements can be complex. Together, these make such trials harder to reproduce and their risk of bias harder to assess.

SPIRIT-ROUTINE, a new extension to the SPIRIT 2025 guideline, responds to these challenges. It offers a checklist and explanation to improve the reporting of trial protocols that rely on cohorts or routinely collected data. Investigators, funders, ethics committees, journal editors and peer reviewers can use it to make these protocols more complete, transparent and usable, supporting better research, healthcare decisions and patient outcomes.

Kearney, P. et al. (2026) BMJ. doi:10.1136/bmj-2025-087095

[Read more about SPIRIT-ROUTINE →](#)