NWORTH CTU

Newsletter

Issue no. 3 - Autumn 2025

Welcome to the third edition of our NWORTH newsletter

We're pleased to say that over the summer NWORTH successfully relocated to our new home in Ardudwy (pictured). We are located on the first floor of the building which we now share with Centre for Health Economics and Medicine Evaluation (CHEME) and Dementia Service Development Centre (DSDC).

This completes NWORTH's second move in a matter of months. All the NWORTH staff have been amazing at chipping in, packing boxes, moving trial data and archives securely, cleaning, organising and collaboratively arranging their new shared office spaces. I even channelled my inner Bob the builder to dismantle desks to allow extraction from Y Wern. This is all on top of ensuring the CTU continued to function. NWORTH teamwork at it's best.

As a team we'd also like to thank the huge efforts from the other research teams (CHEME and DSDC) in relocating within Ardudwy to facilitate the NWORTH team being grouped together - everyone has been very welcoming and accommodating. We look forward to sharing this space and creating a vibrant research community together.

In the rest of this update are thoughts about MHRA inspections, study highlights, team news and our latest publication/ outputs

Dr Zoë Hoare, NWORTH Director

Take part in our 2025 stakeholder survey

We would be very grateful if you could take a few minutes (no more than 5–10) to complete our stakeholder survey, which will help us understand how best to build new and effective partnerships Your views are valuable — whether or not you've previously worked with us.

QR link to the survey

MHRA inspections—a current hot topic

Thoughts from our team regarding inspection processes

'Medicines and Healthcare products Regulatory Agency (MHRA) inspections' have become a prominent topic of discussion across the UK Clinical Research Collaboration (UKCRC) and the UK Trial Managers' Network (UKTMN). Recent meetings and roundtable discussions have offered valuable insights into the inspection process, highlighting several key points:

1. Inspections can be both time- and resource-intensive for the Clinical Trials Unit (CTU) and institution.
2. Inspections can incur substantial costs for the institution.
3. They may occur with minimal notice, leaving limited time for preparation.

Inspectors do not always focus on the highest-risk studies. As a CTU, it is essential that we remain *inspection ready*. NWORTH has a dedicated Standard Operating Procedure (SOP) for *Preparation for Inspection*, and all staff within the unit have received training on this SOP. **Kirstie Pye, CTU Manager**

I recently attended the QA National Meeting in Leeds on 09/10/2025. The day was really informative and offered an excellent networking opportunity. The main focus of the meeting was MHRA inspections. A useful panel session featured CTU's that had recently been inspected, who shared their experiences.

A key theme was that although inspections are demanding and time consuming, they bring the whole team together and provide a great sense of teamwork. During the inspections, all CTUs commented on the large number of requests they received from inspectors and the tight deadlines for responding to them.

Another key takeaway was that if you're unsure of an answer, it's ok to state that you will find out instead of stating that you don't know. It's also important to be concise during inspection interviews as providing too much information can open the door to further queries

Lil Denis, Quality assurance support officer

At the recent Trial Managers operation group annual meeting the focus was on MHRA inspections, what to expect during an inspection and what the MHRA are focussing on.

Discussion covered the timelines between first being notified about the inspection to the final report, in some cases this has taken 833 days.

Inspections are costly not only in financial terms but also in staff time. Quite a lot of documents are requested before and during the inspection and some timelines can be outside office hours.

Therefore, preparation is the key word, ensure all processes are reviewed and ensure everything is tested, and not just once. Ensure everything that needs to be in the Trial Master File (TMF) is in there and not on someone's desktop! Don't panic, you can learn a lot from an inspection

Alison Jenkins, Trial Manager

As MHRA inspections have gained significant attention and discussion this year, it's important to remember that MHRA oversight plays a crucial role in ensuring consistent quality, data integrity, and the safety of participants and patients by assessing the effectiveness of our Quality Management System (QMS). From a Quality Assurance perspective, maintaining compliance with all applicable regulations, guidelines, and internal processes is essential. Listening to others share their experiences with MHRA inspections provides valuable insights, allowing us to reflect on our own QMS and review our processes and documentation for continuous improvement.

Always remember: If it isn't documented then it didn't happen!

Karolina Rusiak, Quality Assurance officer

Study News

Continued success and collaboration with King's College

Our ongoing collaboration with Prof John Marsden, King's College London, has continued to grow. As we draw to a close some exploratory mediation work on the relationship of craving and the treatment group in EXPO, the final piece of the EXPO puzzle, we have the pleasure of starting two new studies in collaboration with John and the Kings CTU team.

SUPPORT (Funded by NIHR HTA 168126) - For patients successfully completing treatment for alcohol, cannabis, ococaine or opioid use disorder, the SUbstance dependence ProsPective Outcome Recovery trial (SUPPORT) will determine if a 12-month Recovery Check-In (RCI) intervention is effective and cost-effective - a £3.6 million trial looking to recruit a sample of 1938 participants running from September 2025 until June 2029.

MEDCO (Funded by NIHR EME 166797) - The MEDications for COcaine Use Disorder (MEDCO) study will determine the efficacy of an 18-week pharmacotherapy with a stimulant and an anti-depressant (evaluated singly and in combination) to help adults with cocaine addiction abstain from cocaine and recover. A £3.8 million study looking to recruit 200 participants, running from September 2025 until September 2029

iSupport trial outputs

iSupport is an online, self-guided training program created by the World Health Organization to support carers of people living with dementia. It includes modules on the caring role, self-care, daily care tasks, and managing behavior changes. The Wales Dementia Services Development Center evaluated iSupport in a trial funded by the NIHR, (NIHR130914) with the aim of determining its effects on reducing stress and depression in dementia carers.

As part of the study, the team also created several adaptations of iSupport, including a Welsh translation, a version for young carers aged 11–17, adaptations for carers of people with rare dementia, and culturally relevant versions. Participants—many of whom had significant caring experience—reported that iSupport helped them feel more reassured, valued, and confident in seeking help. They also reported a more positive attitude towards their caring responsibilities and the needs of the person living with dementia.

The main results of the trial were published in The Lancet Regional Health, with the process evaluation included in Behavioral Sciences. All versions of iSupport developed through this work are available at: https://www.isupportdementiacarers.co.uk/

Being Kind to Ourselves Study

We are delighted to announce that the "Being Kind to Ourselves" study—a full Randomized Controlled Trial (RCT) evaluating Compassion Focused Therapy (CFT) for improving depression and anxiety in people with dementia—has been awarded NIHR RfPB funding (NIHR209908) in August 2025.

This RCT builds directly on the success of the earlier feasibility trial (NIHR203524), which showed promising results for group CFT in this population. Data collected during the feasibility phase will be carried into the full trial, where 73 of the required 304 participants have already been recruited and randomised. Recruitment for the remaining 231 participants will begin in January 2026, with the study expanding beyond the original 7 sites to include new locations and enhance recruitment.

This marks the first time the Trials Unit has used this funding model, providing a valuable opportunity to optimize resources and accelerate the trial timeline

Pictured: Trial Manager Mel Melville and PPI representative Keith Oliver

NEWS FROM THE TEAM

Introducing REDCap: NWORTH's New Electronic Data Capture (EDC) System

We are excited to announce the launch of REDCap, NWORTH's new Electronic Data Capture (EDC) system, replacing MACRO.

This upgrade brings a more flexible, efficient, and user-friendly platform for managing clinical trials. REDCap offers improved data collection, enhanced collaboration, and greater efficiency with real-time validation, automated workflows, and seamless data exports. Its customisable features and scalability make it ideal for trials of complex interventions, strengthening our data quality and streamlining our processes.

Getting to this point has been a team effort, and we appreciate everyone's contributions. We are pleased to say that as of September 2025, REDCap is live for operational use!

Validating and installing a new EDC system - a personal viewpoint

Replacing NWORTH's previous EDC solution, MACRO v4.13, began in December 2023 with a system evaluation initiative to assess and compare various EDC systems available. Of 12 systems that were reviewed, Vanderbilt University's Research Electronic Data Capture (REDCap) system was chosen.

Installation and validation began with documentation outlining user and functional requirements, technical specifications, installation steps, and system testing. REDCap was initially deployed via Azure in February 2025, followed by Operational Qualification (OQ) to test system functionality and Performance Qualification (PQ) to confirm user requirements were met.

I have really enjoyed being a part of the process of implementing a new EDC system at NWORTH and have learnt a lot about Computer Systems Validation. Going through the validation process, especially the OQ testing, has helped me to develop a really good understanding of REDCap and its functionality. This knowledge and experience will enable me to provide better support and training for REDCap users within the NWORTH team and wider trial teams.

Casey Nolan, Clinical Trials IT Delivery Facilitator.

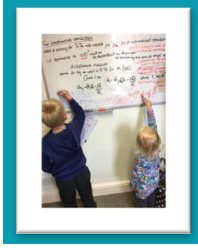
NWORTH relocates — Saying goodbye to Y Wern 2009 to 2025

NWORTH was given it's own building in 2009 and made it's move from Ardudwy down the hill on Normal Site to Y Wern. Later in 2013 NWORTH also established a presence in Meirion building even further down the hill on Normal Site—think we were heading for the Menai Straits! After vacating Meirion in 2024 and consolidating into one building NWORTH have now just completed the move back up the hill to return to Ardudwy. This relocates some of the health based research groups together in one building. As we vacate a very damp dilapidated Y Wern we asked NWORTH staff about their memories from the building:

"*The dreaded walk down the corridor for my interview/presentation, only to be faced with 4 interviewers! I can smile about it now, but not having an interview for 21 years, it was a little daunting back then!"* Huw Williams, IS Functional lead

"*I can remember not being able to find the entrance to Y Wern before my interview, many moons ago"* Andy Brand, Trial Statistician

"*The random smell of cigar smoke on the stairwell*" - a memory from our inaugural QA officer Debbie Skelhorn (She was the only person who ever smelt it)

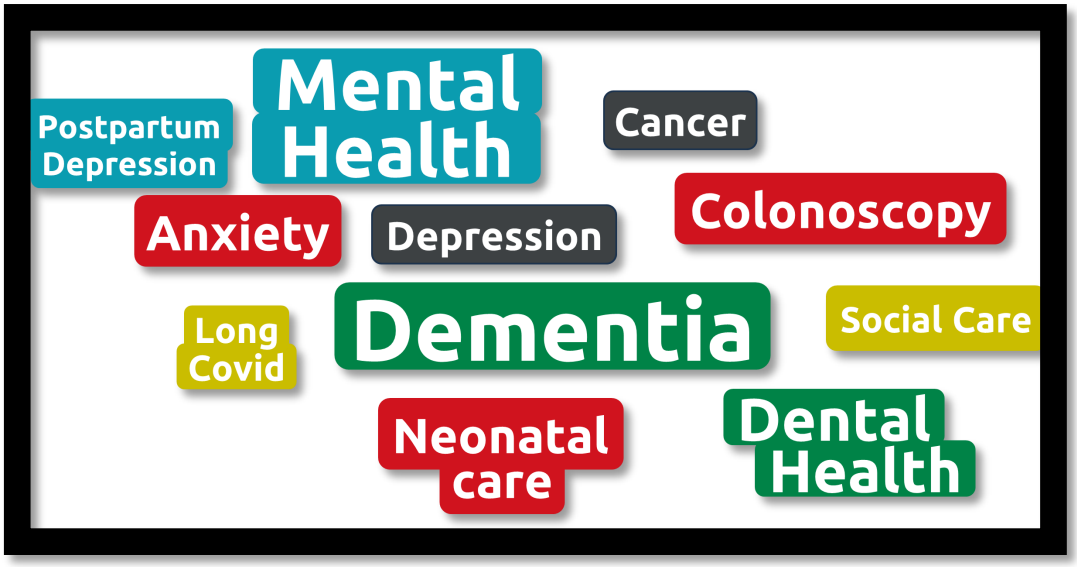


"*My eldest two children remember playing marbles along the top corridor and scribbling on my whiteboard whilst waiting for me to finish work"* Zoë Hoare, Director. As we locked up for the last time we had a chance to recreate the marble experience 8 years on!

Farewells NWORTH has also recently said farewell to Tom Goff, Data Systems Officer. Tom has been at NWORTH for 3 years. Tom always looked to provide practical solutions to problems and will be missed - we wish him all the best in his move to Yorkshire Water.

Recent Publications

1. A feasibility study of the costs and consequences of improving the oral health of older people in care homes: findings from the TOPIC study BMC Oral Health
2. Extended-release buprenorphine treatment for opioid use disorder: A mixed-methods study of response and experience Addiction
3. Carer administration of as-needed subcutaneous medication for breakthrough symptoms in people dying at home: the CARiAD feasibility RCT BMJ Open
4. Improving the Oral Health of Older People in Care Homes: Results From a Randomised Feasibility Study . Community Dentistry and Oral Epidemiology
5. Cost-consequence analysis of an e-health intervention to reduce distress in dementia carers: results from the iSupport randomised controlled trial . BMJ Open
6. Does noise on my neonatal unit matter? Multiple-cohort professional opinion survey BMJ Paediatric Open
7. The psychometric properties of a new outcome measure of resilience for people living with dementia: The Bangor Dementia Resilience Scale BMC Psychology
8. CHOSEN: A randomized controlled feasibility trial. Journal of the American Heart association
9. Better Living with Non-memory-led Dementia: study protocol for a randomised controlled trial of a web-based caregiver educational programme (BELIDE trial) BMJ Open
10. A Process Evaluation of the UK Randomised Trial Evaluating 'iSupport', an Online e-Health Intervention for Adult Carers of People Living with Dementia Behavioural Sciences
11. Group cognitive stimulation therapy for people with intellectual disability and dementia: feasibility randomised controlled trial BJPsych Open
12. Cost-consequence analysis of an e-health intervention to reduce distress in dementia carers: results from the iSupport randomised controlled trial BMJ Open
13. Using Role Substitution to Improve Oral Health in Care Homes: A Process Evaluation Gerodontology



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NWORTH

North Wales Organisation for Randomised Trials in Health & Social Care
Sefydliad Hap-Dreialon Iechyd a Gofal Cymdeithasol Gogledd Cymru

PRIFYSGOL BANGOR UNIVERSITY

ABOUT US

NWORTH is a UKCRC registered clinical trials unit, which specialises in the design, conduct, analysis and reporting of multicentre trials of complex interventions. We are based in the North Wales Medical School at Bangor University.

If you'd like to collaborate on a study, please get in touch.