



Centre for
Trials Research
Canolfan
Ymchwil Treialon



Annual Report 2025/26



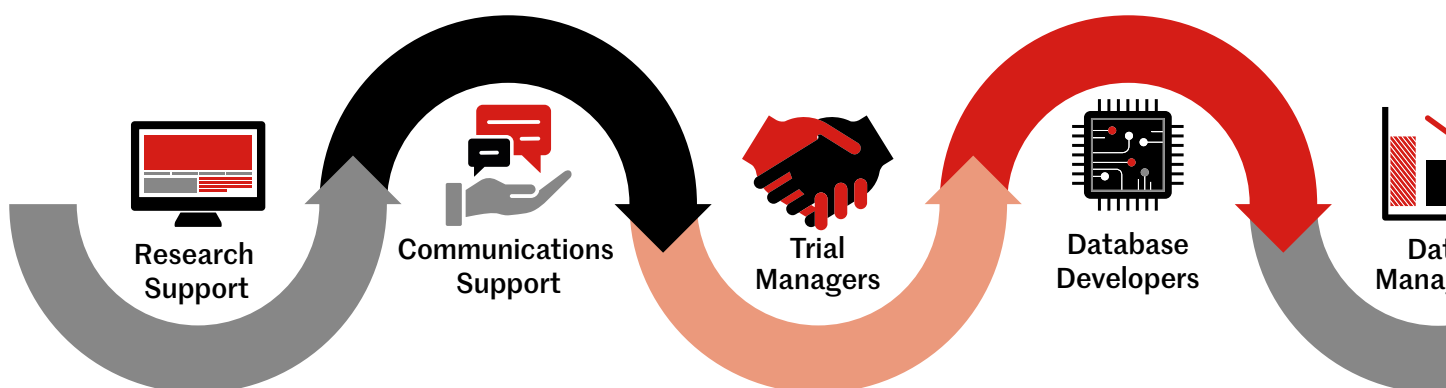
Ymchwil Iechyd
a Gofal Cymru
Health and Care
Research Wales



Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

www.cardiff.ac.uk/centre-for-trials-research

The Centre for Trials Research (CTR) at Cardiff University is a registered clinical trials unit with the UK Registered Clinical Trials Unit Network.

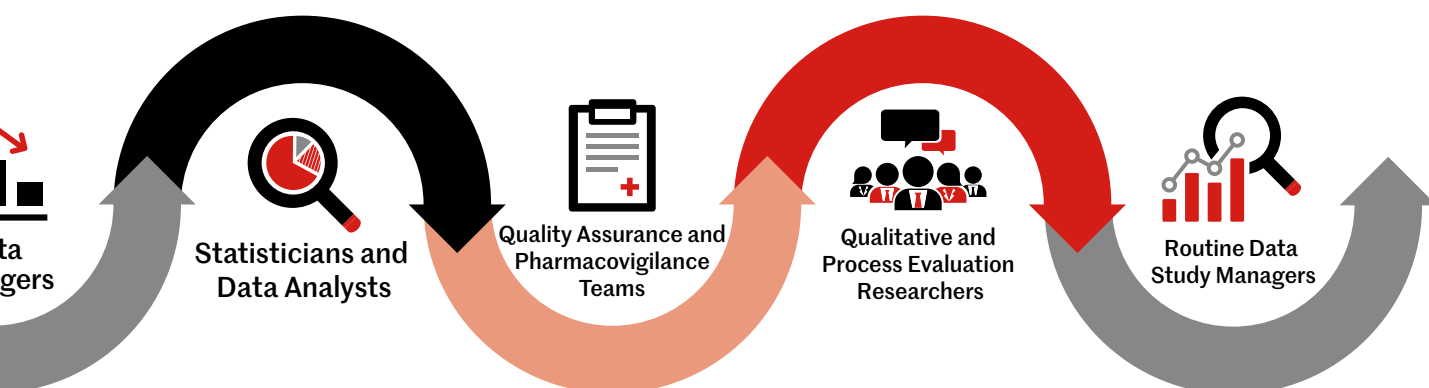


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Glossary

AML	Acute Myeloid Leukaemia	MHRA	Medicines and Healthcare products Regulatory Agency
APL	Acute Promyelocytic Leukaemia	NHS	National Health Service
CBT	Cognitive Behavioural Therapy	NIHR	National Institute for Health and Care Research
CI	Chief Investigator	PPI	Patient and Public Involvement
ctDNA	Circulating tumour DNA	QoL	Quality of Life
CTR	Centre for Trials Research	RCT	Randomised Controlled Trial
EDC	Electronic Data Capture	REDCap	Research Electronic Data Capture
FDA	Food and Drug Administration	SAIL	Secure Anonymised Information Linkage
GP	General Practitioner	TAU	Treatment As Usual
HDR UK	Health Data Research UK	WP	Work Package
HTA	Health Technology Assessment Programme		



Executive summary

Research through partnership

In our annual report two years ago, we reflected on the primary working model of our centre, that of team science. That remains core to our way of working and in the last year we have sought to extend that approach more explicitly in our partnerships with other research centres in Cardiff and across Wales. This sees our Centre as a connector to other research groups to enable better, bigger and more relevant research to answer societally driven questions.

Our core support from Welsh Government, via Health and Care Research Wales, and from Cardiff University provides the methodological and professional services capacity to connect to the expertise across Wales and beyond required to address complex questions and provide impactful solutions. Significant evolution in our senior team in the last year reflects the need for and success of leaders in the Centre in creating, sustaining and extending effective research partnerships.

Quality, assurance and innovation

Some of our significant achievements in the last year may be less eye-catching than others but underpin the quality of the work done in the Centre. This includes a successful inspection of the Centre by the regulator, the MHRA. While this centred around a week-long on-site inspection in August 2025, the planning and preparation process started in February and actions to respond to findings will continue into early 2027. Coordinated by our Head of Quality Assurance & Regulatory Affairs, this was a whole centre operation involving significant activity across all our resource group teams as well as particular responsibility for those trial teams that were the main focus of the inspection.

This was our first inspection since CTR's inception in 2015. Whilst few in the Centre would be seeking a repeat inspection any time soon, many found the outcome validating of the work we do, valued the whole team approach adopted throughout the inspection process, and affirmed changes that we were already in the process of implementing. It was a magnificent team effort which happened in parallel to ongoing trial delivery and critically provides reassurance to the investigators we work with.

In our report we place some focus on methodological innovation that happens across all of our teams, some of which may be less obvious to those who are unfamiliar with what trials units do, and specifically what this trial unit does. We also highlight some of the public involvement and engagement work we do, including work from staff across the Centre in raising the profile of trials to younger members of the public via Geoffrey the Giraffe. Both methodological innovation and public involvement and engagement are supported by our core funding and, in turn, enable our research portfolio which is the main content of the rest of our report. We hope you will enjoy reading about the exciting work initiated and delivered in the last year across our four divisional areas.

A shared effort

Thank you for taking the time to read about our work. We aim for our report to be of interest to as wide a group of stakeholders as possible. Please do contact us if you have any thoughts, questions or suggestions. We would like to acknowledge our funders, research partners, staff and collaborating investigators. Finally, we would like to thank all the patients, families and members of the public who have so generously given their time to take part in our studies. Our work is only possible with the collective contribution of all these people, and we thank you all.



Foreword

Mission and strategic aims

CTR is dedicated to tackling the big health and social concerns of our time. We work with investigators to produce research evidence for policy leaders, service commissioners and practitioners about treatments and services that may improve the health and wellbeing of the public.

Everyone, regardless of who they are, where they live, or what they do deserves the best health and care, and we will provide the evidence to make that happen.

Key programme partners and beneficiaries

CTR receives infrastructure funding from Welsh Government, via Health and Care Research Wales, as well as from Cardiff University. Until October 2025, we were also receiving funding from Cancer Research UK. This funding allows us to invest in core activities to support the design and oversight of high-quality studies and to win external funding to allow their conduct, analyses and publication. Most of our work involves external investigators undertaking applied research in health or social care (or both). The range of potential beneficiaries is broad, reflecting the diversity of studies and investigators we work in partnership with. These will include patients, social care service users, members of the public, health and social care service providers, health and social care policy makers. We also develop and utilise innovative methods and share these across the research community. These beneficiaries will be in Wales, the rest of the UK and in countries outside of the UK. CTR has a long-established record in promoting inclusive research and in producing evidence to support the care of traditionally underserved groups.

How we work

Our researchers and professional staff work across our four divisions and within cross-cutting teams (including Statistics, Information Services and Technology Solutions, Quality Assurance and Regulatory Affairs, and Professional Services). Our current research portfolio includes evaluations of drugs and complex health and social care interventions, studies of mechanisms of disease and treatments, cohort studies and trials informing health and social care policy and practice.

Activities embedded across these areas of work are public involvement and engagement, commercial/industry engagement and collaboration, NHS and social care professional engagement and collaboration, engagement with Welsh Government funded research infrastructure and communications, publicity and knowledge transfer.

Across everything we do we work to a clear set of values and principles.

Who's Who at The Centre

Professor Mike Robling is Director of the Centre for Trials Research, with Dr David Gillespie as Deputy Director.

The Centre's Executive leadership team comprises Professor Mike Robling (Director), Dr David Gillespie (Deputy Director), Professor Richard Adams (Clinical Director), Damian McAuliffe (Centre Manager), Dr Rachel McNamara (Director, Brain Health and Mental Wellbeing), Professor James White (Director, Population Health and Social Care Trials), Dr Emma Thomas-Jones (Director, Infection, Inflammation and Immunity Trials), Angela Casbard (Director, Cancer Trials),

Dr Rebecca Playle (Statistics and Methodology), Dr Fiona Lugg-Widger (Director for Data), and Dr Jeremy Segrott (Learning and Development and Deputy Director, Population Health and Social Care Trials).

Operational leadership is contributed by Dr Cheney Drew (Deputy Director, Brain Health and Mental Wellbeing), Dr Lisette Nixon (Deputy Director, Cancer Trials), Dr Philip Pallmann (Deputy Director, Infection, Inflammation and Immunity Trials), Dr Lucy Brookes-Howell (Qualitative Research Group), Dr Rachel Lowe (Trial Management), Nigel Kirby (Data and Technology), and Kelly Gee (Quality Assurance and Regulatory Affairs).

Centre for Trials Research Values

Making a difference

Improving health, wellbeing and sustainability of society

Innovating and researching

Empowered to be creative and questioning in everything we do

Building trust and confidence

Growing together as partners

Leading and collaborating

Developing true partnerships (nobody wins unless everybody wins)

Aspiring and inspiring

Helping everyone to be their best and to do their best

Protecting integrity and quality

Designing, delivering and publishing high impact research through academic and professional excellence

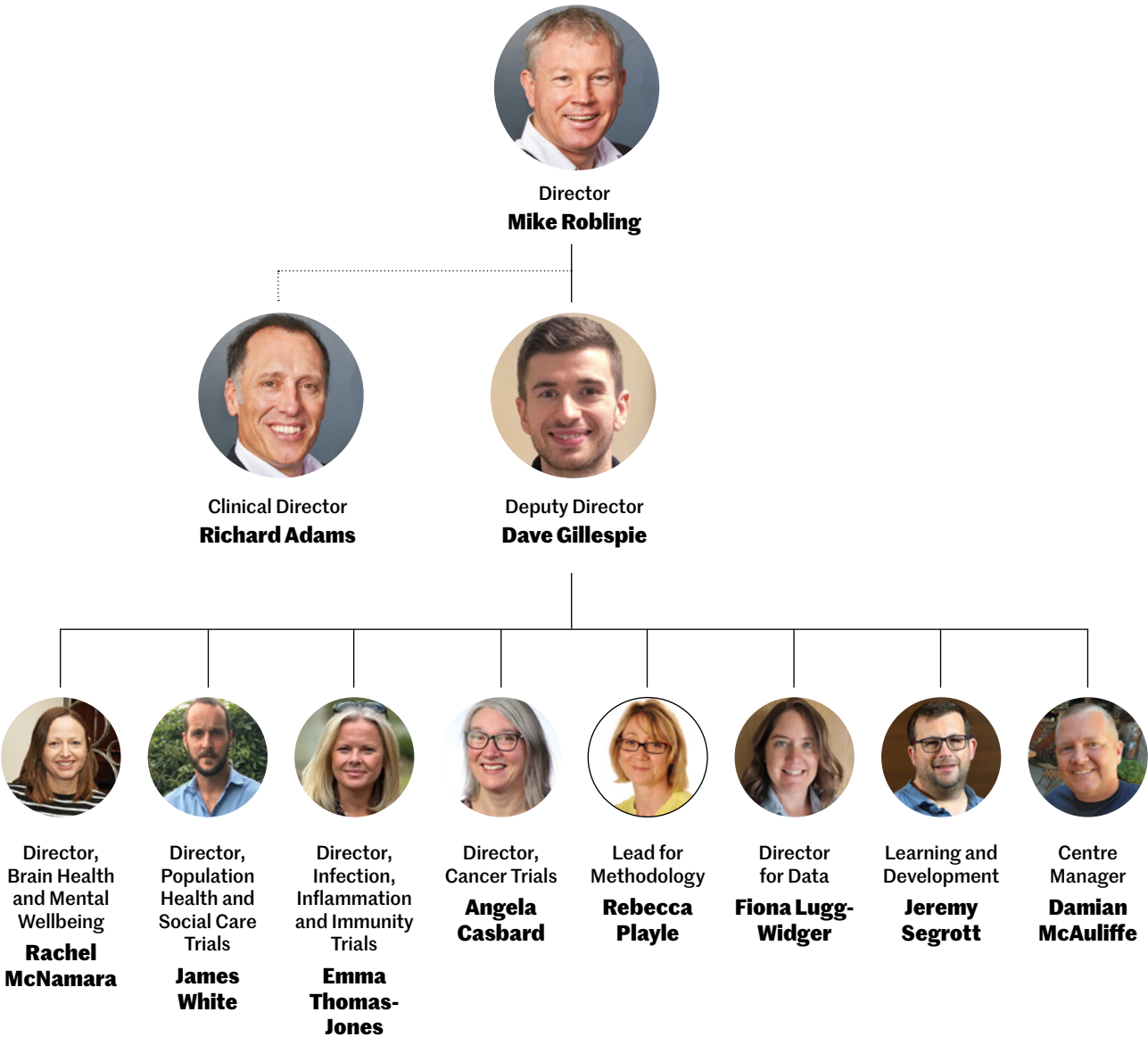
Respecting individuality

Recognising different needs and aspirations of every individual in society

Recognising

Celebrating success, openness and transparency

Centre for Trials Research Executive Leadership Team



Centre for Trials Research Divisions



Work packages

Our work funded by Health and Care Research Wales is organised into six work packages.

Work Package 1:
Managing our work

Work Package 2:
Working with other groups

Work Package 3:
Developing new studies

Work Package 4:
Overseeing funded studies

Work Package 5:
Ensuring methodological and
professional development

Work Package 6:
Development of All Wales
approach

Throughout this report, these graphics identify and introduce you to each section:

Cross-cutting themes

At the start of each work package throughout the report, you will see icons that represent our six cross-cutting themes below. This is to identify the ways in which our work has wider impact across the NHS, industry, social care, within Welsh Government and for the public. We hope you will find this a simple and easy way to navigate this report.



Public
involvement
and
engagement



Social care



NHS
engagement
and collaboration



Commercial /
industry
engagement and
collaboration



Engagement
with Welsh
Government
funded research
infrastructure



Communications,
publicity and
knowledge
transfer

Core Metrics

Reporting period: 2025/2026

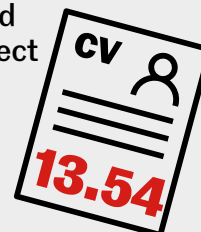
Health and Care Research Wales Infrastructure award to the group

Direct funding awarded

£869,294



Jobs created through direct funding



Grants won during reporting period

Grants won	Led by group	Group collaborating
Number	13	27
Value	£8,496,191	£36,385,899
Funding to Wales	£6,401,925	£5,974,494
Funding to group	£3,052,809	£3,430,137
Additional jobs created for Wales	66.26	50.18
Additional jobs created for group	36.60	37.02



Number of publications



Number of public engagement events



Number of public involvement opportunities

Clinical Trials Unit metrics



40

Number of studies awarded



27

Number of studies led by Welsh Chief Investigators



141,005

Total number of participants recruited



0.44

% participants from Wales



1

Work Package 1 Managing our work

Recruiting and supporting
staff and developing working
practices to make sure we meet
high standards for research



Our successes are due to the skills of the individuals working in the CTR amplified by the team structure to which they all form a part.

Leadership, Governance and Accountability

During 2025–26, CTR implemented a significant leadership refresh to ensure clear accountability, resilience and capacity to deliver high-quality research at scale. Key appointments and confirmations during the reporting period included:

- **Dr David Gillespie** – Deputy Director, Centre for Trials Research
- **Professor James White** – Director, Population Health and Social Care Division
- **Dr Jeremy Segrott** – Deputy Director, Population Health and Social Care Division
- **Angela Casbard** – Director, Cancer Division
- **Dr Lisette Nixon** – Deputy Director, Cancer Division
- **Dr Emma Thomas-Jones** – Director, Infection, Inflammation and Immunity Division
- **Dr Philip Pallmann** – Deputy Director, Infection, Inflammation and Immunity Division
- **Dr Mandy Lau** – Deputy Director of Statistics
- **Dr Fiona Lugg-Widger** – Director of Data
- **Mr Nigel Kirby** – Head of Data and Technology

These appointments strengthened Centre-wide, divisional and methods leadership, aligned responsibility with a growing and complex portfolio, and ensured robust oversight across trial design, delivery, data and governance.

Cardiff University Celebrating Excellence Award: Dr Sofia Vougioukalou recognised for co-creation and participative leadership

Sofia Vougioukalou, Research Fellow at Cardiff University's Centre for Trials Research and the Centre for Adult Social Care Research (CARE), has won the 2025 Cardiff University Celebrating Excellence Award for Co-creation and Participative Leadership.

The award honours her decade-long commitment to placing people with lived experience at the centre of research leadership. As academic lead for public involvement in CARE and the dementia thematic group, and across wider cross-centre roles, Sofia has embedded genuine co-production into research design, delivery and governance.

Through sustained trust-building in community spaces including parks, festivals, kitchens and arts groups, she has enabled more than 100 participants from British Sign Language, visually impaired, ethnic minority, LGBTQ+ and other marginalised communities to shape studies, co-author publications, lead dissemination and serve as named co-applicants on successful bids worth more than £1 million to the National Institute for Health and Care Research, the British Academy, Health and Care Research Wales and the Economic and Social Research Council.

This recognition underscores the value of long-term, inclusive public involvement in strengthening both the quality and reach of health and social care research.



Regulatory Confidence and Quality Assurance

During 2025, CTR underwent its first Medicines and Healthcare products Regulatory Agency (MHRA) inspection since formation. This represents a major milestone for CTR and an important independent assessment of CTR's systems, governance and operational delivery. The inspection report, published in November 2025, identified no critical findings, providing external assurance of high standards across trial management, pharmacovigilance, data integrity, quality assurance processes and essential documentation.

The inspection involved significant coordinated preparation and input from teams across CTR, including Quality Assurance and Regulatory Affairs, trial management, data and information systems, statistics, pharmacovigilance and operational leadership. Particular recognition was given internally to Kelly Gee and the Quality Assurance and Regulatory Affairs team for leading the process. Feedback from inspectors highlighted both the professionalism of individual staff and the strength of CTR's collaborative approach to delivering a complex portfolio of regulated studies.

The inspection reinforced the maturity of CTR's harmonised systems and infrastructure developed since achieving unified registration with the UK Registered Clinical Trials Unit Network.

As with any major regulatory inspection, the process identified areas for further strengthening and refinement, including pharmacovigilance processes, Principal Investigator oversight and ongoing development of electronic Trial Master File systems. The inspection therefore also provides an opportunity for organisational learning and continuous improvement. For Chief Investigators, collaborators and funders, the successful inspection provides confidence that studies are being delivered within a robust regulatory environment capable of supporting complex Clinical Trials of Investigational Medicinal Products (CTIMPs) and other regulated research across Wales and the wider UK.

2

Work Package 2 Working with other groups

Working in collaboration with
researchers from other organisations
across Wales and beyond



We will only be successful if we are effective in reaching out to key stakeholders and then working in partnership with them.

For this year's annual report, we have focused on public stakeholders in this section.

Evidence-to-Policy Collaboration

Synthetic data looks and behaves like real data, but doesn't include personal information about real people. It is designed to copy some patterns and features of real datasets so that researchers can practise using it, test their ideas, or develop new tools, all without risking anyone's privacy. In January 2026, Centre researchers presented work on public involvement and trust in synthetic data at Westminster as part of the launch of the UK Synthetic Data Governance Framework. Led by Dr Fiona Lugg-Widger and Dr Robert Trubey, the *Discussing Data* project demonstrated how structured public dialogue can directly inform national data governance and policy.

The project involved workshops with members of the public from across the UK. The aim was to establish recommendations for how data owners should make and share synthetic data, and how they should talk to the public about it. The project's recommendations were made available as an infographic, booklet and PDF, with video interviews also shared.

Civic Mission and Cultural Collaboration

CTR contributed to a range of collaborative civic and cultural activities, including the *Luna's Light* book launch at the Pierhead Building and the Eight Voices in Darkness engagement project. These activities brought together researchers, partners, artists and communities to connect research evidence with lived experience and public dialogue.



Photo: James Richardson

Luna's Light

Luna's Light / Skye & Luna is a children's book created to support families affected by baby loss and Sudden Infant Death. Written by Philippa Atkins following the loss of her daughter Luna, the project brings together lived experience, bereavement expertise, charities and community partners to help families navigate grief with compassion and openness.

In November 2025, CTR supported the launch event at the Pierhead Building in Cardiff Bay, bringing together policymakers, clinicians, researchers and families to highlight the importance of bereavement support across Wales. As part of its maternal and child health programme and wider civic mission, CTR has supported the project through governance, institutional backing and connections with health boards, charities and wider networks.

The initiative reflects CTR's commitment to research and engagement that improves support for families during some of the most difficult moments of their lives, helping ensure children and families affected by loss are not left isolated or forgotten.

Eight Voices in Darkness

An interdisciplinary public engagement project combined lived-experience storytelling, photography and sound to highlight the mental health impact of sight loss. Delivered with charities, artists and academic partners and showcased as part of the Being Human Festival, the project strengthened collaboration across health, social care and the cultural sector while amplifying under-represented voices.

Eight Voices in Darkness was a collaborative public engagement exhibition exploring the mental health impact of sight loss. Developed by Cardiff University, Wales Council of the Blind, Sight Life and Anglia Ruskin University, the exhibition combined lived experience stories, photography and sound to highlight the experiences of people living with visual impairment alongside depression and anxiety.

Held at Chapter Arts Centre in Cardiff as part of the 2025 Being Human Festival, the exhibition aimed to improve awareness and understanding across health, social care and the wider public. The project included portraits created by members of Sight Life's photography club and an immersive sound installation designed to amplify lived experiences often overlooked in traditional healthcare settings.

The work forms part of wider research activity led by Dr Claire Nollett, who works in CTR and Centre for Vision Services Research, and collaborators to improve mental health support and access to services for people with sight loss. Alongside the exhibition, the team also delivered workshops for professionals working across vision and mental health services.



3

Work Package 3 Developing new studies

Designing new studies and winning
the funding to make them happen



In this section we tell you about some of our new studies. These are drawn from across all four of our divisions and reflect some of our longest established research themes as well as newly emergent areas of focus. Featured studies reflect building programmes of research over several projects led by external local and nationally based investigators as well as those led from within CTR by our own researchers.



Brain Health and Mental Wellbeing

DAISY

The digital family support study

A randomised controlled trial (RCT) of a digital parent support programme for parents of children with intellectual disabilities.

Chief Investigator: Professor Kylie Gray

Funder: National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (HTA)

The DAISY study will evaluate whether an online parent support programme can improve emotional and behavioural outcomes for children with learning disabilities, while also supporting parent carer wellbeing.

Many families caring for children with learning disabilities face significant challenges accessing support. Digital approaches may offer a more flexible and accessible way for families to receive help, particularly for those balancing caring responsibilities, financial pressures, or barriers to attending services in person.

The study will recruit 432 families with children aged 2–11 years. Families will either receive the Stepping Stones Triple P (SSTP) Online programme immediately or at a later stage through randomisation. Alongside the online programme, some families will receive additional peer support from parents with lived experience of caring for a child with learning disabilities.



Researchers will assess outcomes over 12 months and gather feedback from families and peer supporters to understand their experiences of the programme.

A strong focus of the study is inclusion and accessibility. Parent carers have been involved throughout the development of the project, helping shape the research design, identify barriers to participation, and ensure the programme reflects the realities of family life. The study team will also support families who may face digital exclusion by helping provide internet access or suitable devices where needed.

The findings will help inform future support for families of children with learning disabilities and will be shared with families, services, policymakers, and organisations across the UK.

OAMHS

Open access mental health support in Wales

Evaluating whether Wales's open-access mental health model improves access, equity, outcomes and value across mental health services.

Chief Investigators: Dr Chris O'Connor and Dr Rachel McNamara

Funder: NIHR Programme Grants for Applied Research

People who need mental health support in the UK face long waits for services. Mental health services across Wales will be made 'open access' from now on. This means that people seeking mental health care can choose the type of support they receive. They will also be able to get support the same day they ask for help. We know from research evidence that giving people choice and early support can improve outcomes. This has not yet been tested on a large scale. Wales would be the first country in the world to do this.

We will look at whether 'open access' means it is easier to get help, and whether access to support is equal in all groups who might need it (e.g. across genders and ethnicities). We will also look at whether people have fewer symptoms because of engaging with the new service model. We will explore outcomes for mental healthcare professionals (e.g., job satisfaction) and for services (e.g., waiting times). We will explore the costs and benefits to the NHS and society of adopting this approach. We will describe how the model has been implemented and which factors help or hinder success.

We will carry out several related streams of work (work packages) to answer our research questions using different methods.

- **Work package (WP) 1a:** Lived Experience Panels. Children, young people and adults with experience of mental health difficulties will help us develop our methods. **WP1b:** A Stakeholder Group (people with lived experience, professionals) will meet regularly to guide research and understand results.
- **WP2.** We will measure indicators before the change was introduced using data that is routinely collected (e.g., waiting times for a service, patterns of mental health-related activity across Wales, including referrals and access to services, prescriptions for medicines).
- **WP3 and 4.** Using data from interviews, questionnaires and routine data, we will explore whether the new model is helpful for people with mental health difficulties. We will look at what works best, for whom and in what contexts. We will also look at costs and benefits of the new approach (WP5) and explore how best to apply the model in different settings.

People with lived experience of mental health difficulties have helped to shape the project. They advised us how we can best include all groups in society who most need mental health support. People with lived experience will contribute throughout the project, using codesign methods (where public contributors have an equal say to researchers).

Results of the research will be shared with key stakeholders as they emerge. We will develop a plan for sharing knowledge and describe how materials will be adapted to suit needs of different groups. Information will be shared in multiple ways including academic outputs, social media, press releases, videos, animations and newsletters.



Cancer

QuicDNA Max

QuicDNA liquid biopsy programme expansion

A £2.52 million investment expanding liquid biopsy circulating tumour DNA (ctDNA) testing from lung cancer into colorectal, cancer of unknown primary and prostate cancer across all Welsh health boards to support earlier diagnosis.

Chief Investigators: Dr Magda Meissner, Professor Richard Adams, Dr Sonali Dasgupta

Funders: Eli Lilly, Merck Sharp & Dohme, Office for Life Sciences, Menarini, AstraZeneca, and Amgen

In December 2025, a £2.52 million investment was announced to support the next phase of the QuicDNA programme, QuicDNA Max. Funding from Welsh Government, the UK Office for Life Sciences and industry partners will expand liquid biopsy testing beyond lung cancer into colorectal, cancer of unknown primary and prostate cancer, embedding genomic diagnostics across all Welsh health boards, supporting earlier diagnosis and improved patient outcomes.

SCC-AFTER

Adjuvant radiotherapy in patients with high-risk primary cutaneous squamous cell carcinoma after surgery

A phase III trial testing whether patients with squamous cell carcinoma can safely avoid adjuvant radiotherapy after surgery, reducing unnecessary treatment and burden.

Chief Investigators: Professor Catherine Harwood and Dr Agata Rembielak

Funder: NIHR HTA

CTR coordinated the development and initiation of the SCC-AFTER trial, a large phase III trial testing whether patients with squamous cell carcinoma can safely avoid adjuvant radiotherapy, reducing unnecessary treatment and associated patient burden.





OVATION

A randomised comparison of oral and intravenous arsenic trioxide (ATO) consolidation therapy in acute promyelocytic leukaemia

A UK-wide phase 3 Blood Cancer UK-funded trial evaluating a fully oral at-home arsenic regimen for APL to improve quality of life while maintaining non-inferior clinical response.

Chief Investigator: Dr Steven Knapper

Funder: Blood Cancer UK

A new UK-wide clinical trial led from Cardiff secured £750k funding from Blood Cancer UK to evaluate an oral, at-home arsenic treatment for acute promyelocytic leukaemia (APL). Although most patients diagnosed with APL are now cured, the burden that prolonged hospital-based treatment places on patients and families is substantial. After an initial intravenous based treatment, patients must continue long-term consolidation therapy. In OVATION, a prospective, multi-centre, phase 3, RCT, we seek to establish a new fully oral consolidation treatment schedule, based around the oral ATO formulation Arsenol, as the new standard of care in APL by demonstrating both superior patient quality of life (QoL) and non-inferiority of clinical response when compared with current intravenous ATO-based consolidation therapy. 240 patients with APL who have responded to their initial ATO therapy will be recruited from approximately 80 acute leukaemia-treating centres over 3 and a half years.

VALTIVE-C

Validation of Tie2 as the first tumour vascular response biomarker for vascular endothelial growth factor (VEGF) inhibitors

A phase III randomised Cancer Research UK-funded trial expanding the TIE-2 biomarker approach from ovarian cancer, comparing biomarker-guided versus clinician-based treatment decisions in colorectal cancer.

Chief Investigators: Professor Gordon Jayson and Dr Michael Braun

Funder: Cancer Research UK

The VALTIVE-1 trial was set up to evaluate the utility of the TIE-2 biomarker in identifying patients who respond well to bevacizumab treatment in ovarian cancer. Following on from this, the biomarker test has now been expanded into colorectal cancer in the phase III, randomised, VALTIVE-C study. The trial was recently funded by Cancer Research UK and will randomise patients between a biomarker guided approach - where bevacizumab treatment may be stopped for non-responding patients, and a clinician-based approach - where the biomarker result will not be available for treatment decisions.



VESPER

Intravesical preparations for recurrent urinary tract infection prevention

A UK-wide trial evaluating intravesical treatments against standard second-line antibiotics for women with recurrent uncomplicated urinary tract infections, now recruiting across 20 sites.

Chief Investigator: Mr Chris Harding

Funder: NIHR HTA

In May 2025, the first patient was recruited to the VESPER trial, coordinated by CTR across 20 UK sites. The trial is evaluating the clinical and cost-effectiveness of intravesical treatment strategies for women with recurrent uncomplicated urinary tract infections.

Recurrent urinary tract infections affect thousands of women and can have a significant impact on quality of life, with many patients requiring repeated or long-term antibiotic treatment. VESPER will compare two bladder-administered therapies against current standard second-line antibiotic care, helping explore more sustainable and effective treatment approaches. The study aims to generate evidence that could improve future care pathways while reducing long-term reliance on antibiotics.

VESPER was in response to a commissioned call from the Health Technology Assessment (HTA), so is recognised as a highly relevant area of research, addressing a major unmet clinical need.

REFINE

Respiratory viral testing in the management of febrile infants presenting to emergency care

A Health and Care Research Wales-funded pilot testing whether rapid point-of-care viral diagnostics can safely reduce invasive procedures, admissions and antibiotic use in febrile infants under three months.

Chief Investigators: Dr Jordan Evans and Dr Joanne Euden

Funder: Health and Care Research Wales

The REFINE pilot study launched in October 2025 to test whether rapid point-of-care viral diagnostics can reduce invasive procedures, hospital admissions and antibiotic use in febrile infants under three months. The study is funded by Health and Care Research Wales and designed as a feasibility step towards a future UK-wide trial.

Fever is one of the most common reasons infants are brought to emergency departments, with very young babies often requiring invasive investigations to rule out serious infection. REFINE is exploring whether rapid viral testing can help clinicians safely identify infants at lower risk, potentially reducing unnecessary procedures and supporting quicker discharge home with families. The research brings together clinicians, researchers and patient representatives across Wales to explore how rapid diagnostics could improve care for vulnerable infants and their families.

The study highlights working with a new CI (Jordan Evans) and promoting internal staff to become co-CIs (Jo Euden). Jordan also had support for this bid through the CTR scheme developing aspiring researchers.

EVITA

Evaluation of intravenous therapy in asthma

A £2.3 million NIHR HTA trial comparing three intravenous treatments for children with severe acute asthma.

Chief Investigators: Professor Graham Roberts, Professor Damian Roland, Dr Katrina Cathie

Funder: NIHR HTA

Coordinated by CTR in partnership with Liverpool Clinical Trials Centre, EVITA will compare three intravenous treatments currently used in the UK – aminophylline, magnesium sulfate and salbutamol - to establish which leads to the fastest recovery, best patient experience and greatest value for money.

Asthma affects around one in 11 children and young people in the UK and remains one of the leading causes of childhood hospital admissions. Severe acute asthma can be life-threatening and current treatment approaches vary across hospitals due to limited evidence on which medicine works best.

The trial opened in December 2025 and will recruit approximately 357 children and young people aged 2–18 years across 20 hospitals in the UK. Outcomes will include clinical recovery using a validated asthma severity score, length of hospital stay, side effects, acceptability to patients and families, and cost-effectiveness. The study was designed with strong patient and public involvement (PPI), including parents and young people, to ensure relevance and acceptability of trial processes and outputs.



EXCISE

Examining antibiotics for ulcerated skin cancer surgical excision

A £1.4 million NIHR HTA trial investigating whether prophylactic antibiotics reduce wound infection risk following surgery for ulcerated skin cancer.

Chief Investigators: Dr Rachel Abbott and Dr Emma Thomas-Jones

Funder: NIHR HTA

Skin cancer is the most common type of cancer. Every year in the UK, around 200,000 people have their skin cancer removed surgically. Some people develop skin cancers that break through the skin surface, causing a wound on the skin (called an ulcerated skin cancer), which are six times more likely to develop a wound infection after surgery. Doctors often prescribe antibiotics at the time of surgery to prevent wound infections, but we do not know whether antibiotics reduce the risk of getting an infection. Using more antibiotics than is needed may lead to patients having unnecessary side effects and lead to the bacteria causing the infection becoming resistant to antibiotics, which then work less well in the future.

The trial opened in February 2026 and will recruit 380 patients across 15 hospitals in the UK. It also features a Centre for Trials Research co-PI, Dr Emma Thomas-Jones.





Population Health and Social Care

CARE Lab

Social care linked data lab

The NIHR-funded project linking adult social care, health, census and children's social care records in SAIL Databank to generate evidence on outcomes and inequalities.

Chief Investigators: Professor Jonathan Scourfield and Dr Fiona Lugg-Widger

Funder: NIHR Research Programme for Social Care

The NIHR-funded Social Care Linked Data Lab (CARE Lab) launched to strengthen the evidence base for adult social care through secure, large-scale data linkage. Co-led by the Centre for Adult Social Care Research (CARE) and CTR, the study links newly available adult social care datasets in Wales with health, census and children's social care data within the Secure Anonymised Information Linkage (SAIL) Databank. This creates a unique resource for understanding how people in Wales move through social care and health systems enabling researchers and policymakers to identify opportunities to improve outcomes and reduce inequalities.

Grounded in public and lived-experience involvement, CARE Lab combines data science with co-production approaches to ensure research priorities reflect real-world needs and that findings are meaningful for people who use and deliver services. The study aims to generate policy-relevant evidence to support improvements in adult social care in Wales and beyond.

Working with collaborators at the London School of Economics and Political Science (LSE), Welsh Government and Administrative Data Research (ADR) Wales, CARE Lab will use linked data to evaluate the impact of social care services, policies and innovations, helping decision-makers understand what works, for whom, and under what circumstances. In parallel, a horizon-scanning work package will bring together emerging policy priorities, data developments and research opportunities across the UK, supporting a shared, forward-looking research agenda for adult social care. It also features a Centre for Trials Research co-PI, Dr Fiona Lugg-Widger.

4

Work Package 4 Overseeing funded studies

Running studies to a high quality
and producing outputs that will
make a difference to the public



In this section we give an overview of how we oversee and deliver our funded studies to a high quality, producing outputs that will make a difference to the public.



Brain Health and Mental Wellbeing

DEVISE HD

Developing evidence for antidepressant choice to treat depression in Huntington's disease

A feasibility RCT testing sertraline versus placebo in people with Huntington's Disease and mild-to-moderate depression, designed with strong PPI input to inform a future definitive trial.

Chief Investigators: Dr Duncan McLauchlan and Dr Cheney Drew

Funder: Health and Care Research Wales

Huntington's Disease (HD) causes problems with movement and thinking, both worsening over time. People with HD also get depression and other mental health problems. Depression is common in HD and has effects on quality of life and people's ability to do things. We know that the inability to do everyday things is the main reason HD has high healthcare costs. We think that by properly treating depression, we can improve quality of life for people with HD and their families and that this will reduce their need to use expensive healthcare services.

Our data shows that depression in HD is different from depression in people without HD. As such, anti-depressant medicines might work differently in people with HD. We do not know how well anti-depressants work in HD or what is the best way of measuring depression in HD. The first step in answering this question is to test how well a RCT of anti-depressants may work.

Forty people with HD who report mild or moderate symptoms of depression to their doctor will take part. Half of participants will

be treated with a standard antidepressant (Sertraline), and the other half will be given a dummy pill (placebo) for six months. We will measure depression and other HD symptoms at the beginning of the study and again after six months. We will also collect blood and the fluid surrounding the brain to see if anti-depressant treatment changes substances the body normally produces in response to damaged cells (inflammation). We will use the data to see if people with HD are willing to join the study, if they stay in the study and what the best way of measuring depression is.

We have worked with people with HD and family members to develop this research question, and they have provided input to this application. In addition to our PPI co-applicant, we will involve people with lived experience in the delivery of the study. The PPI research partners will lead the discussion on communicating with study participants and sharing study results with the broader public.

The results of this study will be used to design a full RCT to answer our question about what, if any, antidepressants are best for treating depression in HD. We will share our results with the study participants and the broader HD community via HD Buzz and patient-focused organisations. The results will be presented to other doctors and researchers at scientific conferences and journals.



SWELL

Skills for adolescent wellbeing

A RCT of online Cognitive Behavioural Therapy (CBT) for young people at high-familial risk of depression.

Chief Investigator: Professor Frances Rice

Funder: The Wolfson Foundation

Depression is common in young people and can lead to long-term mental health difficulties. Young people with a depressed parent are at especially high risk of depression themselves. Depression in adults is sometimes not managed optimally. Therefore, optimising treatment in line with best practice guidelines for parents who are currently depressed alongside the intervention for young people may benefit young people.

This project aims to test the effectiveness of the SWELL intervention in preventing depression in adolescents who have a depressed parent. We will recruit adolescent-parent pairs and optimise treatment for the parent when they are depressed at the start of the study. We will also look at other outcomes in the young person like functioning in day-to-day life.

We will recruit young people with a history of depression in a parent and who have either current elevated depressive symptoms or a history of depression. These young people will be recruited from existing patient cohorts/databanks, from primary care centres, employee support and wellbeing services, schools, social media and via advertisements and leaflets in health and community settings using in-person and online methods. Before the intervention begins, the young person's parent will be assessed for current depression. If the parent is currently depressed, they will be offered the opportunity to enter a 12-week period during which their depression treatment is optimised.

Over 400 young people were assigned randomly to receive the intervention plus usual care or to continue with usual care only. The young person and their parent participate in online assessments about their mental health at the start of the study and again after 3 and 9 months. We have now completed recruitment and are delivering remaining groups and parent optimisation. Follow-up will be completed in early 2027.

VIG-ID

Video interaction guidance for parents of children with intellectual disability

A feasibility randomised trial of remotely delivered Video Interaction Guidance for parents of children with intellectual disability referred to specialist mental health services.

Chief Investigator: Professor Vaso Totsika

Funder: NIHR Research for Patient Benefit

Children with intellectual disability are at higher risk of presenting with behaviours that challenge. Video Interaction Guidance (VIG) is a brief, personalised, strengths-based therapy that focuses on improving the parent–child relationship. A strong parent–child relationship may reduce the risk of behaviours that challenge. Access to support is difficult for families of children with intellectual disability. Remotely delivered support may enhance access to therapy for those who might otherwise struggle to access support.

We conducted a feasibility RCT which aimed to recruit 50 parents of a child with intellectual disability (aged 6–12) referred to specialist mental health services. Participants were randomised to receive VIG plus treatment as usual (TAU) or just TAU. Questionnaires were collected remotely at baseline, 3-month, and 6-month follow-up. A parallel study explored the feasibility of a future economic evaluation, while a process evaluation explored feasibility and acceptability through qualitative interviews.

We carried out a survey of specialist mental health services, to explore what is usually offered to families i.e., to describe TAU. A Parent Carer Advisory Group of 10 parents of children with intellectual disability worked with the research team on design, recruitment, data analysis and interpretation.

We recruited 44 parents to participate in the study and 40 were randomised to the RCT. Of those, 75% remained in the study at 6-month follow-up, and 70% of those offered VIG completed at least 3 cycles. Acceptability of VIG was high among parents and practitioners. Parents identified few barriers to participation when VIG was delivered remotely. Video-feedback interventions are not typically part of TAU: just 15% of 66 specialist mental health services reported offering any video-feedback intervention to parents of children with intellectual disability.

Our findings support the feasibility and acceptability of a future definitive trial of remotely delivered VIG to parents of children with intellectual disability referred for support to specialist mental health services.





QuicDNA

QuicDNA liquid biopsy programme

Chief Investigator: Dr Magda Meissner

Funders: Health and Care Research Wales, AstraZeneca, Moondance Initiative, Illumina, Amgen, Lilly, Bayer

QuicDNA was a Wales-led research programme for patients with suspected advanced lung cancer. The study aimed to demonstrate that early testing of blood (liquid biopsy) for circulating tumour DNA could shorten the time from GP referral to the initiation of targeted treatment, compared to the standard pathway of tissue biopsy testing. It was initiated as a pilot and then extended to all 6 Welsh Health boards.

Recruitment to the QuicDNA study completed ahead of schedule with 743 participants across Wales, generating real-world evidence that supported the commissioning of the ctDNA test in England and Wales during 2025. In December 2025, the QuicDNA study team won the Health and Social Care Industry Collaboration Award at the MediWales Innovation Awards, recognising excellence in cross-sector partnership working. The work of QuicDNA is now being extended into other cancer sites, through the QuicDNA Max programme, which will lead with ctDNA evaluation in colorectal cancer diagnosis, followed by cancer of unknown primary.

FAKTION

Fulvestrant plus capivasertib in advanced oestrogen receptor-positive breast cancer

The biomarker-driven phase II trial whose results directly enabled capivasertib approval for routine NHS use in advanced hormone receptor-positive breast cancer.

Chief Investigators: Professor Rob Jones and Dr Sacha Howell

Funders: AstraZeneca and Cancer Research UK

In 2025, the targeted breast cancer treatment capivasertib was approved for routine NHS use in Wales and England following global regulatory and National Institute for Health and Care Excellence (NICE) approval, representing a major translational success for Welsh-led clinical trials research. The approval followed results from the FAKTION trial, designed and coordinated by CTR in partnership with Velindre Cancer Centre and collaborators across the UK.

The UK-wide, biomarker-driven phase II trial involved 150 patients with oestrogen receptor positive, human epidermal growth factor receptor 2 (HER2) negative advanced breast cancer whose disease had become resistant to standard hormone therapy. Initial findings published in 2020 showed that capivasertib significantly prolonged progression-free survival, with follow-up results in 2022 additionally demonstrating an overall survival benefit. The study also showed that biomarker testing could help identify patients most likely to benefit from treatment.

FAKTION directly informed AstraZeneca's international phase III confirmatory trial and played an important role in securing FDA approval, NICE approval and NHS adoption of the treatment. Approximately 40% of patients with metastatic hormone-driven breast cancer may benefit from the drug, potentially improving survival and quality of life for thousands of patients in the UK and millions worldwide. The approval represents a major example of research led in Wales progressing from early phase clinical trial to international practice-changing impact.



PRONTO

Procalcitonin and National Early Warning Score 2 (NEWS2) evaluation for timely identification of sepsis and optimal use of antibiotics in the emergency department

A 7,667-patient multicentre trial demonstrating a 17% relative mortality reduction with procalcitonin-guided assessment, with the greatest benefit seen in the most deprived communities.

Chief Investigators: Professor Neil French and Dr Stacy Todd

Funder: NIHR HTA

PRONTO is a major multicentre, RCT addressing one of the most urgent challenges in acute care: the early and accurate diagnosis of sepsis. Conducted across 20 emergency departments in England and Wales and involving 7,667 patients, the study evaluated whether adding rapid procalcitonin testing to standard clinical assessment could improve decision-making for patients presenting with suspected sepsis.

Sepsis remains difficult to diagnose, particularly in emergency settings where symptoms overlap with other conditions and there is no single definitive test. This uncertainty can lead to both over-treatment and missed diagnoses, contributing to avoidable harm and wider challenges such as antimicrobial resistance. PRONTO was designed to address this evidence gap and provide robust data to inform clinical practice.

The findings, published in *The Lancet Respiratory Medicine*, demonstrate that while the addition of a procalcitonin-guided algorithm did not change the speed of intravenous antibiotic initiation, it was associated with a meaningful reduction in mortality. The study reported a 17% relative reduction in deaths, equating to around 31 lives saved per 1,000 patients treated for suspected sepsis.



Importantly, the greatest benefit was observed among patients from the most deprived communities, highlighting the potential for improved diagnostic approaches to contribute to more equitable health outcomes.

These results represent a significant step forward in strengthening the evidence base for biomarker-supported diagnosis in sepsis. While further work is needed to understand the mechanisms behind the observed mortality reduction and to support implementation at scale, PRONTO provides high-quality, peer-reviewed evidence that can inform future guidelines, clinical pathways, and health system decision-making.

The study exemplifies the role of CTR in supporting large-scale, complex trials from design through to publication, delivering research that has clear potential to improve patient outcomes and shape practice at a national and international level.



Population Health and Social Care

TRUFFLE 2

Trial of randomised umbilical and fetal flow in Europe

An international study across 54 sites that completed recruitment to determine whether cerebral Doppler-based delivery timing improves perinatal and two-year neurodevelopmental outcomes in late preterm fetal growth restriction.

Chief Investigator: Professor Christoph Lees

Funder: NIHR HTA

Poor fetal growth and physiological compromise are strongly associated with stillbirth, neonatal illness and a 15% risk of hypoxic brain injury. Controversy exists as to when the optimal time is to deliver such babies. The aim of this study was to determine, in situations where fetal growth is poor or fetal size is small between 32 and 36+6 weeks of gestation, whether delivery on the basis of cerebral blood flow redistribution reduces adverse outcome compared with waiting

until the fetal heart rate pattern suggests possible hypoxaemia/acidosis on Computerised Cardiotocography (cCTG). The primary outcome is a composite of perinatal poor outcome, death and short-term hypoxia-related morbidity. Secondary outcomes include follow up of babies to assess neurodevelopmental outcome at two years. The study completed recruitment in April 2025 and involved 54 sites (13 in the UK and 41 non-UK sites).

The primary outcome was assessed in 654 participants, and 5,153 women contributed data to the cohort study comprising women identified with either a small for gestational age or fetal growth restricted fetus, but who did not meet the cerebral Doppler threshold for randomisation. Results will inform both policy and practice worldwide and will be available later in 2026.

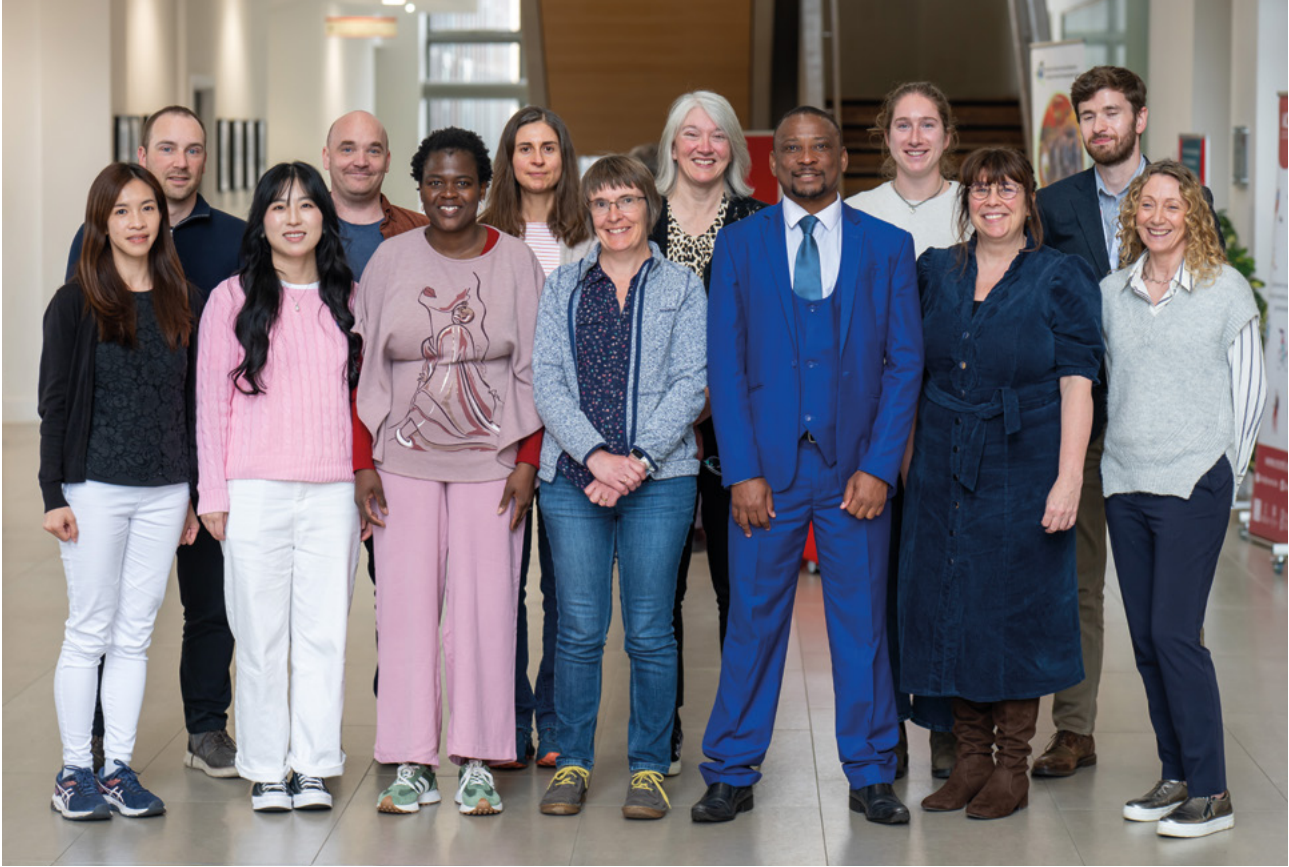
5

Work Package 5

Ensuring methodological and professional development

Developing new ways to answer important
clinical questions and sustaining a dynamic
and professional workforce





Qualitative Research Group (QRG) methodological highlights

CTR's Qualitative Research Group uses qualitative methods to develop novel approaches to trial and study design and optimise trial and study methods. CTR Qualitative Research Group member Nina Jacob (CARE and CTR Research Fellow) has worked with Martina Svobodova (CTR Research Associate and Trial Manager) to use creative participatory methods in 'Let's Talk Research' to engage underserved communities in health research. The team have developed a deeper understanding of how to engage with socio-economically disadvantaged communities which can inform future practice, ensuring an approach which is sensitive to the unique strengths and circumstances of each community.

The Qualitative Research Group continues to develop innovative research recognised at both national and international level. VR-Melody, led by Dr Kim Smallman, was selected by the National Centre for Creative Health as a national case study demonstrating good practice in digital innovation within creative health. Developed through a multidisciplinary collaboration between Cardiff University researchers, industry partners, clinicians and people with lived experience, VR-Melody is a co-produced digital mental health intervention designed to support adults experiencing symptoms of anxiety and

build mental resilience through personalised Virtual Reality (VR) experiences. Combining artificial intelligence, music and immersive home-based therapy, the project followed a user-centred co-design approach grounded in Medical Research Council guidance, with people with lived experience helping shape the intervention throughout development, testing and evaluation.

The CTR Qualitative Research Group contributes to research led teaching and are enthusiastic about inspiring the next generation of qualitative researchers. Year 2 students in the School of Medicine at Cardiff University have been taking part in 'Experience Weeks' on 'Qualitative Research – the 'What', the 'Why' and the 'How' as part of the Student Selected component of their course. The introduction to Qualitative Research in medical and health research was coordinated by Jeremy Segrott from CTR's Division of Population Health and Social Care and the CTR Qualitative Research Group. The course used examples from recent CTR studies and trials to demonstrate the value that qualitative research methods bring, such as creating a greater understanding of the experiences of under-served populations and developing a more complete picture of what went on during a study.



Statistical team methodology highlights

Adaptive Designs Working Group

CTR Principal Research Fellow, Dr Philip Pallmann is the co-lead of the MRC-NIHR Methodology Research Partnership Adaptive Designs Working Group. This is an international collaboration with the Medical Research Council (MRC) Biostatistics Unit in the University of Cambridge together with researchers based at University of Bath, MRC Clinical Trials Unit at University College London (UCL), Sheffield Centre for Health and Related Research (SHARR) and the University of Regensburg, Germany.

The work of the Adaptive Designs Network aims to increase the uptake of adaptive methods, improve knowledge and link with key stakeholders such as regulators and industry in this important area for improving the speed and efficiency of trials. The group have conducted and published comprehensive methodological reviews to summarise statistical methodology implemented in adaptive designs and produced practical guidelines for their use. These methodological guidelines build on the PANDA toolkit which provides a wide range of educational resources and software for trialists and researchers planning and designing adaptive trials.

The Group's most recent publication also highlights the importance of considering ethical dimensions in the choice of trial design methodology with reference to standard trial methods and adaptive designs.

UK Registered Clinical Trials Unit Network collaboration

CTR continues as a key member of and contributor to the UK Registered Clinical Trials Unit Network. Staff attend regular meetings of the subgroups of the network which include groups for Statistics, Quality Assurance, Data & Information Systems and Trial Management. Angela Casbard, CTR Director of Cancer also co-led a project with the UK Registered Clinical Trials Unit Network to carry out a survey among all registered trial units in the UK on central data monitoring. The recently published paper describes the findings of the survey and summarises them into practical guidelines and a checklist for trial units to apply to their trials. CTR will be reviewing its central data monitoring processes and updating them where necessary in line with these new proposals.

Target Trial Emulation (TTE)

TTE is a novel methodology that uses real-world data to replicate a trial to estimate causal effects of interventions when trials aren't feasible or ethical. A framework guides study design and analysis to accurately emulate the trial and avoid methodological biases. In a recent paper published in the *Lancet Obstetrics, Gynaecology & Women's Health*, Dr Rebecca Cannings-John from CTR and colleagues in the Division of Population Medicine reported work which used Welsh health records to emulate a trial assessing whether prophylactic antibiotics for recurrent urinary tract infections increase antibiotic resistance. Among 48,297 women, prophylaxis did not significantly increase hospital admissions with antibiotic-resistant infections. However, it increased resistance detected in urine cultures, including multidrug resistance. With a recent HTA NIHR funding call for TTEs, this methodology is likely to become a part of clinical research, filling evidence gaps where trials cannot be performed.

TOP-CAT – Data-Enabled Trials Training

TOP-CAT (Transforming Outcomes for Patients through the use of health data in Clinical trials Training) launched a national suite of free online training resources via the HDR UK Futures platform to support the safe, ethical and effective use of routinely collected healthcare data in clinical trials. Led by CTR as part of HDR UK's Transforming Data for Trials programme, the initiative is helping build the skills and confidence needed to embed healthcare systems data more effectively into future research.

Routinely collected healthcare data - including hospital records, GP data, prescriptions and diagnostic results - has the potential to make trials faster, more efficient and more inclusive. However, using these data sources requires specialist knowledge in areas such as governance, data utility, public trust and

inclusive engagement. Developed with trialists, data specialists and public contributors, TOP-CAT provides practical guidance and real-world examples to support everyone involved in trials, from statisticians and trial managers to clinical teams and public contributors.

The programme includes in-depth modules and short video resources covering topics such as data utility comparison studies (DUCkS), synthetic data, public trust and engaging underserved communities in data-enabled trials. By making the training freely accessible across the UK, CTR is supporting wider workforce development in this rapidly evolving area of trials methodology and helping research teams design studies that are both scientifically robust and publicly trustworthy.



Technological and methodological developments

The Technical Innovation and Development (TID) team has developed reusable randomisation and investigational medicinal product (IMP) management components to support trial delivery across CTR systems. The randomisation bundle provides configurable, standardised algorithms that can be used within CTR's bespoke electronic data capture (EDC) framework (Phoenix) and through a randomisation service (Kitsune) to support REDCap and other external systems. Alongside this, the IMP bundle supports block allocation and IMP management within Phoenix, with a pathway for future use through a dedicated IMP service (Draig). Both bundles use study-specific configuration, allowing them to be adapted for individual trials without rebuilding the core code. This forms part of a wider move towards shared, maintainable platform development, which over the last 12 months has included around 82,000 lines of shared code and six standardised randomisation algorithms.

This work also highlights the excellent cross-functional working of CTR, whereby the statistics and data analyst teams worked closely with the TID team to deliver the testing, validation and implementation of these new systems and processes which are now being rolled out across the unit. This same cross-working group will continue to develop and deliver staff training for the new processes throughout the coming year.

New software has been developed by Lawrence Raisanen, Senior Data Analyst, CTR. As an active member of the Trials Methodology Research Partnership (TMRP) Outcomes (and adverse events) Working Group he has been able to identify areas of our regulatory audit work that could be improved using technological solutions. He has designed and implemented 'Auto REDCap Audit'. This software carries out analysis, monitoring, and activity oversight to make interpreting the REDCap audit easier.

Sean Johnson, Data Analyst, has led or contributed to two key methodological activities in data sharing:

Data Sharing, Precision Medicine & Collaborative Translational Research:

Sean led the preparation, harmonisation, governance, and release of AML clinical trial datasets and linked biospecimen data, working closely with the Cardiff University Biobank to support national and international academic and commercial collaborations. This included enabling large-scale translational and precision medicine research investigating measurable residual disease (MRD), genomic risk stratification, treatment response, phosphoproteomic biomarkers, single-cell sequencing, and mechanisms of therapeutic resistance in AML. Collaborations with partners including the University of Cambridge and Kinomica supported the application of machine learning, phosphoproteomics, and advanced genomic approaches to improve understanding of disease heterogeneity and treatment response. CTR AML datasets contributed to multiple high-impact collaborative publications, including pooled multicentre analyses of NPM1-mutated AML outcomes and MRD-driven studies in KMT2A-rearranged AML.

Cancer Patient Digital Twin Project (Interdisciplinary Precision Oncology Cardiff Hub (IPOCH) PhD Studentship):

Sean provided supervisory and methodological support for an interdisciplinary PhD project developing Cancer Patient Digital Twins using integrated genomic and clinical trial data from AML studies. The project applies artificial intelligence approaches to investigate disease heterogeneity and predict treatment response, supporting future precision medicine and AI-driven clinical decision-making approaches in AML.

Methodological developments in trial conduct and inclusivity

In November 2025 we completed the TIPTOE 'Study Within a Project' (SWAP) which aimed to understand the barriers to including older people with multiple long-term conditions (MLTCs) in the TIPTOE trial, rapidly develop strategies to support inclusion, and provide methodological guidance for future trials including those that are digitally enabled and/or decentralised. A paper was submitted to Trials and presented by Prof Kate Button at the Osteoarthritis Research Society International (OARSI) conference in the USA (April 2026).

The Health and Care Research Wales-funded CONSULT project to support researchers conducting research involving adults with impaired capacity to consent finished in Feb 2026 after 5 years. We summarised the findings in a 4-page report and an interactive infographic which can also be found on the CONSULT website alongside the resources, publications and other outputs from the project. Findings were presented at the Australian Ethics Network conference (Nov 2025) and the Australasian Bioethics and Health Law conference (Dec 2025).

Building on CONSULT, we conducted the Impact Acceleration Account (IAA) funded OPTIMISE project to develop a framework of evidence-informed recommendations for researchers on designing more inclusive consent processes in trials together with an implementation toolkit. The OPTIMISE recommendations were launched at a webinar (Dec 2025) with 300 registered to attend. A post-webinar survey evidenced attendees' commitment to change practice e.g. "[I'll] link to OPTIMISE resources when engaging in discussions with ethics committees to justify [the] approach taken".



In partnership with Thinklusive we held a co-produced OPTIMISE workshop for researchers on developing accessible information (March 2026) which had excellent feedback and demonstrated a change in participants' knowledge and confidence e.g. "This was very informative, practical and enormously thought provoking", "Really interesting, informative, supportive, thoughtful. I know where to start now!" An OPTIMISE policy brief was developed and disseminated to funders and other organisations (Feb 2026). OPTIMISE has directly informed the Health Research Authority's new guidance on applying a proportionate approach to seeking and evidencing informed consent in health and social care research and the simplified arrangements for seeking and evidencing consent in low intervention clinical trials as part of the new clinical trial regulations.

In March 2026 we started the 8-year Wellcome-funded ACCORD project (Addressing consent-based challenges to improve inclusivity in research) to explore the complex ethical and legal uncertainties surrounding research involving adults with impaired capacity to consent and develop implementable behaviourally informed interventions to improve inclusion.

6

Work Package 6 Development of All Wales Remit/ Approach



In this section we describe, with examples, how we support staff in the NHS and social care in Wales to develop their own research to address the important questions in the care of patients and the public. This year we also flag public involvement and engagement work that connects us to the broader communities of Wales.

External Engagement and Outreach

During 2025–26 CTR continued to strengthen relationships with stakeholders across research, policy, and the wider community through a range of engagement and outreach activities. These interactions form an important part of CTR's role in supporting applied health and social care research in Wales and beyond. Through conferences, public engagement events, and ongoing collaboration with researchers and partners, CTR helps investigators navigate the complex landscape of clinical trials and research governance while building connections across the research ecosystem.

Many of these interactions occur through both formal activities and informal engagement across CTR. CTR staff regularly support researchers through advisory discussions, mentoring and collaborative working during study development and delivery. Engagement with Chief Investigators and collaborators remains particularly important, helping ensure that studies benefit from CTR's expertise in trial design, delivery, and governance while strengthening relationships with the research community.

CTR convenes a monthly Population Health and Social Care research meeting, open to all, bringing together researchers, trialists and partners to discuss emerging studies, collaboration opportunities and communications priorities. The meetings attract regular attendance from colleagues across Cardiff University, Public Health Wales, and partner organisations, providing a forum for sharing learning, strengthening collaboration, and connecting research across the Welsh health and social care research landscape.

Public Engagement

Public engagement plays an important role in raising awareness of clinical trials and inspiring future generations to consider careers in health and care research. In February 2026, colleagues from CTR took part in the annual 'Be A Scientist' event at Sbarc, which welcomed almost 800 booked attendees from across Wales. Designed for children aged 7–12 and their families, the event gave research teams an opportunity to share their work through creative and interactive activities. CTR's stand welcomed more than 180 visitors throughout the day.

Building on the success of last year's activity, the CTR team brought back "Geoffrey the Giraffe" for another fictional clinical trial adventure. This year, Geoffrey became Chief Investigator for a study testing a new treatment for the fictional condition "Blue Nose". Children and families became public contributors to the study, helping Geoffrey decide how the trial should run. Through voting activities, discussion and role play, visitors explored research concepts including trial outcomes, treatment delivery, participant follow up, and communicating study findings.

One young visitor summed up the spirit of the activity perfectly:

**"I would go to the doctor
three times in a week if
it made me feel better
and helped the drug work
better too!"**



Visitors voted on what the most important treatment outcome should be, with faster recovery receiving the highest number of votes (54). Children also considered how the treatment should be delivered, with liquid medicine proving most popular, while others suggested imaginative alternatives including creams, injections, and even wrapping tablets in lettuce. Visitors also discussed trial follow up preferences, with many favouring GP visits over submitting selfies from home because they valued discussing recovery in person.

The final activity invited participants to redesign a deliberately unengaging research poster, producing colourful alternatives featuring key messages and artwork. The popularity of the stand meant additional activity tables had to be added throughout the day, highlighting how effectively science and creativity can work together to create accessible and engaging early experiences of health research.

“Best Engagement Stand 2025” award

A previous outing for Geoffrey the Giraffe won CTR's Professional Services team the “Best Engagement Stand 2025” award at the Health and Care Research Wales Conference in October. The interactive activity demonstrated how randomisation works in clinical trials, and was developed by the team to make complex research concepts engaging and accessible for conference participants.



Associate Members Programme

The Associate Members Programme was created to strengthen collaboration across health, social care, and research communities in Wales by providing tailored mentoring, development opportunities, and structured exposure to clinical trials activity. Open to professionals across sectors, the scheme supports individuals to build research capability, understand the role of a clinical trials unit, and act as champions for research within their organisations, contributing to a more connected and informed research ecosystem.

Between July 2023 and June 2025, 14 mentees were recruited to the scheme. Of these, 10 mentorships have been successfully completed, two postponed, and two remain ongoing. The programme has directly supported research development, resulting in eight grant applications involving six mentees, with two successfully funded. These outcomes demonstrate the value of a pathway for developing research confidence, fostering collaboration, and enabling progression towards funded research activity across Wales.

Public Involvement in developing new Centre studies

What was done

CTR's Study Adoption Group (SAG) brings together senior staff from across all Centre divisions and roles and meets fortnightly. The group reviews all new study proposals to ensure strategic alignment with CTR's aims, scientific quality, and appropriate resourcing. Public involvement has been embedded in SAG meetings since 2024.

Who was involved

Two public members attend each meeting on a rotating basis, drawn from a pool of eight. Over the past year, we have strengthened diversity within this group. In partnership with Health and Care Research Wales, we widely advertised the opportunity and recruited two new members with lived experience of health conditions and/or neurodiversity.

How it worked

New members received an induction led by CTR's Academic Lead for Public Involvement and Engagement and signed a mutual expectations agreement. They joined the meeting rota and were provided with study proposals in advance of each meeting. Public members review the proposals and contribute their perspectives during online discussions. All preparation and attendance time is reimbursed.

What difference it made

Public members make a significant contribution to shaping high-quality, inclusive research. Their input ensures that patient and public perspectives are considered from the earliest stages of study design. In particular, they consistently challenge teams to demonstrate meaningful involvement and to address inclusion of underserved communities.

The SAG co-chair, Professor Robling commented:

"Introducing and then expanding the rotating pool of lay reviewers to the adoption process for new studies has really strengthened our approach. Our research partners bring a broader and different perspective to the studies under consideration. We benefit from their lived experiences, their connections to different communities and in some cases their membership of funding panels. Adoption review means we can improve applications and ensure that the work we embark on is more likely to bring benefits of importance to the public."



Conclusion

Our annual report summarises key areas of activity and reflects achievements and progress towards our vision.

This year has been one of remarkable growth, resilience, and shared purpose for the Unit. Our transition to Welsh Government, via Health and Care Research Wales, as our sole source of external infrastructure funding has given us a clearer foundation on which to build, while our leadership restructure has created the space for fresh ideas, new energy, and a stronger sense of direction for the years ahead.

What stands out most, however, is the dedication and talent of our staff. Their achievements, from winning prestigious awards to securing major funding from NIHR, industry partners, and charitable funders, reflect not only individual excellence but the supportive, ambitious culture we continue to nurture. We are especially proud to have championed new Chief Investigators, many from Wales, and to have seen CTR staff step confidently into co-Chief Investigator roles. These successes strengthen research leadership across our community and signal a bright future for Welsh-led trials.

Completing our first MHRA inspection as a Unit marks another important milestone, demonstrating our commitment to delivering research that is rigorous, safe, and impactful. Beyond our studies, our contributions to policy, public engagement, and civic mission show our determination to ensure research is not only done well, but understood, valued, and connected to the people it serves.

Across all four of our research divisions, we have continued to push boundaries, developing and applying innovative methodologies that improve how trials and other well designed studies are conceived and delivered. Together, these achievements reflect meaningful progress toward our vision and reaffirm our belief in the power of collaborative, high quality research to improve health and care.

We move forward with confidence, purpose, and optimism for what we can achieve next.



Looking forward

Building on ten years

In May 2026, we celebrated the end of our tenth year as a Centre and chose to do so in partnership with the large number of research centres we connect to at Cardiff University. In part, this was a retrospective reflection of how we arrived at where we are today, who we travelled with and the significant ten-year track record of grant capture, projects delivered and impact into policy and practice. More than that, though, it provides a course ahead, working increasingly effectively with a greater range of collaborators across and beyond Cardiff. In what are financially uncertain and frankly challenging times for higher education, centre sustainability will be achieved through interdisciplinary team science, grown from within the Centre and connecting out to researchers who share our goals.

Moving forward we will deepen those areas of our research portfolio which are existing strengths and we will continue to foster collaboration with long-standing partners.

Sustainable growth and future leadership

Moving forward we will deepen those areas of our research portfolio which are existing strengths and we will continue to foster collaboration with long-standing partners. We remain committed to responding to all good new study ideas, not solely in areas which typify our current portfolio. Long-term sustainability means that we need to retain focus on research opportunities that are more likely to bear fruit in the longer-term, that will build upon our strengths, that will benefit society and that can support the actual cost of delivery. Our decision-making about future work will need to be guided by these principles and that will mean doing less of some things.

What encourages me particularly is the evolution within the Centre's leadership in the last year. Most senior roles have benefitted from new appointments from within the Centre and new roles created to lead for emergent priority areas. I am optimistic that by the time of this report's publication that will be matched by successful promotions across the more senior staff in the Centre. That is an indicator of their magnificent track record and their equally vital future leadership role for the Centre and for trials in Wales. I am indeed looking forward to the next steps for our Centre.

Thank you

The Centre for Trials Research at Cardiff University wishes to thank all the members of the public and study participants who give their time to take part in our studies, freely and with great generosity to help improve health outcomes for future generations. It is our vision to produce a more evidence-based culture, so we know what works and what does not. This is impossible without the public's contribution and support.

Thank you to all our Research Partners who give their time to take part in study management groups, steering committees, and are involved in delivering and participating in research. You inform research questions, study design, planning, management and reporting, ensure study materials are helpful for the public – and ultimately help all our studies to progress to successful completion and publication.

Special thanks to our representatives Sarah Peddle and Amanda Wells who work with us as part of our Public Involvement and Engagement (PI&E) Hub to support the public voice in our work.

Contact us

The Centre for Trials Research is willing to consider any well-designed study or trial idea, even those outside its current areas of research. For more information about collaborating with our research team or to keep up to date with news and events:

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