accord
Academic and Clinical Central Office
for Research and Development

THE UNIVERSITY of EDINBURGH

NHS Lothian

2026

Promoting clinical research excellence for the health and wealth of Lothian and Scotland

Contents

Introduction

Welcome to the 2025-26 brochure from the Academic and Clinical Central Office for Research and Development (ACCORD). Sitting at the centre of clinical research activity in Lothian, ACCORD combines research management staff from NHS Lothian and the University of Edinburgh.

Together these staff provide a joint research office that offers central access to professional advice, expert regulatory support and clinical research infrastructure for every stage of the research pathway.

I hope you enjoy this bumper edition of our brochure highlighting the fantastic research being led, coordinated and delivered in NHS Lothian and the range of highly talented staff and associated infrastructure that provide expertise across all parts of the clinical research system. Thank you to everyone who has contributed to this year's brochure.

There are several things in the brochure I would like to highlight. I mentioned last year the current focus on commercial trial delivery in the NHS across the United Kingdom. This remains, with a clear steer to improve all aspects of the trial process including feasibility, setup and time to first patient, recruitment to time and target and financial and billing processes. There is lots of work going on across the system to try and achieve some strict targets that have been set on the back of the additional funding we have received via the VPAG programme. The brochure, in the CATALYST section, highlights some of the great opportunities this additional funding has provided. Ward 22 has opened, and trials are being delivered in the Commercial Research Delivery Centre (CRDC). The new aseptic pharmacy facility at the Western General Hospital is on track to open in autumn 2026. We have also been able to recruit additional staff including research fellows, nurses, pharmacists and provide some funded time for consultants in a range of specialties. Our first Practice Embedded Research Unit (PERU) has opened in Penicuik Medical practice with more being rolled out across Lothian over the next year to enhance our capability of recruiting patients who might not have had the opportunity to be involved in research and enabling trial delivery to be closer to home. This is a truly fantastic initiative. Hopefully this additional capacity across secondary and primary care will enable us to deliver more commercial research that will benefit our patients and NHS Lothian. Despite this, the academic portfolio has performed strongly with recruitment to eligibly funded studies increased by 33%.

> "This brochure provides insight into some of the incredible research being delivered in NHS Lothian, as well as the highly skilled and experienced staff and services, we provide locally to enable it."

Introduction

Once again, the brochure demonstrates some truly exceptional and globally impactful research led by local investigators – some seasoned and others starting their careers as independent researchers. Two trials (DUAL-ACS and A2B) led by local senior investigators Professor David Newby and Professor Tim Walsh demonstrate the importance and impact of large multicentre trials funded by the BHF and NIHR and how they may and may not change practice. Dr Faye Robertson, clinical oncologist and Dr Shahida Din, gastroenterologist describe their careers and the cutting-edge research they are leading in brain tumours and inflammatory bowel disease respectively, supported by NRS clinician funding. In addition, the brochure provides the opportunity to focus on two ongoing areas of research in underserved populations, namely the sexual health of inclusion health communities and the dementia research coordinated from Edinburgh supported by both the NRS Neuroprogressive and Dementia Network and the UK Dementia Trials Network.

I would like to highlight the importance of the NMHAPP research strategy in Lothian. It is exemplar, and the data presented in the brochure demonstrates the opportunity that is available for NMHAPPs to pursue academic careers. Also, another local success is the number of clinicians who have signed up and been supported through the NIHR Associate Principal Investigator scheme. This is a valuable, often first step, into clinical research for many and we need to continue to support this initiative and the new NIHR Principal Investigator Pipeline Programme (PIPP) specific to NMHAPPs, going forward, if we are going to encourage more clinicians to be research active.

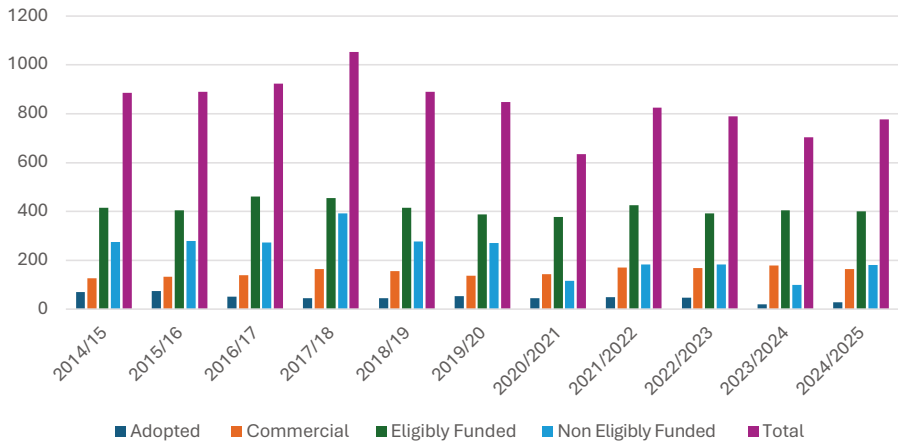
The NHS Lothian R&D Conference took place in May 2025. It was a fantastic day, with great speakers and an enthusiastic group of delegates.

Thank you to everyone who participated and, in particular to Jo Merrifield and Susie Fong from the CRF Education Core who organised the conference. The Education Core coordinates much of the education and training that is required for both research delivery teams and investigators and are an incredible local resource.

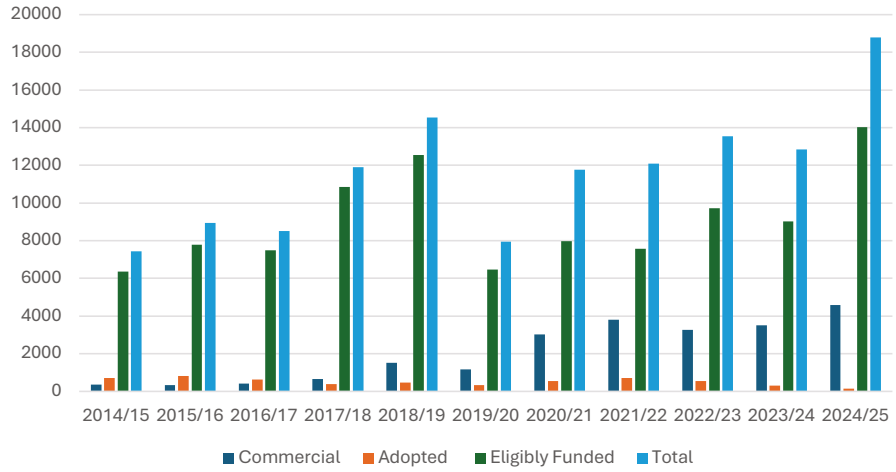
Finally, a number of key staff that are leaving their roles within ACCORD and other parts of the research system. Firstly, Fiona McArdle, Deputy R&D Director, is retiring at the end of May. I would personally like to thank Fiona for her tireless leadership, endeavour and expertise in supporting and developing clinical research in Lothian for over a decade in ACCORD. You will be missed! I would like to welcome Heather Charles into the deputy R&D director's role. Many of you will know Heather, who is currently Head of Research Governance for NHS Lothian. Given her knowledge and experience, I am sure she will hit the ground running. Hazel Milligan our Lead Pharmacist for Clinical Trials, is also retiring. Thank you, Hazel, for all you have done to support drug trials in Lothian. Ben Elliott is taking over as Lead Pharmacist Clinical Trials. Lastly in the NRS Cancer Network, Dot Boyle retired at the end of 2025 with Ramsay Khadeir replacing her as the clinical service manager.

It's been another hectic year and hopefully this brochure provides insight into some of the incredible research being delivered in NHS Lothian, as well as the highly skilled and experienced staff and services, we provide locally to enable it. I hope you enjoy reading our 2025-26 annual report.

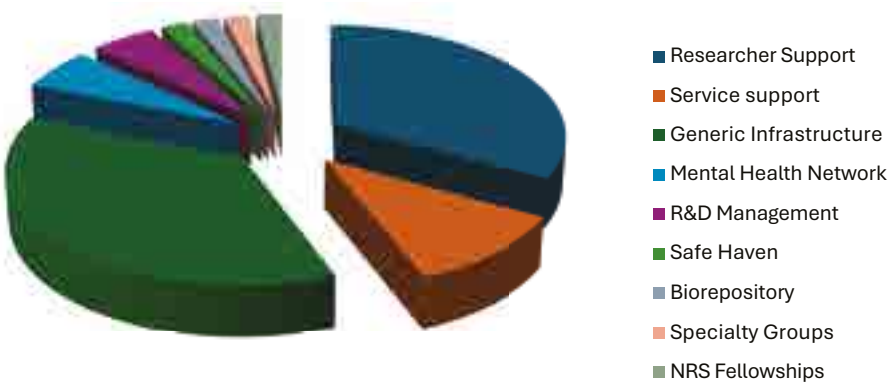
Number of studies by year Edinburgh led and hosted



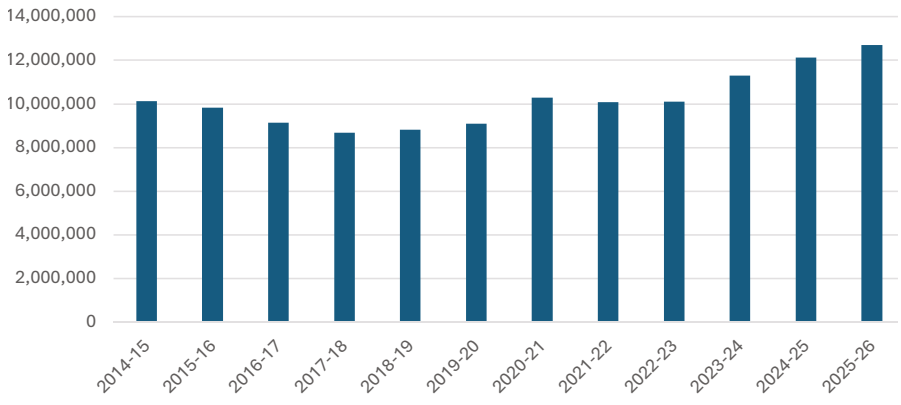
Study recruitment by year



Distribution of NHS Lothian's NRS funding allocation 2025/26



Annual NRS allocation



ACCORD services

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Academic and Clinical Central Office for Research and Development
THE UNIVERSITY of EDINBURGH
NHS Lothian

01 Funding and costing

Research Governance, NHSL R&D Finance, Edinburgh Research Support Teams

- Funding reviews and costings
- NHS resource planning
- Regulatory alignment

02 Sponsorship

Accountability and oversight

UoE Research Governance Team

- University-NHSL co-sponsorship
- Protocol and document review
- Amendment review
- Guidance and support

03 Research facilitation

Enabling complex research

Research Governance Team Facilitators

- Facilitator support
- Regulatory submissions
- Risk Assessment and planning

04 Contracts and agreements

Protecting research

UoE and NHSL Legal/Contracts Teams

- Contract development and negotiation
- Data and tissue transfer
- Collaboration and financial contracts

05 NHSL R&D permissions

Authorising NHS research

NHSL R&D Research Governance Team

- NHSL R&D management approvals
- Site capacity review
- Caldicott Guardian approvals

06 Monitoring

Safeguarding study integrity

Monitoring Team

- Risk-based monitoring
- Site visits and data verifications
- Regulatory support and compliance

07 Pharmacovigilance

Ensuring participant safety

Pharmacovigilance Team

- SAE and SUSAR reporting
- Safety oversight
- MedDRA coding and annual reporting

08 Quality assurance

Research oversight

QA Team

- Regulatory support and compliance
- SOPs and resources
- Audit programme

09 Data and governance

UoE Research Data Support, NHSL Information Governance and IT Security

- Data management and transparency
- Data protection
- IT security risk assessments

10 Training and education

Developing research excellence

All Teams, CRF Education Programme

- GCP and specialist training
- Skill-building workshops
- Informative seminars

Collaborative Accelerator for Commercial Clinical TriAL DeliverY in ScoTland

New research ward at the Western General Hospital

Over the past year, Lothian hosted 165 commercial studies and recruited over 4,600 participants.

On 11 December 2025, the Lothian Commercial Research Delivery Centre (CRDC) was officially opened by its Director, Professor Alasdair Gray, with the aim of strengthening support for these studies. The development of CRDCs in Scotland has been made possible through funding from the 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG). This agreement, between the UK Government and the Association of the British Pharmaceutical Industry (ABPI), involves an investment programme across the four UK nations, including the establishment of 21 CRDCs.

In Scotland, CRDCs are supported by the CSO and coordinated by the NRS. Each CRDC collaborates closely with NHS boards, local research teams, and national research infrastructure to ensure that clinical trials are accessible, inclusive, and well supported. CRDCs are designed to make it easier for commercial sponsors to conduct and deliver trials in Scotland more efficiently, by supporting all phases of the research delivery pathway, from early feasibility through to recruitment and implementation.

Located in one half of Ward 22 at the Western General Hospital, the Lothian CRDC will support the expansion and enhancement of NHS Lothian's capacity to deliver commercial pharmaceutical clinical trials as well as academic research. Managed through the **Edinburgh Clinical Research Facility**, the Lothian CRDC has recruited additional staff to support research groups across NHS Lothian in running these trials. This research ward is intended for all research groups in NHS Lothian, not just those based in the north of the city. Research groups interested in using the space with their own staff or with the addition of CRDC nursing and clinical research fellow support, are encouraged to approach Fiona Maxton, Commercial Research Nurse Manager.

> This research ward is intended for all research groups in NHS Lothian, not just those based in the north of the city.

Collaborative Accelerator for Commercial Clinical TriAL DeliverY in ScoTland

> NHS Lothian also achieved a significant milestone when the CIRG recruited the first participant globally to a study investigating an anti-fungal agent for use in adults with chronic pulmonary aspergillosis.

The other half of Ward 22 has become home to the Clinical Infection Research Group (CIRG). CIRG has hit the ground running by delivering three major commercial studies, including two rapidly recruiting seasonal trials: the Anchor study which evaluated a novel long-acting antiviral designed to prevent influenza and the NOVA study assessing the safety and efficacy of a new norovirus vaccine. NHS Lothian also achieved a significant milestone when the CIRG recruited the first participant globally to a the MR907-2502 study investigating an anti-fungal agent for use in adults with chronic pulmonary aspergillosis. The CIRG team has continued this momentum, recruiting an additional five participants to date, and is among the top recruiting sites globally.

CRDC research fellows, Dr Adeniji and Dr Newton in the new CRDC unit.

Tallulah Armstrong, clinical trials assistant for CIRG utilising the new sample processing facilities.

Collaborative Accelerator for Commercial Clinical TriAL DeliverY in ScoTland

Establishing research-active General Practices: launching the first practice embedded research unit

Primary care is often described as the "sleeping giant" of research delivery: a part of the healthcare system with significant, largely untapped potential.

While most people's contact with the NHS is through their GP practice, research activity has traditionally centred on hospitals. This means that many patients who could benefit from taking part in research never have the opportunity, and studies miss out on the rich diversity of people routinely encountered in community settings.

To help shift this balance, NHS Lothian has taken an ambitious step by establishing Scotland's first Practice Embedded Research Unit (PERU) in collaboration with the NRS Primary Care Network. Designed to bring research directly into general practice, the PERU provides the dedicated support, infrastructure and governance needed to make primary care a fully active player in Scotland's research landscape.

Penicuik Medical Practice has played a key role in driving this forward by successfully converting one of its consultation rooms into a dedicated space for research delivery.

The initial funding for the renovation of the building and the provision of equipment was provided by the NHS Lothian Charity.

This has resulted in the development of a successful blueprint that can be quickly replicated not only in Lothian, but also in other locations across Scotland.

A new model for primary care research

The PERU model is built around a simple idea: research should be an integral part of primary care, rather than an additional burden. To achieve this, participating practices are supported by a dedicated research team including clinical research nurses, administrative support, and protected GP time, as well as close links to NHS board research governance and operational systems. This joined-up structure enables studies to be delivered safely, efficiently and consistently, without disrupting practice workflows.

Crucially, the model protects the autonomy of practices. Rather than research being "done to" primary care, PERUs place GPs, nurses and practice staff at the centre of decision-making, supported by specialist expertise in study delivery.

> By working with our colleagues in secondary care, we hope to deliver research in a more collaborative way. This will give NHS Lothian an advantage by removing the traditional primary/secondary care silos and providing an approach that benefits both patient and sponsors.

Collaborative Accelerator for Commercial Clinical TriAL DeliverY in ScoTland

By working with our colleagues in secondary care, we hope to deliver research in a more collaborative way. This will give NHS Lothian an advantage by removing the traditional primary/secondary care silos and providing an approach that benefits both patient and sponsors.

Growing interest and early success

The first PERU, now established within NHS Lothian, has attracted significant interest from practices and patients. Early work has focused on enhancing capabilities, including delivering Good Clinical Practice training, streamlining processes for study setup, and embedding the confidence required for practices to undertake more complex research.

Initial feedback shows that embedding research staff within practices makes a significant difference. It helps to normalise research, encourages clinical teams to become more engaged and establishes a more sustainable model for delivering both academic and commercial studies in the community. This foundation will be crucial as Scotland prepares for the increased commercial research activity anticipated under the current CRDC/VPAG funding stream.

Bringing research closer to home

One of the biggest advantages of a PERU is the improved accessibility it offers to patients. Being able to take part in research at a familiar local practice rather than having to travel to a hospital site, reduces barriers relating to transport, mobility, confidence and time. For many people, this can mean the difference between participating and not taking part at all.

This shift towards community-based delivery supports a more inclusive and equitable research system. It aligns with the national ambition to increase access, participation and diversity across clinical research, ensuring opportunities reflect the communities the NHS serves.

Supporting Scotland's research ambitions

A PERU is designed to support research delivery across the full spectrum from observational studies and academic trials to commercial Phase III work. Primary care is particularly well placed to facilitate large-scale recruitment, long-term follow-up, and collection of real-world data, all of which are becoming increasingly important for both industry and public health research.

Beyond delivery, PERUs also play a role in culture change. By embedding research in practices and supporting clinicians to take part, the model nurtures a more research-aware workforce, strengthens links between primary and secondary care, and provides new career development opportunities for nurses and GPs interested in research.

Scaling for the future

Over the next year, the focus will be on expanding the model to additional practices and health boards, building on early learning and refining the approach. The long-term ambition is to establish a network of research-active practices across Scotland, capable of supporting high-quality, large-scale research in community settings.

The launch of the first PERU is an important milestone that begins to unlock the full potential of primary care as a research delivery environment. By bringing research closer to patients and creating the structures that enable practices to lead with confidence, the PERU is helping to build a research system that is more inclusive, resilient and future-ready in Scotland.

Collaborative Accelerator for Commercial Clinical TriAL DeliverY in ScoTland

NHS Lothian Delivery of Advanced Therapies – Pharmacy Update

Between 2021 and 2026, the NHS Lothian Pharmacy Department set out an ambitious goal: to build the capability needed to safely deliver Advanced Therapy Medicinal Products (ATMPs) and Advanced Therapy Investigational Medicinal Products (ATiMPs).

This work was essential not only to meet the growing demands of cutting edge clinical research, but also to ensure that NHS Lothian remained a competitive and attractive partner in the wider Research and Development (R&D) landscape.

However, the region's existing aseptic facilities were already operating at full capacity. Without a dedicated, compliant unit for ATiMP preparation, NHS Lothian risked missing out on opportunities for research participation, along with the associated financial and reputational benefits. In order to secure the future of ATiMP delivery, the organisation identified the need for a specialised gene therapy suite for handling both class 1 and class 2 replication competent products.

Financial support was secured through the Voluntary Scheme for Branded Medicines Pricing and Access (VPAG). This provided funding for five years for new pharmacy technical staff and a dedicated ATiMPs pharmacist, as well as funding for the creation of an appropriate aseptic environment. The project board was assembled in 2024 and included members from NHS Lothian's Pharmacy Service, NHSL Research & Development, Hospital Site Management, Soft and Hard Facilities Management, Capital Planning and Projects, Capital Finance and Infection Prevention and Control team. Authorising engineers for water, ventilation and electrical services were also consulted as needed.

Following an assessment of the options, the Western General Hospital (WGH) was selected as the site for a new standalone modular Genetically Modified Organisms (GMO) aseptic unit. Its flexibility was a key advantage; unlike a permanent build, if future funding became unavailable, the unit could be relocated or sold. Following a formal public procurement process and NHS Lothian capital governance, Cleanroom Projects was appointed as the preferred supplier. By early 2026, the design of the aseptic unit had been finalised and production had begun.

The new modular facility will house two negative pressure isolators, enabling NHS Lothian to safely prepare ATiMPs and ATMPs and expand its research capacity without placing additional strain on existing services. With a projected lifespan of more than 20 years, the facility offers long term value, and the investment is supported through VPAG funding and current and future Pharmacy Services R&D income.

The recruitment of specialist pharmacy staff began in 2025, and the modular unit is scheduled for delivery and installation in July 2026. Following a comprehensive commissioning and validation process, the GMO aseptic unit is anticipated to be operational by late October or early November 2026. The risk level for the current timelines has been assessed as low, on the basis that all site preparation work for the delivery of the modular unit will stay on track.

Once open, the unit will be managed by the Pharmacy Aseptic Services team, who will work closely with colleagues from Clinical Trials and Quality, Risk & Governance to support the safe and effective delivery of advanced therapies for years to come.

NHS Lothian Nurses, Midwives, Allied Health Professionals, Pharmacy Professionals and Healthcare Scientists

NHS Lothian continues to hold a prominent position among Scottish health boards for clinical academic development initiatives for Nursing, Midwifery, Allied Health Professions, Pharmacy professionals, and Healthcare Scientists (NMAHPPS).

Lothian NMAHPPS Research Strategic Plan 2026-2030

Over the past year, NMAHPPS leaders have embarked on a process in partnership with colleagues in the university sector to implement the Lothian NMAHPPS Research Strategy. Since the life cycle of this strategy has come to an end, we have been working closely with a variety of stakeholders to develop a new and refreshed strategic plan. In November 2025, we held a successful stakeholder event involving delegates from a variety of different 'constituencies'. Participants provided excellent ideas about their priorities for the new plan. A short life working group is currently collating, organising and prioritising these ideas to develop the new draft strategic plan. A high-level group, including the Directors of these services and the Deans and Heads of Schools of our academic partners (the University of Edinburgh, Edinburgh Napier University, Queen Margaret University, the University of Stirling, the University of Strathclyde and the Robert Gordon University), which meets twice a year, will be invited to endorse this draft in Spring 2026. Recent discussions look likely to lead to an extension of our partners to include Heriot-Watt University at some stage over the next few months, although this has yet to be formalised.

NHS Lothian NMAHPPS Research Strategic Plan Stakeholder Event November 2025

Investment in research capacity building

Between 2015-2023, NHS Lothian's investment in building research capacity in collaboration with its academic partners saw the number of doctoral (PhD and Clinical Doctorate) students increase steadily, reaching a peak of 43 (Figure 1). However, over the past three years, the numbers have decreased to its lowest level since 2016. No specific funding has been allocated to joint NHS Lothian/academic PhD studentships since 2020, and the last Clinical Doctorate studentship was awarded in 2023. This decrease is due to a combination of the successful completion of part-time PhDs that were funded during the peak period and fewer funding opportunities open to NMAHPPS in NHS Lothian and across Scotland compared to the rest of the UK. However, there has been a small increase in the number of NMAHPPS working in Lothian at postdoctoral level.

Figure 1: NHS Lothian NMAHPPS research capacity building 2010-2026

NHS Lothian Clinical Academic Research Gateway Awards

The NHS Lothian Clinical Academic Research Gateway Awards scheme was established in 2022 following the award of £250,000 funding over a five year period by the NHS Lothian Charity.

These awards can be taken forward in a range of universities and provide (where applicable) salary backfill for agreed study leave, tuition fees, and/or course/conference fees. The five levels of awards are:

- First Steps into Research – an experiential placement in an active research group plus £500 funding for personal research development
- Research Master's Degree – salaried funding plus tuition fees for part-time research Master's degree study
- Pre-doctoral Bridging – allowing salaried preparatory time with mentorship to build a competitive application for an externally funded doctoral opportunity
- Post-doctoral Bridging – allowing salaried time with mentoring to further develop doctoral research outputs, network-building, and applications for externally-funded post-doctoral fellowship awards
- Advanced Methodologies – fees expenses to attend an advanced methodological training course in an area congruent with current doctoral students' research study.

Over the past year, the Gateway Awards scheme has continued to attract applicants from a wide range of professions and career stages. Figure 2 shows that over the five year lifetime of the scheme, 92 applications have been received from staff in nine different professions, and 60 of these have been offered and accepted an award. By far the most common type of award made has been the First Steps into Research placement, although all levels have proved attractive. The number of applications has remained fairly consistent year-on-year, averaging approximately 18 per year, with no sign of decline. Applications have been received from all parts of NHS Lothian (see figure 3).
The future of this successful scheme is somewhat uncertain, as current funding will end in March 2027. The Gateways team is currently considering different avenues for funding the scheme beyond that point.

Figure 2: Lothian Clinical Academic Research Gateway Awards 2022-2026 Dashboard

All but two of the 36 award recipients in cohorts 1-3 have now completed their awards and the remainder will complete theirs very soon. All members of cohort 4 have completed, or are close to completing their awards, with the exception of two recipients of a funding award for a 2-year, part-time research master's study. The scheme has received very positive feedback in terms of the experiences of recipients, their managers, and university mentors/supervisors. A notable outcome is that cohorts 1-3 have subsequently generated £964,000 of external research fellowship or grant income.
This represents a return on investment of 6.4x.

Figure 3: Job location of Gateway Awards applicants, 2022-2026


Gateway Awards cohort 4 April 2025

Doctoral students and completions

Currently, there are 29 NMAHPPS doctoral students working in NHS Lothian across a range of professions (Figure 4). This group along with others interested in pursuing doctoral study, is supported through peer networking by the Lothian NMAHPPS Researcher Network, which meets four times a year. Although just under half of the group are nurses, physiotherapy remains the profession within the NMAHPPS grouping with the highest percentage of employees undertaking doctoral study.

Figure 4: Professional Profile of NHS Lothian NMAHPPS doctoral students

There were three new NMAHPPS doctoral students in 2025 and four doctoral completions, with a further two finalising amendments after viva.

Royal College of Nursing Scotland Nurse of the Year for Nursing Innovation and Research

Kath Williamson, Senior Clinical Nurse Specialist in Bariatric Care, won the RCN Scotland Nurse of the Year Award 2025 in the Inspiring Excellence - Nursing Innovation and Research Award. Described as a pioneering nurse and researcher, Kath is dedicated to improving care for people living with severe obesity. While working as a district nurse, she identified a critical gap in services for housebound patients, subsequently pursuing a PhD to better understand their needs and experiences, as well as the associated costs of care. Her mixed-methods research has revealed fragmented services, widespread stigma, and significant unmet needs among this vulnerable group. With the support of her CSO Early PostDoctoral Research Fellowship, Kath established the NHS Lothian Bariatric Forum: a multidisciplinary group working to improve care coordination and outcomes for patients with complex obesity. Despite the limited number of clinical academic pathways available to nurses in Scotland, Kath continues to lead innovative research, mentor others, and advocate for greater nurse involvement in academic work.

Scotland's Allied Health Professional of the Year

Congratulations to Claire Yerramasu, Advanced Practice Physiotherapist and Midlothian Community Respiratory Team Lead who was voted AHP of the Year at the Scottish Health Awards in November 2025. She was recognised for her innovative data-driven work in respiratory care, reducing hospital admissions, enabling earlier discharges, and establishing a multidisciplinary, patient-centred model that is now recognised across Scotland. Claire is also studying for a PhD part-time at the Usher Institute, University of Edinburgh, funded by a CSO Innovation Fellowship. Her research focuses on the co-development of data-driven risk stratification dashboards for use in respiratory care.

NHS Lothian Allied Health Professionals (AHP) Innovation, Research, and Improvement Strategy 2022-2027

Our AHP services in NHS Lothian continue to make significant progress in the implementation of their Innovation, Research and Improvement Strategy (IRI) launched in November 2022. Over the past year, the following actions have been achieved:

- producing accessible guidance for the AHP workforce on information governanance requirements that must be considered prior to commencing different types of data gathering project
- developing a business plan and job description, and engaging in discussions with university partners regarding joint funding, for the first in a series of postdoctoral clinical academic AHP posts
- using survey methodology to reveal the extent of evidence, research and development-related activity during AHP pre-registration students' practice-based learning placements – with a view to improving opportunities for this type of activity and raising awareness at an early stage of a career
- engaging in discussions to establish a network of AHP mentors to enhance the support available to the AHP workforce in this pillar of practice
- organising promotional events to raise awareness of this strategic work among NHS Lothian AHPs

External fellowships awarded to NHS Lothian NMAHPPS

The following are to be congratulated for being awarded the following national fellowships during the past year:

CSO Clinical Academic Fellowship (doctoral)

- Holly Jenkins, Midwife and PhD student, Edinburgh Napier University

SO NHS Researcher Development Fellowship

- Anuka Boldbaatar, Senior Research Nurse, Royal Infirmary of Edinburgh (pre-doctoral bridging)
- Cesario Panchina, Chief Cardiac Physiologist, Royal Infirmary of Edinburgh (pre-doctoral bridging)
- Georgia Brayley, Speech and Language Therapist, Musselburgh Primary Care Centre (pre-doctoral bridging)
- Kate Morrison-Wynne, Staff Nurse, Royal Hospital for Children and Young People (pre-doctoral bridging)
- Kirsty Burns, Paediatric Allergy Nurse Specialist, Royal Hospital for Children and Young People (First Steps)

Biannual NMAHPPS research symposium

NHS Lothian NMAHPP research leads and their university partners have committed to holding an online research symposium twice a year. The first of these took place on the afternoon of 23 April 2026 and focussed on presentations by early career researchers, as well as two masterclasses focusing on (a) writing grant and fellowship applications and (b) designing impactful research for clinical practice.

NMAHPP-Research-Symposium-Programme-23rd-April-2026.pdf

For more information, visit the Lothian NMAHPPS Research Symposium Teams site

NRS Clinician:
Dr Faye Robertson

I am a Consultant Clinical Oncologist at the Edinburgh Cancer Centre and an Honorary Clinical Senior Lecturer at the University of Edinburgh. In April 2023, I became an NRS Career Research Fellow and am now an NRS Clinician. I hold a PhD in glioma stem cell biology and my research focuses on the development of new treatments for glioblastoma.

Glioblastoma (GBM) is the most common malignant brain tumour and is currently incurable. With optimal treatment, the median overall survival is around 15 months and there has been little improvement in over 2 decades. We have failed to develop effective new treatments for GBM for several reasons, chief among them the heterogeneity of the disease. This genetic, epigenetic and phenotypic heterogeneity is seen between tumours but also between cells within the same tumour. Furthermore, the blood-brain barrier poses challenges for drug delivery and the specialised immune microenvironment within the brain limits the impact of systemic immunotherapy. In Professor Steven Pollard's laboratory, where I spent several years doing an ECAT/CRUK PhD and to which I retain a close affiliation, we looked for exploitable commonalities between GBM stem cells and aimed to develop treatments which will destroy tumours whatever their molecular features. The group developed a novel genetic immunotherapy treatment, which is described in detail in our forthcoming publication in Nature.

Stem-like cells within GBM have universally high levels of certain transcription factors, regulatory proteins which activate gene expression. Our therapy comprises two genetic 'payloads' that are controlled by a synthetic 'superenhancer', which is a genetic 'switch' that has been

Dr Faye Robertson delivering the top-scoring abstract presentation at the Society for Neuro-oncology annual conference 2025.

> This genetic, epigenetic and phenotypic heterogeneity is seen between tumours but also between cells within the same tumour.

designed in the laboratory to respond to these transcription factors. The DNA is introduced into the cells by adeno-associated virus (AAV1), a viral vector used for delivery of gene therapy. The 'switch' is activated in tumour cells, but not in non-malignant cells, which do not express high levels of the relevant transcription factors. One of our genetic payloads codes for a toxic protein that kills the cell from within, while the other codes for IL-12, an immunomodulatory cytokine, leading to immune activation, resulting in tumour cell death as well as immunological memory.

The preclinical data are compelling. Using an established GBM model in mice with intact immunity, developed in the Pollard laboratory, we showed that over 80% of mice completely cleared their tumours when treated with this therapy. They survived long-term and were immunised against any attempt to induce a further tumour. When I saw these incredible responses, I began planning how to bring this therapy to patients with GBM as quickly and safely as possible.

In 2022, I started laying the foundations of the clinical project, collaborating with Professor Steven Pollard and my colleague Paul Brennan (now Professor of Neurosurgery) to determine which non-clinical data would be essential prior to treating patients. In 2023, I was appointed to an NRS Career Research Fellowship, and this project formed a key part of my proposal. I wrote the first full draft of the clinical protocol in the summer of 2023. Around that time, Professor Pollard's spin-out company, Trogenix, was established. Trogenix has done a phenomenal job of securing substantial investment (£70 million) in the technology underpinning this therapy and in the GBM programme. I have worked alongside them, as Clinical Lead, to refine the trial design and ensure a smooth path to the clinic.

When I saw these incredible responses, I began planning how to bring this therapy to patients with GBM as quickly and safely as possible.

Given the nature of investor funding and the poor prognosis of the disease, rapid readouts are needed to generate further interest in the therapy. Demonstrating safety in a small cohort of patients is not enough. I designed the trial accordingly, to determine an optimal biological dose and to demonstrate robust early signals of efficacy.

From the outset, we proposed this as a treatment for newly-diagnosed GBM. Over time, and with treatment, these tumours change and develop immune-evasive mechanisms. Too often, novel therapies are tested in the recurrent setting, once all other options have been exhausted. When efficacy is not demonstrated, the therapy is abandoned, but pre-treated GBM is an incredibly challenging context in which to show efficacy. In GBM, the standard of care is never curative; it provides modest benefits.

Trogenix team with Dr Faye Robertson, Prof Steven Pollard, Prof Paul Brennan and the Ohio State team.

From the early discussions to the opening of the trial, my work on this project has led me to diverse extraordinary experiences, including investor pitches, patient groups, international conferences and transatlantic collaborations.

Therefore, it seems reasonable to add experimental treatments at an earlier point in the patient pathway, ahead of standard-of-care treatment. The therapy must be delivered ahead of surgery, so that we can access the resected tissue – this is essential to the trial concept. This will enable us to understand the reasons behind any success or failure of the treatment and to address issues, such as inadequate distribution, as they arise. However, delaying surgery, even by two weeks, requires the agreement of patients and regulators. I conducted several consultations with patient groups, and I am very grateful for their feedback.

It is clear that there is an appetite for this type of therapy among patients and that potential risks will be acceptable to many. Regulators agreed that there were sufficient data and rationale for treating patients at initial diagnosis in the first-in-human trial. Accordingly, the trial will recruit patients with newly-diagnosed high grade glioma as well as patients with recurrent GBM. The design consists of a combined dose-finding phase, followed by parallel signal-of-efficacy phase 2 cohort. I am the Chief Investigator for the trial, which is due to open within a month.

From the early discussions to the opening of the trial, my work on this project has led me to diverse extraordinary experiences, including investor pitches, patient groups, international conferences and transatlantic collaborations (our second site is the Ohio State University Medical Center). I have forged very strong collaborative relationships with Professor Steven Pollard, the Trogenix team and Professor Paul Brennan. I am also grateful for the sage advice of Professor Stefan Symeonides, my NRS mentor.

This work has also led me to take two national positions. Along with Paul, I co-lead the Emerging Therapies workstream within the recently formed NIHR Consortium for Brain Tumour Research. The Consortium aims to facilitate the rapid development and roll-out of high-quality, hypothesis-driven clinical trials and to consolidate the UK's position in the field of therapeutic development for brain tumours. Additionally, I will sit on the ACT-BT panel, a national initiative which will match brain tumour patients to available clinical trial opportunities.

NRS Clinician:
Dr Shahida Din
A cross disciplinary systems approach to harm reduction in Inflammatory Bowel Disease

Dr Shahida Din is a consultant gastroenterologist with a special interest in Inflammatory Bowel Disease (IBD) and colorectal cancer. Appointed as a Consultant Gastroenterologist in 2015, she was an NRS fellow (2016-2020) and is now an NRS Clinician. She is the current chair of the British Society of Gastroenterology IBD Committee (2024 -2027) and sits on the MHRA Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group (2021-2027).

Her current academic programme has been structured around a central theme: cumulative inflammatory burden is the major driver of long-term complications in IBD, including bowel damage, hospitalisation and colorectal cancer. The programme integrates translational science, clinical trials, predictive analytics, healthcare implementation and national leadership. Its goal is to reduce long-term harm by improving care across the entire patient journey from early diagnosis to prevention of complications.

Quantifying harm

Randomised placebo-controlled trials have historically been the standard method for evaluating new therapies in IBD. However, patients randomised to placebo may remain untreated despite having active inflammatory disease. Dr Din's research demonstrated that exposure to placebos in trials of biologics and small molecules in IBD is associated with a clinically significant deterioration in active IBD. Published in The Lancet Gastroenterology & Hepatology (2024), this work reframed placebo exposure as a period of avoidable inflammatory injury rather than a neutral comparator. These findings have contributed to international discussions on improving clinical trial design. Current collaborative work is evaluating alternative approaches such as active comparator trials and adaptive platform studies, including TOTAL-CD, which aim to reduce unnecessary placebo exposure while accelerating therapeutic innovation.

Figure 1

> "Cumulative uncontrolled inflammation is the central driver of long-term morbidity in inflammatory bowel disease. Preventing that harm requires coordinated reform across diagnostic pathways, early therapeutic intervention, molecular stratification, surveillance systems, trial design, and national service infrastructure."
>
> Dr Shahida Din, Consultant Gastroenterologist

Dr Din' s work also highlights the economic implications of uncontrolled inflammation. In the UK, approximately 500,000 people live with IBD, with estimated annual direct healthcare costs approaching £3 billion. Active disease accounts for the majority of this burden, with healthcare expenditure nearly three times higher than in remission. Lost productivity associated with IBD is estimated at approximately £800 million per year. These findings emphasise that improving disease control is not only a clinical priority but also essential to reduce the economic burden of disease.

Clinical trials

Clinical trials are a major component of Dr Din's research programme. She has served as site Principal Investigator on multiple commercial and investigator led national and international trials evaluating new therapeutic strategies in IBD. These studies span the full spectrum of disease, including early intervention, refractory disease and acute severe inflammatory disease requiring hospital admission. The PROFILE trial demonstrated improved outcomes when effective therapy is introduced earlier in Crohn's disease. The ASTIClite trial evaluated immune "resetting" strategies in patients with refractory Crohn's disease, while the IASO and ACESO trials focus on treatment strategies for acute severe ulcerative colitis. Dr Din has also been involved in trials investigating nutritional approaches to disease modification, including CD-TREAT, ADDapt, BIOPIC and OCEaN. These studies explore the role of diet and the intestinal microbiome in controlling intestinal inflammation.

Alongside therapeutic innovation, her research evaluates treatment safety. Pharmacovigilance studies examining herpes zoster risk in patients receiving advanced therapies contributed to the expansion of eligibility for the Shingrix vaccine for severely immunocompromised adults in the UK. Collaborative work examining JAK inhibitor–associated acne has also improved understanding of the safety profile of emerging treatments.

Reducing pre-diagnosis harm: primary care pathways

Preventing cumulative harm begins before diagnosis. Delays in referral and diagnostic testing can allow intestinal inflammation to progress unchecked in patients with IBD. Dr Din co-led development of a national diagnostic pathway for patients presenting with lower gastrointestinal symptoms. This initiative was developed in collaboration with five patient charities and three professional organisations,

supported by implementation funding from the Helmsley Charitable Trust. The pathway provides a framework for improving referral systems between primary and secondary care and is being piloted in NHS Lothian and Portadown, Northern Ireland. Within NHS Lothian, her research group has developed predictive models that combine stool biomarkers with routinely available laboratory data to better identify patients most likely to have IBD. These models enable improved prioritisation of patients awaiting colonoscopy and aim to reduce delays in diagnosis. The TRIAGE-IBD (Triage using Routine Investigations and Artificial-intelligence for Gastrointestinal Endoscopy in IBD) protocol is currently undergoing external validation across multiple UK centres. This work also addresses alternative diagnoses that may mimic IBD, including microscopic colitis and bile acid diarrhoea, ensuring that diagnostic pathways remain clinically comprehensive.

From standards to implementation: secondary care transformation

Although clinical guidelines exist, national benchmarking has shown significant variation in the quality of IBD care across UK hospitals. This highlights the need for measurable standards and implementation frameworks to ensure that patients consistently receive high-quality care. Dr Din has contributed to defining national standards of care through her work within the British Society of Gastroenterology IBD and Colorectal Surveillance Guidelines. In response to the variation seen in IBD care, national Key Performance Indicators (KPI) for IBD care were determined in 2023. Funding from the BSG has been secured to pilot KPI-aligned data collection across 14 centres in England, Scotland, Wales and Northern Ireland through the OPTIMISE-IBD programme. This work provides the governance infrastructure needed to reduce variation in IBD care and aligns with national quality improvement initiatives such as the NHS England Getting It Right First Time (GIRFT).

Figure 2 OPTIMISE-IBD Site Map

Unmet need programme 1: IBD-associated colorectal cancer

Patients with long-standing IBD have an increased risk of developing colorectal cancer. Colonoscopy surveillance is used to detect early cancer and pre-cancerous changes however is limited by sub-optimal implementation in clinical practice. Controlling inflammation through effective therapies may reduce cancer risk in patients with colonic IBD. Dr Din's IBD-associated colorectal cancer (IBD-CRC) programme integrates mechanistic cancer biology, biomarker discovery and national surveillance reform. Early work characterised the mutational landscape of IBD-associated cancers, while subsequent studies identified genomic changes associated with disease progression. Recent translational

work has shown DOCK2-related immune and microbiome dysfunction in IBD-associated neoplasia. Further collaborative research with cancer biology teams at the University of Edinburgh and Glasgow aims to develop improved biomarkers of cancer risk.

At a national level, Dr Din served as Scottish Government National Clinical Lead for IBD colonoscopy surveillance between 2020 and 2024. This work resulted in the development of a national prioritisation framework for patients awaiting surveillance colonoscopy. Her team is now leading prospective studies to improve cancer risk prediction through the multisite BALANCE-IBD (Biomarker-based Assessment of colonoscopy surveillance waiting lists to Leverage Available NHS Capacity and dEmand in IBD) and multi-national FORECAST-IBD (Framework for Observational Retrospective Evaluation of a Cancer-risk Assessment and Stratification Tool in IBD) clinical protocols.

Unmet need programme 2: Crohn's Disease Fibrosis

In Crohn's disease, cumulative inflammation can cause scarring and narrowing of the intestine (fibrosis), which is a major reason why many patients eventually require surgery. Dr Din contributes to the Helmsley-funded Human Gut Cell Atlas programme ($2.5M collaborative award), a major international collaboration investigating the biological mechanisms underlying fibrostenosing Crohn's disease.

This work integrates single-cell transcriptomics, spatial tissue mapping and digital pathology to define the cellular and molecular pathways driving intestinal fibrosis. The development of a clinically based anatomical framework enables consistent mapping of disease across patient samples, while computational tools allow integration of histology with large-scale molecular datasets.

Recent findings published in the Journal of Pathology (2026) demonstrate immune–stromal interactions within fibrotic lesions, providing potential targets for future anti-fibrotic therapies. This work aims to support the development of clinical trials evaluating new treatments for Crohn's disease fibrosis.

Mentoring the next generation

Mentorship is central to Dr Din's academic practice and the sustainability of translational research in inflammatory bowel disease. She supports the development of clinical academics, postgraduate students, allied health professionals and trainee research networks such as ScotRIGHT through supervision, collaborative research and structured mentorship. She currently co-supervises doctoral students investigating colorectal cancer immunobiology and microbiome-based therapies in IBD and has supervised Masters and undergraduate projects focused on IBD-colorectal cancer genomics and IBD diagnostic pathways. Several trainees she has mentored have progressed to competitive academic fellowships and peer-reviewed publications. Her research group includes clinical trial fellows, specialist nurses and dietitians participating in research programmes, strengthening multidisciplinary collaboration and capacity for translational gastroenterology research.

Conclusion

Dr Din's programme demonstrates how integrated translational research can improve patient outcomes while informing healthcare policy and service design. By combining mechanistic science, clinical trials, predictive analytics and healthcare implementation, this work aims to prevent cumulative inflammatory harm in IBD and improve long-term outcomes for patients living with chronic inflammatory bowel disease.

Education Core

The Education Core at the Edinburgh Clinical Research Facility continues to provide a comprehensive portfolio of short courses for the local and national clinical research community. Our programme includes both in-person and virtual learning opportunities, designed to be engaging, high quality and accessible to a wide range of professionals.

Our experienced team works collaboratively with colleagues across the sector, including the UK Clinical Research Facility (UKCRF) Network Education Group, NIHR Nursing and Midwifery Office and the NRS Training Forum, contributing to and benefiting from a strong national network of clinical research educators and leaders.

The Edinburgh CRF Education Team (L-R), Jo Merrifield, Susie Fong, Lorna Aikman and Marie Leslie

> "The training you do is simply brilliant"
>
> Course attendee, 2025

A year in numbers

In 2025, we delivered 81 courses and events across 117 sessions, welcoming more than 1,500 attendees. We introduced several new courses, including *Doing PPI with Underserved Groups, Research Management: Research Finances and Contracts, and Using Mixed Methods*. We also developed a bespoke, proportionate Good Clinical Practice (GCP) Awareness course for clinical colleagues in haematology, supporting delivery of an ATIMP study.

Throughout the year, we provided 1,179 free or funded places for staff and students from NHS Lothian and the University of Edinburgh, reinforcing our commitment to accessible professional development.

In addition, we managed and facilitated the 2025 NHS Lothian R&D Conference at the John McIntyre Conference Centre on behalf of ACCORD, bringing together 273 attendees and speakers for a successful and engaging event.

> "One of the best courses I've had all academic year!"
>
> Using Mixed Methods attendee, 2025

> "It's great to have this opportunity. I couldn't have attended otherwise"
>
> Funded place attendee, 2025

> "Excellent conference that was extremely well done. Very professional and outstanding content and speakers"
>
> NHS Lothian R&D Conference attendee, 2025

> "Extremely informative, a lot of my anxieties around research were explained in great detail. I am very new and come from a clinical background and felt very lost, but the info provided and resources have helped!"
>
> Welcome Day attendee, 2025

Welcoming and developing the research workforce

We encourage all new staff in clinical research roles across Lothian to attend the Lothian Clinical Research Welcome Day. Hosted twice yearly, the event welcomed over 50 participants in 2025. The day provides an overview of the research landscape in Lothian, introduces key resources and support services, and provides valuable networking opportunities.

From 2026, the Education Core will lead the organisation of twice-yearly training days for NRS Fellows and Clinicians, further strengthening structured development opportunities across the region.

Responding to changes in UK clinical trials regulations

Following the introduction of changes to the UK Clinical Trials Regulations, we have been proactively reviewing and updating our programme to ensure all our courses align with the new standards. We have supported ACCORD in delivering webinars outlining the practical implications of the regulatory updates at a local level. In addition, our NRS GCP trainers have completed training on the new course content and began delivering the updated courses in February 2026.

In recognition of the significance of these regulatory changes, it is expected that all staff involved in Clinical Trials of an Investigational Medical Product (CTIMP) complete the new GCP update course within a reasonable timeframe. To support this requirement and meet anticipated local demand, we have increased both the capacity and frequency of our GCP training provision.

Building the next generation of Principal Investigators

We continue to support the NIHR Associate Principal Investigator Scheme across Lothian. This six-month development programme provides healthcare professionals who are not currently working in research with the opportunity to gain practical experience in study delivery, with support from an experienced Principal Investigator mentor. The programme is designed to encourage greater research engagement among clinical colleagues and help cultivate the next generation of the research workforce.

Thanks to the proactive engagement of our local champions, as well as the support from Principal Investigators and research teams, awareness and participation continue to grow. In Lothian, applications increased by over 25% in 2025 compared with 2024. As of February 2026, there were 54 active Associate Principal Investigators across the region.

Associate PI Scheme Champions:

Jo Merrifield | jo.merrifield@ed.ac.uk

Julia Boyd | julia.boyd@ed.ac.uk

We were also delighted to launch the second Scottish cohort of the NIHR Principal Investigator Pipeline Programme in February 2026. This cohort of the 18-month programme brings together 15 research nurses and Allied Health Professionals from five regions across Scotland. Designed to strengthen the capacity and confidence of NMAHPPS Principal Investigators, the programme aims to enhance research delivery capability and expand opportunities for patients to participate in high-quality research.

National leadership in continuing professional development

In her role as Education Group Chair within the UKCRF Network, Jo Merrifield has led the development of a national Continuing Professional Development (CPD) Directory and accompanying guidance for clinical research delivery staff and managers.

The directory signposts national training opportunities and can be tailored for local use. The guidance highlights a broad range of CPD opportunities - from experiential, work-based learning to formal accredited study - with a strong emphasis on equitable access to professional development.

Sharing career stories

In January 2025, we launched the *Clinical Research Careers Conversations* podcast, showcasing the variety of careers in clinical research and the opportunities these roles provide. Designed to inspire the next generation of professionals, we have published 19 episodes to date, achieving over 2,600 downloads worldwide.

UKCRF Poster Winner for 'Outstanding Leadership' category.

In July 2025, a poster highlighting the podcast won the 'Outstanding Leadership' category at the joint UKCRF Network and NIHR Biomedical Research Centre Conference in Birmingham. We are extremely grateful to all the contributors who have shared their stories and insights, helping us to create engaging content.

Expanding access to learning

Alongside our taught programme, we maintain an online resource bank featuring over 140 free external eLearning resources related to clinical research. We continue to welcome suggestions to help us keep this collection relevant and valuable to our community.

Significant progress has also been made this year in transferring our courses onto the University of Edinburgh's Short Course Platform. This substantial project has involved reworking our internal processes and systems, and we are currently in the pilot phase. Although some adjustments are still being made, we are confident that the new platform will provide a more user-friendly booking experience and open up exciting opportunities in eLearning. We are grateful for our community's patience and support during this transition.

Contacts

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CRF Education Core email | Edinburgh CRF website

Duration of Dual Anti-Platelet Therapy in Acute Coronary Syndrome

Coronary heart disease is the commonest cause of death worldwide. It occurs when the blood vessels that supply the heart become narrowed due to a build-up of coronary atherosclerotic plaques.

If these plaques break and cause a blockage in the blood vessels, this can cause a sudden decrease in the flow of blood and oxygen to part of the heart muscle, resulting in Acute Coronary Syndrome (ACS).

The standard medical treatment following acute coronary syndrome is dual anti-platelet therapy. Despite substantial evidence supporting the use of dual anti-platelet therapy in patients with ACS, there is still significant uncertainty about the optimal duration of therapy. Recent evidence suggests that shorter courses of dual anti-platelet therapy are preferable because of the potential for increased risk of major bleeding and death associated with longer durations.

The aim of the DUAL-ACS study was to determine whether the default strategy for the duration of dual antiplatelet therapy should be three or 12 months. This multicentre, international, open-label, randomised controlled trial involved patients with type 1 myocardial infarction. It was funded by the British Heart Foundation and co-sponsored by NHS Lothian and the University of Edinburgh via ACCORD.

Patients were identified and recruited from the cardiology and general medical wards in hospitals in the UK and internationally. Those patients who consented to participate in the study were randomised 1:1 to receive either three or 12 months of dual anti-platelet therapy.

Following randomisation, participants were not required to attend any follow-up study visits, as all clinical outcomes and compliance with the duration of therapy were assessed using routinely collected electronic health record data. Follow-up was performed for 15 months via data linkage. The primary outcome measure was all-cause mortality, as it was considered the only outcome that could accurately reflect the balance of benefits from avoiding recurrent cardiovascular events in the acute term and the harms from bleeding in the longer term. The secondary outcome measures included cardiovascular death, myocardial infarction, non-cardiovascular death, and major bleeding.

Between April 2018 and April 2022, 5,094 participants were recruited and randomised from 45 sites across three countries. Recruitment in the UK stopped in November 2021. The median time from index myocardial infarction to randomisation was 2 days [interquartile interval 1 to 3] (range 0-93 days). After randomisation, 42 patients were excluded primarily due to a revised diagnosis of type 2 myocardial infarction following subsequent

The aim of the DUAL-ACS study was to determine whether the default strategy for the duration of dual anti-platelet therapy should be three or 12 months. This multicentre, international, open-label, randomised controlled trial involved patients with type 1 myocardial infarction.

invasive coronary angiography, resulting in the discontinuation of dual anti-platelet therapy. Therefore, the intention-to-treat trial population consisted of 5,052 patients who were equally distributed between the 3-month and 12-month groups (2,526 patients in each group).

Participants had a mean age of 63±11 years and were predominantly men (73%), with a high prevalence of cardiovascular risk factors. Index myocardial infarction management was medical therapy only in 23% of cases (1,154 out of 5,052), percutaneous coronary intervention in 71% of cases (3,591 out of 5,052) and coronary artery bypass graft surgery in 6% of cases (307 out of 5,052). In addition to aspirin, all participants received a P2Y12 receptor antagonist with 53% receiving clopidogrel, 43% receiving ticagrelor and 5% receiving prasugrel.

Clinical follow-up for the primary endpoint was available for all participants. The incidence of all-cause death at 15 months was 2.69% (68 out of 2,526) of patients in the 3-month group and 3.44% (87 out of 2,526) of patients in the 12-month group (hazard ratio: 0.78; 95% confidence interval: 0.57 to 1.07; p=0.1232).

At 15 months, the secondary efficacy endpoint of cardiovascular death or non-fatal myocardial infarction occurred in 9.3% (236 out of 2,526) of patients in the three-month group and 8.9% (226 out of 2,526) of patients in the 12-month group (hazard ratio: 1.05; 95% confidence interval: 0.87 to 1.26; p=0.6149).

There were no demonstrable differences in the other secondary efficacy endpoints including cardiovascular death, myocardial infarction, stroke, repeat coronary revascularisation and stent thrombosis.

The secondary safety endpoint of non-cardiovascular death or non-fatal major bleeding occurred in 4.12% (104 out of 2,526) of patients in the three-month group and 5.03% (127 out of 5,256) of patients in the 12-month group (hazard ratio 0.81; 95% confidence interval 0.63 to 1.06; p=0.1220). There were no demonstrable differences in the other secondary efficacy endpoints including non-cardiovascular death, fatal or major non-fatal bleeding and hospitalisation for bleeding.

This trial suggested that the prolonged treatment beyond three months has little benefit in preventing heart attacks but there were signs that the risk of bleeding was higher, which has the potential to increase harm. These findings contribute to the growing evidence suggesting that shorter treatment durations may be more beneficial for patients who have had a heart attack.

The A2B trial: alpha2-agonists for sedation to produce better outcomes from critical illness study registration

Background

Most mechanically ventilated (MV) intensive care (ICU) patients require sedation and analgesia for comfort and to enable treatments. Currently, sedation is usually provided with the drug propofol alongside an opioid drug for analgesia, as recommended in evidence-based guidelines. Propofol is an intravenous anaesthetic and sedative that acts via 'GABA' receptors (similar to benzodiazepines). Despite being the standard of care, it risks over-sedation which is associated with poorer ICU outcomes. It may also increase the risk of delirium, a common ICU complication associated with poorer outcomes, including higher mortality and worse long-term cognitive function. Alternative sedative drugs include the alpha2-agonists dexmedetomidine and clonidine. Dexmedetomidine is a drug that was developed and is licensed for ICU sedation and is thought to provide sedation while allowing the patient to be easily roused yet remain comfortable. The patient can also be kept relatively 'awake' during treatment. Previous research has suggested that this might improve important outcomes such as the duration of MV and delirium. Clonidine is an 'old' drug that was developed in the 1960s as an anti-hypertensive. It has much lower alpha2-receptor specificity, is a weaker sedative, and has a less predictable metabolism, particularly in sick patients. In the UK, clonidine is widely used in practice as an 'off-license' adjunctive sedative, especially for managing agitation and delirium.

Around 2015, it was recognised that the use of dexmedetomidine, which was expensive at the time, was increasing. Systematic reviews

revealed uncertainty regarding the clinical and cost-effectiveness of dexmedetomidine compared with propofol and noted that there was remarkably little evidence to support clonidine use. In 2017, the National Institute for Health and Social Care Research (NIHR) Health Technology Assessment Agency (HTA) commissioned a research programme to establish the clinical and cost-effectiveness of both alpha2-agonists compared to current usual care. Following a competitive application process, this became the A2B trial programme (ClinicalTrials.gov: NCT03653832).

The A2B trial programme was led from Edinburgh and ran from 2018 to 2025. It was designed with and managed by the Edinburgh Clinical Trials Unit (ECTU) and co-sponsored by the University of Edinburgh and NHS Lothian via ACCORD. Recruitment started in late 2018 but was 'hit hard' by the COVID19 pandemic, especially as it was an ICU-based trial. Despite these challenges, and the need for a costed extension from the HTA, we successfully completed the trial in 2024. Most of the main findings were published in 2025.

The trial recruitment graph tells the 'story' of a challenging clinical trial undertaken during the COVID19 pandemic (figure 1). Successful completion was highly dependent on the dedication of the many trial and research managers who worked on A2B during its conduct (including Julia Boyd, David Hope, Alix MacDonald, Gayle Beveridge, Annabel Giddings, and Sîan Irvine, the ECTU methodologists and statisticians (including Chris Weir, John Norrie, Richard Parker, and Sharon Tuck), and the ACCORD team (Lorn Mckenzie, Paul Dearie, Fiach O'Mahony, and Liz Craig among others) who supported all stages of the trial. As the Chief Investigator I am enormously grateful to these collaborators, many others in Edinburgh, my co-investigators, and the 41 ICUs around the UK that participated.

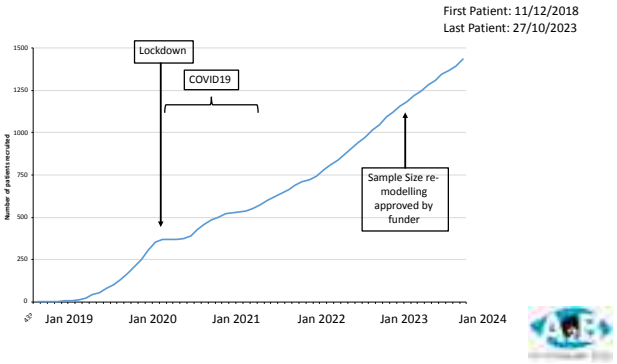


Figure 1: Recruitment graph for the A2B trial, showing the impact of the COVID19 pandemic on the trial, and the subsequent recovery to completion of a revised sample size (300 patients less that initially planned but with the same power for the primary outcome).

Trial objectives, design, and setting

The A2B trial aimed to evaluate the clinical, cost-effectiveness and safety of the alpha2-agonists dexmedetomidine and clonidine compared with propofol for sedating adult ICU patients.[1] It was a pragmatic open-label three-arm trial with an embedded process and economic evaluation. The trial was undertaken in 41 ICUs across the United Kingdom, recruiting the target number of 1,437 adults within 48 hours of starting MV. In all groups, the bedside algorithms aimed to achieve a state of light sedation, which is considered the best practice, unless clinicians requested deeper sedation. The three groups received propofol sedation (usual care), dexmedetomidine-based sedation, or clonidine-based sedation. Other aspects of care were at the discretion of the care team. Our primary outcome was time to successful extubation from MV, analysed with death as a competing risk, as around 20-25% of patients were not expected to survive their ICU illness. The secondary outcomes included mortality, sedation quality, rates of delirium, and cardiovascular adverse events. Long-term outcomes included: experience of ICU care; anxiety, depression, and post-traumatic stress; cognitive function; and health-related quality of life.

Findings

We found no evidence that either dexmedetomidine or clonidine-based sedation resulted in clinically or statistically significant reductions in the duration of MV. Similarly, we also found no effects in pre-defined sub-groups according to age, the presence of sepsis, illness severity or baseline risk of ICU delirium. We found no evidence that either alpha2-agonist improved the quality of ICU sedation or pain compared to propofol, and delirium rates in ICU were also similar in all groups. Unexpectedly, agitation occurred at higher rate than propofol with both alpha2-agonists. The rates of severe bradycardia, a known risk associated with alpha2-agonists, were 60% higher with both alpha2-agonists compared with propofol. Furthermore, more adverse events were reported. However, we found no differences in length of stay in the ICU or hospital, long-term patient-reported outcomes, or mortality over 180-days follow-up period. Overall, therefore,

A2B found no evidence of clinical benefits from either dexmedetomidine, or clonidine-based sedation compared to current usual care sedation with propofol. There were also some signs of increased patient risk. These main findings were published in JAMA in May 2025[2], alongside an infographic summarising the trial (figure 2).

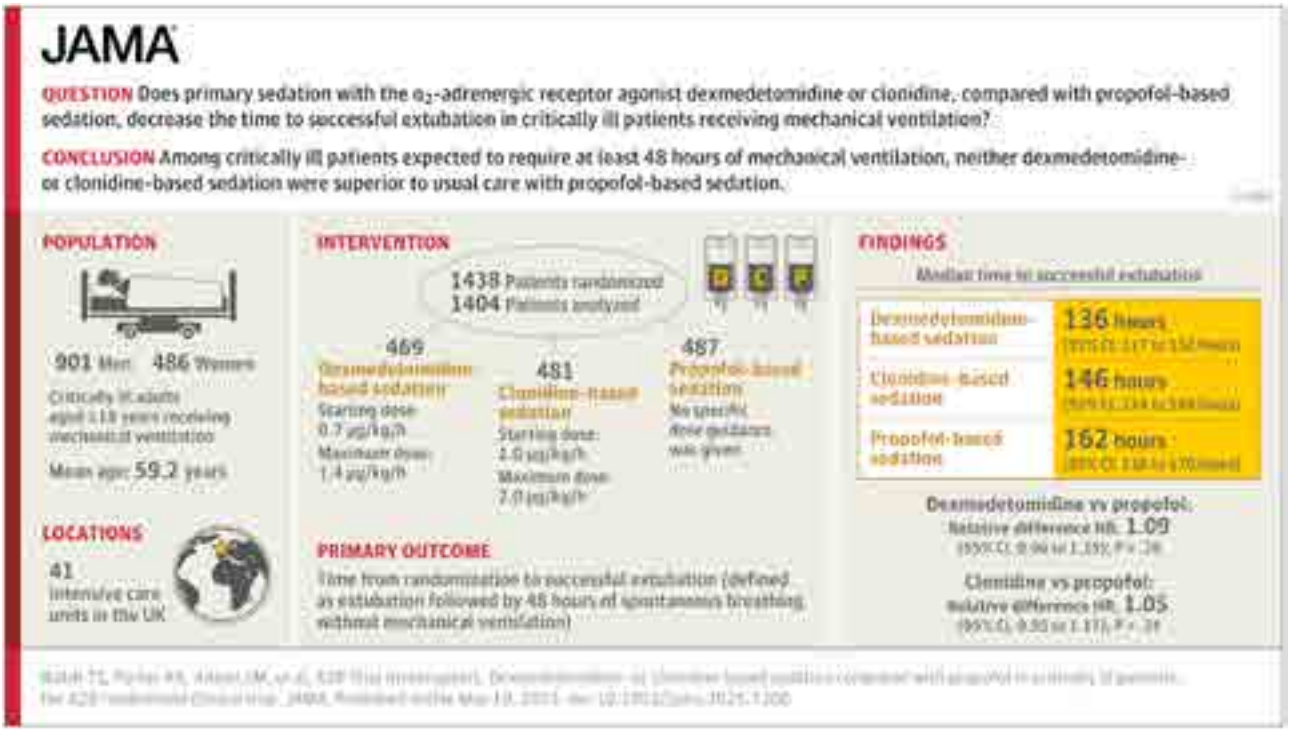


Figure 2: Infographic summarising the results of the main trial

The A2B trial included a health economic evaluation, based on death rates, health-related quality of life (as measured by the EQ-5D-5L questionnaire), and healthcare resource use over six months follow-up period. This was undertaken in collaboration with Professor Steve Morris in Cambridge. Given the trial failed to show clinical benefits, unsurprisingly we did not find that alpha2-agonists were cost-effective. This was despite the fact that the cost of dexmedetomidine decreased to around 30-40% of the initial cost because the drug became 'off-patent' during the trial resulting in price reductions. We were pleased that the JAMA Network published the health economic evaluation simultaneously with the main manuscript.[3]

Several other pre-planned articles have also been published.[4-7] ICU sedation is a complex healthcare intervention, because it involves continuous clinician decision-making for dose-titration according to perceived individual patient need. The HTA funding included a process evaluation to explore a range of factors relevant to understanding the trial, which were set out in a protocol[4], and published in two articles[5,6]. This detailed analysis of interviews with research and clinical staff involved in the trial provided important contextual understanding at both the individual and system levels that influenced the delivery of the intervention, including: ICU culture, prior clinician opinions and beliefs, staffing pressures (exacerbated by the COVID19 pandemic),

clinician experience, and concerns about alpha2-agonist side-effects. There was an interesting correlation between staff concerns about safety and the adverse events observed in the trial, particularly bradycardia and other cardiovascular effects.

Conclusions

Successfully completing the A2B trial under the most challenging circumstances was a massive achievement for everyone involved. Our findings that no clinical or economic benefit from alpha2-agonists, and are likely to have greater adverse effects, are already influencing practice and guidelines. We have presented the trial at a range of international critical care meetings, and we were invited to present the novel design and methodology at the prestigious NIH Pragmatic Trials Collaboratory Series[8]. Personally, I am incredibly proud of the teamwork and dedication of the ECTU and Edinburgh Critical Care Research Group teams. Together we learnt a great deal about novel approaches to trial design and the delivery of complex interventions in critical care, as well as the value of resilience to 'keep going'.

> "A clinical trial is like a symphony – it is only beautiful if all the players work in harmony"
>
> Tim Walsh (Chief Investigator A2B trial)

References

1. Walsh TS, Aitken LM, McKenzie CA, Boyd J, Macdonald A, Giddings A, Hope D, Norrie J, Weir C, Parker RA, Lone NI, Emerson L, Kydonaki K, Creagh-Brown B, Morris S, McAuley DF, Dark P, Wise MP, Gordon AC, Perkins G, Reade M, Blackwood B, MacLullich A, Glen R, Page VJ. Alpha 2 agonists for sedation to produce better outcomes from critical illness (A2B Trial): protocol for a multicentre phase 3 pragmatic clinical and cost-effectiveness randomised trial in the UK. BMJ Open 2023 Dec 10;13(12):e078645. doi: 10.1136/bmjopen-2023-078645
2. Walsh TS, Parker RA, Aitken LM, McKenzie CA, Emerson L, Boyd J, Macdonald A, Beveridge G, Giddings A, Hope D, Irvine S, Tuck S, Lone NI, Kydonaki K, Norrie J, Brealey D, Antcliffe D, Reay M, Williams A, Bewley J, Creagh-Brown B, McAuley DF, Dark P, Wise MP, Gordon AC, Perkins GD, Reade MC, Blackwood B, MacLullich A, Glen R, Page VJ, Weir CJ; A2B Trial Investigators. Dexmedetomidine- or Clonidine-Based Sedation Compared With Propofol in Critically Ill Patients: The A2B Randomized Clinical Trial. JAMA. 2025 Jul 1;334(1):32-45. doi: 10.1001/jama.2025.7200
3. Morris S, Lone NI, McKenzie CA, Weir CJ, Walsh TS; A2B trial investigators. Cost-Effectiveness of α2 Agonists for Intravenous Sedation in Patients with Critical Illness. JAMA Netw Open. 2025 May 1;8(5):e2517533. doi: 10.1001/jamanetworkopen.2025.17533
4. Aitken LM, Emerson LM, Kydonaki K, Blackwood B, Creagh-Brown B, Lone NI, McKenzie CA, Reade MC, Weir CJ, Wise MP, Walsh TS. Alpha 2 agonists for sedation to produce better outcomes from critical illness (A2B trial): protocol for a mixed-methods process evaluation of a randomised controlled trial. BMJ Open. 2024 Apr 5;14(4):e081637. doi: 10.1136/bmjopen-2023-081637.
5. Aitken LM, Emerson LM, Kydonaki K, Blackwood B, Creagh-Brown B, Lone N, McKenzie C, Parker R, Reade MC, Weir CJ, Wise MP, Walsh TS. An exploration of the factors influencing successful implementation, delivery and outcomes in an intensive care sedation study: process evaluation of the A2B RCT. Health Technol Assess. 2025 Nov 12:1-18. doi: 10.3310/GJTW0620.
6. Emerson LM, Blackwood B, Kydonaki K, McKenzie C, Walsh TS, Aitken LM. The experiences of bedside nurses delivering an intensive care sedation study: A process evaluation within the A2B trial. J Intensive Care Soc. 2025 Nov 6:17511437251381951. doi: 10.1177/17511437251381951.
7. Walsh TS, Parker RA, Aitken LM, McKenzie CA, Glen R, Weir CJ. Relative and bedside nurse assessment of comfort and communication during propofol, dexmedetomidine, or clonidine-based sedation: pre-planned analysis within the A2B RCT. Health Technol Assess. 2026 Jan 14:1-18. doi: 10.3310/GJTW2718.
8. Grand Rounds August 15, 2025: Dexmedetomidine- or Clonidine-Based Sedation Compared with Propofol in Critically Ill Patients: The A2B Randomized Clinical Trial – Addressing a Complex Clinical Question with Novel Integrated Methodological Approaches (Tim Walsh, MD, FFICM; Chris Weir, PhD; Richard Parker, MsC)

Inclusion health – exploring access to cervical cancer screening and prevention for inclusion health populations

Could opportunistic service provision help address inequalities in cervical cancer?

A research team from the University of Edinburgh and specialist sexual health services in NHS Grampian, Lothian, and Greater Glasgow and Clyde are exploring the feasibility of providing opportunistic human papillomavirus (HPV) vaccination and screening for people with experience of homelessness, transactional sex, prison, or addiction.

Why health inequalities matter

Health inequalities fundamentally challenge the principles of fairness and justice, with individuals' equitable access to healthcare and the opportunity to achieve optimal health hindered by social, cultural and economic factors. Moreover, disparities in health have broader implications, impacting not just the individuals but also society as a whole. These disparities perpetuate cycles of disadvantage and injustice, disproportionately affecting marginalised communities.

Addressing health disparities is not only an ethical imperative but also an economic necessity. In the long term, health disparities can lead to increased healthcare costs and reduced productivity, placing a substantial burden on healthcare systems and the economy.

As many disparities arise from systemic issues within policy and practice, they may be avoidable and open to change. Through targeted interventions, which tackle causes of these inequalities, sustainable improvements in health equity can be achieved. This approach benefits disadvantaged individuals and strengthens the health infrastructure, promoting long-term societal and economic well-being.

Cervical cancer prevention and detection, and inclusion health populations – the HPV Equity Study

Individuals who have experienced homelessness, substance use/addiction, transactional sex, and incarceration face significant health inequalities across a wide range of health conditions. This inequity includes cervical cancer with individuals in these populations less engaged with both the routine HPV vaccination and cervical cancer screening programmes, yet also at higher risk of developing cervical cancer.

Addressing inequalities, including in cancer prevention and treatment, is an important public health aim across many high-income countries.

However, inclusion health populations are often missing from health data, records, policy documents, and healthcare guidance. For example, in relation to cervical cancer, while the Joint Committee on Vaccination and Immunisation (JCVI) recommends opportunistic HPV vaccination for mid-adults (25-45 years old) from some inclusion health groups, there is no specific guidance, explicit national vaccination programme, or dedicated funding to support this recommendation. Instead, the interpretation of this recommendation and decisions around it are left to clinicians' discretion, and funding for vaccine provision is decided and sourced locally on a case-by-case basis.

What we are doing

HPV Equity is a mixed-methods study that seeks to generate evidence to inform optimal delivery of HPV vaccination and cervical screening to women from inclusion health populations in Scotland.

The study comprises four broad components:

1. Baseline HPV testing to assess the type-specific prevalence of HPV in our study population.
2. The provision of opportunistic HPV vaccination during routine sexual health clinics to assess the feasibility, uptake and course completion of this form of service provision.
3. Qualitative exploration of the perspectives of women from our study population on HPV vaccination and cervical screening.
4. A systematic review of international clinical guidelines relating to HPV vaccination and cervical screening for women with experience of transactional sex, homelessness, living in custody, or substance use/addiction.

> "Women with severe and multiple social disadvantage are frequently forgotten about. Their voices are unheard as they do not have capacity to make a noise about their needs due to the pressure of managing their difficult lives, dealing with abuse, negotiating housing and surviving exploitation. This study advocates for their importance in relation to healthcare priorities in preventing longer term disease. This group of women is 12 times more likely to die prematurely than other women so their disease burden is huge. The fact that they have been felt to be important enough for someone to do research is, in itself, hugely impactful for them"
>
> Alison Scott, Consultant Gynaecologist and Clinical Lead for Inclusion Health, NHS Lothian

Progress so far and provisional results

The study is underway in three regions of Scotland: NHS Lothian, NHS Greater Glasgow & Clyde, and NHS Grampian. We are conducting opportunistic vaccinations and swab collections in prisons, specialist sexual health clinics, and as part of community outreach services. Our first participants have now reached the follow-up vaccination stage.

It is too early to share the results. We have had steady recruitment, particularly through our outreach services and in prisons. Some participants have tested negative for HPV, while others have tested positive, including for high-risk types 18, 51, and 52. Participants with high-risk HPV have been followed up and offered full cervical screening with cytology.

The qualitative interviews are almost complete. Participants have highlighted issues impacting their uptake of standard screening, vaccination, and other healthcare services, and have provided valuable feedback on our opportunistic service.

The systematic review is now complete. We included 49 clinical practice guidelines covering topics relevant to HPV vaccination and cervical screening from both national and international professional organisations in 18 different countries. However, we found that only a few of those guidelines included recommendations or consideration of inclusion health populations and most of these were limited to a brief mention, such as in a list of 'other' populations with additional needs. Nevertheless, by examining the guidance as a whole, we were able to identify best practice for building cervical cancer prevention services for inclusion health populations.

Next steps

Data collection will continue. Our aim is to recruit 300-500 participants for the prevalence component. Once the data collection and analysis are complete, we will carry out Patient and Public Involvement and Engagement (PPIE) work to ensure that the perspectives of those most affected are included in our interpretations and recommendations.

We anticipate that the results will inform the future provision of cervical cancer services and provide a template for the provision of other preventative health services for inclusion health populations in Scotland.

The study's Principal Investigator is Dr Christine Campbell and the lead researcher is Dr Mia Closs (both Usher Institute, University of Edinburgh); co-investigators are Dr Kate Cuschieri and Dr Alison Scott (NHS Lothian), Dr Daniela Brawley (NHS Grampian) and Dr Alexandra Maxwell (NHS Greater Glasgow and Clyde), supported by sexual health and prison nursing teams. The study is funded by the Chief Scientist's Office and co-sponsored by the University of Edinburgh and NHS Lothian via ACCORD.

Advancing dementia research in NHS Lothian

Working collaboratively to improve opportunities for early-phase dementia research

The Lothian team of the NHS Research Scotland (NRS) Neuroprogressive and Dementia Network has a long-standing track record of investigating new treatments for dementia and related conditions in Phase 2b and 3 clinical trials. As part of the national NRS network, the team works closely with clinical services to provide people living with dementia with access to high-quality research opportunities. We are delighted to share the exciting news that we will soon start running earlier phase trials of novel dementia treatments.

UKDTN

The NIHR-funded UK Dementia Trials Network (UKDTN) sits alongside multiple other significant UK-wide initiatives. These include the UKRI Dementia Challenge, which focuses on reducing the time it takes to receive a diagnosis; the UK Government Dame Barbara Windsor Dementia Goals, which includes the Dementia Trials Accelerator and the Neurodegeneration Initiative; the NIHR Research Delivery Network; and the Dementias Platform UK Trial Delivery Framework. The UKDTN is at the forefront of efforts to make the UK a 'go-to' place for early phase dementia clinical trials through a tiered network of three pilot sites, eight member sites and 30 affiliate sites across the country. This includes a specialised cohort of Phase 1b-ready sites and a broader cohort capable of delivering Phase 2 trials, creating a robust national infrastructure.

We were delighted to host Professor Catherine Mummery from University College London and the UKDTN team at the Wellcome Trust Clinical Research Facility (WTCRF) at the Western General Hospital last Autumn. Earlier this year, we began the process of becoming a UKDTN member site, the second in Scotland after our colleagues in Glasgow were selected late last year and the ninth in the UK. Since both Scottish sites are part of the national NRS network, we will be able to work together to facilitate recruitment of participants to these trials and provide cross-cover of raters, for example for the specialist assessments required in dementia trials.

The UK Dementia Trials Network has four key aims:

1. Accelerating set up for dementia clinical trials
2. Increasing industry engagement for early phase dementia trials in the UK
3. Embedding patient support: enhancing recruitment, support, and diversity
4. Increasing capacity and expertise across the UK, democratising access, and making the UK a 'go-to' place for early phase dementia trials

NRS Neuroprogressive and Dementia Network Lothian team
Jess Crossan, Emma Fleming, Ruth Moss, Bev Goldberg, Marian Montanha

To support UKDTN, Alzheimer's Society has committed £3 million to fund the first dedicated network of specialist dementia research nurses across the UK. Training sites are geographically dispersed across the UK and prioritise demographic diversity. The UKDTN works closely with industry partners and the wider dementia and neurodegeneration ecosystem to change the future of dementia trials, bringing treatments and trial opportunities to all.

Established infrastructure for Early-Phase research

NRS NDN team run their dementia clinical trials at the WTCRF, Scotland's only MHRA Phase 1-accredited unit. The facility provides 24-hour research capacity, oversight from a dedicated Phase 1 Study Review Committee, and substantial early phase trial experience in other disease areas. Across NHS Lothian more widely, we can boast access to advanced imaging including 3T MRI and growing PET tracer capability, in addition to secure laboratory and biobanking support.

A multidisciplinary team with broad experience

The NRS NDN team is an experienced clinical research team bringing together expertise from psychiatry, neurology, and geriatric medicine, supported by skilled research nurses, trial coordinators, pharmacists, and operational staff.

Dr Tom Russ

- PI, UKDTN Edinburgh site
- NRS Clinical Lead for Neuroprogressive and Dementia Research
- Reader in Old Age Psychiatry, University of Edinburgh
- Honorary Consultant Psychiatrist, NHS Lothian

Dr Tim Wilkinson

- UKDTN Clinical Trial Fellow
- Honorary Consultant Neurologist, NHS Lothian

Through UKDTN membership, the team will benefit from additional funded research nurse and Principal Investigator (PI) time, helping to strengthen early-phase dementia trial delivery across NHS Lothian and partner boards. Over time, there may also be additional funding to further increase our capacity to run early phase dementia clinical trials.

Participant-centered recruitment and inclusive practice

The aim of the NRS NDN is to offer everyone in Scotland with mild cognitive impairment, dementia, or a related condition, the opportunity to take part in research. This is done through multiple routes including the Scottish Dementia Research Interest Register (a GDPR-compliant 'consent-to-consent' register where people can register their interest in finding out more about research opportunities in Scotland relevant to them), the UK-wide Join Dementia Research, SHARE, and partnerships with third-sector organisations – especially Alzheimer Scotland. Improving diversity remains a key priority, with a dedicated member of staff focusing on 'underserved' communities, including people living in remote and rural communities (including the islands), minority ethnic groups, and people living in care homes.

Over the last few years, NRS NDN staff have provided a bespoke training day to all Alzheimer Scotland staff to help them have 'Confident Conversations' about research with the people they support. We are now offering this to NHS staff teams and have had excellent feedback from training offered to the Memory Assessment and Treatment Service and Community Mental Health teams for older adults in NHS Lothian. We would be very happy to hear from any teams who would like to receive this training – email our national administrator Gillian Curr or call 01382 423086.

> Over the last few years, NRS NDN staff have provided a bespoke training day to all Alzheimer Scotland staff to help them have 'Confident Conversations' about research with the people they support. We are now offering this to NHS staff teams and have had excellent feedback from training offered to the Memory Assessment & Treatment Service and Community Mental Health teams for older adults in NHS Lothian.

Collaborative working across specialties and regions

Close collaboration across three medical specialties is essential for high-quality dementia research and having this wide expertise in the team supports consistent trial delivery. Joint pathways with the Anne Rowling Clinic and cross-board work with NHS Fife and NHS Forth Valley extend opportunities for participation. The BRAIN-E group provides a shared forum for clinical academics involved in neurodegeneration research.

The NRS NDN works hard to put people with lived experience of dementia (either someone with a diagnosis themselves or a relative, friend, or supporter) at the centre of all activities. We have a very active lived experience group who named themselves 'Partners in Research' and who are supported by Dr Rosalie Ashworth.

> The NRS NDN works hard to put people with lived experience of dementia (either someone with a diagnosis themselves or a relative, friend, or supporter) at the centre of all activities.

Partners in Research have co-produced conference programmes with us, sat on interview panels for new posts, and recently co-authored a book about their experiences – good and bad – of taking part in research entitled 'Challenging assumptions around Dementia: user-led research and untold stories.' Thanks to a generous grant from the Chief Scientist Office (CSO), this book is available to download free of charge from the publisher's website. We are always keen to hear from anyone who would like to join in this aspect of our work.

And finally…

This is an exciting time for dementia research in NHS Lothian! Joining the UKDTN allows us to expand our expertise to early phase dementia studies and improve pathways for identifying individuals who may be interested in research. If you would like further information about anything in this article, please do get in touch.

Relevant links:

- NRS NDN Lothian website
- UKDTN Website
- NRS NDN national website
- Sign up to the Scottish Dementia Research Interest Register
- Request involvement from our lived experience group, Partners in Research
- Our Partners in Research book about taking part in dementia research (open access)

Research Governance in ACCORD

Clinical research in Edinburgh is supported by a close partnership between the University of Edinburgh and NHS Lothian, bringing together academic expertise and NHS operational insight. Through ACCORD, this collaboration provides comprehensive research governance, regulatory oversight and operational support for around 1,000 studies each year from student projects to large international clinical trials.

The ACCORD partnership

The University of Edinburgh and NHS Lothian share a long-standing and productive partnership in clinical research. They combine academic excellence with frontline healthcare expertise to support robust, ethically sound and impactful studies. Central to this collaboration is ACCORD, a joint office that brings together research governance and support teams from both institutions.

This integrated structure supports around 1,000 clinical research projects each year, ranging from small student-led initiatives to large-scale, multicentre international trials. Researchers across the UK and internationally rely on this partnership to secure funding, approvals, sponsor and R&D governance oversight and operational support within the University and NHS Lothian, regardless of whether studies are academically or commercially led.

The research governance support offered by ACCORD enables researchers to navigate the complex regulatory and ethical frameworks that underpin clinical research in the UK. This support them to conduct studies safely in NHS Lothian and at other locations in the UK and beyond.

The research governance support offered by ACCORD enables researchers to navigate the complex regulatory and ethical frameworks that underpin clinical research in the UK.

ACCORD supports

- ~1000 research studies each year
- Academic and commercially sponsored research
- Studies ranging from student projects to international trials
- Research conducted in NHS Lothian and globally

Profiles, initiatives and awards

University of Edinburgh Research Governance team

Within the College of Medicine and Veterinary Medicine, the Research Governance team plays a central role in providing ethical and regulatory oversight for clinical research sponsored by the University, NHS Lothian, or co-sponsored by both organisations. In clinical research, sponsorship refers to the legal and ethical responsibility for ensuring that studies are conducted in line with regulatory requirements, safety standards and approved protocols.

The team is led by the University of Edinburgh Head of Research Governance, Marise Bucukoglu, and includes Clinical Research Facilitators and Research Governance Coordinators, alongside a Global Health team that supports studies conducted in low and middle-income countries.

Clinical Research Facilitators

They typically become involved in studies at an early stage of study development, working closely with researchers planning regulated clinical trials and medical device investigations. They advise on study design, costings, regulatory pathways, risk assessment, and the preparation of documentation required for formal approvals, including modifications.

Paul Dearie, Research Facilitation Manager, leads the Facilitators, Fiach O'Mahony and Tiago Santos.

Paul Dearie

Fiach O'Mahony

Tiago Santos

Research Governance Coordinators

They play a critical role in reviewing non-regulated studies and steering them through the ethics review process. They also support researchers in responding to feedback and amending study documentation.

Managed by Jo-Anne Robertson, Research Governance Manager, the team includes two Coordinators, Chris Coner and Conni McCarthy.

Jo-Anne Robertson

Chris Coner

Conni McCarthy

Global Health

This team provides specialist governance advice in settings where regulatory and ethical environments may differ. They ensure that both regulated and non-regulated global health research meets high ethical and governance standards.

Laura Rankin, Global Health Facilitator and Lucy Kessler, Research Governance Assistant.

Laura Rankin

Lucy Kessler

Profiles, initiatives and awards

As Sponsor representatives, Facilitators and Coordinators advise on areas such as data protection and information governance. They support research teams in meeting their obligations under UK GDPR and related legislation. They also provide expert guidance on consent processes, ensuring that participant information sheets and consent materials are clear, proportionate and ethically robust.

Beyond regulatory and ethical compliance, the University Research Governance team plays an active role in advancing diversity and inclusion in clinical research. They collaborate with researchers to consider who is included in studies, and who may be unintentionally excluded from studies, encouraging the adoption of inclusive recruitment strategies and appropriate engagement with diverse communities. This supports wider sector priorities to improve equity in research participation and ensure that research findings are relevant to the populations they aim to serve.

The team is also closely involved in promoting research transparency, supporting good practice around trial registration, the public availability of study information and the appropriate reporting of research outcomes. By embedding transparency expectations at an early stage in the research lifecycle, the team helps strengthen public trust in research and supports compliance with funder, regulatory and institutional requirements.

Early engagement with the University Research Governance team enables researchers to ensure that studies are appropriately sponsored, governance considerations are embedded from the outset, and clear points of contact are in place throughout the study lifecycle.

The NHS Lothian Research Governance (R&D Management Approval) team

While the University team is responsible for sponsorship and research governance oversight of studies led from Edinburgh, the NHS Lothian R&D team in ACCORD provides complementary support for all research conducted within NHS Lothian involving NHS patients (including data and tissue), staff, facilities and/or resources. Studies hosted in NHS Lothian, whether sponsored locally or by another academic or commercial organisation, require R&D management approval before commencing, confirming that local organisational policies, capacity and capability considerations and national governance standards are met.

Heather Charles, NHS Lothian Head of Research Governance, leads the R&D teams, overseeing the portfolio of studies taking place in NHS Lothian and providing R&D management approvals.

Profiles, initiatives and awards

R&D Non-Commercial team

The R&D Non-Commercial team oversees studies sponsored by academic and non-commercial organisations that take place in NHS Lothian. This includes studies sponsored by the University of Edinburgh and NHS Lothian.

They review study documents and modifications against UK study-wide governance criteria and advise researchers on NHS-specific requirements. This ensures compliance and confirms that the necessary infrastructure, funding and staff support are in place for the successful set-up and delivery of the study. The team issues R&D management approval once all compliance criteria are confirmed and NHS Lothian's service and support departments have confirmed their capacity and capability to begin the research.

The team is managed by Kenneth Scott, NRS Generic Review Manager and includes Elizabeth-Ann Alexander, Eloise Candlish, Caroline King and Manisha Khatri.


Elizabeth-Ann Alexander


Eloise Candlish


Caroline King


Manisha Khatri

R&D Commercial team

This team is responsible for oversight of the portfolio of studies sponsored by commercial companies, typically pharmaceutical or biotechnology companies, and hosted in NHS Lothian. They work closely with industry Sponsors and Contract Research Organisations (CROs) to manage the distinct regulatory, contractual and operational requirements associated with commercially sponsored research. They align these requirements with NHS systems to ensure that contracts, governance documentation, and resource planning are appropriate and robust.

This team also ensures that all studies undertaken in Lothian are fully costed in accordance with national requirements. Where necessary, the team also leads the National Contract Value Review (NCVR) on behalf of all UK study locations.

The R&D Commercial team is led by Melissa Taylor, R&D Commercial Lead and includes Fiona Bairstow, Lisa Robertson, Glenn Robinson and Bilkis Ali.


Lisa Robertson


Glenn Robinson

Profiles, initiatives and awards

Together, the R&D Non-Commercial and Commercial teams enable NHS Lothian to support both academic and industry-driven research, contributing to a vibrant clinical research ecosystem that drives innovation, improves patient outcomes and accelerates the translation of research into clinical practice.

A collaborative research environment

The ACCORD University and R&D Governance teams are co-located within the Usher Building on the BioQuarter site. This arrangement fosters close collaboration, facilitates effective communication and streamlines the process of securing all necessary approvals for conducting research in Lothian.

By combining academic rigour with NHS operational insight, this partnership ensures that studies are well designed, ethically reviewed and conducted safely, and are fully compliant with regulatory standards and NHS requirements. Whether advancing new health interventions, improving care pathways or delivering global health research, the research governance teams provide essential expertise that underpins high-quality clinical research led from Edinburgh.

Contact details for the teams can be found on our website.

The Research Governance teams in ACCORD are supported by Kasia Bialonowski and Lesley Saeed, who manage the shared mailboxes. By triaging incoming queries and coordinating the allocation of work across the teams, they ensure that researchers receive timely guidance and that study support requests are quickly directed to the most appropriate team member.

Contact:

For sponsorship and research approval enquiries, email the ACCORD facilitators and coordinators.

For enquiries related to conducting research in NHS Lothian, please contact the ACCORD R&D team.

Profiles, initiatives and awards

R&D Contracts team

Meet the NHS Lothian R&D Contracts team

Dr Douglas Young, Principal R&D Manager, has been the lead for contracts at NHS Lothian R&D, HISES and DataLoch since 2010. Michael Adamson joined the R&D Contracts team in 2021 as R&D Contracts Manager and is responsible for advising on all research contracts.

Dr Douglas Young, Principal R&D Manager.

Michael Adamson, R&D Contracts Manager.

What is a contract?

A contract is a legally binding document that details the obligations and liabilities of the parties involved. Nearly every research study requires a contract between the Sponsor and the trial site. These can range from the simple Organisation Information Document (OID) for basic research studies, to a more detailed Model Clinical Trial Agreement or Model Non-Commercial Agreement (mCTA or mNCA) for commercial and non-commercial interventional studies or a complicated multi-party collaboration agreement, which details the roles and responsibilities relating to grant- funded research.

Why are contracts important?

Contracts are important because they clearly set out the parties' responsibilities and help protect their interests with regard to confidentiality, liability, indemnity, intellectual property and funding. They also provide a legal basis for sharing personal data under the UK GDPR, and define the roles, expectations and duties of each party as part of the study. Most importantly, a well-drafted contract removes any ambiguity between the parties, eliminating the need for costly litigation.

National perspective

Many of the contracts that are used for both commercial and non-commercial research are UK-wide templates, which can be found at IRAS Help - Preparing and submitting applications - templates for supporting documents. Douglas represents Scotland on the UK Four Nations' Contracting Leads Group.
The group meets fortnightly and is responsible for drafting, reviewing and publishing the suite of UK research contracts (including the aforementioned OID, mCTA and mNCA, among others). Michael is the deputy representative on behalf of Scotland and substitutes on behalf of Douglas when required.

> The R&D Contracts team works closely with the University of Edinburgh Contracts team, and together we have developed a number of co-sponsorship and site agreements for research studies that are co-sponsored by NHS Lothian and the University of Edinburgh.

Profiles, initiatives and awards

Collaborations

The R&D Contracts team works in close partnership with the University of Edinburgh Contracts team to develop co-sponsorship and site agreements for jointly sponsored research studies. This collaboration is supported by a robust Research Framework Agreement, which clearly defines the roles and responsibilities of each party.

Under this arrangement, the University of Edinburgh Contracts team leads on the set-up and execution of contracts for co-sponsored studies, while the NHS Lothian R&D Contracts team manages all hosted commercial and non-commercial study agreements within NHS Lothian.

We also work with R&D teams in other NHS boards in Scotland, NHS Trusts, and Higher Education Institutions across the UK and beyond. This ensures that appropriate contracts are put in place for all research studies and collaborations, where necessary.

We also work with R&D teams in other NHS boards in Scotland, NHS Trusts, and Higher Education Institutions across the UK and beyond. This ensures that appropriate contracts are put in place for all research studies and collaborations, where necessary.

How we can help

If you are going to participate in a hosted commercial or non-commercial study, the contract will automatically be submitted to R&D for review as part of the study submission via NHS Research Scotland. The contract will be reviewed by the NHS Lothian Research Goverance team, who will consult the R&D Contracts team if necessary. If you are planning to carry out your own investigator led study, you should first contact the Research Governance team. They will then involve the relevant Contracts team, either from the University of Edinburgh or from R&D, who will advise on the necessary contracts. If you are approached to participate in a study and the Sponsor requests that you complete a confidentiality agreement or non-disclosure agreement, please forward it to the R&D Contracts team for review and completion.

How to contact us

If you would like further advice, or if you would like us to help you with a contract for your research study, please email either Douglas Young or Michael Adamson.

Selected developments and partners

Edinburgh Clinical Research Facility (CRF)

Edinburgh CRF is a partnership between NHS Lothian and the University of Edinburgh, with 25 years experience of supporting and delivering excellence in multidisciplinary clinical research.

2025 has seen investment in the Edinburgh CRF clinical facilities. In addition to our MHRA Phase 1 Accredited CRFs at the Western General Hospital (WTCRF) and the Royal Infirmary of Edinburgh (RIECRF), as well as the Children's CRF at the Royal Hospital for Children and Young People (RHCYP), we have recently established the new Lothian Commercial Research Delivery Centre (CRDC). This is one of four new centres in NHS Scotland, building on existing clinical research delivery infrastructure and managed by the Edinburgh CRF.

The laboratory and research support cores are located at the WTCRF and the Queens Medical Research Institute (QMRI), including Image Analysis, Mass Spectrometry, Genetics, IT, Administration, Epidemiology and Statistics, Education, and Patient Public Involvement (PPI). Education and PPI core updates can be found here.

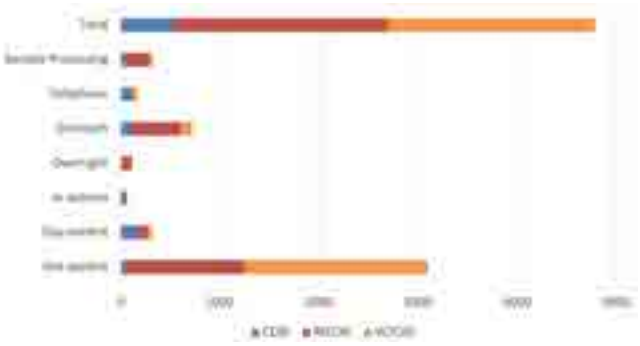
2025 spotlight on Nursing and Clinical, Image Analysis and Mass Spectrometry cores

Nursing and Clinical core:

In 2025, the Nursing and Clinical (N&C) core supported 154 active studies, 103 of which required direct nursing input. A total of 4,784 participant research visits were completed across all active studies, including 320 sample processing visits. Of the 166 new studies that applied for support across all of the CRF's cores, 75 were seeking N&C support.

2025 has also seen engagement with new Principal Investigators from various clinical specialties including paediatric endocrinology, clinical genetics and anaesthetics. The latter has resulted in an increase in collaboration between the RIECRF and Edinburgh Critical Care Research Group (ECCRG) nursing teams to deliver research.

CRF Study Visits 2025



Type classifications: Out-patient <4 hours; Day-patient >4 and <8 hours; In-patient >8 hours on same day; Overnight visit starts and ends on different days; Outreach e.g. community or ward visit; Telephone; Sample processing.

Selected developments and partners

The CCRF has been working hard to raise the profile and visibility of clinical research at RHCYP. This has included circulating a quarterly newsletter and hosting promotional stands in the hospital concourse on 'Red for Research Day'. The CCRF and the importance of the work they are involved with featured in the media when founders of The Natasha Allergy Foundation visited the facility and were filmed by STV, discussing their pioneering research programme into food allergies alongside a local child and their family who participate in the Natasha Clinical Trial at the CCRF.

In 2025, the RIECRF has seen an increase in requests to support studies run by the Mental Health Network, due to relocation of the network team to the Bioquarter. This has meant fewer mental health studies being hosted in the WTCRF. However, with an increasing number of trials exploring psychedelic drugs, a clinic space within the WTCRF is currently being refurbished to support these studies safely and provide an appropriate space for participants. We look forward to being able to support this pivotal work.

The RIECRF continues to support the majority of the Phase 1 trials run through the Edinburgh CRF. For the N&C team at the RIECRF this provides valuable experience in delivering these early phase trials whilst adhering to the highest standards regarding participant safety, quality data and regulatory compliance. All of our Phase 1 trials across the three facilities, benefit from the expert support of our Phase 1 Lead Nurses.

In December 2025, the WTCRF N&C team exceeded their recruitment target of 6,000 participants for the SCOT-HEART 2 study, achieving a final figure of 6,139. This was a monumental achievement for the N&C team, as seeing up to eight participants a day for five years was no mean feat. However, this would not have been possible without the support of the N&C administration team, who worked tirelessly to schedule appointments, manage communication and adapt to changes as they occurred. This achievement is testament to the teamwork displayed across Edinburgh CRFs.

Ailsa Geddes, Lead Clinical Research Nurse Educator, continues to build on learning and development opportunities in the CRF. This has involved reviewing and updating the established induction programme for all staff groups. Ailsa has also delivered the UKCRF Lab Skills Workshop locally. As well as internal staff attending these sessions, she has welcomed research staff external to the CRF onto the course, enhancing training in the wider research community in Lothian. The CRF continues to promote clinical research as a career for nurses by engaging with open days at local universities and supporting student placements.

The new appointments to the senior nursing team in 2025 are Scott Farley-Simpson, Lead Research Nurse at the RIE and Rachel Woods, Lead Nurse for Phase 1/Education. Rachel is replacing Marta Adamczyk, who left Scotland at the end of 2024 to travel. After nine years as CCRF Director and Associate Director of Edinburgh CRF, we bid farewell to Professor Steve Cunningham and look forward to working closely with Dr Don Urquhart who has replaced Professor Cunningham in this role.

Selected developments and partners

Image analysis Core:

Our specialist imaging and image analysis facilities play a central role in enabling high quality, high impact research across retinal and brain health. As well as providing access to advanced hardware, we offer deep methodological expertise, bespoke software development, and hands on scientific collaboration that allows complex studies to be delivered with rigour, reproducibility, and scientific ambition.

A key strength of our facilities is the translation of novel analytical tools developed in Edinburgh into research impact. Our team engineers, validates, and disseminates cutting edge software pipelines that enable external collaborators to interrogate retinal structure. For example, methods originating in the Image Analysis Core are underpinning major national studies such as The Deep and Frequent Phenotyping study[1], enabling UK-based researchers to extract subtle retinal signatures relevant to early neurodegeneration. By providing these tools alongside expert guidance, we accelerate discovery and ensure that methodological advances benefit the wider scientific community.

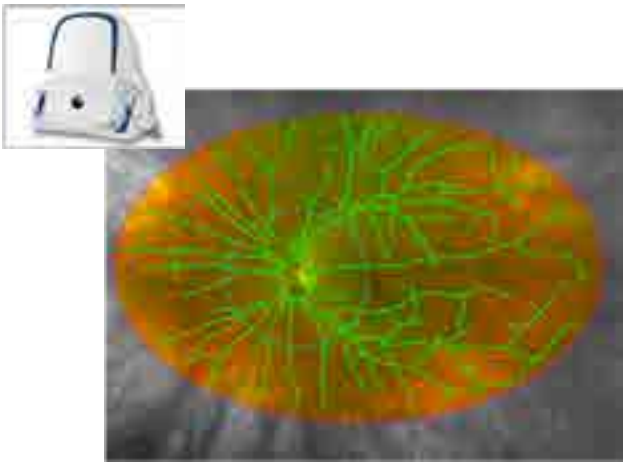


Image 1: automatically detecting and measuring the retinal vasculature in ultra-widefield fundus imaging as a marker of microvascular dysfunction in the brain.

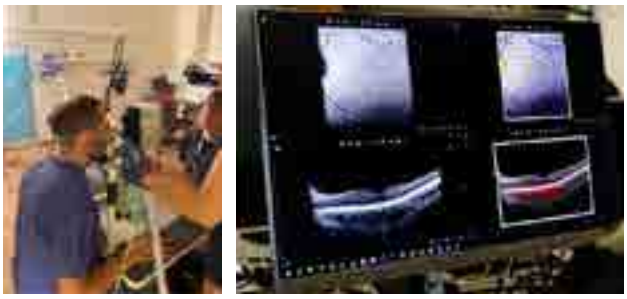


Image 2: imaging of the retina with optical coherence tomography and scanning laser ophthalmoscopy during a gas challenge. Measuring how well the vessels react using computational analysis techniques.

Our facilities are also integral to the successful delivery of complex, multi-modal studies that require meticulous imaging protocols, robust data handling, and specialist analytical insight. A study looking at retinal vascular reactivity and associations with white matter hyperintensities and dysfunctional cerebrovascular reactivity in cerebral small vessel disease[2] exemplifies this contribution. The Image Analysis Core supported every stage from protocol optimisation and imaging workflow design to quality assurance and advanced vascular analysis, ensuring that the retinal component of the study met the scientific and operational standards required to interrogate microvascular health in the context of brain disease. This level of involvement is essential for studies seeking to link ocular biomarkers with cerebral small vessel disease (contributing to stroke and dementia), where precision and consistency directly determine scientific validity.

Together, these contributions demonstrate how the Image Analysis Core functions not only as a technical resource, but also as a collaborative research partner. By combining specialist imaging capability, innovative analytical methods, and strategic scientific support, we enable investigators to ask more ambitious questions, generate higher quality data, and advance understanding.

Selected developments and partners

Mass Spectrometry core:

The Mass Spectrometry core team, led by Dr Natalie Homer and based at the QMRI on the BioQuarter campus, continues to develop metabolomic, lipidomic and small molecule mass spectrometry methods for clinical researchers at the University of Edinburgh and beyond. Engaging in over 30 studies last year we analysed more than 8,000 samples including blood and saliva. Dr Homer, Professor Ruth Andrew, Scott Denham and Dr Jo Simpson successfully secured funding from the Biotechnology and Biological Sciences Research Council (BBSRC) for a new triple quadrupole mass spectrometer. This is now installed and is our most sensitive instrument, able to detect picogram amounts of steroids.

Mass Spec Core team and Mass spectrometry students and researchers attending the British Mass Spectrometry Society annual meeting in September 2025.

The team have co-authored 14 publications this year, including steroid analysis in a study on long COVID and menstruation[1], fruitful collaborations investigating cancer immunity with the University of Cambridge[2,3] and culmination of a long-term collaboration with the University of Pennsylvania investigating epicardial adipose tissue in pulmonary arterial hypertension[4].

Dr Shazia Khan continues to develop mass spectrometry imaging methodologies, working closely with Core Director Professor Ruth Andrew. Recent publications using mass spectrometry imaging have investigated spatial lipidomic profiles in atherosclerotic plaques[5] and pharmacological inhibition to preserve cardiac function[6]. In 2026 we look forward to embarking on a large Norwegian cohort study profiling steroids to assess health outcomes in relation to prenatal exposure to plastic chemicals in collaboration with Professor Bonnie Auyeng and Professor Gro Dehli Anderson.

References

Image Analysis

1. Mitchell J, Nasr N, McLaughlin E, Thayanandan T, Lawson J, Lovestone S, Raymont V, Threlfall A, MacGillivray T, Peto T, Lengyel I, Csincsik L. Retinal biomarkers for Alzheimer's disease in the prodromal and preclinical population - The Deep and Frequent Phenotyping study. Alzheimers Dement. 2025 Dec 25;21(Suppl 2):e101540. doi: 10.1002/alz70856_101540. PMCID: PMC12740294.
2. Blair GW, MacCormick IJC, McGrory S, MacGillivray T, Hamilton I, Shi Y, Chappell F, Thrippleton MJ, Stringer MS, Doubal F, Wardlaw JM. Retinal vascular reactivity is associated with white matter hyperintensities and dysfunctional cerebrovascular reactivity in cerebral small vessel disease. J Cereb Blood Flow Metab. 2025 Dec;45(12):2301-2315. doi: 10.1177/0271678X251366079. Epub 2025 Aug 6. PMID: 40770920; PMCID: PMC12331647.

Mass Spectrometry

1. Maybin, J. A., Walker, C., Watters, M., Homer, N. Z., Simpson, J. P., Robb, C., Gibson, D. A., Jeanjean, L., Critchley, H. O. D., Kountourides, G., Olszewska, Z., & Alvergne, A. (2025). The potential bidirectional relationship between long COVID and menstruation. *Nature communications*, 16(1), 8187.
2. Zhao, Q., Pramanik, J., Lu, Y., Homer, N. Z. M., Imianowski, C. J., Zhang, B., Iqbal, M., Shaji, S. K., Morris, A. C., Roychoudhuri, R., Okkenhaug, K., Qiu, P., & Mahata, B. (2025). Perturbing local steroidogenesis to improve breast cancer immunity. *Nature communications*, 16(1), 3945.
3. Pramanik, J., Shaji, S. K., Zaman, M., Brown, B., Zhang, B., Yamashita-Kanemaru, Y., Homer, N. Z. M., Hussein, H. A. M., Zhao, Q., Okkenhaug, K., Roychoudhuri, R., Mukhopadhyay, A., & Mahata, B. (2025). Drug repurposing reveals posaconazole as a CYP11A1 inhibitor enhancing anti-tumor immunity. *iScience*, 28(5), 112488.
4. McCarthy, B. E., Feng, R., Torigian, D. A., Tong, Y., Fritz, J. S., Minhas, J. K., Mazurek, J. A., Smith, K. A., Palevsky, H. I., Pugliese, S. C., Homer, N. Z., MacLean, M. R., Udupa, J. K., & Al-Naamani, N. (2025). Epicardial Adipose Tissue as an Independent Risk Factor for Mortality in Pulmonary Arterial Hypertension. *Chest*, 167(5), 1481–1492.
5. Ntshangase, S., Khan, S., Bezuidenhout, L., Gazárková, T., Kaczynski, J., Sellers, S., Rattray, N. J., Newby, D. E., Hadoke, P. W., & Andrew, R. (2025). Spatial lipidomic profiles of atherosclerotic plaques: A mass spectrometry imaging study. *Talanta*, 282, 126954.
6. Al Disi, S., Ascione, R., Khan, S., Johnson, T., Sammut, E., Bruno, V. D., Baz Lopez, D., James, C. A., Simpson, J., Homer, N. Z., Millar, M., Singh, T., von Kreigsheim, A., Mills, N. L., Walker, B. R., Andrew, R., Webster, S. P., Whittaker, A., Freeman, A., & Gray, G. A. (2025). Pharmacological inhibition of hydroxysteroid 11-beta dehydrogenase type 1 (11-βHSD1) after myocardial infarction preserves cardiac function in a translational mini-pig model. *British journal of pharmacology*, 10.1111/bph.70297. Advance online publication.

Selected developments and partners

Lothian NRS Biorepository: supporting research and innovation with advance pathology

The Lothian NRS Biorepository, also known as BioResource, is a key member of the national NRS Biorepository network. This network was established by the Chief Scientist Office (CSO) and NHS Research Scotland (NRS) in partnership with the other health boards in Scotland.

Research involving the use of human tissue, or information derived from it is a fundamental cornerstone to cutting-edge translational medical research. Translational research, both in academia and industrial settings, is integral to advancing our understanding of disease and improving the diagnosis and treatment of patients. It is necessary to create and sustain an environment that fosters research, in the interests of patients and the public.

The Biorepository continues to provide a governance infrastructure and ethical framework that facilitates the collection, storage, and use of patient tissues (including blood and urine) that are surplus to diagnosis, for research and development, and innovation projects within NHS Lothian, and other institutions and organisations, including Universities of Edinburgh and St Andrews. This ensures that samples are collected and retained in accordance with the appropriate ethical, governance and regulatory requirements.

Based within the Laboratory Medicines Department at the Royal Infirmary and the Western General Hospital, our expert team, supported by clinical pathologists and advanced biomedical scientists, has supported numerous projects, ranging from pilot studies to leading national initiatives. We support academic and commercial projects locally and internationally and have established an advanced pathology laboratory to enhance research through specialised services and digital pathology capabilities.

The Management Group also provides guidance and support on legal, ethical and regulatory requirements regarding the use of human tissue or patient samples in research.

Research tissue bank

The Lothian NRS Biorepository has Research Tissue Bank ethical approval from East of Scotland Research Ethics Services (ref: 25/ES/0030). This approval must be renewed every five years as standard, and the current approval was successfully renewed for a fourth term in spring 2025. This approval enables us to support a wide and diverse range of studies from both academic and commercial researchers. Furthermore, it also allows the Biorepository to delegate ethical approval to these research projects, after appropriate assessment.

The Biorepository provides access to a wide range of human tissue samples including surplus materials from diagnostic and surgical procedures from informed, consenting patients. The Biorepository also provides access to pathology archival specimens and diagnostic samples that are no longer clinically

Selected developments and partners

required, provided the appropriate governance and approvals are place.

De-identified samples provided have been used in a wide range of study types such as *in vitro* pharmacology, cell culture, digital imaging, diagnostic, prognostic and predictive biomarker assay development, proteomic studies, DNA analysis and genome sequencing.

NRS accreditation

The human tissue legislation in Scotland differs from that in the rest of the UK. The Lothian Biorepository is therefore accredited under the NRS-CMT Accreditation Scheme for Biorepositories. This is an independent accreditation scheme set up on behalf of the Chief Scientist Office to ensure that the collection and provision of tissue from NHS Scotland is comparable with the rest of the UK. The accreditation is based on governance standards adopted from those used by the Human Tissue Authority for the licensing of research tissue banks in England, Wales and Northern Ireland.

The most recent accreditation cycle took place in autumn 2025 and following a successful submission, the Lothian Biorepository accreditation was renewed in January 2026. This accreditation will run until 31 January 2029, subject to the submission of annual certification.


NHS

NHS Research Scotland (NRS) Lothian Biorepository

CERTIFICATE OF ACCREDITATION

01/02/26 - 31/01/29

Local tissue banks and collections that register with the Biorepository and demonstrate that they meet this scheme's standards are also covered by this accreditation.

Advanced pathology services

As biomedical research evolves, the demand for advanced tissue-based technologies such as digital pathology, multiplex imaging, and spatial transcriptomics, has grown significantly. However, access to these specialised, expensive technologies and in particular the technical expertise required to use them, remains limited across Scotland.

Access to expertise and technology has been identified as a significant hurdle for researchers. Busy academic laboratories often lack the bandwidth to help, and commercially available services, especially for small exploratory or academic studies, may be too expensive.

Therefore, in 2025, Lothian NRS Biorepository took the strategic decision to establish a facility that facilitates ethical access to tissue but also underpins key technical requirements. The model employs senior biomedical scientists with advanced technical skills to support researchers in specialist tissue processing, digital imaging, and analysis.

The aim of the Advanced Pathology Laboratory is to provide integrated support to research groups throughout the 'tissue research' pathway, from tissue provision to laboratory analysis. The laboratory also aims to establish a collaborative, cost-effective model that facilitates access to advanced tissue technologies and expertise, thereby supporting high-quality translational research and precision medicine.

Selected developments and partners

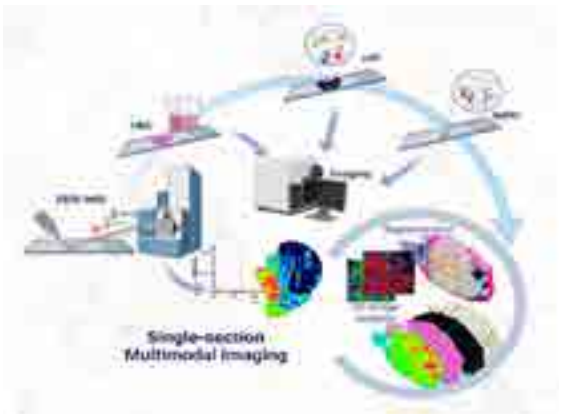
Building on the platform of CSO funding for an ethically established biorepository, we provide advice, support, expertise and facilities particularly directed to help research groups, representing key components of the triple helix within the Research and Development and Innovation (R&D&I) landscape.

Advanced Pathology Laboratory support for science and innovation

The Biorepository Advanced Pathology Laboratory has ready access to a range of equipment and techniques. This, coupled with the experience of the staff, means the support provided by the Biorepository includes the construction of large, tissue microarrays (TMAs) using formalin-fixed paraffin-embedded (FFPE) blocks with linked data, frozen section TMAs for spatial transcriptomics, the preparation of tissues and patient-derived organoids for use in 10x Genomics VisiumHD and Xenium pathways, low-plex immunofluorescence (IF) and immunoperoxidase (IP), DESI spatial mass spectrometry and co-registered IF/IP and digital imaging including five channel fluorescence microscopy.

Services include:

- Histology and special stains
- Immunohistochemistry
- Slide scanning and imaging
- Multiplexed immunohistochemistry
- Multiplexed immunofluorescence
- Whole slide, low-plex immunofluorescence and immunoperoxidase
- Digitisation of whole slide images in brightfield and fluorescence
- Cryostat sectioning for spatial transcriptomics
- Construction of tissue microarrays
- Digital image analysis
- DESI spatial mass spectrometry



(Ref. Zickhur et al. 2024, https://doi.org/10.1007/s00216-024-05339-0)

To explore whether the Advanced Pathology Laboratory can support your research please contact the Biorepository to find out more (See page 57 for contact details).

Selected developments and partners

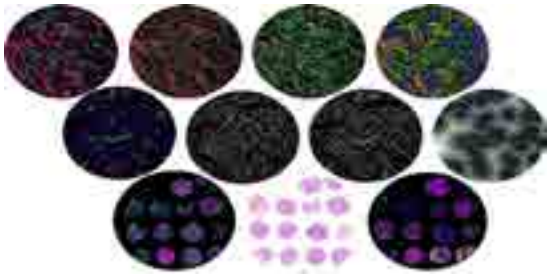


Figure 1: Example of multiplexed immunofluorescence (IF) and image analysis.

Top Row- Multiplexed IF image showing immune cells (red), blood vessels (green), Immune cell segmentation, vessel classification, merged view showing segmented immune cells and classified vessels.

Middle Row- Same format as above, demonstrating low immune cell infiltration.

Bottom Row- Multiplexed immunofluorescence panel with corresponding H&E-stained section from the same slide.

Digital pathology

The Biorepository has a Leica Aperio GT450 DX digital scanner that enables us to conduct research slide imaging and provide high-quality Whole Slide Images (WSI) for research purposes. This complements two Zeiss Axioscan microscopes that are used for digitisation of whole slide, five-channel, multiplex immunofluorescence images. The capability to provide de-identified WSI, as well as ready access to and support from expert pathologists, has enabled NHS Lothian and its academic partners to participate in numerous digital pathology AI projects, both academic and commercial, during 2025. We have also been able to provide a high throughput scanning service for local researchers working on other projects.

During this time, the Biorepository has also developed 'CALADH', a secure digital pathology research image management system. This is a repository of de-identified H&E and immunostained whole-slide images from various cohorts that can be used for further research. The development of this system was lead by consultant pathologists associated with the Biorepository, with the aim to maximise the research potential of WSI available and ensure equitable access for researchers in a streamlined and efficient manner, subject to the appropriate approvals being in place.

Tissue microarray construction

Throughout 2025, one of the key services of the lab has been the creation and provision of TMAs, using a 3DHISTECH TMA Master 2 tissue microarrayer.

The Biorepository has constructed numerous bespoke TMA on behalf of local research groups. These ranged in size from 15 to 500 cases and covered tissue types such as liver, ovarian, lung, colorectal and breast cancers, as well as liver disease of various aetiologies. These have traditionally been used for immunohistological analysis such IHC, FISH or ISH. However, current research has primarily focused on the provision of TMA for use in proteomics and spatial transcriptomics projects. This enables research groups to maximise the number of tissue samples that can be analysed and take advantage of this evolving technology. Each TMA constructed has since been used to support numerous studies, in addition to the original projects, thus maximising the research potential.

We also have a collection of previously constructed, stored TMAs with linked clinical data, that can be accessed for research purposes.

Selected developments and partners

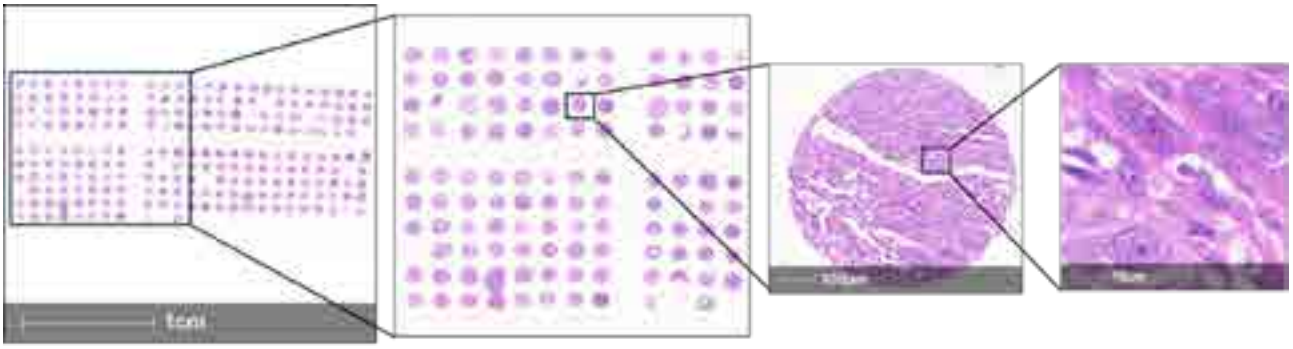


Figure 2: High-resolution magnification of a tissue microarray (TMA) core. Magnified view of a selected core from a previously constructed TMA, showing detailed cellular and structural features at progressively higher resolutions.

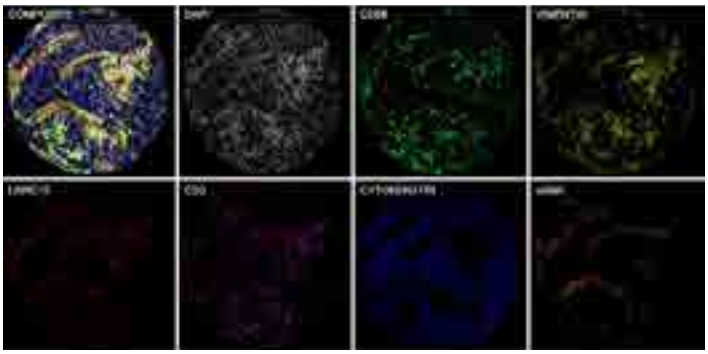


Figure 3: Example of Multiplexed immunofluorescence (7plex) on lung cancer core.

The core shows a high density of CD68 and CD3 positive immune cells. Cytokeratin, Vimentin and a SMA were used to classify tumour areas and stromal areas. LRRC15 expression was seen in stromal cells rather than in cancer cells.

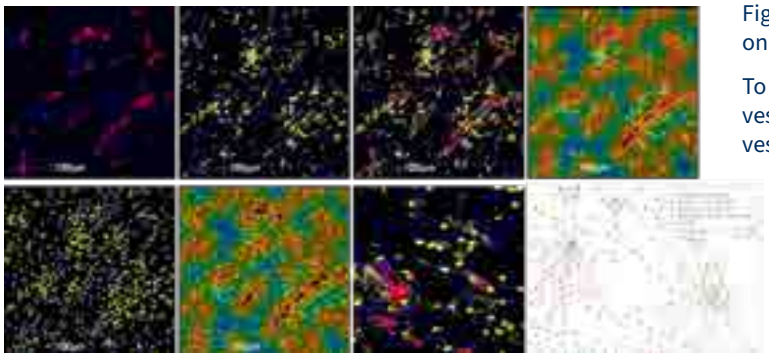


Figure 4: Example of digital image analysis performed on tumour tissue.

To quantify immune cells' density near the blood vessels, the infiltration analysis was utilised - Blood vessels (red), immune cells (yellow), Nuclei (blue)

Researchers interested in using patient samples from NHS Lothian for research or using any of the laboratory services provided by the Biorepository Advanced Pathology laboratory, should contact the Biorepository management team, Craig Marshall or Vishad Patel early in the project planning process to discuss the services and support the Biorepository can provide to facilitate their research.

Selected developments and partners

DataLoch: improving opportunities for research through linked primary and secondary care data

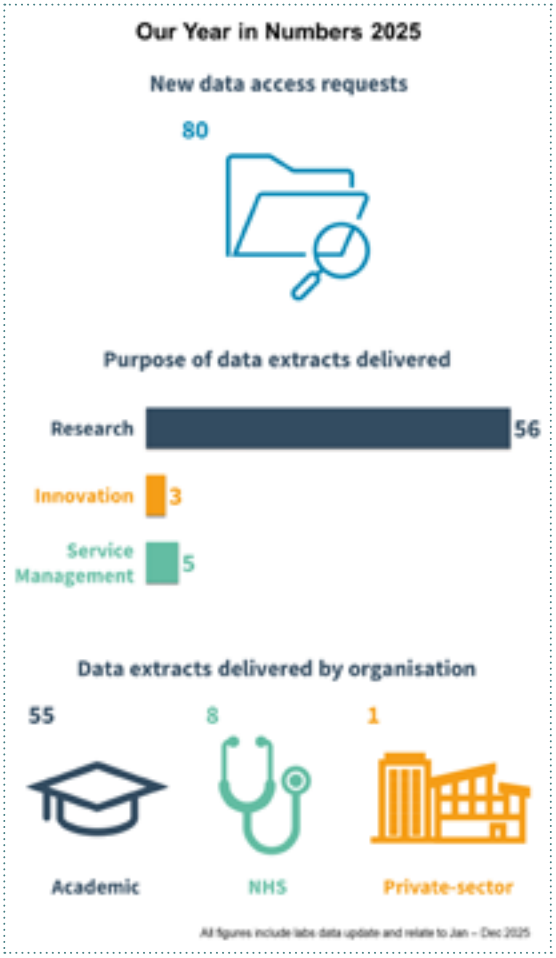
Introduction

DataLoch is a data service that has been developed by the University of Edinburgh and NHS Lothian. It brings together and links routine data – including primary care records – collected as part of people's day-to-day interactions with health and social care services. It supports service-management, research, and innovation projects that will make a tangible, positive difference to the lives of patients and care-service users.

Over the past year, the team has focused on enhancing its collaborations with Research Data Scotland and the other Regional Safe Havens in Scotland. A key part of this work has been to make it simpler for researchers to apply for granular data from across Scotland's Regional Safe Havens with a single application and approval pathway.

In addition, the DataLoch service has introduced several application improvements. These include the introduction of new standard variable sets to simplify data selection; changes to selecting study populations to give greater control around data analysis; and an updated and more intuitive application form. Together, these improvements make the application process more straightforward than ever before.

DataLoch maintains a detailed Metadata Catalogue which describes the core data available. However, there are several datasets that have not yet been incorporated within this catalogue. Therefore, researchers are actively encouraged to email Dataloch to enquire about these additional NHS Lothian datasets – such as radiology orders, National Early Warning Score (NEWS), 4AT delirium assessment – and explore the potential use within their projects.



DataLoch has also been successful in securing funding to support several projects that will enhance the data available for research and the NHS. The first of these projects is STAR-TRE (see page 60), which has already started, and focusses on the potential of new technologies to reliably de-identify free-text records.

Discover more about the service on the following pages or visit the Dataloch website to start a conversation about your project.

Selected developments and partners

How DataLoch supports researchers and improves research opportunities

Federated Governance: streamlining access to granular Scottish data

Alongside other members of the Scottish Safe Haven Network (SSHN), DataLoch is developing a simpler, federated governance system for all of Scotland's Safe Havens. The main ambition is to enable researchers to submit a single application for access to regional data from multiple Safe Havens. De-identified data extracts from each service would then be transferred to a single Trusted Research Environment for the researcher to access and analyse.

This process would complement, rather than replace, the existing National Safe Haven (NSH) service. The NSH can provide population-level data from Scottish Morbidity Records, Accident and Emergency, Scottish Medical Imaging, and other national datasets. The federated system permits access to linked regional data from primary and secondary care, as well as specialist datasets including ChemoCare, Pharmacy Prescribing, and locally curated data.

Find out more about Federated Governance.

Research enabled by DataLoch: highlighting the value of data linkage for dementia ascertainment

In February 2026, Rose S. Penfold et al. published a study in age and ageing that focused on how dementia is recorded across linked GP, hospital, and community prescribing records. The study used data from 133,407 adults over the age of 65 from the NHS Lothian region.

While most dementia diagnoses (95%) were recorded in primary care, there was an incomplete overlap with hospital and prescribing records, suggesting issues with the transfer of information across care settings.

Between 2016 and 2020, a further 7,359 people were newly diagnosed with dementia and over 20% of these diagnoses were first recorded in hospital data. However, only 36% of these new hospital-based diagnoses appeared in the relevant GP records within a year or at the time of death (if sooner).

These data gaps may prevent patients from accessing appropriate medical care and post-diagnostic support following a new dementia diagnosis. This issue could be addressed by improving data transfer between primary and secondary care systems in routine clinical practice. View the open-access article.

Selected developments and partners

STAR-TRE project: exploring how new technologies could support free-text de-identification

Free-text data from administrative records contain rich contextual information, such as symptoms descriptions and life events. These are critical for understanding complex needs, situations and outcomes.

However, these data are rarely shared for research purposes due to the unpredictable presence of indirect identifiers, such us recognisable locations, social circumstances, and familial relationships. When these indirect identifiers appear individually, the possible privacy risk is relatively small, but when combined they may reveal someone's identity.

Based on public and stakeholder engagement, the STAR-TRE project is exploring whether locally hosted large language models could consistently support the assessment of privacy risks in free-text. This work could safely unlock data that is currently inaccessible for vital research into sticky, societal problems.

Overview of the STAR-TRE project.

DataLoch's public involvement and engagement

The team continues to work closely with its Public Reference Group, which now has two firmly established panels:

1. The Communications Advisory Panel ensures that public-facing information is more easily understood.
2. The Public Value Assessment Panel checks the potential public value of each research application and advises on the next steps for the overall service.

Beyond these ongoing relationships, DataLoch engages more widely to ensure that new developments align with societal expectations. For example, within the STAR-TRE project, DataLoch commissioned Ipsos to co-develop and deliver a four-nations public consultation to explore perspectives on the possible use of large language models to identify privacy risks in free-text. This project has produced several recommendations that are being incorporated into the design of a privacy risk toolkit to be made available to Trusted Research Environments across the UK. A poster covering the key findings was presented at the Patient and Public Involvement Event in Stirling. The final report for this public consultation will be published on the DataLoch website soon.

STAR-TRE public consultation poster.

Seeking access to routine data

For researchers and innovators considering the secure use of linked routine data for their project ambitions, a top-level summary of DataLoch datasets can be found on their website.

If you cannot find the data for your project via the above link, please contact the team directly. They can either grant you access to their complete Metadata Catalogue or start discussions about bringing together the relevant data to support the development of your proposal.

Selected developments and partners

Edinburgh Clinical Trials Unit (ECTU)

ECTU Director update

ECTU and research colleagues said a fond farewell to Professor Steff Lewis, who retired in July 2025. We would like to thank Professor Chris Weir, who acted as Interim Director until October 2025, when ECTU was delighted to welcome Professor Amanda Farrin as Director.

Amanda previously spent more than 20 years at the University of Leeds, where she had established and led the Complex Interventions Division at the Leeds Clinical Trials Research Unit.

Professor Amanda Farrin

This unit is now recognised as a leading centre for innovative, complex intervention trials research.

Amanda has almost 30 years of experience working as a trialist, methodologist and statistician. She has worked in academia, the NHS, and the pharmaceutical industry, where she has developed and evaluated complex health, social care, and behavioural change interventions, with the aim of improving the lives of people living with stroke, ageing, frailty, poor psychological or physical health, cancer and multiple long-term conditions. Her wide-ranging expertise covers Phase 2, 3 and implementation trials, including parallel-group, factorial, cross-over, cluster-randomised, data-enabled and decentralised trials. She is also experienced in complex, innovative designs such as fractional-factorial, MOST, SMART, multi-arm, multi-stage and adaptive platform trials.

Under Amanda's leadership, ECTU will continue to design and deliver high-quality and efficient clinical trials, across primary, secondary and community care. These trials align with NHS and public priorities, informing national and international clinical practice and guidelines. Building on Amanda's experience as an NIHR Senior Investigator and NIHR Funding panels member, our aim is to increase the number of NIHR-funded trials led from Edinburgh, in close collaboration with ECTU multi-disciplinary trial teams. ECTU will continue with its coaching scheme for Chief Investigators who are new to collaborating with ECTU and we plan to develop further accessible resources and support for clinical academics and other researchers looking to develop a career in clinical trial leadership.

We will ensure that ECTU trials are underpinned by the latest methodological research findings, which are designed to improve the design, conduct, analyses and dissemination of trials. We also plan to expand ECTU's methodological research portfolio, to contribute to innovation in trial methods and conduct and increase our impact in the field. This research will build on Edinburgh's existing strengths, such as the efficient use of healthcare systems data for trials and the design and conduct of efficient, adaptive trials. These trials will include early-phase evaluations and evaluation of AI, digital and device interventions, as well as innovation in methods to increase inclusion and diversity.

Selected developments and partners

Research highlights

We have two great examples of teamwork and research collaboration to share this year.

The A2B trial: alpha2-agonists for sedation to produce better outcomes from critical illness study registration

The A2B trial methodology was designed in collaboration with the ECTU statistics team and Professor Tim Walsh. The aim was to evaluate the safety, clinical and cost-effectiveness of the alpha2-agonists dexmedetomidine and clonidine, compared with propofol for sedating adult ICU patients. Professor Walsh provides a fuller description of the trial earlier in the brochure and we share his sentiment regarding the great teamwork, collaboration and resilience required to deliver this trial under the challenging circumstances presented by the COVID pandemic.

The A2B study is unusual in that the sedative drugs being evaluated are administered by the bedside nurse caring for the patient, rather than by the research team. The aim is to keep the patient in a light sedation state except if otherwise indicated as described in the protocol. Data is collected by the bedside nurse throughout the shift relating to the level of sedation, incidence of delirium etc. The complexities of conducting a trial in a large ICU setting became apparent, highlighting the fact that consistent data collection and adherence to the protocol varied across sites. This was managed via regular reporting of data completeness and protocol adherence to the trial management and monitoring teams. From a data management perspective, the lessons learned from the A2B trial regarding data collection models have informed future studies, improving processes relating to data queries and quality control checks.

From a statistical perspective, the delivery of A2B included novel features of study design and analysis. In terms of the study design, the team implemented a hierarchical hypothesis testing framework. This enabled multiple hypotheses to be investigated in three stages: (1) the superiority of each of clonidine and dexmedetomidine compared to the propofol-based sedation in usual care; (2) the superiority of dexmedetomidine compared to clonidine and the non-inferiority of clonidine to dexmedetomidine; and (3) the superiority of clonidine compared to dexmedetomidine. As hypotheses were only tested if the relevant test in the preceding stage was significant, this design allowed strong control of the type I error rate (the risk of a false positive result).

The statistical analysis of A2B also involved some particular complexity due to the competing risk of death when recording the primary outcome of time to successful extubation. This was accommodated by fitting a marginal Fine and Gray proportional hazards model, which took account of the competing risk and the clustering of data by site. The statistics team then faced the further challenge of estimating, as recommended in the CONSORT reporting guidance, the treatment effect expressed as an absolute difference. This was ultimately achieved by using the estimate of the difference in the model-based cumulative incidence curves at seven days and then using bootstrapping to calculate its 95% confidence interval.

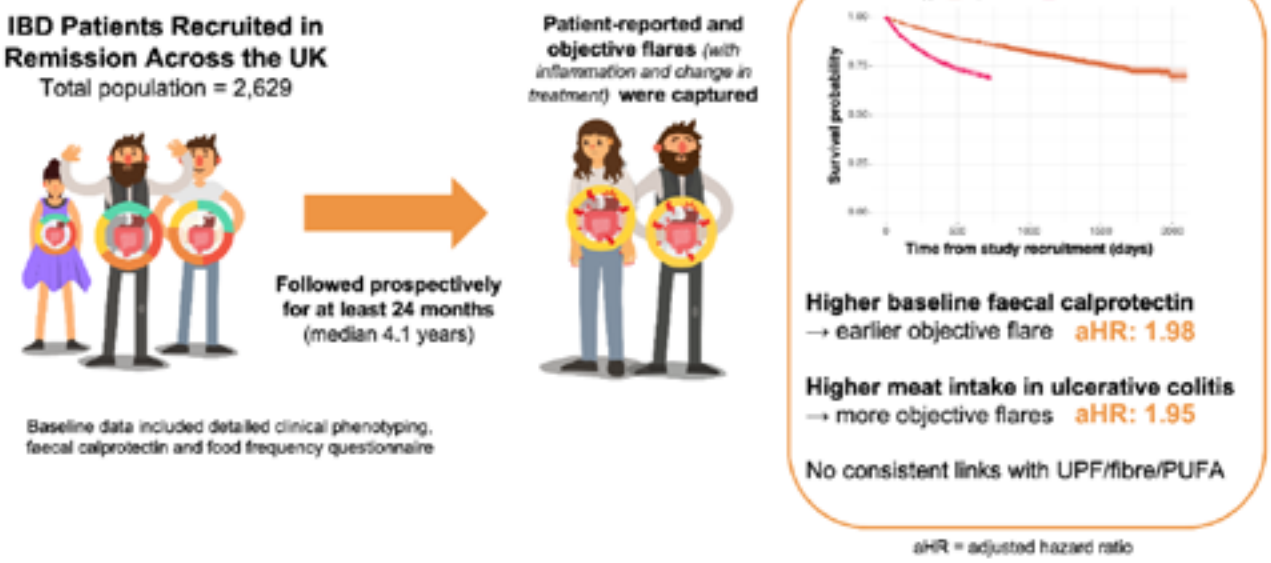
Whilst challenging at times, the participation and delivery of the A2B trial was extremely rewarding and has influenced ECTU's practice and processes for future trials.

Selected developments and partners

PREdiCCt: The PRognostic effect of Environmental factors in Crohn's and Colitis

In the PREdiCCt study, the trial management and statistics teams assisted Professor Charlie Lees in exploring if everyday diet plays a role in triggering inflammatory bowel disease flares.

Inflammatory bowel disease, which includes Crohn's disease and ulcerative colitis, affects nearly one per cent of the UK population. People often experience long periods of remission, followed by sudden and debilitating flares of symptoms such as pain, diarrhoea and fatigue.



To address this, the PREdiCCt study followed 2,629 people with IBD who reported being in remission at the start of the study. The participants were recruited from 47 NHS centres between 2016 and 2020.

At enrolment, participants completed a food-frequency questionnaire and provided clinical information, including blood tests and a stool test measuring faecal calprotectin, which is a marker of gut inflammation. They then completed monthly symptom questionnaires and were followed for a median period of four years. ECTU oversaw the administration and delivery of monthly questionnaires for this substantial participant cohort. This was made possible through collaboration between the trial management, data management, programming, and statistical teams.

Researchers recorded both symptom-based flares and 'objective' flares, where inflammation was confirmed by tests and treatment needed to be escalated.

They found that faecal calprotectin was a strong early warning signal, even when people felt well. Higher levels at baseline were linked to a much greater risk of future flares.

In ulcerative colitis, the chance of an objective flare within two years increased from around 11% in people with low calprotectin levels to 34% in those with high levels.

The researchers also found that diet was linked to the flare risk in ulcerative colitis. Those who consumed the most meat had around double the risk of an objective flare as those who consumed the least. However, this pattern was not seen in Crohn's disease, and no consistent links were found between flares and fibre intake, ultra-processed foods, polyunsaturated fats or alcohol.

Selected developments and partners

Experts say that, as PREdiCCt is an observational study, it cannot prove that eating meat causes flares. However, they believe that the study's findings support the idea of conducting future clinical trials to test whether reducing meat intake, alongside routine inflammation monitoring, could help prevent relapses in people with ulcerative colitis. The study, which is published in the journal Gut, also involved nutrition researchers from the University of Aberdeen. It was funded by UK Research and Innovation (UKRI), the Scottish Government's Chief Scientist Office and Cure Crohn's Colitis.

The delivery of PREdiCCt was achieved through great teamwork and collaboration with multiple stakeholders. Lisa Derr, the Trial Manager for the study, summarises this achievement:
"This study was such an incredible achievement for everyone involved, and I'm proud to have played a part in its success. Bringing sites on board across the whole of the UK was a huge undertaking, but it showcased what can be accomplished when teams pull together with a shared purpose. Throughout the process, I gained so much experience and learnt an enormous amount from colleagues across ECTU, ACCORD, WTCRF, the Edinburgh IBD unit, and many others who contributed along the way. The collaboration, dedication, and collective problem solving were truly inspiring, and it's been a privilege to work alongside such committed professionals."

> "Bringing sites on board across the whole of the UK was a huge undertaking, but it showcased what can be accomplished when teams pull together with a shared purpose."
> Lisa Derr, the Trial Manager

For more information on trial support visit The University of Edinburgh website or email the ECTU team.

Selected developments and partners

Patient and Public Involvement in research 2025-2026

The Patient and Public Involvement (PPI) team enables meaningful and inclusive involvement of patients and public partners in research. We support a wide range of activities, including working with local communities and planning and delivering PPI programmes for research projects. This section highlights key developments from 2025-2026.

Staff changes

Our Patient and Public Involvement Lead, Carol Porteous, has sadly left the team for a PPI Lead role for a research trial at the University of Oxford. She is greatly missed, and we wish her the best of luck in her new post!

We are in the process of filling the role to join Sammy Waite and Alisa Anokhina, pictured right.

Sammy Waite, Patient and Community Involvement in Research Officer.
s.waite@ed.ac.uk

Alisa Anokhina, Patient and Public Involvement in Research Coordinator.
alisa.anokhina@ed.ac.uk

Community involvement

Inclusive research practices are essential for addressing health inequalities and ensuring that everyone can benefit from healthcare innovations. Sammy Waite supports researchers in building meaningful and reciprocal relationships with under-served local communities. Last year, the Shared Language Project, invited community members to co-develop better ways for researchers and members of the public to communicate about research. The project's results and practical recommendations were presented as the keynote address at the NRS PPI Conference in Stirling in March.

The insights gained from the project are now being put into practice through the Community Conversations Project. Clinical and academic researchers are invited to community events where they can meet people from under-served communities and discuss their research in a supportive setting. The project's outcomes are expected later this year.

In 2025 Sammy Waite was awarded Excellent Newcomer in the Staff Recognition Awards and was jointly shortlisted with Carol Porteous for the Community Engagement Award.

Selected developments and partners

Research culture

As outlined in last year's report, PPI is increasingly recognised as both an expectation and a responsibility for researchers across all health-related fields. For example, the upcoming updates to the UK Clinical Trial Regulations and Good Clinical Practice standards, which take effect in April 2026, emphasise the need for inclusive and patient-centric practices.

The "Edinvolve" study, led by Alisa Anokhina, aims to understand the PPI culture across the University of Edinburgh and inform positive culture change within our team. Interviews with researchers, PPI professionals and support staff are helping us to build an understanding of the benefits of PPI in different research areas, the barriers to involving public partners and the opportunities for cultural change.

Results are expected later this year.

In the meantime, we are collaborating with multiple stakeholders to:

- Improve awareness of PPI and its impact in different research areas
- Share inspiring case studies
- Encourage researchers new to PPI to attend training and gain relevant experience
- Develop better resources and infrastructure
- Involve patients and members of the public in research

A PPI Advisory Group, chaired by Alisa Anokhina, was established in 2025 within the College of Science and Engineering. The group is identifying strategic solutions for enabling PPI in pre-clinical research projects.

> The scope of our PPI support ranged from developing comprehensive involvement programmes for major grant applications to addressing specific practical challenges. If it relates to PPI, we're ready for the challenge!

Projects

In 2025, our team supported over 80 projects, led by Principal Investigators from both the University of Edinburgh and NHS Lothian. These projects covered a wide range of topics, including:

- COPD
- Mental health
- Cancer
- Diabetes
- Stroke
- Cardiovascular disease

The scope of our PPI support ranged from developing comprehensive involvement programmes for major grant applications to addressing specific practical challenges. If it relates to PPI, we're ready for the challenge!

Selected developments and partners

Training

We offer a variety of PPI courses through the Clinical Research Facility. These range from introductory courses for those new to PPI to advanced modules focusing on specific aspects of involvement. These courses are popular, attracting researchers from the Lothians, but also from further afield.

We have also been developing training tailored for pre-clinical researchers. Major funders in these areas, such as the Medical Research Council (MRC) and the Engineering and Physical Sciences Research Council (EPSRC), increasingly expect meaningful PPI. Earlier this year, we successfully piloted a new 'training + experience' programme for students in biomedical innovation, led by Alisa Anokhina, to address the unique challenges of pre-clinical PPI.

Working with under-served groups remains one of our most popular and frequently requested training topics. In 2025, Sammy Waite developed a training module for researchers with a specific interest in this area.

The course has been refined based on insights from community projects and will be offered again in 2026.

> "There were lots of really useful tips for my 'toolbox' in this course. I've written plenty of notes so I can build a plan when I'm back in the office."
>
> 2025 course participant

Selected developments and partners

Edinburgh Imaging Facility

The Edinburgh Imaging Facility has installed Scotland's first photon-counting CT Scanner, set to advance multi- organ research and improve patient diagnosis and care

- The University of Edinburgh becomes the first site in Scotland to install photon-counting CT.
- Supports both clinical practice and cardiopulmonary and neurovascular research.
- Ultra high-resolution results in sharper, clearer images to help improve care for patients.

Photon-counting CT Scanner.

In June 2025, the University of Edinburgh became the first institution in Scotland to install a photon-counting CT scanner from Siemens Healthineers. The NAEOTOM Alpha with Quantum Technology, jointly funded by the university and the British Heart Foundation (BHF), represents a significant advancement in imaging, and is one of only a few in operation in the UK. This advanced system will support the University's cardiovascular and neurological research by providing ultra-high-resolution and spectral imaging data, which enhances precision in diagnosing and studying conditions affecting the heart, lungs, brain and blood vessels.

The new scanner will play a central role in advancing cardiovascular studies, including projects like SCOT-HEART 2, a BHF-funded trial investigating how coronary CT angiography can help prevent heart attacks by identifying risk factors earlier than standard assessments do. The scanner's imaging capabilities will enable scientists to visualise the heart and

> "This is the next generation of CT scanning. For the first time, we can see structures and processes in the body that were not previously visible. The ultra-high-resolution capabilities of the NAEOTOM Alpha will make existing diagnoses more accurate and open up entirely new avenues for discovery, transforming our understanding of disease."
>
> Michelle Williams, Professor of Cardiovascular Imaging at the University of Edinburgh

Selected developments and partners

> "Photon-counting CT represents a fundamental shift in diagnostic imaging, delivering image clarity, richer data, and the potential to transform clinical decision-making. This technology is about redefining the future of precision medicine. It is an exciting milestone that sets a benchmark for innovation and will influence future clinical practice across Scotland, the UK, and internationally."
>
> Carl Smith, Business Area Lead for CT at Siemens Healthineers

blood vessels in striking detail, supporting studies that aim to improve the early detection, risk assessment as well as the understanding of disease progression. This will strengthen the University's capability to translate scientific discoveries into better care.

Unlike conventional CT systems, which convert X-rays into visible light before processing, the NAEOTOM Alpha uses photon-counting detectors that capture and count each individual X-ray photon individually. This allows the scanner to gather more information with each scan, producing images with greater detail and clearer contrast than previously possible. Researchers will use this new level of image detail to improve the visualisation and measurement of complex cardiovascular and neurological conditions, supporting studies that explore new imaging biomarkers, evaluate treatment responses, and inform future clinical applications.

Michelle Williams, Professor of Cardiovascular Imaging at the University of Edinburgh, states: "This is the next generation of CT scanning. For the first time, we can see structures and processes in the body that were not previously visible. The ultra-high-resolution capabilities of the NAEOTOM Alpha will make existing diagnoses more accurate and open up entirely new avenues for discovery, transforming our understanding of disease."

Carl Smith, Business Area Lead for CT at Siemens Healthineers in Great Britain and Ireland, states: "Photon-counting CT represents a fundamental shift in diagnostic imaging, delivering image clarity, richer data, and the potential to transform clinical decision-making. This technology is about redefining the future of precision medicine. It is an exciting milestone that sets a benchmark for innovation and will influence future clinical practice across Scotland, the UK, and internationally."

Selected developments and partners

Health Innovation South East Scotland

Health Innovation South East Scotland (HISES) is one of Scotland's three NHS Regional Innovation Hubs, established by the Scottish Government's Chief Scientist Office to turn innovative ideas into real healthcare solutions and deliver a healthier and wealthier nation.

The hubs act as a key delivery partner in the delivery of the Scottish Government policy objectives and the major changes required under the Health and Social Care Service Renewal Framework and Scotland's Population Health Framework. They work to deliver new, targeted innovations to drive these changes.

Hosted by NHS Lothian, in partnership with NHS Borders and Fife, HISES plays a pivotal role in supporting the development, testing and adoption of new solutions that address prevalent health and social care challenges.

Providing a collaborative environment where innovation can be safely trialled in real NHS settings, the hub offers life sciences companies access to clinical expertise, governance and digital infrastructure - demonstrating the impact of emerging medical technologies.

HISES enables research-led innovation to be translated into products and services that benefit patients, strengthen NHS services and support economic growth across the region.

Recent investment through Scotland's Life Sciences Strategy has further reinforced the hub's role in connecting businesses with NHS opportunities.

New funding from the Scottish Government for the Regional Innovation Hubs will improve the Enterprise Agency support with opportunities for Scottish-based SMEs, seeking to work with the NHS in Scotland. This will facilitate secure and ethical access to expertise across the NHS in Scotland at regional and national levels

> HISES enables research-led innovation to be translated into products and services that benefit patients, strengthen NHS services and support economic growth across the region.

to develop and grow their products and/or businesses and work to design and implement innovations at scale.

If you would like to find out more, submit a project for consideration or enquire about collaborative opportunities, please get in touch with the HISES team. We welcome contact from researchers, clinicians and industry partners.

Contact us

Email HISES | HISES website | HISES LinkedIn profile

Selected developments and partners

We can provide access to project management, digital infrastructure and information governance/NHS IT security to allow innovative ideas to be developed into viable products or services that improve patient care. This enables innovative solutions to be tried out in a real-world environment and ensures they are fit for purpose – clinically, financially, and operationally.

By embedding innovation in all its systems and processes, the NHS in the South East of Scotland can lead the way in transforming healthcare, ensuring it remains sustainable, efficient, and patient-centred. Collaboration, investment, and a commitment to continuous learning will be pivotal in achieving this vision.

The day to day business of HISES is to help our partners navigate through the NHS from testing and development to adoption.

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Selected developments and partners

What we do

Our purpose is to support the development, attraction of external funding, and implementation of impactful innovation projects, with the potential to transform health and social care and to address demographic, economic, and workforce challenges. The ambition is to support end to end innovation with the aim of evidence generation for implementation back into our NHS.

From 2025, Professor Alasdair Gray became responsible for Innovation as well as Research and Development (R&D) in NHS Lothian. Having a Regional Research, Development and Innovation (RD&I) Director has been pivotal to building relationships and promoting the support available from HISES across the region. Engagement with RD&I departments, clinical teams, medical management and board members, has strengthened partnership working and enhanced visibility.

HISES can support you at every stage of your innovation journey, from defining an initial challenge or innovation idea to real-world evaluation and implementation.

Creating evidence and proving value

This has been a pivotal year for HISES – a year marked by progress, partnership, purpose and growth. As we move closer to improving local people's lives, transforming care, and boosting the economy through innovation, we find ourselves at a critical moment in our journey.

HISES delivers a broad portfolio of innovation activities across multiple care settings, population health and disease areas, from the early stages of discovery to solution development and deployment of innovation.

It takes time for the full benefits of innovation to be delivered, but we are already seeing promising outputs, outcomes and impacts from our work. Our 2024-2025 annual report highlights the impact of our key programmes of work and other notable projects.

This has been a pivotal year for HISES – a year marked by progress, partnership, purpose and growth. As we move closer to improving local people's lives, transforming care, and boosting the economy through innovation, we find ourselves at a critical moment in our journey.

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