accord
Academic and Clinical Central Office for Research and Development

THE UNIVERSITY of EDINBURGH

NHS Lothian

2025

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

Contents

Introduction

Welcome to the 2024-25 annual brochure from the Academic and Clinical Central Office for Research and Development (ACCORD). ACCORD combines research management staff from NHS Lothian and the University of Edinburgh who together 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 in NHS Lothian. I really hope this year's brochure reinforces to you the vibrant research environment that we have locally in Edinburgh and Lothian.

As ever, we have designed the brochure to highlight some of the excellent research that we want to celebrate and key local investigators and teams we feel you should know about. In addition, it's vitally important that we also provide you information on some of the essential individuals and services that work and support you in our research system and the career development and educational opportunities that are available. Please read on to find out more.

"As ever, we have designed the brochure to highlight some of the excellent research that we want to celebrate and key local investigators and teams we feel you should know about."

There are a few things I would like to take this opportunity to let you know about that will be extremely important for clinical research in NHS Lothian in the next few years. Many of you will be aware of the concerns relating to the fall of commercial trial activity within the NHS in the UK over the last 10 years, accelerated by COVID-19. This led to a review of commercial trial activity by Lord O-Shaughnessy, presented to the House of Lords in 2023[1]. This report made several important recommendations to enable the UK to be able to increase its capability of delivering commercial trials efficiently within the NHS. In August 2024, the UK government announced the Voluntary Scheme for Branded Medicine Pricing, Access and Growth (VPAG) Investment Programme[2]. This programme will invest significantly in the UK's health and life sciences sector over the next few years, supporting economic growth and improving the global competitiveness of the UK's life sciences sector. It is the first major public-private collaboration of this scale in the world.

So what does that mean for the NHS and in particular Scotland and Lothian? The UK, as a whole, will receive substantial additional funding to increase commercial research delivery focused around 20 commercial research delivery centres (CRDC), supported by an overarching network. In Scotland there will be four CRDCs in Edinburgh, Glasgow, Dundee and Aberdeen, with additional research teams to deliver the anticipated growth in commercial research. In Lothian, the CRDC is being developed in a refurbished ward at the Western

Introduction

General Hospital – Ward 22. It will be shared with the highly successful Clinical Infection Research Group (CIRG) – see a report of their work in the research highlights section of the brochure. It is anticipated it will be open in late summer 2025. We are currently recruiting additional consultant staff to lead and support the programme, alongside nursing and other research staff. The CRDC will be managed by the Clinical Research Facility team but importantly, we see this development to be of benefit to all researchers and patients wherever they are in NHS Lothian - more to follow...
In addition, the programme will support the development and staffing of a new aseptic pharmacy unit, again at the Western General site, which is planned to be open in 2026. These investments in our infrastructure are vital if we are going to achieve the objectives of the programme which are to deliver new medicines to patients in trials as quickly and efficiently as possible.

Advanced therapies have the potential to revolutionise the medical care and outcomes of many diseases that currently have limited treatment options. We are developing an Advanced Therapy Investigational Medicinal Product (ATiMP) strategy and delivery plan, in collaboration with the Northern Alliance Advanced Therapy Treatment Centre (NA-ATTC)[3] led by Professor Marc Turner. The goal is to increase the research opportunity for patients to receive advanced therapies. Dr Victoria Campbell describes some of the ATiMP developments in haematology, in the research highlights section of this brochure.

Finally, Jo Merrifield and Susie Fong, based in the Clinical Research Facility, have organised a fantastic research programme for our first R&D conference since 2019. The conference, which takes place in May, is entitled: 'The Evolving Landscape of Clinical Research in NHS Lothian'. There are sessions on Advanced Therapy trials and industry collaboration, presentation of high impact trials led by local investigators, a free paper session and poster viewing. It is great to see the conference fully booked and almost 60 abstracts submitted from local researchers. Importantly in the opening session we have both Professor Caroline Hiscox, Chief Operating Officer for NHS Lothian and Professor Dame Anna Dominiczak, Chief Scientist for Health, Scottish Government telling us about their thoughts on the future of research and innovation in NHS Lothian and Scotland respectively. It should be a highly informative and enjoyable day.

As ever it's been a busy year and hopefully this brochure provides you insight into some of the incredible research being delivered in NHS Lothian and the highly skilled and experienced staff and services, we provide locally to enable this. I hope you enjoy reading our annual report for 2024-25.

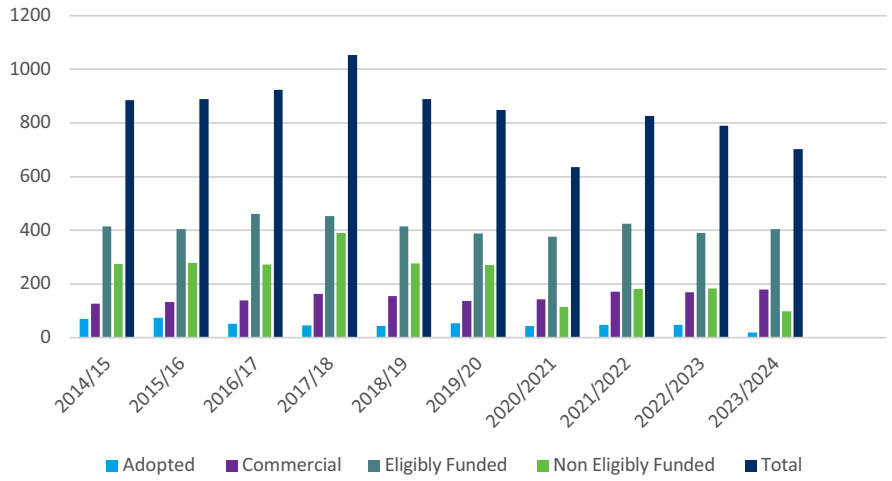
Alasdair Gray

NHS Lothian R&D Director

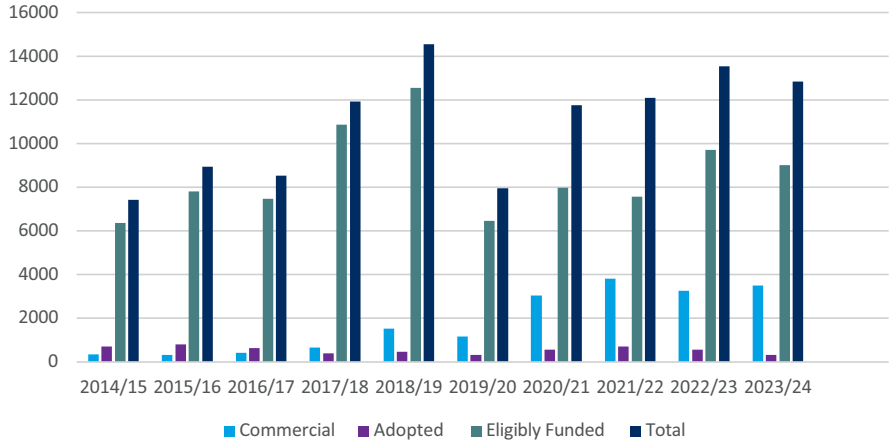
References

1. Commercial clinical trials in the UK: the Lord O'Shaughnessy review – final report; (2023). https://data.parliament.uk/DepositedPapers/Files/DEP2023-0476/Clinical_Trials_Review.pdf
2. https://www.gov.uk/government/news/uk-secures-400-million-investment-to-boost-clinical-trials
3. https://www.theattcnetwork.co.uk/centres/northern-alliance

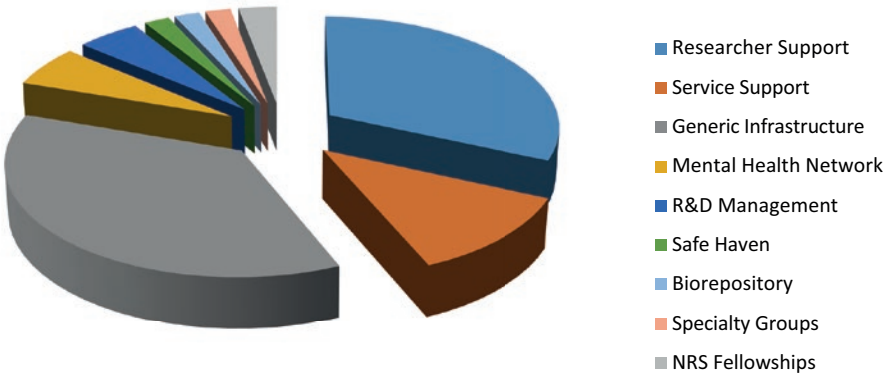
Number of studies by year



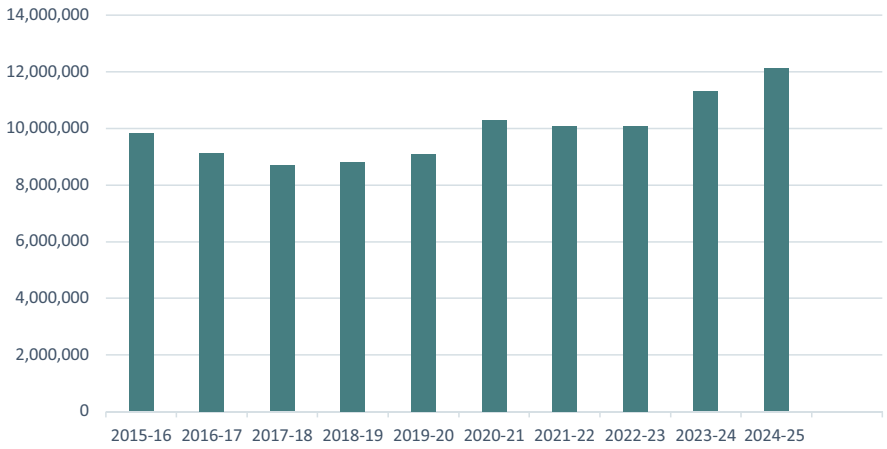
Study recruitment by year



Distribution of NHS Lothian's NRS funding allocation 2024/25



Annual NRS allocation



Funding proposals

Research Governance, NHS Lothian R&D Finance, Edinburgh Research support teams

Working closely with the Edinburgh Research Office, we review funding applications to identify important costs such as regulatory fees, trial management, monitoring, trial intervention and labelling, data management, archiving, NHS resources and facilities.

Sponsorship

Research Governance team

The role of 'Sponsor' is defined in the UK policy framework for health and social care research and in the UK clinical trials regulations as an organisation responsible for ensuring arrangements to initiate, manage, finance and indemnify a study.

The Research Governance team review all clinical research led from Edinburgh that involves people, their tissues or data and identifies if single or co-sponsorship by University of Edinburgh and/or NHS Lothian is appropriate. Co-sponsorship by both organisations is the default sponsorship model.

A lead Sponsor Representative is assigned to review the protocol, study documents such as participant information sheets, consent forms and the Integrated Research Application System (IRAS) application for ethics and R&D management submissions.

The Sponsor Representative also provides advice and document templates to help ensure submissions are swift and successful. Throughout the research study, they are available for advice, and to review amendments for submission as they arise.

Facilitation team

Clinical research regulated under the clinical trials or medical device regulations or considered to be complex or high risk is assigned a Clinical Research Facilitator. Facilitators provide support with the protocol and study documents design, and Combined Review application for ethics, R&D management and regulatory submissions. They can also help with sourcing investigational supplies and work closely with the Monitoring team to hand over for trial set up.

Regulated and more complex research undergoes a risk assessment to identify any risks and ensure appropriate mitigation is in place. The risk assessment feeds into a risk-based monitoring and audit plan for the Monitoring and Quality Assurance (QA) teams.

Monitoring team

Monitoring of clinical trials is performed on a risk-based approach to ensure that the rights and well-being of participants are protected, reported data are accurate, complete and verifiable from source documents and the conduct of the research is in compliance with the approved protocol, amendments, SOPs, Good Clinical Practice (GCP) and regulatory requirements.

Clinical Research Monitors support researchers with trial set up and help to ensure compliance throughout the lifetime of the trial to closure. Monitoring visits are conducted on-site or remotely in accordance with the research monitoring and source data verification plans.

Sponsorship (continued)

Pharmacovigilance (PV) team

The PV team are responsible for Pharmacovigilance on regulated trials, receiving reports of Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs), maintaining a safety database and onward reporting all SUSARs to ethics committees and regulatory authorities.

The PV team prepare SAE listings, complete MedDRA coding for annual Data Safety Update Reports (DSURs) for all regulated trials and provide safety line listing reports to Data Monitoring Committees (DMCs).

Pharmacovigilance also involves a regular review of the Reference Safety Information (RSI) for regulated trials to ensure continual participant safety and quarterly reviews of all SAEs to perform trend analysis on clinical research.

Quality Assurance (QA) team

The QA team provides regulatory support and resources for researchers and independent oversight of trial related activities. This includes management and oversight of trial risk assessments, deviations, violations and serious breaches, approval of vendors (e.g. labs, third party suppliers) and computer system validation checks (e.g. electronic case reports forms, databases).

QA maintains the ACCORD Quality Management System (QMS) that includes a library of ACCORD policies, Standard Operating Procedures (SOPs), guidance documents, templates and forms, which are designed to provide clear written instructions and tools to help researchers.

The team also manage an audit programme to ensure ongoing compliance of ACCORD internal functions, local and external facilities involved in clinical research and of specific research studies that may have been identified as high risk.

Contracts

Legally binding agreements are often required between organisations participating in clinical research to set down arrangements for collaboration, finance, insurance, publication and intellectual property, regulatory compliance, provision of drugs or equipment, human tissue transfer, data sharing and more.

Sponsor Representatives work closely with the University and NHS Lothian Legal and Contracts teams to identify any agreements that are required for clinical research. The Legal and Contracts teams fulfil drafting, review, negotiating and signing of these agreements.

Research Data support

ACCORD promotes the importance of research data management and transparency. The University of Edinburgh Research Data service provides tools and support to help researchers store, manage and share data responsibly. ACCORD provides advice and support to ensure clinical research is appropriately registered and results are posted within the required timeframes.

Sponsorship (continued)

Information Governance and Information Technology Security

ACCORD works closely with University of Edinburgh and NHS Lothian Information Governance (IG) and Information Technology (IT) Security teams to ensure compliance with all aspects of data protection legislation and confidentiality.

The Sponsor review usually covers everything necessary for projects involving processing or transfer of personal data, access etc. Where required, research studies are referred to IG/IT security for relevant input and support. This could involve an additional data protection impact assessment, IT security risk assessment and/or Caldicott Guardian approval.

R&D Management permissions

NHS Lothian Research & Development (R&D) Governance team

The relevant NHS organisation(s) must issue NHS R&D permission before research involving the NHS can begin. Permissions are obtained in Scotland and Ireland via a national R&D process, while Health Research Authority (HRA) approval is needed for research involving the NHS in England and Wales.

The R&D Governance team advise on R&D submissions to all NHS organisations involved in the research study. They also help with other requirements such as Research Passport applications and Caldicott Guardian approvals.

In Edinburgh, although a research study is reviewed by the Research Governance team for sponsorship, the NHS Lothian R&D team also need to review to assess the impact of the research on the NHS and confirm local capacity and capability for NHS Lothian to take part in the research.

Training

ACCORD Research Governance, Facilitation, QA, Monitoring, R&D and PV teams deliver training courses in many areas of clinical research and are always happy to discuss research team requirements for training and refresher courses.

The Wellcome Trust Clinical Research Facility Education Programme delivers a variety of courses relevant to researchers in Edinburgh and the UoE Research Data Service run a range of workshops, online courses and tailored training on research data. The programme also includes a Clinical Research Welcome Day for research staff new to Lothian.

NHS Lothian Nurses, Midwives, Allied Health Professionals, Pharmacists, Psychologists and Healthcare Scientists

NHS Lothian continues to be recognised as the leading health board in Scotland to support clinical academic development for the Nursing, Midwifery, Allied Health Professions, Pharmacy, Psychology and Healthcare Science (NMAHPPS) professions.

Lothian NMAHPPS Research Strategy 2022-2025

Over the past year NMAHPPS leaders have continued to work in partnership with colleagues in the university sector to implement the Lothian NMAHPPS Research Strategy. A high level group including the Directors of these services and the Deans and Heads of Schools of our academic partners at Edinburgh Napier University, Queen Margaret University, the University of Edinburgh, the University of Stirling, Robert Gordon University and the University of Strathclyde meets twice a year to shape the implementation of this strategy and progress a concrete action plan. Following the highly successful NHS Lothian NMAHPPS Collaborative Research Conference held at the John McIntyre Conference Centre, University of Edinburgh in 2023, the partners are in early discussions about the possibility of organising a similar event in 2026 – although no final decision has yet been made.

Investment in research capacity building

Since 2010, NHS Lothian's investment in building research capacity in collaboration with its academic partners has been around £1.9m the number of doctoral students undertaking research training has increased steadily between 2015-2023. The majority of this investment (£1.3m) has been through the Clinical Academic Research Careers (CARC) scheme, which ended in 2022. It has also included NHS Lothian/University of Stirling jointly funded clinical doctoral studentships (fees only) since 2017, and a small number of NHS/academic jointly funded PhD studentships (fees and stipend). Over the past two years, growth in doctoral student numbers has plateaued. There has been no further investment in NHS Lothian/academic PhD studentships since 2020. The majority of NMAHPPS doctoral students (92% in 2025) undertake their studies on a part-time basis.

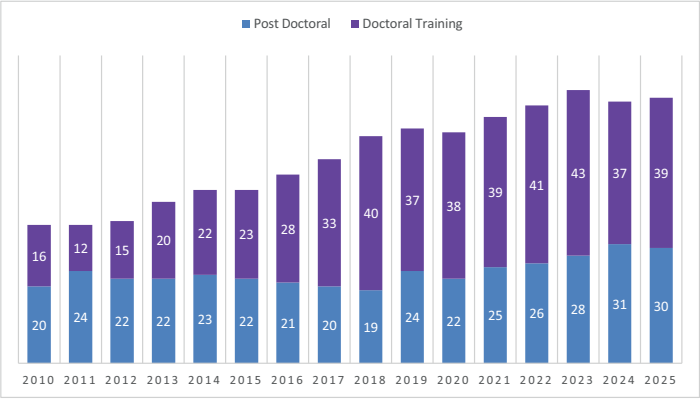


Figure 1: NHS Lothian NMAHP research capacity building 2010-2025

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 worth of 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 internship 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

The Gateway Awards scheme has so far proved very successful in terms of its appeal to applicants from a wide range of professions, the quality of applications, the number of awards made across all five categories and some of the early outcomes seen. The dashboard in Figure 2 shows that in the first 4 rounds, 71 applications have been received from staff at different stages of their career in 9 different professions, 59 applicants have been shortlisted and 45 of these have been offered and accepted an award.

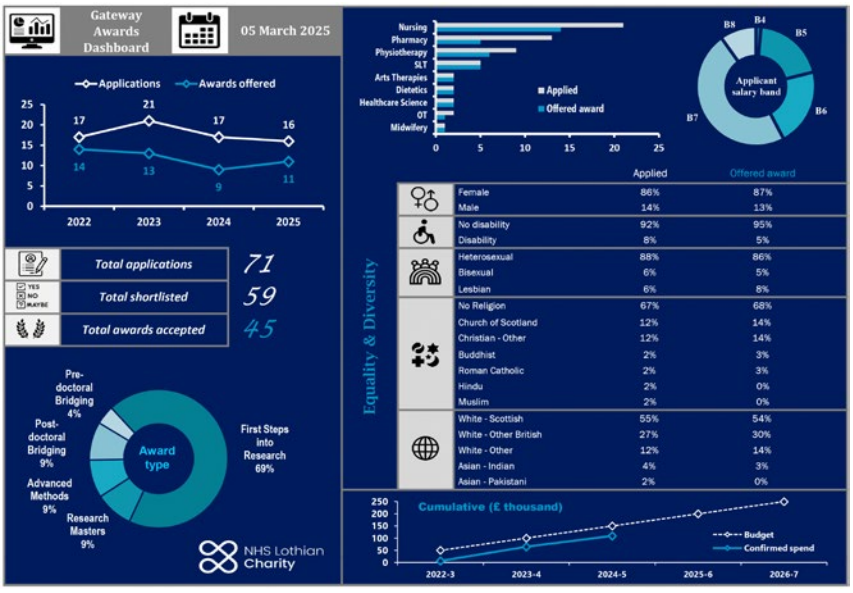


Figure 2: Lothian Clinical Academic Research Gateway Awards Dashboard, March 2025

By far the most common type of award made has been the First Steps Into Research placement, although all levels have proved attractive. There has been a fairly consistent number of applications year-on-year, averaging 17-18 per year, with no sign of waning.

All recipients in Cohort 1 have completed their awards as have most in Cohort 2 while the majority of Cohort 3 are well over halfway through. In general, the scheme has received very positive feedback on the experience for all stakeholders and the outcomes for award recipients.

Cohort 1

Cohort 2

Cohort 3

One particularly notable recent outcome is:

Dr Kath Williamson, District Nurse and Manual Handing Advisor, who was awarded a Postdoctoral Bridging Gateway Award for 12 months in 2023, subsequently became the first nurse in Scotland to be awarded a **CSO Early Postdoctoral Fellowship**. Kath will carry out her fellowship at the University of Glasgow whilst being seconded from NHS Lothian for 3 years, maintaining a 20% clinical role. The focus of her research is 'Bringing obesity care home: Housebound Obesity Pathways and Engagement (HOPE)'.

Doctoral students and completions

There are currently 39 NMAHPPS doctoral students working in NHS Lothian across a range of professions (Figure 3). This group (and others with an interest in proceeding to doctoral study) are supported in terms of peer networking through the Lothian NMAHPPS Researcher Network, which meets four times a year. Nurses make up 50% of the total but physiotherapy remains the profession within the NMAHPPS grouping with the highest percentage of employees in doctoral study.

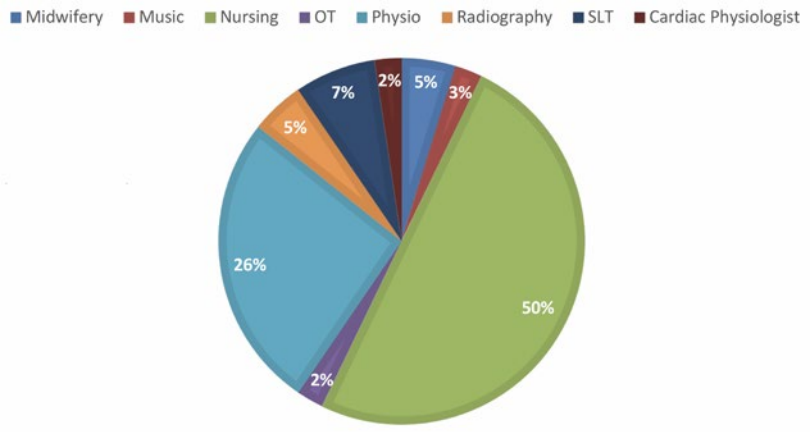


Figure 3: professional profile of NHS Lothian NMAHPPS doctoral students

There were 2 new NMAHPPS doctoral students and one doctoral completion in 2024:

- Lee Burgum, Cardiac Physiologist at the Royal Infirmary of Edinburgh, commenced a part-time PhD at Edinburgh Napier University
- Chloe Farmer, Health Inclusion Nurse in Midlothian HSCP, was awarded a CSO Clinical Academic Fellowship to support doctoral study at the University of Stirling starting last year
- Dr Melanie Philips, Transplant Coordinator at the Royal Infirmary of Edinburgh, is to be congratulated on the award of her PhD titled 'Becoming transplanted: a constructivist grounded theory approach on the diabetic with renal failure- from transplant waiting list to transplantation' by the University of Edinburgh – especially as Melanie did not require any corrections or amendments following her viva – rare indeed!

Dr Melanie Philips

RCSLT Award

Congratulations also go to Dr Kate Toft, Joint Clinical Lead Speech and Language Therapist - Head and Neck/ENT/Oncology, who was awarded the **Excellence in Research and Development Award** for 2024 by the Royal College of Speech and Language Therapists. This was for a **publication** arising from her doctoral study evaluating the clinical utility and psychometric properties of the MD Anderson Dysphagia Inventory for patients with head and neck cancer.

Dr Kate Toft with Nick Hewer, RCSLT President

Royal College of Nursing (RCN) Scotland Nurse of the Year Awards 2024

Professor Juliet MacArthur, Chief Nurse Research & Development in NHS Lothian, was jointly awarded RCN Scotland Nurse of the Year 2024 for Research & Innovation. The award was made for her contribution to advancing clinical academic careers and research partnerships in various health care disciplines across Edinburgh and the Lothians. She was nominated by Cohort 1 of the Lothian Clinical Academic Research Gateway Awards and her colleagues expressed their gratitude and admiration for her vision and dedication to supporting clinical academic research partnerships.

Professor Juliet MacArthur

NHS Lothian Allied Health Professionals (AHP) innovation, research and improvement strategy (2022-2027)

AHP services in NHS Lothian continue to work on the implementation of their innovation, research and improvement strategy (IRI) launched in November 2022. This work is led by Andy Peters, AHP Strategic Lead for Research and Development and Lucie McAnespie, Head of Adult Speech and Language Therapy. Actions that have been achieved over the past year include:

- launching an intranet-based digital hub as a repository for the various resources being generated to support AHPs in this pillar of practice
- producing staff guidance on approaches to patient and public engagement/involvement in data projects
- producing searchable, up-to-date lists of IRI training and funding (e.g. grants, fellowships etc.) opportunities
- a series of promotional events to raise awareness of this strategic work among Lothian AHPs

Ongoing work includes:

- early discussions on best approaches to AHP IRI practice-based learning for AHPs in training
- development of accessible project governance guidance for AHP staff on issues such as approvals, ethics, consent, data protection, Caldicott requirements for different types of projects
- establishment of a network of AHP IRI mentors/advisors and shaping the support infrastructure required to facilitate AHP data project work in the future
- establishment of guidance for AHP staff on accessing routine clinical data (e.g. held in TRAK) for data project purposes

Contributions to wider clinical academic developments

CSO NHS Researcher Development Fellowships

CSO launched its NHS Researcher Development Fellowships as a new type of award for the NMAHPPS in 2023 and recognises that these were based on the First Steps into Research and Pre-Doctoral Bridging Awards models developed for the NHS Lothian Clinical Academic Research Gateway Awards. All NHS Lothian systems and processes for application, shortlisting and interviews were adopted by CSO. In the first round of applications NHS Lothian performed very well (winning 38% of all awards), with the following being awarded a fellowship:

- Fiona McKeown, Highly Specialist Neonatal Physiotherapist, Royal Hospital for Children and Young People (Pre-doctoral Bridging)
- Mary-Ann Robertson, Integrated Care Pharmacist, Edinburgh HSCP (Pre-doctoral Bridging)
- Kerry Jacks, Charge Nurse, Paediatric Critical Care Unit, Royal Hospital for Children and Young People (First Steps)
- Nadine Hare, Acting Team Lead Speech and Language Therapist, Head and Neck, Western General Hospital (First Steps)
- Michalina Nesbitt, Specialist Speech and Language Therapist, Child and Adolescent Mental Health Service, Midlothian HSCP (First Steps)

> "Congratulations to them all!"

> "There are currently around 50 members from virtually every health board in Scotland who meet five times per year."

Scottish Health and Social Care Research Leads Network

Prof Juliet MacArthur, Chief Nurse Research, Andy Peters, AHP Strategic Lead for Research and Development and Elaine Rankine, Head of Pharmacy Education, Research and Development are founding members of this Scotland-wide network established three years ago. It exists to promote best practice in research capacity and capability building and to advocate for the development of greater numbers of research training and clinical academic career pathway opportunities for NMAHPPS at a national level and consistency of research infrastructure support for these professions across the regions of Scotland. There are currently around 50 members from virtually every health board in Scotland who meet five times per year. The network also plays an important role in articulating the NMAHPPS clinical academic landscape in Scotland and learning about initiatives from colleagues elsewhere in the UK through participation in the Healthcare Professionals Roles and Career Pathways Implementation Network (CARIN).

NRS Clinician:

Dr Gourab Choudhury
COPD research team

I am a Respiratory Consultant Physician and lead the NHS Lothian (NHSL) Chronic Obstructive Pulmonary Disease (COPD) clinical and translational research team based at the Royal Infirmary of Edinburgh. I am also the Scottish National Lead for COPD Improvement work and Chair the NHSL Respiratory Managed Clinical Network. Both have innovation as a priority area.

My research interests are in early detection/ risk stratification of COPD patients, effective phenotyping of the patients and respiratory infections. The COPD research team currently consists of a Lead Research Nurse, two Senior Research Nurses, a Clinical Research Fellow and a Secretary. The team has undertaken a number of research studies for COPD and Alpha-1 Antitrypsin Deficiency (AATD) in collaboration with the Clinical Research Facility (CRF). I also co-supervise two PhD Fellows in a couple of COPD projects. The Research Fellow post has recently been developed and has proved to be a great step in academic development for post foundation year doctors who want a taster year in research.

NHSL COPD clinical and translational research team.

Dr Gourab Choudbury presenting at a RCPE hosted meeting

COPD trials

COPD is a chronic respiratory condition that is associated with significant health and economic burden worldwide. Research shows that its incidence will continue to increase over the next few decades.

My team is currently involved in seven clinical trials (combination of phase 2 and 3 clinical trials; randomised controlled trials (RCTs), observational studies and others).
We are also preparing to collaborate with the CRF team on an exciting phase 1 trial to commence from mid 2025.

The most recent COPD trials of note in my team are TEMPESTAS and BEACON.

We have recently completed data collection for TEMPESTAS, a multi-centred, open label RCT to look at the effects of inhaled corticosteroids on the airway microbiome in patients with COPD and associated bronchiectasis. While the use of corticosteroids is beneficial for COPD, there is a risk of developing pneumonia. This study aims to assess the risk versus benefit of using these inhaled corticosteroids by assessing the clinical status (exacerbations/ symptom burden) and the microbial diversity in the test and control groups. I am the Chief Investigator for this trial (funded by GSK as an academic trial), sponsored by and in collaboration with the University of Edinburgh.

BEACON (British Early COPD Network Cohort Study) is another important COPD study we are involved in, sponsored by the Asthma Lung UK and led by the Imperial College. I am the Scottish lead for this trial. The main objective is to study the early stages of COPD development. We recruited a novel cohort of young adult smokers and following their trajectories of lung function/CT scans to prospectively identify those at risk of early significant decline.

Alpha 1 antitrypsin deficiency (AATD) trials and database

AATD is a genetic condition that can cause damage to the lungs and/or the liver due to deficiency of the alpha-1 antitrypsin protein. We are currently the primary site in Scotland for running AATD trials and accept referrals from all over Scotland and the North of England.

I've been involved in several AATD studies, namely ARO-AAT, a phase 2 study that has been extended as the TAK-999 phase 3 trial.

> "My team is currently involved in seven clinical trials (combination of phase 2 and 3 clinical trials; RCTs, observational studies and others)."

These trials aim to evaluate the efficacy of a new drug called Fazirsiran compared to placebo in improving measures of liver fibrosis in AATD and slowing the progression to decompensated liver disease. The results of the ARO-AAT trial were recently published in a NEJM publication, which I co-authored. These studies were conducted with consultant hepatologist Dr Michael Williams. TAK-999-3001 and TAK-999-3003 are the ongoing studies.

The research team in Edinburgh is also well trained to perform necessary tests needed as part of these complex trials (fibroscans, spirometry, oscillometry etc.) with input from the hepatology team for liver biopsies as needed.

NHSL houses the only facility in Scotland to carry out AATD blood tests: quantifying serum levels of alpha-1 antitrypsin protein and genotyping it. This blood test is the gold standard for diagnosing this condition. Currently there is no dedicated database to hold information about the patients with AATD in Scotland. The team has recently been working with the Digital Innovation team in NHSL to create a clinical database to help track and recruit patients for future research. We hope to eventually extend this to other health boards in Scotland. Edinburgh has recently been initiated as a site for the creation of a Europe- wide AATD database as part of the European Alpha-1 Research Collaboration (EARCO). This will facilitate the creation of a database that can be used to identify the right patient cohorts for future AATD studies.

Digital innovation

I have also been involved in a major innovation project in Lothian, to develop a COPD dashboard to collect data on clinical outcomes, with a view to optimal risk stratification of patients and timely targeted interventions. This is an ongoing project in conjunction with a highly skilled team of collaborators, including the Usher Institute (The Dataloch team, Professor Julie Jacko, Professor Timothy Walsh, Ahmar Shah), Edinburgh Clinical Trials Unit (ECTU), the NHSL Health and Social Care Partnerships (Claire Yerramasu, Matthew Curl, Elouise Johnstone), industry partners (AZ, Pogo), PPE (Carol Porteous) and the third sector team (Chest Heart and Stroke Scotland). This could be a vital link for relevant health care professionals in both primary and secondary care to access data on shared COPD patients in the future.

Ultimately, the aim of this project is to co-create improved COPD care pathways involving COPD patients, members of the PPE group, COPD clinical experts, systems engineers, and our social care partners.

> "I hope to continue to build on the momentum of these meaningful research exercises, maximise opportunities to integrate collaboration between NHS Lothian, University of Edinburgh and industry partners, initiated by my team in the coming years."

Engagement with Patient and Public Involvement (PPI)

We have successfully established a PPI group in Edinburgh led by Carol Porteous and Claire Yerramasu, to hear the patients' voices on research and innovation. So far, we have had five workshops in Lothian and have collected valuable feedback which has been invaluable in shaping our COPD projects.

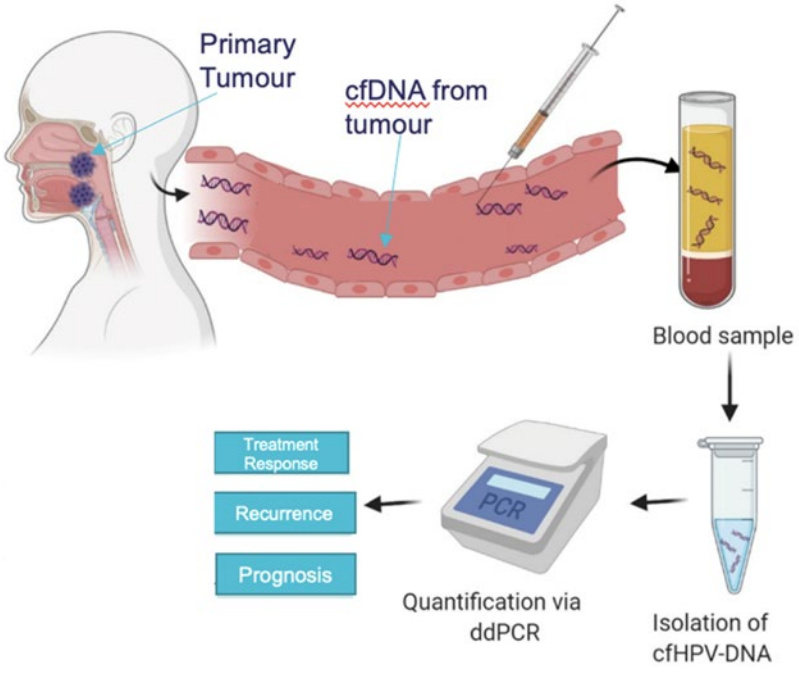
I hope to continue to build on the momentum of these meaningful research exercises, maximise opportunities to integrate collaboration between NHS Lothian, University of Edinburgh and industry partners, initiated by my team in the coming years.

NRS Clinician:
Mr Iain Nixon
Increasing research opportunities for patients with ENT Diseases

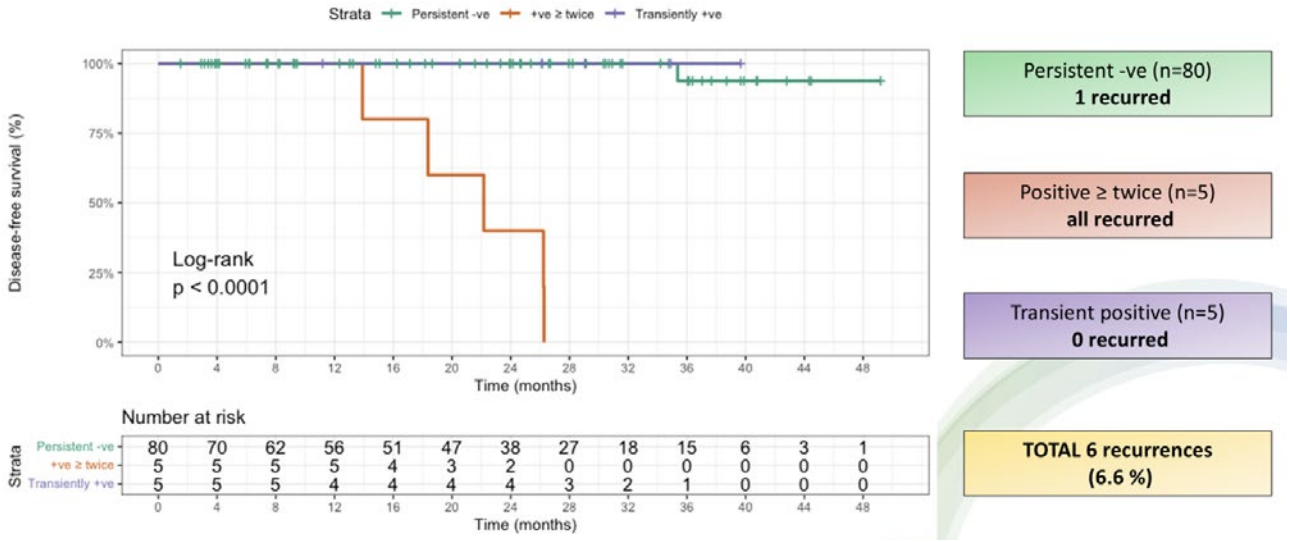
Mr Iain Nixon is the Clinical Director for Ear, Nose and Throat (ENT) Surgery and part of the head, neck and thyroid cancer team for NHS Lothian. Having started in Edinburgh in 2015, he became an NRS Fellow in 2018 and is now an NRS clinician. Much of his early work focused on outcomes for patients with thyroid cancer but in recent years he has developed a portfolio of trials in NHS Lothian in areas including head and neck cancer, thyroid cancer and gene therapy to minimise complications following treatment for these diseases.

Liquid biopsy in head and neck cancer

In 2018, collaborating with Professor Tim Aitman and his lab from the Institute of Genetic and Cancer, the team at The Edinburgh Cancer Centre started a major study on the role of liquid biopsy in head and neck cancer. As cells divide, small fragments of DNA are released into the bloodstream, and then can be detected in the plasma. When cancer cells divide more frequently and exert immune control over their microenvironment, the released DNA can potentially be used as a disease marker. Using digital droplet PCR, a cost effective and rapid technique for DNA assessment, the team has demonstrated an association between DNA levels and disease.



Process for liquid biopsy in head and neck cancer.



Recurrence free survival for head and neck cancer patients who do (red) or do not develop (green and blue) evidence of persistently positive liquid biopsy during follow up.

This is particularly true for viral driven (human papilloma virus) head and neck cancers, which have become increasingly common worldwide in the last few years.

As well as being the first and so far only UK group to demonstrate the accuracy of these to date, the team have now shown that monitoring results can be an effective tool post-treatment disease surveillance. What started as a single centre cohort in Edinburgh has grown to a national, multi-centre study spanning the three cancer networks in Scotland, recruiting over 250 patients from across the country. Initial funding was received from ENT Scotland which led to Chief Scientist Office grant support with clinician time supported by the NRS group.

Research in this field has presented a number of opportunities for research in this area, including collaborations within the UK and globally. Outside of direct cancer surveillance, the potential for use in the diagnostic setting has been explored in a preliminary cohort with a view to adoption as a national clinical trial. An important step has been the transition of this technology from the academic setting to the NHS where the technique is now used in the NHS Reference Laboratory in NHS Lothian. The group is now in discussions with groups such as Healthcare Improvement Scotland and the leads for Innovation in order to try and translate this technology from "bench to bedside" in the management of patients with head and neck cancer in NHS Scotland.

> "The association with deprivation, smoking and alcohol means that research into head and neck cancer has tended to lag behind other cancers. Hopefully work such as ours helps address that imbalance."

Iain Nixon - Consultant Surgeon Ear, Nose and Throat

Education Core

The Education Core at Edinburgh Clinical Research Facility (CRF) offers a diverse range of short courses to the local, national, and international clinical research community. We deliver online and in-person courses and pride ourselves on the quality and accessibility of our courses. We are an experienced team and work closely with the UKCRF Network Education Group and the NRS Training Forum, sharing with and learning from a wide network of clinical research educators nationally.

Courses

In 2024, we delivered 72 courses across 100 sessions. New courses included: Generative AI for the Researcher, Cost Effectiveness Modelling, Conducting Interviews in Qualitative Research and Using Mixed Methods in Clinical Research. We have also been piloting the UKCRF Lab Skills course aimed at staff who are involved in sample processing in clinical areas.

NRS Good Clinical Practice (GCP) training remains core to our programme, providing eight Introduction and eight Update courses per year. This training is Transcelerate compliant, reviewed by MHRA Inspectors and is regularly updated to remain current with regulatory and process changes in clinical research. Our GCP Trainers are members of the national NRS Training Forum and meet quarterly to discuss updates and share best practice.

> "Well run, engaging, informative and motivating couple of days in a great venue with knowledgeable and approachable staff. Thank you very much to the whole team."
>
> ECTMC attendee, November 2024

> "I felt that this was one of the best courses I've been on in my time as a researcher."
>
> Cost Effectiveness Course attendee, April 2024

We also continue to support larger courses and, in 2024, we collaborated with NHS Health Innovation South East Scotland (HISES) to deliver an Innovation event aimed at educating NHS Lothian staff about the process of innovation and promoting networking in the innovation space. We also successfully organised the delivery of the Edinburgh Clinical Trial Management Course (ECTMC) with new course directors and a refreshed programme, receiving excellent feedback from attendees.

Find out more about our courses on the Edinburgh CRF website.

> "Overall, an amazing course, would highly recommend to anyone and everyone."
>
> Generative AI Course attendee, October 2024

Lothian Clinical Research Welcome Days

The Lothian Clinical Research Welcome Days continue to be popular and currently run in-person on the BioQuarter campus twice a year. These events are aimed at staff who have been in a research post less than six months. The day introduces them to ACCORD and the clinical research community in Lothian. It involves networking activities and provides signposting to multiple support departments. Since its launch in November 2023, we have now held five of these events with over 150 participants.

Find out more information about the Welcome Days on our website.

> "This is a very valuable event. I can highly recommend this to anybody starting to work with clinical trials."
>
> Welcome Day Attendee, February 2024

Funded places

In August 2023 we introduced fully-funded places for NHS Lothian and University of Edinburgh staff and students on the majority of our courses. In 2024, we were able to offer over 1,000 free or funded places across our programme. This was not only to reduce the direct cost to attendees and their departments, but also reduce the administrative burden of processing course fees. Realising the benefits of these places and successfully balancing finances has allowed us to continue to offer this opportunity, ensuring we continue to provide accessible essential research training to local staff and students with the aim to promote high quality research delivery in Lothian.

> "This was an excellent opportunity to get involved in a course that I would otherwise struggle to find the funds for."
>
> Course attendee, October 2024

> "These funded places help break financial barriers to CPD opportunities."
>
> Course attendee, October 2024

NIHR Associate Principal Investigator Scheme

The Education Core actively promotes the NIHR Associate Principal Investigator (API) Scheme in Lothian. This is a six-month opportunity for clinical staff who are not in a research role to gain hands-on experience of delivering research under the mentorship of an experienced PI. The Lothian API champions for this scheme have been working hard to promote this opportunity. Following a marketing campaign in October 2024, we are delighted that 13 new APIs have registered on the scheme.

Visit our website to find out more about the Associate Principal Investigator Scheme

Associate PI Scheme Champions:

Email Jo Merrifield Email Julia Boyd

NIHR Principal Investigator Pipeline Programme (PIPP)

Following our three-year strategic plan, our current focus is on the development of our existing research workforce. One notable success here is opening up the NIHR Principal Investigator Pipeline Programme (PIPP) for Research Nurses and Midwives to Scotland. This has only been possible through successful negotiation with the NIHR and an agreement for the Education Core to manage the administration of the course on behalf of the NIHR for Scotland and support its delivery in collaboration with Glasgow CRF. This opportunity has been met with great enthusiasm and we are thrilled that our first cohort will be starting in March 2025 with 16 attendees from eight different health boards across Scotland.

Principal Investigator (PI) training videos

Working in collaboration with ACCORD, we have developed a suite of training videos outlining the role and responsibilities of a PI. These were developed using a central slide-set developed by the NRS Training Forum and have been localised to include processes and signpost to relevant contacts in Lothian.

You can watch these videos on the Principal Investigator Development tab of our website.

Educational resources

As well as delivering our own training, we have also created a resource bank on our website which contains over 140 free external online learning resources relating to clinical research. Since its launch in November 2023, analytics show we have had over 1,200 unique visitors to the site. We are always keen to hear of any suggestions of useful resources to add.

Visit our resource page on our website for more information.

Contacts

Email CRF Education Core Manager: Jo Merrifield

CRF Education Core email

Edinburgh CRF website

The evolving landscape in treatment for aortic stenosis

Doctors could use MRI scans to help guide the timing of major intervention for patients with a severe heart valve narrowing but no symptoms.

The EVOLVED randomised clinical trial, conducted by an international team of cardiologists, provides evidence supporting early intervention strategies to reduce emergency hospitalisation and prevent limiting symptoms.

Aortic stenosis: a growing concern

Aortic stenosis is a common and potentially life-threatening condition characterised by the narrowing of the aortic valve, which restricts blood flow from the heart to the rest of the body. With no medical treatment to slow the progression of the disease, many patients require major intervention to replace the aortic valve. Although conventional practice has favoured a "watchful waiting" approach until patients develop symptoms, the EVOLVED trial demonstrates significant potential benefits of proactive, earlier intervention.

The study design

The EVOLVED trial enrolled over 200 participants from 24 centres across the United Kingdom and Australia between 2017 and 2022. Eligible patients had severe aortic stenosis and evidence of heart muscle scarring on an MRI scan, but no symptoms at the time of enrolment. Participants were randomly assigned to two groups:

- **Early intervention group:** referred immediately for aortic valve replacement
- **Routine care group:** standard care with regular monitoring until the onset of symptoms and referral for aortic valve replacement by their own cardiologist.

The study looked at the impact of early intervention on rates of all-cause death, unplanned hospital admissions due to aortic stenosis, as well as symptom burden at 12 months.

> "In totality the results of these trials support a paradigm shift towards considering early valve intervention in patients with severe aortic stenosis, even in the absence of symptoms. Early treatment may prevent the progressive and irreversible cardiac damage that often occurs while waiting for symptoms to develop."
>
> Professor Marc Dweck, EVOLVED trial lead investigator

Key findings

- Early intervention did not reduce the primary endpoint of the rate of death/ emergency hospitalisation
- With respect to secondary endpoints:
  - early intervention did not reduce the rate of death from any cause compared with routine care
  - The rate of emergency hospitalisation due to aortic stenosis was significantly lower in patients who underwent early intervention
  - Early intervention prevented the onset of limiting symptoms

Importantly, the trial found that early intervention was safe, with no increase in major complications compared to conservative management.

Clinical implications

The findings of the EVOLVED trial have been published alongside other randomised controlled trials which demonstrated similar findings. A meta-analysis confirmed that early intervention reduces emergency hospitalisations without reducing all cause death. Together these data are expected to influence clinical guidelines for the treatment of aortic stenosis. Professor Marc Dweck, the trial's lead investigator, emphasized that "in totality the results of these trials support a paradigm shift towards considering early valve intervention in patients with severe aortic stenosis, even in the absence of symptoms. Early treatment may prevent the progressive and irreversible cardiac damage that often occurs while waiting for symptoms to develop."

One of the key components of the trial was the use of advanced cardiac imaging techniques to identify patients at the highest risk of adverse outcomes despite being asymptomatic. MRI scans, specifically designed to look for scarring in the heart muscle, were used to guide patient selection.

Dr. Neil Craig, a co-investigator, noted that "integrating sophisticated imaging assessments into clinical practice may be helpful in informing patients of their individual risk and helping to guide the timing of intervention on an individual level."

Results in context

A large study conducted in the United States, which included over 900 patients with severe but asymptomatic aortic stenosis reported their findings in October last year. This study showed similar results, with no impact of early intervention in reducing mortality, but importantly reduced hospitalisation due to heart failure. Dr Phillipe Genereux, Chief Investigator of the EARLY TAVR trial, said "The most important finding is that there's no evidence of harm from the early intervention strategy. There doesn't seem to be any benefit to waiting."

Conclusion

The EVOLVED trial has contributed to a potential step forward in the treatment of aortic stenosis. The consistent clinical trial data support the potential benefits of early intervention, to allow for fully informed discussions about the risks and benefits of intervention in patients with aortic stenosis but no symptoms.

Motor Neurone Disease Systematic Multi-Arm Adaptive Randomised Trial (MND-SMART)

Led by Professor Siddharthan Chandran and Professor Suvankar Pal and anchored at the Euan MacDonald Centre for Motor Neuron Disease Research, University of Edinburgh and the UK Dementia Research Institute, MND-SMART aims to expedite delivery of new treatments for Motor Neuron Disease (MND).

Motor Neuron Disease (MND) is an incurable and rapidly fatal neurodegenerative disease. The average survival for people living with MND is 18 months from diagnosis and there is only one licensed therapy in the UK, Riluzole, which prolongs life by 2-3 months. Over 125 trials have failed to identify alternative treatments. MND-SMART aims to address this major unmet need by rapidly and definitively testing new treatments that could improve outcomes.

In February 2020, Professor Chandran and Professor Pal launched one of the most ambitious clinical trials - co-produced with pwMND - aimed at improving outcomes for MND. MND-SMART heralds a new era of innovative trials for progressive neurodegenerative diseases. It is the first multi-arm multi-stage (MAMS) adaptive statistically advanced trial design for any neurodegenerative disease globally, pioneered from cancer medicine and COVID trials which have transformed the outlook for those conditions. It also remains the largest academic trial ever delivered in the UK. The MAMS adaptive design means that multiple drugs can be tested at the same time, with the ability to drop drugs that are ineffective and add new drugs as evidence emerges. MND-SMART delivers a nationwide, interdisciplinary, phase 3 trial platform of globally leading MND clinicians and scientists, patient representatives, experts in trial design, statistics, and drug discovery [1-2].

A platform trial

Since its launch in 2020, MND-SMART has definitively tested and published results on the first two treatment arms, memantine and trazodone, in the Lancet Neurology [3]. Neither Memantine and Trazodone showed any significant improvement in the rate of MND progression compared to placebo (figure 1) and both arms were withdrawn from the trial within 3.5 years following their implementation, demonstrating the efficiency of the MAMS approach in reaching definitive conclusions faster than traditional fixed-design trials.

In 2023, a third treatment arm, Amantadine, was seamlessly introduced in the trial by substantial amendment - this arm is currently open for recruitment and follow up. In 2024, MND-SMART received regulatory and ethical approval to introduce an additional treatment arm, Tacrolimus, a drug re-purposed for its use as an immunosuppressant in transplant medicine.

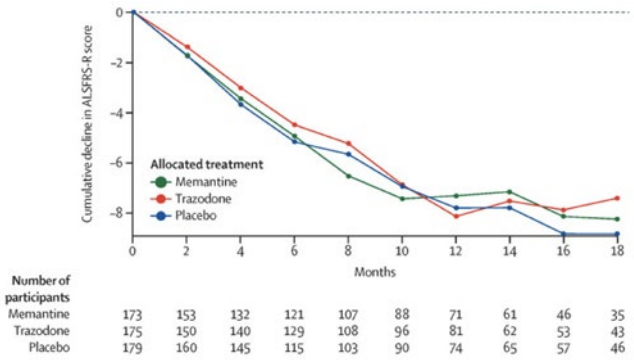


Figure 1. Cumulative bimonthly rate of change in ALSFRS-R in Memantine and Trazodone vs Placebo. ALSFRS-R=Amyotrophic Lateral Sclerosis Functional Rating Scale Revised [3].

The addition of Tacrolimus required significant further innovation to the MND-SMART protocol design due to differences in its formulation and safety monitoring requirements compared to the existing study drugs. Tacrolimus was selected by an interdisciplinary panel of experts in cancer drug discovery and neurology based on compelling evidence from high throughput screening studies on preclinical MND models. The MND-SMART Patient Advisory Group endorsed the selection of Tacrolimus and encouraged the trial team to be ambitious in selection of drugs despite the change in eligibility criteria and safety monitoring requirements.

A growing network of expertise in innovative trials

As of 1 March 2025, there are >900 participants recruited to the trial (figure 2) and 22 actively recruiting centres across all 4 UK nations (figure 3). 14 of these sites had never run an MND trial before. Historically, only 5% of people with MND had taken part in a clinical trial. MND-SMART aims to increase equity of access to trials so that pwMND can take part regardless of geographical location. Since its launch, over 2500 people have registered their interest in taking part in MND-SMART. One of the most notable aspects of the trial has been its inclusivity and patient-centred approach. Innovations in trial design including remote video consultation appointments, use of a remote consent system, couriering of trial drug to participants' homes, use of clinical results, use of electronic diaries and questionnaires, and community assessments, has promoted inclusivity and reduced attrition to <10%. This year, we are working to set up recruitment in York, Scarborough, University College of London, Imperial College London and Liverpool, where there is still unmet need and socioeconomic and ethnic diversity.

> "The plan to introduce new drugs for testing in MND-SMART opens a new avenue of hope for all of us. Unless we try new things, we are stuck in the same place."
>
> MND-SMART PPI member, 2023

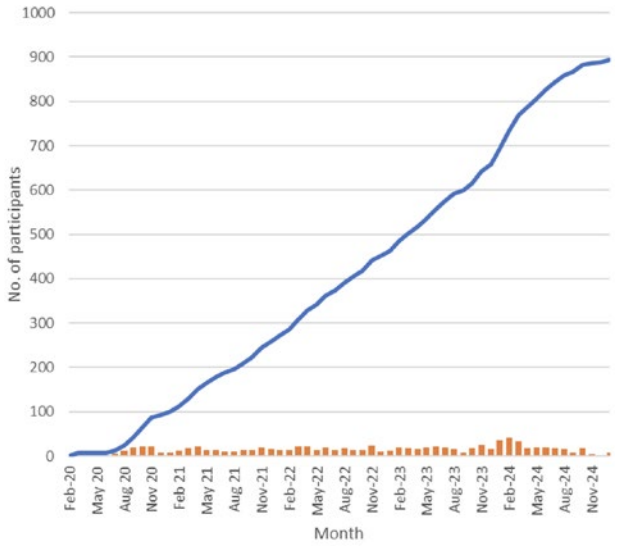


Figure 2. MND-SMART recruitment since launch in February 2020.

Figure 3. MND-SMART research sites. Actively recruiting sites are presented in green. Sites in set up are presented in yellow.

Future plans

The MND-SMART trial team will continue to add treatment arms to the trial in line with emerging scientific evidence, and in particular, test combination therapies and collaborate with the pharmaceutical industry. We will continue to expand and build on existing trial infrastructure and expertise to establish new biomarker sub-studies and open new trial sites to provide more opportunities for people with MND to take part in research.

Figure 4. MND-SMART Investigators, Drug Discovery Scientists, Research Nurses, Drug Manufacturers, Trial Management team and Patient Advisory Group

Sponsors and funders

MND-SMART is supported by the Anne Rowling Regenerative Neurology Clinic and funded by the Euan MacDonald Centre for Motor Neuron Disease Research, MND Scotland, My Name'5 Doddie Foundation, The Alan Davidson Foundation, Baillie Gifford, LifeArc, and the MND Association.

> "The trial is important in that I genuinely feel it to be a crucial component of my overall care package. The opportunity to meet with the research team, together with the repeated completion of testing and blood sampling, gives me an up to date measure of my level of stability or indeed, the extent of any progression. It is also therapeutic in that I have a safe space where I can offload to someone not connected to me directly, i.e. family & friends. For myself and my family it creates a sense of hope, a life jacket, that prevents us from emotionally drowning. The solution to cracking the MND code will come and after experiencing, and feeling, the expertise of those working on finding those solutions, I am more confident than I have ever been that positive change is only over the horizon; we will see it soon."
>
> MND-SMART PPI member, 2024

References

1. Parker, R.A., Weir, C.J., Pham, T.M. et al. Statistical analysis plan for the motor neuron disease systematic multi-arm adaptive randomised trial (MND-SMART). Trials 24, 29 (2023).
2. Wong C, Dakin RS, Williamson J, et al Motor Neuron Disease Systematic Multi-Arm Adaptive Randomised Trial (MND-SMART): a multi-arm, multi-stage, adaptive, platform, phase III randomised, double-blind, placebo-controlled trial of repurposed drugs in motor neuron disease BMJ Open 2022;12:e064173. doi: 10.1136/bmjopen-2022-064173
3. Pal et al. 2024. Safety and efficacy of memantine and trazodone versus placebo for motor neuron disease (MND SMART): stage two interim analysis from the first cycle of a phase 3, multiarm, multistage, randomised, adaptive platform trial. The Lancet Neurology, Volume 23, Issue 11, 1097 – 1107

NHS Lothian's Clinical Infection Research Group (CIRG) tackles global infection research questions through national and international collaborations

CIRG was founded as a collaborative organisation to build, support and facilitate infection research in Edinburgh. It brings together researchers from across NHS Lothian, the University of Edinburgh (UoE) and partners in academia and industry nationally and internationally. Chaired by Meghan Perry and lead Research Nurse Amy Shepherd, its activity is continuously growing. Its membership now includes a dedicated team of Research Nurses, a Clinical Trials Assistant, Research Fellows and 14 active Principal Investigators (PI). Two of our PIs are supported by NRS clinician sessions funded directly by our own research activity. CIRG provides training and research opportunities for a wide range of doctors, nurses and allied health professionals and is represented on the Executive Committee of UoE's Edinburgh Infectious Diseases.

CIRG's research portfolio is diverse and represents the broad infection interests of our members. Our research activity in 2024 illustrates this; it includes 25 clinical studies with key trials highlighted below.

Figure 1: CIRG Team, Front Row (left to right): Meghan Perry (CIRG Chair), Jackie Henderson (Senior Research Nurse), Amy Shepherd (Lead Research Nurse). Back Row (left to right): Angus McCance (Clinical Research Fellow), Tallulah Armstrong (Clinical Trials Assistant), Anne Saunderson (Senior Research Nurse), Susie Ferguson (Senior Research Nurse). Not Pictured: Louise Sharp (Senior Research Nurse), Connor Dalby (Clinical Trial Assistant)

Vaccine development

CIRG NRS clinician Rebecca Sutherland has led and facilitated the growth and reputation of CIRG as a vaccine trials centre. Following on from being a key collaborator in the Oxford AstraZeneca vaccine trial, CIRG has continued to support several influenza and COVID vaccine trials including Moderna's Fluent mRNA vaccine trial in 2024.

Also in 2024, with CIRG NRS clinician Oliver Koch as PI, CIRG took part in Moderna's NOVA 301, which compared a multivalent mRNA vaccine to prevent Norovirus infection against placebo as there is no licensed vaccine for Norovirus. This vaccine has the potential to have a significant impact on public health, particularly in frail and elderly populations in healthcare settings.

Figure 2: CIRG NRS Clinicians, Rebecca Sutherland (left) and Oliver Koch (right)

> "Through its achievements up to and including 2024, CIRG is positioning itself as a valued partner in driving forward cutting-edge advances in infectious disease research."

Investigating medicinal products that harness the immune system to treat HIV

The history of clinical infection research in NHS Lothian is based around HIV, with Professor Leen, involving Edinburgh in all available innovative HIV therapy trials from the 1990s onwards, ensuring that our HIV patients had access to the newest treatments. These trials led to the establishment of the highly active antiretroviral therapy (ART), which is taken lifelong by HIV positive patients today.

CIRG has continued to be involved in trials investigating innovative approaches to HIV. In 2024, led by PI Matt Adam, CIRG took part in a multi-centre phase 1/2 trial evaluating the potential of a monoclonal T-cell receptor to eliminate latent HIV reservoirs in HIV-positive participants who are virologically suppressed on ART. These virus reservoirs are not targeted by ART and the aim is that this novel T-cell receptor will help to reduce or ultimately eliminate the HIV-infected cells in the body, thereby controlling HIV without the need for lifelong ART.

In 2024, CIRG also collaborated with UCL and Oxford University on another novel approach to HIV therapy (PI Rebecca Sutherland), investigating two broadly neutralising antibodies against HIV to see if they can induce prolonged virological suppression without ART in HIV- positive patients who have previously been fully suppressed with ART.

Optimising therapies in infectious diseases with high morbidity and mortality

Following on from the pivotal work of the adaptive platform Recovery trial, which crucially demonstrated the benefit of dexamethasone in the treatment of COVID, CIRG continues to recruit for the Recovery trial (PI Oliver Koch), which is now focused on community-acquired pneumonia and influenza, investigating the efficacy of steroids and antivirals in these conditions.

The international SNAP trial (PI Rebecca Sutherland), led by the University of Melbourne, is also using this adaptive platform design to investigate how to optimise therapy for *Staphylococcus aureus* bacteraemia, which has a mortality rate of approximately 30%. CIRG is currently recruiting patients to evaluate alternative and adjunctive therapies and early oral switch in this common and serious condition.

Figure 3: CIRG Research Register, poster including QR code to enable easy registration for those interested in taking part in research

Patients suffering from recurrent *Clostridium difficile*, a potentially fatal form of colitis, can now be enrolled in Vedanta (PI Meghan Perry), an international trial evaluating the efficacy of bacterial consortia capsules in preventing further recurrences. This approach aims to replace the requirement for the complex procedure of faecal microbiota transplant to prevent *C.diff* recurrence.

Valuable contributions to infectious diseases surveillance and epidemiology

CIRG is involved in multiple different cohort studies and registries monitoring national and global presentations and outcomes in HIV (PI Claire Mackintosh), tropical and imported diseases (PI Oliver Koch), antimicrobial resistance (PI Simon Dewar), respiratory (PI Oliver Koch) and fungal infections (PIs Iain Page and Simon Dewar).

Global education and empowerment to combat antimicrobial resistance

Through its partnership with the UoE's Edinburgh Infectious Diseases, CIRG members have become mentors to the Fleming Fund fellows. The Fleming Fund is dedicated to improving antimicrobial stewardship and resistance diagnostics and surveillance in Africa. This has been a wonderful opportunity for consultants and trainees to engage with the challenges of infection management in low and middle income countries and to inspire future antimicrobial resistant advocates.

The CIRG team and a new volunteer registry

Involvement in these groundbreaking studies is made possible by our incredible team of Research Nurses, led by Amy Shepherd. A key achievement of the team in 2024 was the establishment of a 500-strong volunteer research registry in partnership with the Travel Clinic at Western General Hospital. The registry has significantly streamlined the process of enrolling participants in vaccine trials and other studies.

Looking forward

CIRG is poised for continued growth and innovation in 2025, with the relocation to the new Clinical Research Delivery Centre. This move to shared premises with the Clinical Research Facility will provide a fresh environment for collaboration and development.

Through its achievements up to and including in 2024, CIRG is positioning itself as a valued partner in driving forward cutting-edge advances in infectious disease research. These achievements are closely aligned with the goals set out in the O'Shaughnessy Report, which emphasised the need for sustainable, high-impact research in infectious diseases. CIRG's work and the resultant advances in patient therapies and addressing of global infection challenges enhance the care received by patients in NHS Lothian.

The advance of clinical trials in haematology

It is an exciting time to be involved in haematology. The clinical trials portfolio has doubled since 2021, and there is now a well-established early phase unit providing for a range of haematological malignancies, receiving referrals from across Scotland and the North of England.

Although relatively new to early phase clinical trials, the team has already made a big impression, being the first UK centre to recruit into two phase 1 studies, and the second highest recruiter in another. Predicted recruitment targets are routinely met, if not exceeded; with the work recognised through authorship and the PI presenting data at international conferences. To support this rapid expansion in activity, significant investment has been made in the team with the appointment of a new Research Clinical Fellow, an additional Research Nurse, a Data Manager and a Clinical Trials Support Officer. The whole team prides itself on providing a patient-focused service, seeing the patients quickly following referral, advocating for studies to address areas of unmet clinical need and patient choice and collecting high quality data to ensure trial integrity and maximise patient care. The Lead Research Nurse, Rachael McAngus recently presented at the Scottish Haematology Society, and our Clinical Fellow (Dr Joanna Parsons) received an Abstract Achievement Award for work she will be presenting at the annual British Society of Haematology meeting this April, a highly regarded international event. Lois Eddie, a former member of the team, was successful in applying for a post at CRUK. Dr Victoria Campbell has led this change within the Haematology Clinical Trials team after returning from her Wellcome Trust funded PhD, and while she recognised that 'wet' laboratory science might not be for her, she was determined to support the transition of science from bench to bedside, to improve patient choice and hopefully patient care over the years.

Alongside these advances, NHS Lothian has been developing institutional readiness for advanced therapy medicinal products (ATMPs) using a multi-disciplinary and multi-specialty approach in partnership with the Scottish National Blood Transfusion Service (SNBTS), which plays a key role in the collection of source material, manufacture, and storage of cellular advanced therapy products.

> "To be able to positively impact the wider patient population of Scotland is a huge privilege."

Dr Victoria Campbell, Consultant Haematologist, Clinical Lead for Haematology Clinical Trials.

Haematology Clinical Trials team.

ATMPs are innovative medicines that use genes or cells, offering a new form of therapy for a range of diseases.

The use of ATMPs is most advanced in the field of haematology where they have transformed the outcomes for many patients previously considered palliative, often with only months to live. Importantly, as our knowledge and experience within this field grows, not only are the indications expanding to other areas of unmet need, but our ability to manage their unique toxicities is improving, making these treatments accessible to more patients.

The haematology service is an approved and accredited centre for the provision of ATMPs, having achieved JACIE accreditation (an inspection against >300 international standards) in 2022. This was a huge multi-disciplinary effort demonstrating the dedication and ambition of the whole team to ensure that patients in Scotland have access to these innovative and transformative therapies, for many closer to home.

NHS Lothian has initiated a number of highly innovative advanced therapy research studies across a range of disciplines - 6 ATMP studies (five currently open, one in follow up), four genetically modified (GM) studies (two open, two in follow up). This is supported by an AT/GMS committee and an approved medicines governance policy for the use of ATMPs.

The ATGMS committee was convened in 2019 and has a broad membership. It currently consists of 20 employees from either NHS Lothian or the University of Edinburgh, building on the expertise already developed in this field. It works alongside ACCORD in reviewing and assessing these complex studies, assessing the risk to the board, staff and patients, the capacity/infrastructure whilst providing the necessary expertise to ensure successful setup and recruitment.

> "The changes within haematology over the last four years have been immense, with the benefits seen throughout the multidisciplinary team and invaluable to patient care. As the team now moves to support the delivery of ATMPs for a range of indications, beyond haematological malignancies, we are entering a new and exciting chapter where research sits alongside standard clinical care. This move will provide career development opportunities, support an already dynamic and thriving service and continue to make haematology an incredible area to be involved in."
>
> Dr Victoria Campbell, Consultant Haematologist, Clinical Lead for Haematology clinical trials

The Quality Assurance and Monitoring team

The Quality Assurance (QA) and Monitoring team maintain independent oversight of clinical trial-related activities, ensuring that NHS Lothian and the University of Edinburgh fulfil their legal obligations and responsibilities as co-Sponsors of clinical research in accordance with the trial protocol, Good Clinical Practice (GCP) and applicable regulatory requirements.

Meet the Team

Our Quality Assurance (QA) Manager, Lorn Mackenzie, has been in post since 2016 and has a background in research governance in NHS Lothian and Greater Glasgow and Clyde (NHSGGC) Research and Development (R&D) departments.

Lorn is responsible for leading and implementing the ACCORD quality management strategy, which includes maintaining a system of continuous quality improvement that meets the requirements of evolving clinical research legislation and UK-wide guidance.

In her role as QA Manager, Lorn is responsible for leading and managing all co-sponsor activities associated with statutory inspection of NHS Lothian and the University of Edinburgh by the Medicines and Healthcare products Regulatory Agency (MHRA).

Lorn also holds a national role as one of the NHS Research Scotland (NRS) Good Clinical Practice (GCP) trainers in Lothian.

Working closely with Gavin Robertson (QA Coordinator) and Roisin Ellis (QA Administrator), Lorn performs audits on research studies, internal systems, processes and third-party suppliers. Audits evaluate compliance with study protocols, policies, guidelines, Standard Operating Procedures (SOPs), GCP and any regulatory requirements and can reveal systemic issues providing opportunities for improvement.

Our Senior Clinical Trial Monitors, Elizabeth (Liz) Craig and Alice Graves, have over 20 years combined experience of monitoring clinical trials. Alice also has experience of monitoring commercially sponsored trials as a Clinical Research Associate (CRA) for a Contract Research Organisation (CRO).

As Senior Monitors, Liz and Alice are responsible for the ACCORD monitoring programme, developing, implementing and maintaining our monitoring systems.

The Senior Clinical Trial Monitor's role includes contributing to planning, development and delivery of research governance training packages. At the request of the R&D Forum, Liz recently developed and delivered a training course in the 'Practical application of monitoring in a health and care setting'. This is now part of the R&D Forums prospectus of courses.

Liz and Alice have a team of six Clinical Trial Monitors; Lynn Smith, Mhairi Moore, Laura Flett, Caroline Garth, Vanessa Wareham and Laura Garcia Puerta.

The team conduct monitoring visits at hospital sites in Lothian and across the UK to ensure our research is being conducted in accordance with trial protocols and applicable legislation. The team utilises risk-based monitoring techniques to develop a bespoke monitoring strategy for each trial that meets our criteria for combined risk assessment.

Profiles, initiatives and awards

The QA and Monitoring team.

Why is Quality Assurance important?

Quality Assurance ensures that all planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented and reported in compliance with GCP and the applicable regulatory requirements are of the highest quality possible.

As quality is integral to clinical research, ACCORD has a comprehensive Quality Management System (QMS) managed by the QA team. This consists of detailed policies, guidelines and Standard Operating Procedures (SOPs) designed to minimise the risk of errors and inconsistencies by ensuring that everyone involved in a research study follows the same procedures.

To find out more information regarding QA and how the team can help with your study, please email the Quality Assurance team.

What is clinical trial monitoring?

The purpose of monitoring is to verify that:

- the rights and well-being of the trial participants are protected
- the reported trial data are accurate, complete and verifiable from source document
- the conduct of the trial is in compliance with the currently approved protocol, with GCP and the applicable regulatory requirements

A trial specific monitoring strategy will consider potential risks related to the Investigational Medical Product (IMP)/intervention, the phase of study, the participant population and the complexity of the protocol and data collected. Research studies or activities assessed as high risk will be subject to more frequent monitoring than those classified as lower risk. The monitoring strategy will be documented in a trial specific Monitoring Plan and a Source Data Verification (SDV) Plan.

Email the monitoring team if we can be of any assistance.

All ACCORD documents required by research teams involved in trials sponsored by NHS Lothian and the University of Edinburgh, are available on the ACCORD website.

> "Our QA and Monitoring team has a wealth of knowledge and experience and is committed to working with Investigators, Trial Managers and their teams to support the successful set-up and delivery of trials in Lothian and across the UK."
>
> Dr Heather Charles, Head of Research Governance, NHS Lothian

Profiles, initiatives and awards

Ellie McMaster

Global Health Clinical Research Facilitator

After graduating in Biochemistry from the University of St Andrews in 2011, I spent a few years in Inverness working for Johnson & Johnson as a research assistant in blood glucose monitoring. In 2016, I moved to Edinburgh to join the ACCORD team and in 2018 I completed my MSc in Clinical Trials at the University of Edinburgh. I took on the role of Global Health Clinical Research Facilitator in 2020.

What is Global Health research in ACCORD?

The University of Edinburgh (UoE) is involved in multiple international healthcare research partnerships, working with colleagues from universities and organisations in many countries. In my role, I manage the Global Health (GH) team in ACCORD which currently consists of myself and the Research Governance Assistant. We take on the role of Sponsor Representatives for all international health/social care related research studies led by UoE researchers. As Sponsor Representatives, we support GH researchers through the life cycle of their projects, from the funding application stage, through research governance reviews, and assistance with the required approval submissions, to reviewing amendments and providing general advice on all stages of a GH research project.

UoE is committed to working respectfully and collaboratively with international partners in GH research, with the shared aim of implementing high research governance and ethical standards. The role of ACCORD is to provide processes to help assess, record and monitor research activity; to comply with relevant regulatory frameworks; to ensure that GH researchers are familiar with and comply with the relevant UoE research support systems; and to maintain the highest standards of research excellence, rigour and compliance. In practice, the ACCORD Sponsorship Review provides UoE researchers with the resources they need to achieve this. A set of ACCORD GH Sponsorship processes and study document templates (GH001) have been developed specifically for UoE researchers to help them meet the research governance requirements that apply to their work.

> "As Sponsor representatives, we support GH researchers through the life cycle of their projects, from the funding application stage, through research governance reviews, and assistance with the required approval submissions, to reviewing amendments and providing general advice on all stages of a GH research project."

Profiles, initiatives and awards

The ACCORD GH team also works closely with the Edinburgh Medical School Research Ethics Committee (EMREC) to ensure that research governance and ethical principles are embedded in GH research projects from their inception, through implementation and to authorship and impact. The UoE follows UK Research & Innovation (UKRI) guidance that research involving human participants requires approval from an independent ethics committee in the UK, and an ethical opinion from an independent ethics committee in the country where participants will be recruited. This dual ethics review is essential to ensuring that local ethics committees bring the additional expertise to consider local norms and cultural practices, and to ensure that research involving local participants follows best practice.

Useful additional resources for UoE GH researchers:

UoE EMREC: Global Health

UoE Global Health Ethics toolkit: Ethical Action Homepage | Ethics

UKRI Research in a global setting: Research in a global setting – UKRI

Management of Global Health trials: Management of global health trials: MRC guidelines – UKRI

The Global Health Network offers several eLearning courses which look at some of the specifics of conducting research overseas.

Global Health Academy

Profiles, initiatives and awards

Laura Rankin

Research Governance Assistant

After graduating from Monash University in Melbourne, Australia, I have worked in a research governance setting for the past six years, overseeing regulated and non-regulated clinical trials and other types of social, legal, and policy research within the Research Ethics and Governance team at Deakin University. I moved to Edinburgh in 2024, and took up the post of Research Governance Assistant within ACCORD.

As a Research Governance Assistant, I work with international student researchers and their supervisors to support the set-up of student health/social care research studies – advising on University of Edinburgh (UoE) requirements, sponsorship, ethics review processes, data governance, and international research considerations. I liaise with Edinburgh Medical Research Ethics Committee (EMREC) and Programme Directors to streamline the management of international student health/social care research requirements by developing guidance documents and templates for students. I keep abreast of leading UoE and industry developments in areas such as equitable global health research methodology and generative artificial intelligence to offer clear and dependable advice to student researchers.

ACCORD – support for UoE international student researchers

International students conducting health/social care related research must submit their Study Document Package (GH001) and Student Ethics Form to ACCORD for review. Following ACCORD Sponsor approval, ethics review takes place - whilst EMREC oversees ethics review for the College of Medicine as a whole, and reviews student PhD projects directly, most undergraduate, Masters, and PGT student programmes have a devolved specialised ethics group to oversee the ethics processes for their own programme. Students can contact their programme tutor or director for information about their ethics group. International research students will then usually seek local ethics approval from an appropriate body following approval by UoE ethics.

> "I keep abreast of leading university and industry developments in areas such as equitable global health research methodology and generative artificial intelligence to offer clear and dependable advice to student researchers."

Profiles, initiatives and awards

Key considerations for UoE international student researchers:

- Contact ACCORD early, so that we can work alongside students and their supervisors to identify sponsorship and ethics requirements at the project's initiation.
- Students should work through the relevant approval processes with their UoE supervisor, who can advise on relevant UoE-specific requirements. It is also beneficial to have a local supervisor in their home country to assist with any local obligations.
- ACCORD templates (GH001) for the protocol and associated study documents should be used where possible - the more detail provided in these documents for review, the quicker ACCORD can provide feedback and approval.
- Data governance: students should aim to include detail in their study protocol details of how they intend to collect, store, retain, and dispose of their study data. Students collecting personal data out with UoE systems will also need to submit a Data Protection Impact Assessment (DPIA). UoE students must comply with UK data protection legislation and the UoE Data protection impact assessment. However, it is important that international students also comply with the regulations and institutional policies of the country in which they are collecting data; identifiable data that does not fall within the UK/EU GDPR jurisdiction is primarily subject to the laws of the country of origin.

Contact details:

If you have any questions related to research governance of GH health/social care related research, please email the ACCORD Research Governance team.

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.

The Edinburgh CRF clinical facilities include two adult CRFs at the Western General Hospital (WTCRF) and the Royal Infirmary of Edinburgh (RIECRF), and one Children's CRF at the Royal Hospital for Children and Young People (CCRF). Laboratory and research support services are located at the WTCRF and the Queens Medical Research Institute (QMRI).

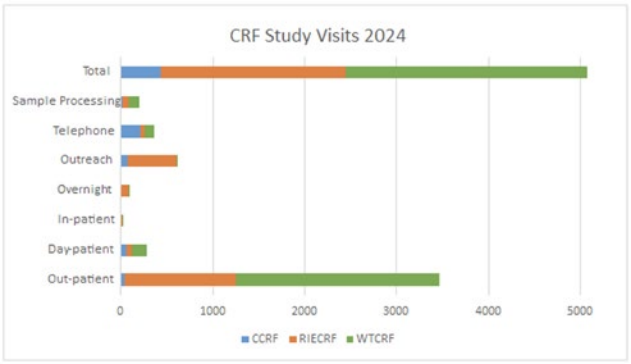
We are looking forward to expanding our clinical facilities in 2025 to include a new Commercial Research Delivery Centre (CRDC) funded by the CATALYST programme.

Nursing and Clinical Core

In 2024, the Nursing and Clinical (N&C) Core supported 147 active studies with 111 of which required direct nursing input. A total of 5,072 participant research visits were completed across all active studies, including 208 sample processing visits. 64 new studies applied for N&C support, out of a total of 135 new studies across all the scientific cores, e.g. genetics. New Principal Investigators were supported in the clinical specialties of Ear, Nose and Throat and Paediatric Neurology.

The N&C Core has bid farewell to two of our longest serving Clinical Research Nurses, Gerry Cummings and Heather Spence. They started their research nursing careers at the WTCRF and progressed to senior positions in the department, with Gerry as Research Nurse Manager and Heather as Lead Research Nurse. We wish them well in their retirement and thank them for the huge contribution they have made, in shaping and influencing the Nursing and Clinical Core over the past 20+ years.

New appointments to the senior nursing team in 2024 include Fiona Mitchell, Research Nurse Manager, Garry Tucker and Marta Adamczyk, Lead Nurses for Phase 1 research.



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.

Finally, after a busy start to 2025 which saw us undergo MHRA Phase 1 re-accreditation and a GCP inspection, we are pleased to report that our clinical facilities will retain MHRA Phase 1 Accreditation status. A huge thank you to everyone involved in supporting us through this. The successful outcome is a result of the hard work and dedication of our nursing and clinical team and our Quality Assurance Lead, James Gibson.

Selected developments and partners

Genetics Core

The Genetics Core has purchased a new sequencing platform from Oxford Nanopore Technologies called the PromethION P24. This innovative technology can perform single-molecule sequencing of long reads in real time. It can sequence DNA, to identify genetic variants while providing details of methylation markers. The long reads can also provide details of insertions, deletions and rearrangements in the chromosomes. Analysing these together provides a powerful tool for understanding the human genome, particularly in the field of cancer. We are using the platform, with Professor Colin Smith, to sequence brain tumours to see if we can use this technology to classify tumour types. This could lead the way to faster and more accurate diagnosis of Central Nervous System tumours, ensuring that patients receive the best treatment at the right time.

Mass Spectrometry Core

The Mass Spectrometry Core underwent major changes in 2024. We moved into newly refurbished laboratory space in May 2025 and received funding from the Biotechnology and Biological Sciences Research Council (BBSRC) for a new instrument, which has now been delivered and automated for sample preparation.

Sciex Engineer Ross Telford, Sciex Sales contact Iain Mayer and Deputy Core Manager Scott Denham.

We continued to develop novel bioanalytical methods for clinical researchers at the University of Edinburgh and beyond. We conducted 25 studies last year, analysing over 8,000 samples and contributing to 11 publications. Highlights include a clinical study evaluating corticosterone as an alternative steroid treatment (Kyle et al 2024), our mass spectrometry profiling methodology (Denham et al 2024), adapted and applied to steroid profiling in a Finnish pregnancy cohort (Lahti-Pulkinnen et al 2025). From humans to cells we contributed to studies assessing glucocorticoid action (Boyle et al 2025), the role of epicardial adipose tissue in pulmonary arterial hypertension (McCarthy et al 2024) and steroidogenesis in tumour growth (Sandro et al 2024).

Selected developments and partners

Dr Shazia Khan continues to develop mass spectrometry imaging methodologies, working closely with Professor Ruth Andrew, with a key publication demonstrating the application of the technology to atherosclerosis imaging (Ntshangase et al 2025).

We have hosted four visiting researchers from Oxford, Nepal, Austria and Italy, school pupils, two summer undergraduate studentships and public engagement in local primary and secondary schools, to share the fun of separation science.

Dr Jo Simpson, Dr Hamish Miller from Oxford University and Sudan Kumar from the Nepal Police laboratories

The team is looking forward to experimenting with and introducing our new mass spectrometry capabilities to the facility in 2025 and improving the sensitivity and scope of the metabolic pathways we can measure.

Dr Natalie Homer and Dr Jo Simpson at a public engagement event discussing chromatography on International Women's Day at Frogston Primary School, Edinburgh.

Image Analysis Core

Deep learning and genome-wide association meta-analyses of bone marrow adiposity in the UK Biobank:

This study explored the genetic determinants and functions of bone marrow adipose tissue (BMAT), a distinct adipose subtype of fat that accounts for more than 10% of fat mass in healthy humans. The IA Core facilitated the use of deep learning to measure bone marrow adiposity in several regions, including the femoral head, total hip, femoral diaphysis, and spine, from MRI scans of approximately 47,000 UK Biobank participants.

Key findings:

- Determine heritability and genome-wide significant associations for bone marrow adiposity at each site
- Identify a large number of independent significant single nucleotide polymorphisms (SNPs) and map them to specific genes for each bone region
- Perform transcriptome-wide association studies, colocalisation analyses, and sex-stratified meta-GWAS to resolve functional and sex-specific genes associated with bone marrow adiposity
- Perform a multi-ancestry meta-GWAS to identify genes associated with bone marrow adiposity across different bone regions and ancestry groups
- The findings will provide insights into BMAT formation and function, offering a basis to study the impact of BMAT on human health and disease

Selected developments and partners

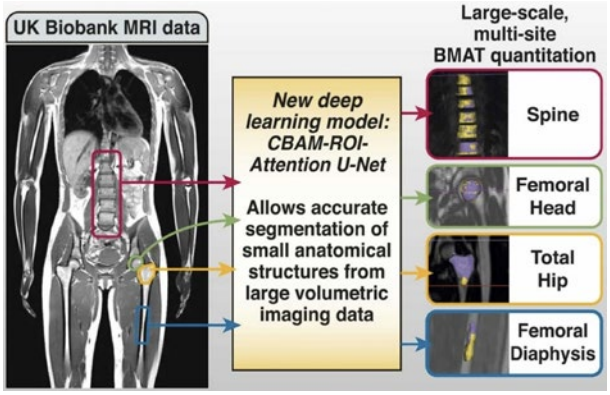


Figure: A new deep learning method for analysing small structures in MRI scans, enabling high-throughput bone marrow fat fraction measurement in the UK Biobank.
The findings reveal new pathophysiological insights, highlighting the potential of this novel clinical biomarker.

Image from Morris DM, et al. A novel deep learning method for large-scale analysis of bone marrow adiposity using UK Biobank Dixon MRI data. Comput Struct Biotechnol J. 2023 Dec 27;24:89-104.

Analysing the retina in the PREVENT Dementia study:

The PREVENT Dementia study aims to identify the earliest signs of dementia, which can occur in the brain decades before symptoms appear. The study recruited healthy volunteers aged 40-59 to identify biological and psychological factors that may increase their risk of dementia in later life. In this multi-centre effort various assessments including MRI scans, cognitive tests, and the collection of biological samples such as blood, saliva, urine, and spinal fluid. The aim is to find ways to predict who is most at risk of developing dementia and to develop early intervention programmes to prevent the disease.

Edinburgh is the only site where retinal images are being collected to gain information about changes in small blood vessels and nerve tissue at the back of the eye, as an indicator of what is happening to less accessible structures in the brain. More than 180 people have been recruited and imaged. The IA Core has led the development of bespoke software tools to analyse the different types of retinal imaging we collect in PREVENT including colour fundus images and optical coherence tomography scans.

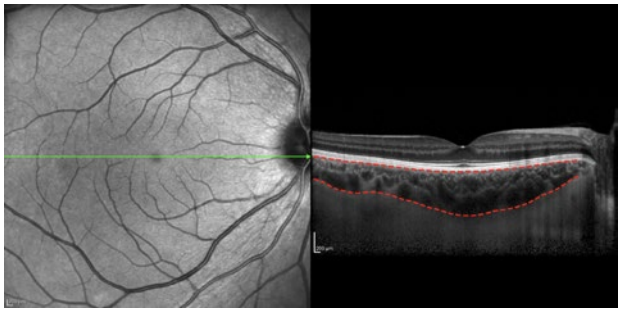


Figure: Analysing the choroid using OCT scanning.
The choroid is layer of small blood vessels underneath the retina that can be used as an indicator of microvascular health in the brain.

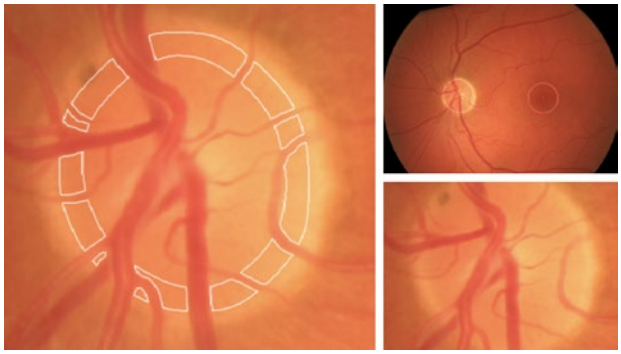


Figure: Analysing the appearance or pallor of the optic nerve head in colour fundus photography. A paler optic nerve can indicate a loss of nerve tissue indicative of neurogenerative changes occurring in Parkinson's and Alzheimer's.

Selected developments and partners

Key findings to date from the image analysis:

- The pale appearance of the optic nerve on fundus imaging was associated with enlarged perivascular spaces in the basal ganglia, suggesting that this analysis may provide insights into changes in brain health associated to small vessel disease in the brain
- The deeper lying choroidal vasculature at the back of the eye was progressively larger between groups of the PREVENT participants ordered by Alzheimer's risk factors
- APOE ε4 carriers had thicker choroids than non-carriers, and a similar trend was observed for those with a family history of dementia

(Gibbon et al 2024 & Burke et al 2025)

References

Burke J, Gibbon S, Low A, Hamid C, Reid-Schachter M, Muniz-Terrera G, Ritchie CW, Dhillon B, O'Brien JT, King S, MacCormick IJC, MacGillivray TJ. Association between choroidal microvasculature in the eye and Alzheimer's disease risk in cognitively healthy mid-life adults: A pilot study. Alzheimer's Dement (Amst). 2025 Jan 16;17(1):e70075. doi: 10.1002/dad2.70075. PMID: 39822299; PMCID: PMC11736711.

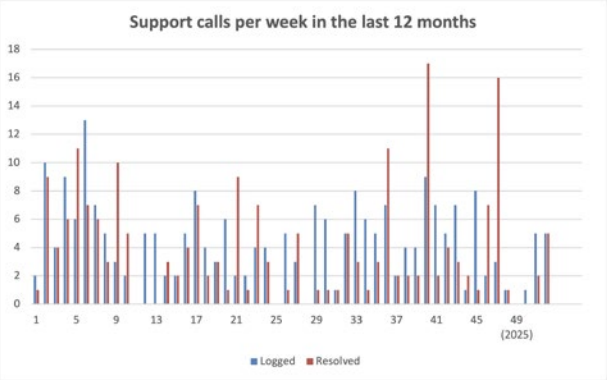
Gibbon S, Low A, Hamid C, Reid-Schachter M, Muniz-Terrera G, Ritchie CW, Trucco E, Dhillon B, O'Brien JT, MacGillivray TJ. Association of optic disc pallor and RNFL thickness with cerebral small vessel disease in the PREVENT-Dementia study. Alzheimer's Dement (Amst). 2024 Aug 8;16(3):e12633. doi: 10.1002/dad2.12633. PMID: 39119001; PMCID: PMC11307169.

Xu W, Mesa-Eguiagaray I, Morris DM, Wang C, Gray CD, Sjöström S, Papanastasiou G, Badr S, Paccou J, Li X, Timmers PRHJ, Timofeeva M, Farrington SM, Dunlop MG, Semple SI, MacGillivray T, Theodoratou E, Cawthorn WP. Deep learning and genome-wide association meta-analyses of bone marrow adiposity in the UK Biobank. Nat Commun. 2025 Jan 2;16(1):99.

CRFManager® and the IT Core

The IT team supports over 50 clinical research facilities across the UK.

In the last 12 months we have answered over 230 calls and enquiries for CRF Manager, a web-based resource management system primarily used for the administration of clinical research studies and other day-to-day aspects of facility management. Support tickets vary in their nature and time taken to resolve them. Some of them can be resolved in a matter of hours, while others can take days or weeks, depending on their complexity and the requester's response times. Overall, our average completion time is around three days, and our initial response time is within hours.



We also spend a significant amount of time running our software on our own infrastructure, performing server updates, security patches, data backups and data restore tests.

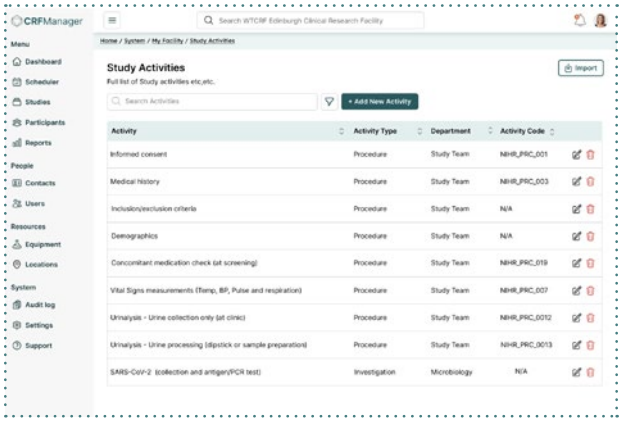
However, our main focus, has been the redesign of CRF Manager, where we have made some major improvements and implemented new features over the last 12 months.

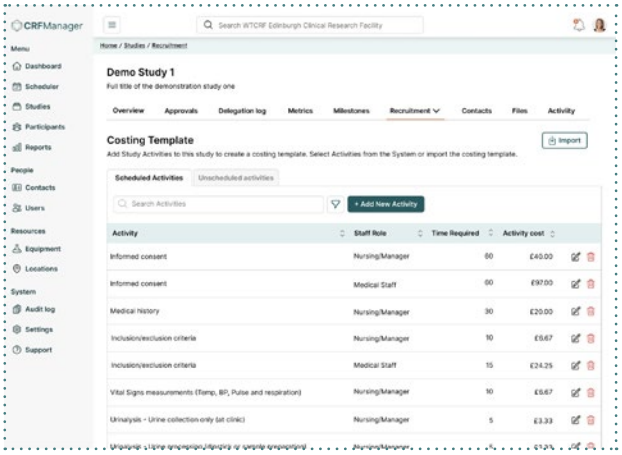
Selected developments and partners

We have held a number of demos to show our users our latest developments and gather feedback. Each time, the attendance has been great, and people have been very enthusiastic about the look and feel of the new software. A lot of attention has been paid to developing a software that is easy to use, but also has all the functionality that our users need to complete their daily tasks. It seems that our efforts have paid off so far as the feedback has been very positive.

The screenshots show how costs can be allocated, calculated and managed by activity in a specific study. They can be created manually within the software or imported from a costing template. Each field is easily searchable so they can be found quickly and edited if necessary. Additional filters are also available to search any field and categorise the table of results by type.

We are getting closer to a release date, but there is still a lot to be done and tested before we can confidently migrate our current users to the new platform.





References

Boyle LD, Miguelez-Crespo A, Paul M, et al. The NE/AAT/CBG axis regulates adipose tissue glucocorticoid exposure. *Nat Commun*. 2025;16(1):545. Published 2025 Jan 9. doi:10.1038/s41467-024-55693-x

Denham SG, Simpson JP, Diez F, et al. A practical approach to supported liquid extraction and measurement of 18 steroids in plasma and serum by targeted liquid chromatography tandem mass spectrometry. *MethodsX*. 2024; 12:102728. Published 2024 May 4. doi:10.1016/j.mex.2024.102728

Kyle CJ, Boyle LD, Nixon M, et al. Proof of concept for a superior therapeutic index of corticosterone compared with hydrocortisone in patients with congenital adrenal hyperplasia. *Eur J Endocrinol*. 2024;191(6):535-544. doi:10.1093/ejendo/lvae144

Lahti-Pulkkinen M, Räikkönen K, Basiukajc A, et al. Determination of steroid reference intervals in a pregnancy population. *J Steroid Biochem Mol Biol*. Published online February 6, 2025. doi:10.1016/j.jsbmb.2025.106691

McCarthy BE, Feng R, Torigian DA, et al. Epicardial Adipose Tissue Is an Independent Risk Factor for Mortality in Pulmonary Arterial Hypertension. *Chest*. Published online November 28, 2024. doi:10.1016/j.chest.2024.11.020

Ntshangase S, Khan S, Bezuidenhout L, et al. Spatial lipidomic profiles of atherosclerotic plaques: A mass spectrometry imaging study. *Talanta*. 2025;282:126954. doi:10.1016/j.talanta.2024.126954

Sandor LF, Huh JB, Benko P, et al. De novo steroidogenesis in tumour cells drive bone metastasis and osteoclastogenesis. *Cell Rep*. 2024;43(3):113936. doi:10.1016/j.celrep.2024.113936

Selected developments and partners

Lothian NRS Biorepository

Human tissue samples are a valuable resource in medical and scientific research, enabling development of new medicines and treatments, improving the detection of many different diseases and developing a better understanding of disease processes, thereby informing prognosis and allowing more accurate prediction of response to treatment.

Lothian NRS Biorepository, or the BioResource, was established in 2010 to provide an infrastructure to facilitate access to human tissue for research, either directly or indirectly, in accordance with appropriate governance and regulatory requirements. Since then, the Biorepository has provided support and governance on collection, storage and release of tissue from informed, consenting patients, as well as facilitating access to tissue held within NHS diagnostic archives.

Research tissue bank

As a REC-approved Research Tissue Bank (Ref: 20/ES/0061), the Lothian NRS Biorepository has approval for the collection, storage, provision and use of tissue and associated data for research, subject to certain conditions. 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. The Biorepository also provides access to pathology archival specimens, with appropriate governance and approvals in 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

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 to the rest of the UK.

Selected developments and partners

This accreditation uses governance standards adopted from those used by the Human Tissue Authority for the licensing of research tissue banks in England, Wales and Northern Ireland.

Lothian Biorepository is currently accredited until 31 January 2026, subject to the submission of annual certification.


NHS SCOTLAND
CENTRAL MANAGEMENT TEAM

NHS Research Scotland (NRS) Lothian

CERTIFICATE OF ACCREDITATION
01/02/23-31/01/26

We confirm NRS Lothian Biorepository working on behalf of NHS Lothian has met the NRS Accreditation Standards. The Accreditation period lasts for 3 years and is subject to an Annual Declaration of Compliance.

Stephen Kelly PhD, Science Manager, NRS-CMT

Professor James Ironside, Chair, Independent Expert Panel

Human Tissue legislation in Scotland differs from that in the rest of the UK. The NRS Biorepositories are therefore accredited by an Independent Expert Panel using criteria comparable to those for research tissue bank licensing in England, Wales and Northern Ireland by the Human Tissue Authority.

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

The Biorepostory team

Our experienced technical staff are embedded within Laboratory Medicine at both the Royal Infirmary and Western General Hospital sites and have close links to Pathology and Blood Sciences. In addition, we are supported by a core group of clinical pathologists who readily provide expert advice and guidance. As a result, we can offer expert pathology, technical and histological support as required, as well as research access to blood and other samples from Blood Sciences and Virology.

The management group advises on and assists with legal, ethical and regulatory requirements regarding the use of human tissue or patient samples in research.

Tissue provision

The Biorepository continues to support requests from a wide range of research projects, both academic and commercial, and for a wide range of tissue types and research areas (note that tissue is an encompassing term that includes blood and other bodily fluids). Projects supported include pilot studies, eligibly funded research, and commercial projects or collaborations, ranging from local spin-out to large pharmaceutical companies.

The majority of requests received continue to be for tissue stored as FFPE blocks, primarily from cancer, but we have also received requests for prospectively collected fresh surplus material, as well as ex-diagnostic samples such as plasma and serum. In addition, the provision and use of microscopic slides to create de-identified images for digital pathology and related artificial intelligence research is an increasing area of activity, which the BioResource is well placed to support with the infrastructure we have in place.

The Biorepository supports the retrieval and provision of archival diagnostic samples for patients enrolled in clinical trials, both locally and at external sites, thus ensuring greater access for patients to participate in trials.

We participate in national and international research programmes and initiatives such as SHARE, research ongoing via the CRUK Scotland centre and wider initiatives such as MANIFEST (UKRI) and KATY (EU).

We are working with DataLoch and other local infrastructure such as the Cancer Informatics team to streamline the process for the provision of tissue-associated data. The aim is to ensure that researchers can access linked data as promptly as possible via the appropriate means, access, and governance.

Selected developments and partners

Lothian Biorepository advanced pathology laboratory

A major development for the Biorepository during the past year has been to establish the Bioresource advanced pathology laboratory.

In addition to providing an ethical and governance framework to enable the appropriate use of tissue surplus to diagnosis, the Biorepository can also provide additional services on a cost recovery basis. We are aware that the provision of tissue is just a start and that further studies are often planned, which is why we have actively sought to expand the services we offer to support researchers. The Biorepository advanced pathology laboratory is staffed by two senior biomedical Scientists, both of whom are registered healthcare scientists, providing an extra level of assurance in terms of quality management and good practice.

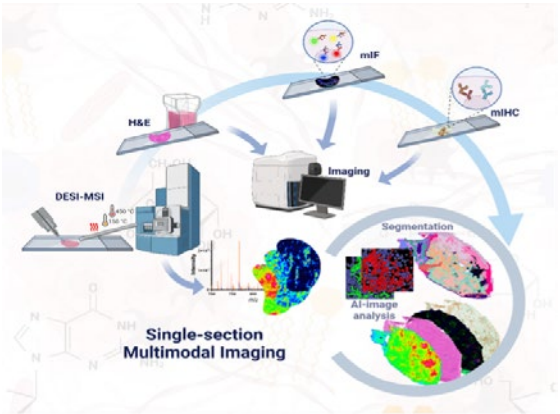
The laboratory has ready access to a range of equipment and techniques that are key to expanding and enhancing the capabilities of the BioResource.

Advanced pathology laboratory support for research

This laboratory and the experience of the staff means that the Biorepository can offer a range of additional services, as listed below. The aim is to ultimately provide integrated support to research groups throughout the 'tissue research' pathway, from tissue provision through to laboratory analysis.

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



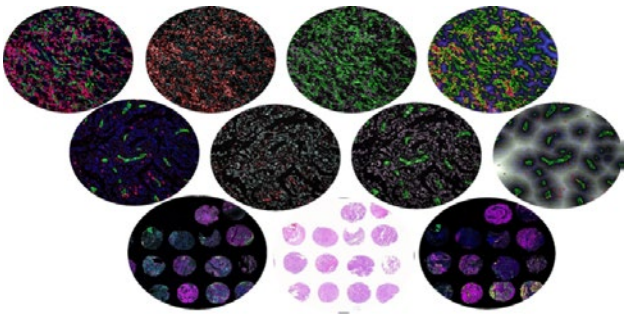
(Ref. Zickhur et al. 2024, https://doi.org/10.1007/s00216-024-05339-0)

The purpose of the laboratory is to support efficient use of precious tissue, and to facilitate good research. To explore whether the advanced pathology laboratory can support your research please contact the Biorepository to find out more.

Selected developments and partners

Digital pathology

The laboratory 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. This complements two Zeiss Axioscan microscopes that are used for digitisation of whole slide, five channel, multiplex immunofluorescence images. This capability to provide de-identified WSI and ready access to and support from expert pathologists has already improved the ability of NHS Lothian and academic partners to participate in digital pathology projects. In addition to this, we have been able to provide a high throughput scanning service for local researchers for other projects.



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.

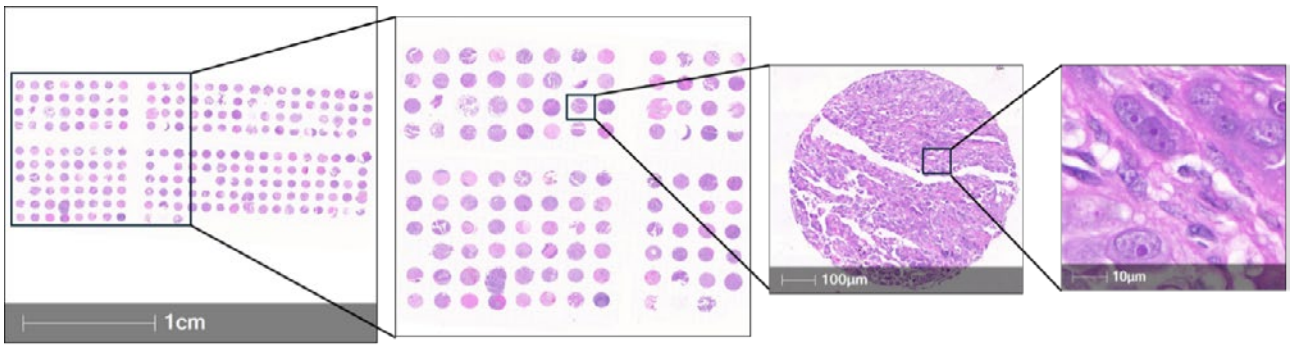
Middle Row- Same format as above, demonstrating low immune cell infiltration.

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

Tissue Microarray construction

The BioResource also provides bespoke Tissue Microarrays (TMAs) using a 3DHISTECH TMA Master 2 tissue microarrayer. During the past year we received numerous requests for the creation of TMA from various tissue types, tailored to the researcher's requirements. The purpose of these have traditionally been for immunohistological analysis such IHC, FISH or ISH. More recently, however, requests have focused on the provision of TMA for use in proteomics and spatial transcriptomics projects, allowing research groups to maximise the number of tissue samples that can be analysed and take advantage of this evolving technology. We are well placed to support this through the expertise within our group and close links with pathologists and other supporting research infrastructure.

In addition to this we have a collection of previously constructed, stored TMAs with linked clinical data, that can be accessed for research.



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.

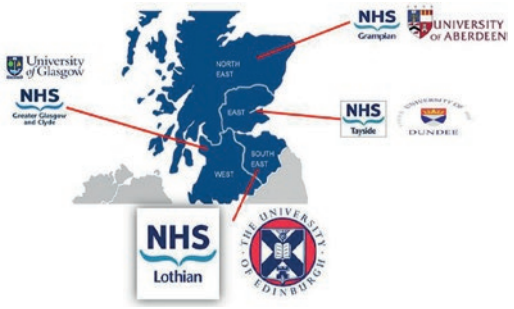
Selected developments and partners

Scottish Biorepository network

Lothian Biorepository is a key member of the national NRS Biorepository network established by the Chief Scientist Office (CSO) and NHS Research Scotland (NRS) in partnership with the other health boards in Scotland. The Biorepository works with colleagues at other nodes to provide streamlined means access to tissue from across Scotland for the research community.

This national approach encourages the use of tissue in research and boosts the availability of tissue, ending the need for researchers to source tissue from more than one NHS board.

Through engagement with the CSO, NRS and other health boards, we continue to develop the network and increase awareness, efficiency, and engagement with the research community.



Streamlined pathway

Feasibility

- One application across Scotland
- Collated feedback to applicant
- National coordinated costs to reflect project requirements

Assessment

- Clinical and pathology support
- Scientific and technical review
- Accredited tissue governance and ethics provided

Delivery

- Wide range of tissue services
- National coordination of tissue acquisition
- National material/data transfer agreement

Researchers interested in using patient samples from NHS Lothian for research 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: supporting the responsible and secure use of data to improve health and social care

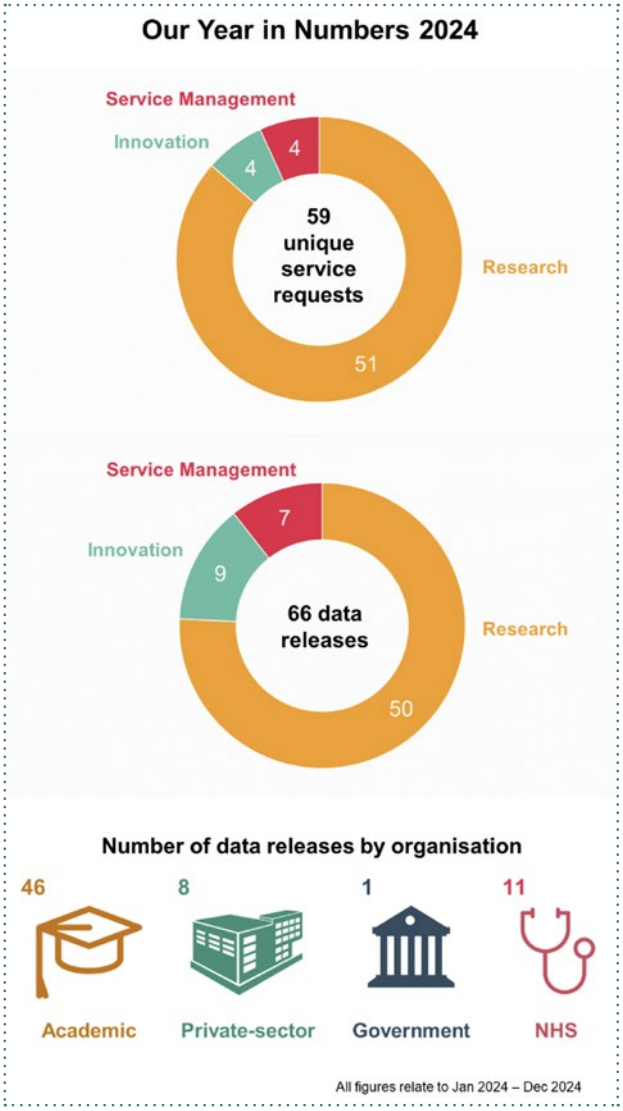
Introduction

DataLoch is a data service that has been developed by the University of Edinburgh and NHS Lothian to bring together routine data collected as part of people's day-to-day interactions with health and social care services. Their ultimate aim is to support service-management, research, and innovation projects that will make a tangible difference to the lives of patients and care-service users.

A crucial part of DataLoch's work is its focus on making data research-ready. Over the past year, they have incorporated hospital inpatient and discharge prescriptions data – and aligned these to community prescribing data – to make the connections more intuitive for researchers and offer new study and service-management opportunities.

They have also integrated more non-medical data in their repository – such as geospatial (location-related) data – to enhance the potential for exploring social and other factors that can impact population health and wellbeing. Furthermore, researchers are actively invited to contact the DataLoch team to discuss NHS Lothian hospital data that may not yet be in their metadata catalogue but could provide valuable insights for those willing to work with these data.

Beyond these additions to the general repository, DataLoch has worked closely with a cardiology research group at the University of Edinburgh to develop the DataLoch Heart Disease Registry: a themed dataset that sits alongside the Respiratory Registry to improve the user experience for all researchers seeking data related to these specialised areas. In addition, DataLoch's new Natural Language Processing programme aims to safely extract further insights from routine data without compromising confidentiality.

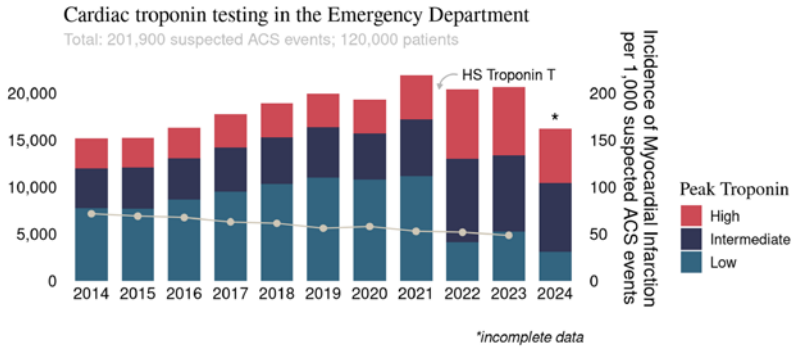


Discover more about the service on the following pages or visit their website to start a conversation about your project: DataLoch website

Selected developments and partners

Examples of how we support research and researchers

The DataLoch Heart Disease Registry: improved support for cardiology research



Over the past decade, significant advances have been made in the assessment and management of patients with possible myocardial infarction (heart attack) and other acute cardiovascular conditions.

To further support these developments, we have collaborated with clinicians and researchers in cardiology to develop the DataLoch Heart Disease Registry. To our knowledge, this is the first curated registry of patients with possible myocardial infarction that offers de-identified health care data for public interest research through a Secure Data Environment. Visit the DataLoch website to discover more about the DataLoch Heart Disease Registry.

Based on data within the DataLoch Heart Disease Registry, the electronic Frailty Index (eFI) has been shown to be a good predictor of patients at high risk of death following myocardial infarction. Therefore, automatically calculating eFI through GP data offers a low-cost method of identifying more vulnerable patients at the point of presentation to hospital, providing an opportunity to better tailor their heart attack care.

View the open-access article.

Safely securing greater value from routine data through Natural Language Processing

Health data can be categorised as either structured (i.e. with a standard format, such as codes for conditions and treatments) or unstructured (e.g. clinical free-text notes). Currently, most research and development using GP and hospital records relies on structured data. Unstructured data hold more nuanced details for understanding disease and treatment, but they are currently under-utilised for research because they often contain patient-identifiable information, or details that can combine to make someone identifiable, such as mentions of family members or unusual locations of accidents.

At DataLoch, we have established an ambitious Natural Language Processing (NLP) programme to safely secure the value of unstructured data for the NHS as well as for research without compromising confidentiality.

Discover more about DataLoch's NLP objectives.

Selected developments and partners

Research enabled by DataLoch: predicting dementia through electronic health records

With dementia rates increasing worldwide, predicting the risk of future dementia is essential for improving prevention strategies. Using linked routine primary and secondary care data between 2009 and 2023, this project sought to evaluate machine-learning predictions of future dementia diagnosis in a cohort of 144,113 older people, who were initially free of cognitive symptoms.

The researchers found that the most important predictive factors were age, deprivation, and frailty. At the end of the 13-year follow-up period, dementia was diagnosed in 32% of the population identified at highest risk. This study demonstrates the value of personalised estimations of future dementia risk using routine data and opens a pathway for proactive care measures for individuals in the pre-symptomatic phase.

View the open-access article.

Collaborative working: tackling environmental impacts on childhood respiratory health

Led by Dr Olivia Swann, DataLoch is collaborating on a novel project to investigate the proportion of pre-school respiratory infections that could be avoided if every home was adequately heated.

The aims of this work require the inclusion of non-health data to effectively explore contributing factors. So far, we have been able to link energy poverty-risk data from prepayment meters with health data for the first time.

Following this initial success, we are now developing an environmental dataset which contains key data on air pollution and weather linked to postcodes, as well as the energy efficiency of an individual's home, which will be available for other research projects.

Find out more on the DataLoch website.

Working with the Public Reference Group

As a critical element of its structure, in early 2024 DataLoch updated its Public Reference Group and formed two parallel panels involving a total of over 20 members of the public in Scotland.

The Communications Advisory Panel acts as a sounding board to ensure that public-facing communications have a plain language basis. This has been particularly important when DataLoch has published new news items and refreshed its website. They now have an updated mission statement for their homepage: "Supporting the responsible and secure use of data to improve health and social care."

The Public Value Assessment Panel continues to provide valuable public perspectives in the assessment of all research and innovation applications received by DataLoch. This assessment process is a collaborative endeavour and panel members review its success and limitations on an ongoing basis.

Selected developments and partners

> "Supporting the responsible and secure use of data to improve health and social care."
>
> Communications Advisory Panel mission statement

Recent adjustments include ensuring that two panel members actively work together in reviewing applications, while each lay summary is specifically assessed and advice is given on how it should be improved before it is used in the public domain.

DataLoch Public Reference Group members consistently provide invaluable insights and continue to offer important support for the service's overall aims.

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 the datasets hosted by DataLoch can be found on their website.

If you do not see the data for your project through the link above, please contact the team directly. They can provide 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 team.

ECTU and research colleagues said a fond farewell to Professor John Norrie in July 2024, celebrating with a lovely get-together and lunch in our beautiful new Usher Building spaces.

Professor Steff Lewis, Personal Chair of Medical Statistics, succeeded John as Interim Director while the process of appointing a new Director is underway.

Professor Steff Lewis

Supporting the clinical trials strategy

We have made a great progress in aligning our project portfolio with the University's clinical trials strategy since its launch in January 2021. We have successfully increased the proportion of randomised control trials in our portfolio, with this category now accounting for over two- thirds of the ECTU project portfolio.

The Clinical Trials Oversight Group (CTOG) has launched a survey to give stakeholders in the clinical trials pathway the opportunity to provide feedback to help review and refresh the clinical trials strategy, which coincides well with the timing of the appointment of a new ECTU Director.

ECTU Start-up Specialist team (SuS) – one year on…

The SuS team's processes and structure have evolved over the past year, including the integration of the SuS team into the Research Development team in August 2024. This has been a very positive step, enabling ECTU to provide a more closely integrated service to support projects at the earliest stages of their lifecycle (grant application and project planning), as well as working to streamline communications with internal and external stakeholders. Over the past year, the SuS team identified all the key stakeholders who are involved in the planning/set-up phase of

Selected developments and partners

studies, and developed a clear understanding of the roles and responsibilities of each support service. The SuS team now have a clearer picture of what is working well, where the gaps are and how they can best help to fill these gaps while working within the current boundaries of what is possible within other stakeholder services to provide the best possible support to the Chief Investigators and projects. One such gap related to the need for statistical support for the SuS team and this was addressed by the end of 2024.

Six projects have benefited from early support from the SuS team in the first year, with successful handovers to the ECTU project delivery teams. The following is a summary team's reflections on its first full year and the lessons learned from its involvement in the six projects:

"Each one of the six studies was complex in nature, raising significant challenges and requiring considerable input. Navigating the regulatory, ethical, contractual and study conduct requirements of each study was challenging at times. Limited expertise in some of the more specialised studies initially provided some challenges, but we learned quickly and the early involvement from the Trial Planning Team (TPT) resulted in the identification of some significant risks and issues that could have resulted in lengthy post- grant activation delays. For example, the TPT introduced early feasibility for the ASPIRING, RESTORE and INTACT-2 studies. This involved collecting and comparing data with the aim of improving recruitment, logistics and other project execution challenges at a much earlier stage in protocol development. Based on the benefits identified, this early feasibility will be implemented for all future high recruiting, multicentre studies. Our evaluation of the first six studies has shown the huge benefits to be gained in early protocol development. This critical phase of project execution helps to identify the challenges and potential gaps that will need to be addressed. By identifying these early we can work with other stakeholders to provide solutions to minimise the barriers that can prevent a project from progressing to the next stage of the Stage Gate process. A review of our progress is currently underway to further improve our processes and better support future studies and we look forward to what the next year will bring!"

> "Our evaluation of the first six studies has shown the huge benefits to be gained in early protocol development."

ECTU hosting the Medical Device Manufacturing Centre (MDMC) Conference in May 2025

ECTU has been part of the Medical Device Manufacturing Centre collaboration for a number of years and we are currently undertaking phase two of the project. This project, funded by Scottish Enterprise, brings together five Scottish institutions to provide medical device developers and manufacturers with advice, technical expertise and facilities to turn medical device concepts into full commercial products. ECTU will host the annual MDMC Conference on 28 May 2025 at the James Watt Centre, Heriot Watt University.

Selected developments and partners

Supporting researchers

In response to feedback from our research colleagues we have updated our website to include more - Guidance for ECTU Chief Investigators | Usher Institute. In this section, you will find the latest version of the Guidance for Chief Investigator document, information on coaching/peer support, the Clinical Director and the Clinical Advisory Group, as well as a section on resources for Chief Investigators.

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

Recent publications involving ECTU

The impact of our research and commitment to advancing healthcare can be seen through our publications. These are a small selection of recent publications in which ECTU has been involved:

Early intervention in patients with asymptomatic severe aortic stenosis and myocardial fibrosis: the EVOLVED randomized clinical trial- PubMed

Intravenous Lidocaine for gut function recovery in colonic surgery: a randomized clinical trial | surgery | JAMA | JAMA Network

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

Selected developments and partners

Patient and Public Involvement in Research 2024-2025

In 2024-2025 our team has expanded again! Alisa Anokhina joined us in September 2024 to work with Researchers in the College of Science and Engineering and those working on pre-clinical topics. The team is pictured below:

Carol Porteous, Patient Public Involvement Lead.
carol.porteous@ed.ac.uk

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

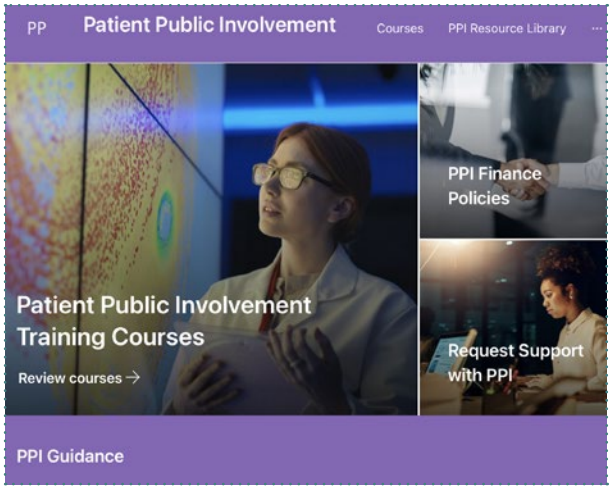
Collaborative working

During 2023-2024 the PPI team has continued to provide strategic support to NHS Lothian, the University of Edinburgh and across Scotland, with a focus on building capacity to meet the growing demand for PPI support.

These activities have included:

- We continued to support education events such as Edinburgh Clinical Research Methodology Course, Edinburgh Clinical Trials Methodology Course and the new NHS Lothian Research days
- AI for Health Conference – invited speaker
- Introduction to PPI for CSE research support and development staff
- PPI workshop for PhD students and early career researchers from QMRI
- Cross-college introduction to PPI at the Good Research Practice Week

Additionally, members of our team attend and/or chair departmental and working group meetings to either bring a PPI perspective or advice to strategic discussions or facilitate collaboration between PPI professionals working across different areas of the University.



Selected developments and partners

Chronic Obstructive Pulmonary Disease (COPD project)

Throughout 2024 the PPI team, critical care and respiratory colleagues worked to establish a large COPD PPI Group from some of our most underserved communities. This group of 30 COPD patients, carers and family members has now met three times, and we will continue to work with them on funding applications and a new digital healthcare pathway for NHS Lothian. Working with underserved communities can be challenging and time consuming but this project has shown that working with our local communities is an asset and an inspiration that drives our work, and we anticipate that our COPD group will be driving our research forward as we continue to put their lived experience at the heart of this research.

Changing culture

A central focus of our activity over the past year has been to keep abreast of developments in UK Research and Innovation (UKRI) and the changing expectations of two major funders: Engineering and Physical Sciences Research Council (EPSRC) and Medical Research Council (MRC). These changing expectations mean that it is necessary to explore what is required of the PPI team. Alisa Anokhina is undertaking the Edinvolve project which was approved by EMREC in February 2025. The aim of the project is to understand the PPI experiences, attitudes and support needs of researchers across the University. We will conduct a series of semi-structured interviews from a diverse cohort of researchers and support staff to inform the training, support and resources we provide. Crucially, the study will enable us to understand common barriers and facilitators for cultural change - this is particularly timely given the changing expectations of funders, as we outlined in the 2024 report.

> "The need for PPI is only going to grow, and we are committed to driving the necessary culture change hand in hand with our public partners and our research community."

Although we will be interviewing researchers from all three colleges, our aim is to focus on CSE to understand the needs of basic and pre-clinical researchers. The study is expected to run until February 2026.

The need for PPI is only going to grow, and we are committed to driving the necessary culture change hand in hand with our public partners and our research community.

CMVM Impact Seed Funds

In 2024, we supported several successful applications to the CMVM Impact Seed Fund and one of our team, Sammy Waite was awarded one of the Seed Funds, to explore language and how to open up conversations about research in order to work with our underserved communities. This work will take place with underserved communities who have little to no experience of health research or who do not trust the health service.
We hope to share the findings of this project in 2025. Our Patient Advisory Group members were also reviewers of this years Seed Fund applications, providing a critical patient and public perspective.

Selected developments and partners

Funding applications

Each year we work with many researchers applying for funding from various funders and many of these projects are successful in their bid for funding. Over the past year we have supported projects in:

- Mental health
- Maternal health
- Sexual health
- Surgical research
- Diagnostic devices

We have supported applications to funders including, EPSRC, MRC, Wellcome Trust, NIHR and a host of charity funders.

National PPI conference

In March 2025, we organised and supported (in collaboration with colleagues in NHS Research Scotland) the second Scottish PPI conference, in Stirling. With over 70 submissions, and over 180 attendees (almost doubling our 2024 venue) this has become an established yearly event and bringing together the community is a major part of our approach to changing culture and solving issues with and for the PPI community in Scotland.

Education and training

During the year we continued to deliver our suite of PPI training courses as part of the Edinburgh Clinical Research Facility Education Programme, training over 150 people on our PPI training courses alone.

Visit the ECRF website for more information on our courses.

We believe that the courses are a critical component in supporting PPI activities across the UoE and NHS Lothian, but to meet the changing expectations of funders we are offering a revised range of courses throughout 2025.

Communications

In order to meet the growing demand for PPI, we are working to raise awareness of the PPI support resources and training available. As part of this, we have:

- Developed a new PPI SharePoint with resources and guidance for a variety of research areas and PPI activities.

Throughout 2025, we will be revising and developing our communication activities to offer support for researchers and inspire our community.

Selected developments and partners

Edinburgh Imaging Facility

The Edinburgh Imaging Facility has installed a Siemens Quadra Total Body PET scanner as part of a £32 million investment to form part of the National PET Imaging Platform

Transforming clinical research

In late 2024, Edinburgh Imaging QMRI facility became home to the Total-Body Positron Emission Tomography (PET) facility for the north of the UK. The installation of the Total Body PET scanner will capture faster, more detailed images of patients' entire bodies, using less radiation than existing scanners.

The Scotland scanner forms part of a new National PET Imaging Platform (NPIP) along with the scanners housed at the Royal Free London NHS Foundation Trust and King's College London.

Unlocking treatments

The NPIP platform, a partnership between the Medicines Discovery Catapult (MDC), the Medical Research Council (MRC) and Innovate UK, aims to advance healthcare research and clinical trials, and unlock new treatments for complex diseases such as cancer, cardiovascular and neurological diseases. These scanners offer a transformational step-change in PET imaging research, unlocking new imaging pathways for drug development.

Collaborative approach

The scanners are part of a £32 million investment in the ground-breaking technology by the UK Government, through the UK Research and Innovation (UKRI) Infrastructure Fund.

> "Current PET technology leaves large sections of the human body out of the field of view, requiring the patient to be repositioned multiple times to obtain a full-body view. Supplied by Siemens Healthineers, the NPIP Total Body PET scanners capture superior images of a patient's entire body in near real time."

The facility, based at the Royal Infirmary in Edinburgh, is a partnership between the Universities of Edinburgh and Glasgow. The Scottish facility brings together the strengths of novel imaging methods developed in Glasgow with clinical translation on the Edinburgh-based scanner.

NPIP's Total-Body PET scanners are more sensitive than current technology and are already revealing new insights into biology and disease. The application of Total Body PET imaging will be expanded over the next few years in partnership across the network, collaborating with industry in large population national research studies.

Selected developments and partners

PET scanning is a non-invasive imaging technique that can detect the early stages of disease. Current PET technology leaves large sections of the human body out of the field of view, requiring the patient to be repositioned multiple times to obtain a full-body view. Supplied by Siemens Healthineers, the NPIP Total Body PET scanners capture superior images of a patient's entire body in near real time.

Higher volume

The new scanners are also faster, exposing patients to much lower doses of radiation, meaning that more patients - including children - can take part in clinical trials to improve our understanding of diseases. The speed of Total-Body PET scanners means that the NPIP scanners will be able to scan more patients, increasing the scale and impact of clinical research projects across the whole of the UK.

This richer picture of human health will help researchers to develop new diagnostics, improve the quality and speed of drug discovery, and bring them to market faster to benefit patients.

NPIP's network of infrastructure and intelligence will provide a complete picture of patients and how they respond to new drugs and treatments.

Uniquely, it will also connect insights from many research programmes and trials. In doing so, it will begin to build a rich bank of data that the wider PET community can access for the benefit of patients.

Total-Body PET scanner.

> "The speed of Total-Body PET scanners means that the NPIP scanners will be able to scan more patients, increasing the scale and impact of clinical research projects across the whole of the UK."

Selected developments and partners

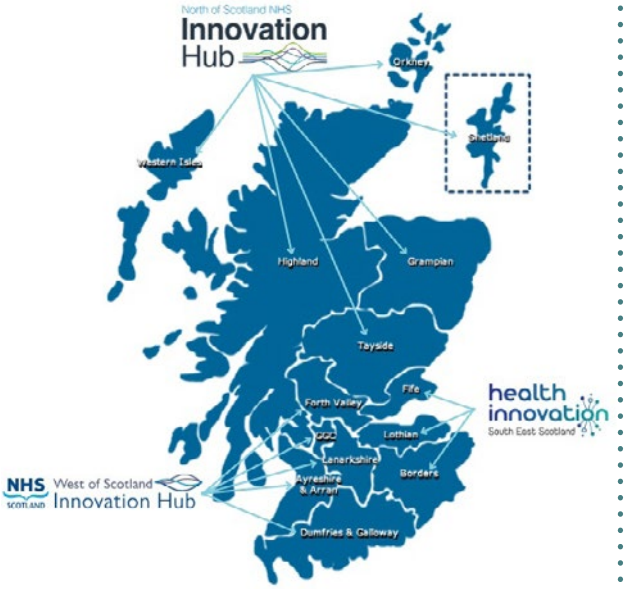
Health Innovation South East Scotland (HISES) – who we are and what we do.

The Chief Scientist Office (CSO) **funds three Regional Innovation Hubs, covering all 14 territorial NHS boards in Scotland. Health Innovation South East Scotland (HISES) is the Innovation Hub based in the South East region, created to deliver the Government's vision to utilise the innovation process to deliver a healthier and wealthier nation for the future. Tracey Gillies, Medical Director in NHS Lothian is the current Executive Director Lead for Innovation, overseeing the core HISES Team based in NHS Lothian, with local Innovation Leads also funded in NHS Borders and NHS Fife.**

Regional Innovation Hubs provide the capacity and capability for the NHS to engage in innovation activity and create the conditions to support the development, delivery, and adoption of new technologies within the health and social care system.

They provide an essential infrastructure for industry, academia and the third sector to collaborate with the NHS, translating research into innovative products and services that can directly benefit patients and improve the NHS. They offer life science companies the opportunity to evidence the potential impact of their technology through access to expertise, governance, and technical capabilities such as trusted research environments, helping them to grow by co-developing within NHS Scotland.

Innovation Hubs allow innovative solutions to be tested in a real-world test bed environment to ensure they are fit for purpose clinically, financially and operationally through evidence-based evaluation to determine any advantage over what is currently available. It is difficult to obtain this evidence without access to patients or clinical facilities to develop and test prototypes or new models, so the Innovation Hubs act as an enabler for this in addition to working on defining the value proposition of any innovative solution.



Role of Innovation Hubs

- Turning ideas and knowledge into products and services
- Facilitate collaborations – co-design, co-develop and co-deliver with NHS, academia and industry
- Provide leadership, support, test bed environment, regulation support, leverage funding and access to NHS teams, healthcare settings, data and governance
- Allow innovators to refine solutions, build evidence, inform strategy and develop thinking, and support scale-up and mainstreaming
- Don't procure/implement solutions already on market, don't provide large-scale business as usual services

Selected developments and partners

National Open Innovation Activity

Since June 2022, nine open innovation competitions have been launched by the CSO Innovation team to address priority challenges faced by NHS Scotland through the development of innovative solutions. Three of these national challenges are being managed by the HISES team: Mental health and Women and children's health in NHS Lothian and Reducing drug deaths in NHS Fife.

Mental health

This innovation challenge aimed at **innovating mental health services in Scotland** launched in June 2022 as part of a two phase competition to develop disruptive innovative solutions that deliver sustainable, accessible, and equitable mental health services.

Phase 2 started in October 2023 for a 12-month period and will come to an end in summer 2025. A total of three companies from Phase 1 were selected to carry out prototyping, piloting, testing and validation of new or improved products, processes, or services in environments representative of real-life operating conditions.

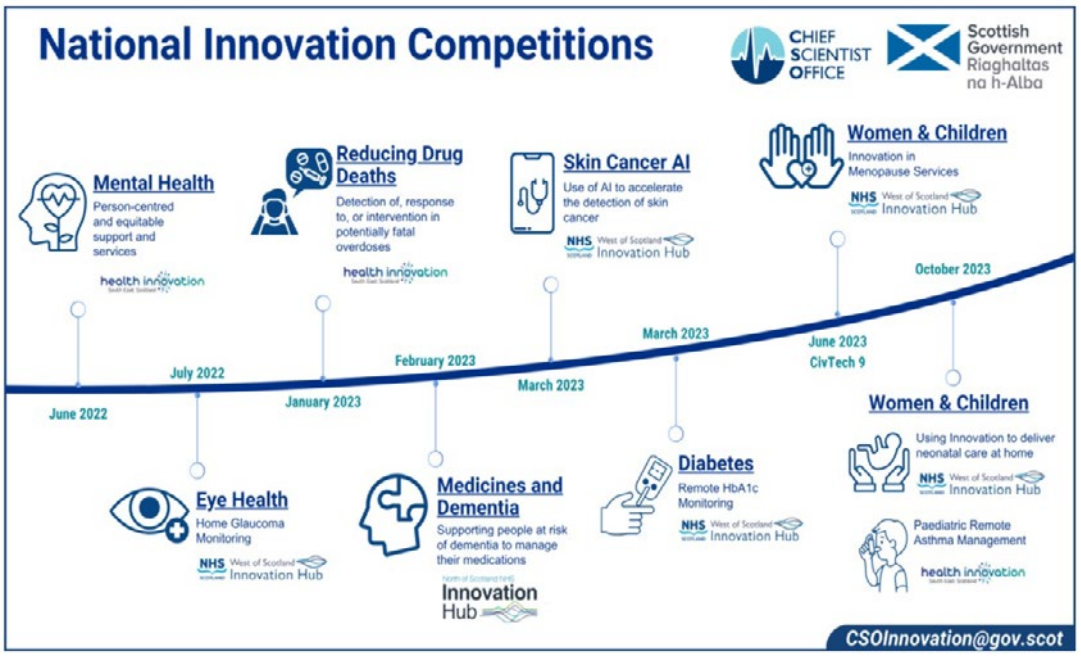
HISES are working with the company **Wysa** who have developed a clinically validated app which uses AI to support emotional health and wellbeing. Phase 2 user testing and evaluation is currently underway with the app being rolled out across 6 secondary schools in Edinburgh and 5 secondary schools in Fife, with over 700 downloads across these sites. Data collected so far suggests that around 95% of users return to the app after their first session. Here is a recently published **article in the Sunday post** with further information on their work and the use of AI therapy.

Paediatric Remote Asthma Management

The **Children and Young People Remote Asthma Challenge** launched in October 2023 and focuses on several aspects of care of children and young people with asthma (5 to 18 years). Phase 1 concluded in late 2024 with two companies participating. Both Phase 1 companies were successfully awarded contracts for prototype development and early clinical evidence to refine their solutions, foster meaningful collaborations, and ultimately deliver tangible benefits to patients and the care they receive. We expect Phase 2 to start in Spring 2025.

> "Three of these national challenges are being managed by the HISES team: Mental health and Women and children's health in NHS Lothian and Reducing drug deaths in NHS Fife."

Selected developments and partners



Reducing drug deaths

In support of the UK's Drugs Strategy, From harm to hope, and Scottish Government's National Mission on Drugs, the UK Office for Life Sciences and the CSO are funding the Reducing drug deaths innovation challenge to develop disruptive innovative solutions focused on detecting of, responding, and intervening in potentially fatal drug overdose episodes. The challenge launched in September 2023 and is being delivered across the four UK nations. Phase I concluded in January 2024, providing 11 companies with up to £100,000 in funding over a period of four months to collaborate with Test Bed research partners across the UK's devolved nations. The initiative focused on the development of innovative technology solutions to reduce drug-related deaths, and brought together a broad consortium of leading universities, healthcare providers, charitable organisations, and industry specialists from England, Scotland, Wales, and Northern Ireland.

Seven companies have been selected to progress to Phase 2, with a budget of up to £500,000 each, commenced in August-September 2024 and will run for 12 months. Phase 2 projects will demonstrate the prototype in a representative environment that will have the potential to be implemented in a real-world environment.

Across the region, there are 30 live innovation projects within the HISES Portfolio including local, regional, and national initiatives. HISES support projects onto the Accelerated National Innovation Adoption (ANIA) Pathway.

Selected developments and partners

Innovation project delivery spotlights

NHS laboratory specimens delivered by drone for first time by project CAELUS

In August 2024, NHS laboratory specimens were delivered by drone for the first time during live flight trials between the Edinburgh BioQuarter next to the Royal Infirmary of Edinburgh and Borders General Hospital in Melrose. These trials are part of project CAELUS, a national innovation project aiming to test the use of drones as a way of delivering vital medical supplies, including essential medicines, blood, samples, and other crucial healthcare items across Scotland.

Currently, laboratory samples which inform urgent clinical decision-making are transported by road and can take up to five hours between NHS Borders and NHS Lothian. Innovation activity conducted by project CAELUS could see this delivery take 35 minutes, enhancing the transport provision, particularly for rural areas.

"Across NHS Lothian, we are continually exploring ways to innovate and enhance our patient experience. Lothian and the surrounding areas are very diverse, from city to country and coastal living. Drones could play an important role in helping to transport samples for testing or speed up the delivery of critical medical supplies. These exciting trial flights have been a collaborative effort between our clinical leads, South East Innovation Hub and partner organisations and I look forward to seeing further developments with this project."

Miss Tracey Gillies, Medical Director and Executive Lead for Innovation, NHS Lothian

Read press release.

> "Drones could play an important role in helping to transport samples for testing or speed up the delivery of critical medical supplies."
> Miss Tracey Gillies, Medical Director and Executive Lead for Innovation, NHS Lothian.

HISES team at NHS Lothian landing site.

HISES team at NHS Borders landing site.

Selected developments and partners

NHS Lothian gives patients access to AI physiotherapy in UK-first

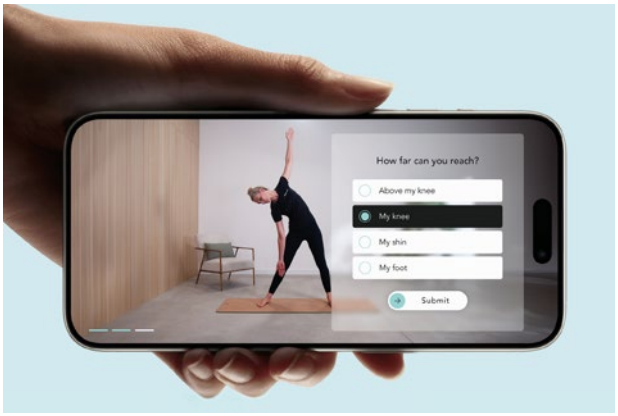
NHS Lothian is the first NHS organisation in the UK to make the new AI clinic, called Flok Health, available to patients across a range of community healthcare settings. The new service has been deployed as a collaboration between Lothian, Flok, and HISES.

Flok have developed an automated digital clinic to deliver gold standard multidisciplinary Musculoskeletal (MSK) pathways on a population scale. Flok's technology – which incorporates a UKCA-marked software medical device – streams interactive generated video appointments direct to patients through a smartphone application.

The NHS Lothian pilot means that anyone registered with any of the 116 GP practices within NHS Lothian can now self-refer directly to Flok's digital MSK clinic via existing self-referral portals or can be referred by participating GP practices. This is the first large-scale pilot in the UK and an exciting opportunity to explore how technological developments such as Flok can complement the range of healthcare services for people with MSK complaints.

Read press release.

Watch STV broadcast.



> "The NHS Lothian pilot means that anyone registered with any of the 116 GP practices within NHS Lothian can now self-refer directly to Flok's digital MSK clinic via existing self-referral portals or can be referred by participating GP practices."

Contact us

Email HISES | HISES website | HISES LinkedIn profile

accord
Academic and Clinical Central Office
for Research and Development

THE UNIVERSITY of EDINBURGH

NHS Lothian

ACCORD

Usher Building

The University of Edinburgh

5-7 Little France Road

Edinburgh BioQuarter - Gate 3

Edinburgh

EH16 4UX

Website: **www.accord.scot**

Contact: **enquiries@accord.scot**

Director of Research & Development

Professor Alasdair Gray

Alasdair.Gray@ed.ac.uk

R&D Deputy Director

Fiona McArdle

0131 242 3335

Fiona.McArdle@nhs.scot

Cover image: ©Hufton+Crow
Design: **Graphic Design Service**, ISG, The University of Edinburgh.