

Research, Innovation and Knowledge

Annual Report 2023-2024



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1. Executive Summary



Dr Christopher McKennaMedical Director and Executive Lead for Research,
Innovation and Knowledge

As the Executive Lead for Research, Innovation and Knowledge (RIK) it is my absolute pleasure to introduce the 2023/24 RIK Annual Report. This report is a reflection of the significant, high-quality work undertaken by the RIK team as well as those enthusiastic clinicians and staff across NHS Fife who make research and innovation a priority in their career portfolio. NHS Fife is developing a growing reputation and profile for high quality research and innovation support and activity.

Our busy clinical research facilities allow people in Fife to participate in research which gives access to treatments that may otherwise not have been available contributing to improved equity and leading to better clinical outcomes. These facilities have seen increasing numbers of participants in 23/24 and NHS Fife has consistently high numbers of patients recruited to national and European clinical trials. Frequently being the first site in Scotland or the UK to recruit a participant to a new study.

The monthly publications bulletin of NHS Fife authors contributing to Journal articles and publications confirms our clinical team's enthusiasm and commitment to research and highlights the breadth and areas of speciality in which we contribute.

We continue to grow and develop our innovation team and on behalf of South East Health Innovation Hub (HISES) 23/24 saw the successful administration of Phase 1 for the £5.5m Reducing Drug Deaths national program, co-funded by Chief Scientists Office and Office for Life Sciences. NHS Fife Innovation team managed 11 companies across all 4 devolved nations working with Academic Health Science Centres and Scotland's Innovation Hubs in the feasibility phase of digital devices and technologies being developed to detect, respond and intervene in the circumstances of risk to life for persons who use drugs.

2023 saw the second Annual Joint NHS Fife and University of St Andrews Research and Innovation Symposium. This second event was very well attended and saw the Director of the McKenzie Institute for Early Diagnosis, Professor Peter Donnelly, step in to cover for the Deputy Chief Medical Officer as the Keynote Speaker. Professor Donnelly delivered an engaging talk on the diversity of research and clinical academic career paths.

The now annual Joint Research and Innovation Symposium is an opportunity for clinicians, academics, clinical researchers, and professional staff to share their enthusiasm for health and clinical research and innovation and provide a forum to make connections and develop collaborative opportunities.

The NHS remains one of the most valuable assets that we have in Scotland, but it is under constant operational and financial pressure. Our ability to conduct and support clinical research and innovation is fundamental to the success and sustainability of this asset for the benefit of Scotland's citizens and future health. I am steadfast in my belief that we can make a difference which is why I will continue to provide my utmost support to the work that the RIK team are committed to.

Dr Christopher McKenna

Medical Director and Executive Lead for Research, Innovation and Knowledge

2. Introduction



Professor Frances Quirk
Research, Innovation & Knowledge
Associate Director, NHS Fife

This period has been one of growth and change for us with new staff in Innovation and Clinical research and a shifting of focus in some of our portfolio to support the development of specialities who are expanding their clinical research activity, such as our Emergency Medicine team.

Our Innovation team have successfully concluded the management of Phase 1 of the National Reducing Drug Deaths Program, the £5.5m program co-funded by the Chief Scientists Office and the Office for Life Sciences supporting the development of solutions to prevent fatal overdose. The team have worked with 11 companies to complete their 12 month feasibility projects, finalise their reports and submit applications for Phase 2, which will commence in 24/25. Three of the companies worked with us directly at NHS Fife with support from the Addictions service and Dr Susanna Galea-Singer, one of our 1st cohort of Clinical Research and Innovation Champions.

The second NHS Fife and St Andrews Joint Research and Innovation Symposium was held at Balbirnie House and was again very well attended. The event provided the opportunity to showcase joint work, including presentations from PhD students and Early Career Researchers and networking in breaks to develop connections. Additional joint appointments both clinical and non-clinical and Honorary Fellowships with the University of St Andrews have produced benefits in terms of closer collaboration and contribution to an expanding NHS Fife research culture.

The benefits of this closer working were realised in a successful submission to the Chief Scientists Office Applied Health Research Program, a team consisting of St Andrews and NHS Fife staff, led by Professor Colin McCowan were awarded £950,000 to progress a program of work focused on use of unscheduled care in the last year of life. The funding is for 5 years and will further cement our leadership in unscheduled care use and end of life care research across the two institutions.

Acknowledging the hard work of our RIK team we reprised the 'Appreciation' Event at the end of the year with an afternoon tea at Pittencrieff Park, including an impromptu piano recital!

A very well meant 'Thank You' to all of our teams for their magnificent efforts over this period, each year seems busier and more successful than the last and we look forward to another successful year in 2024/2025.

Professor Frances Quirk

Associate Director Research, Innovation and Knowledge

3. Research, Innovation and Knowledge Activity and Income

Research

3.1. R&D Studies and Recruitment

The following R&D activity summary includes the studies open to recruitment in NHS Fife at some point or in follow-up, within the 2023-2024 financial year.

Data has been obtained from the NHS Fife R&D database (EDGE) and excludes PIC (Patient Identification Centre) and NLI (No Local Investigator) studies. Data are updated continually, and figures are accurate at the time of collation.

3.1.1. Number of Studies

Research is categorised as 'commercial' (funded by the pharmaceutical or medical device industry) or 'non-commercial.' Non-commercial research is further divided into "eligible" or "non-eligible" (NEF) depending on the organisation(s) funding the study.

Eligible studies are those that are funded by an organisation on the Chief Scientist Office (CSO) eligible funders list (which includes some charitable organisations, research councils or Government bodies). NHS Fife receives funding from the CSO via NHS Research Scotland (NRS) to support the running of these 'eligible' studies. NEF studies are those that either have no funding or are funded by an organisation which is not included on the CSO eligible funders list. NHS Fife does not receive any funding from CSO to support the running of these studies.

A total of 98 studies were actively recruiting participants during this period (Fig 1) and 35 more were in follow-up (Fig 2).

The specialties involved in recruiting to commercial studies were Dermatology (3), Musculoskeletal (2), and Diabetes (1) and Metabolic & Endocrine Disorders (1).

The specialties involved in commercial studies which were in follow-up were: Musculoskeletal (2), Infectious Diseases and Microbiology (1) and Neuroprogressive and Dementia (1).

The top 7 non-commercial research active areas in terms of number of recruiting studies were: Cancer (9), Respiratory Disorders (8), Trauma & Emergencies (8), Stroke (7), Cardiovascular 4, Mental Health (4) and Renal Disorders (4).

The top 7 non-commercial research active areas in terms of number of studies in follow-up were: Cancer (10), Infectious Diseases and Microbiology (3), Mental Health (2). Musculoskeletal (2), Ophthalmology (2), Renal Disorders (2) and Reproductive Health and Childbirth (2).

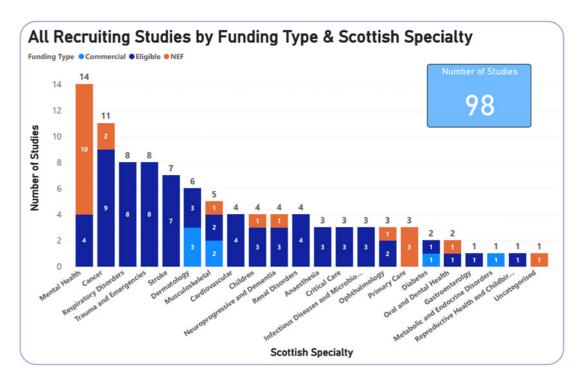


Fig 1

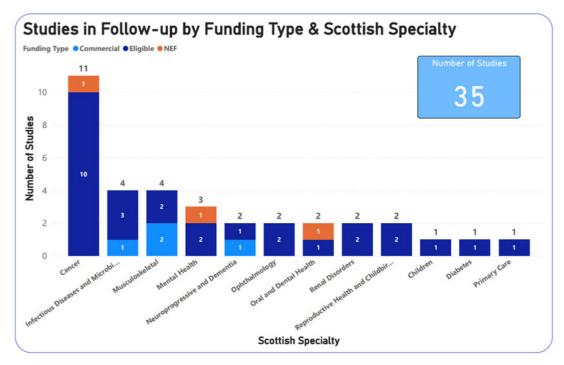


Fig 2

3.1.2 Number of Participants Recruited

There were 1183 new participants were recruited from April 2023 – March 2024 (Fig 3) into Commercial and Non-commercial eligibly funded studies.

Note: Recruitment to non-eligibly funded studies isn't routinely tracked and isn't reflected in the figures shown.

There were 454 participants were recruited into Commercial studies: Diabetes (380), Musculoskeletal (60) and Dermatology (14).

There were A729 participants were recruited into Non-commercial Eligibly funded studies.

The top 6 Scottish Specialties in 2023-2024 in terms of recruited participants for Eligibly funded studies were: Trauma & Emergencies (197), Respiratory Disorders (129), Cancer (98), Renal Disorders (57), Cardiovascular (44) and Mental Health (41).

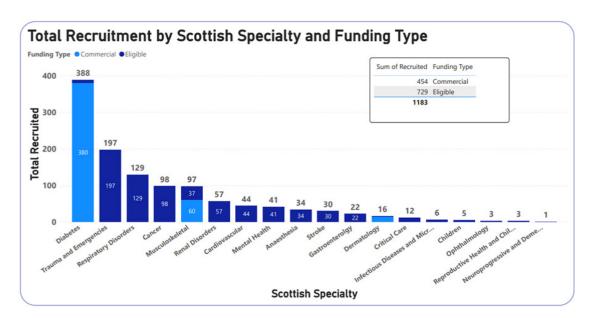


Fig 3

3.1.3 Types of Study

NHS Fife has a balanced portfolio of studies ranging from observational to complex interventional studies (including Clinical Trials of Medicinal Products (CTIMP)) across many therapeutic areas.

Of the total of 98 studies, 25 were Clinical Trials of an Intervention, 22 were Clinical Trials of a Medical Product, and 3 were Clinical Trials of a Medical Device.

The number of studies according to study type and disease specialty are shown in Fig 4 below:

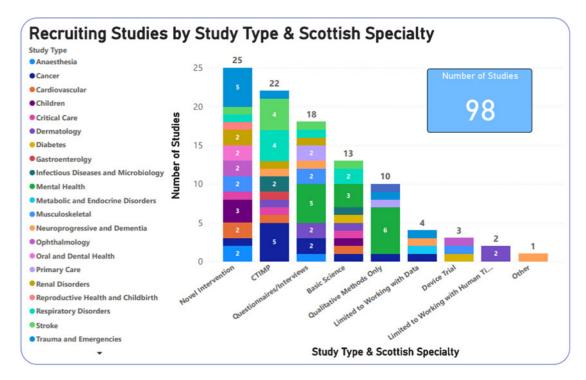


Fig 4

The number of recruits to Commercial and Non-commercial eligibly funded studies according to Study Type & Scottish Specialty are shown in Fig 5 below:

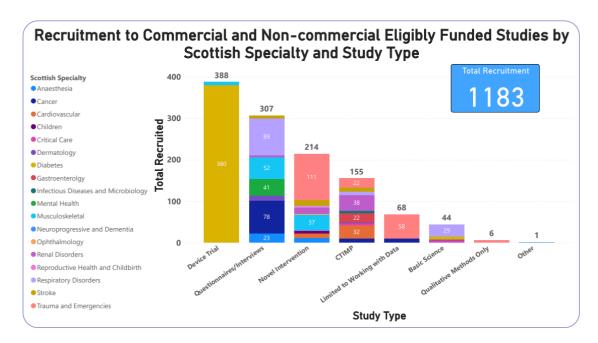


Fig 5

3.2. NHS Fife Sponsored Studies

The UK Policy Framework for Health and Social Care 2017 (UKPF) and The Medicines for Human Use (Clinical Trials) Regulations 2004 require that an organisation taking on the role of 'Sponsor' must ensure that there are proper arrangements in place to initiate, manage, monitor, and finance a study. Before accepting this role, NHS Fife will undertake a review and risk assessment to ensure that sponsorship acceptance is desirable and appropriate.

NHS Fife does not currently have the infrastructure in place to Sponsor CTIMPs (Clinical Trials of Medicinal Products) but between 2023 and 2024 NHS Fife Sponsored 5 Non-CTIMP studies (Fig 6).

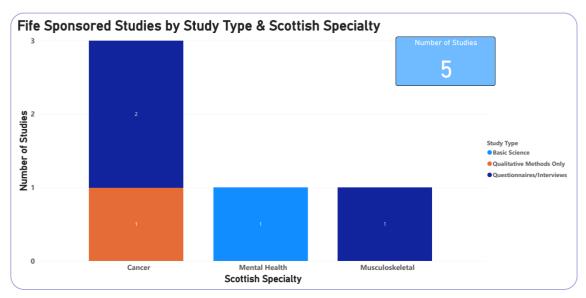


Fig 6

3.3 NHS Fife Research Active Staff

NHS Fife staff can be involved in the delivery of research by becoming the Chief Investigator (CI), or Principal Investigator (PI). The CI is the person designated as having overall responsibility for the design, conduct and reporting of a study, while the PI is the named individual who has responsibility for oversight of the study at a specific site for multisite studies.

3.3.1 NHS Fife Chief Investigators

Twelve NHS Fife staff members acted as Chief Investigator for a research study over this period.

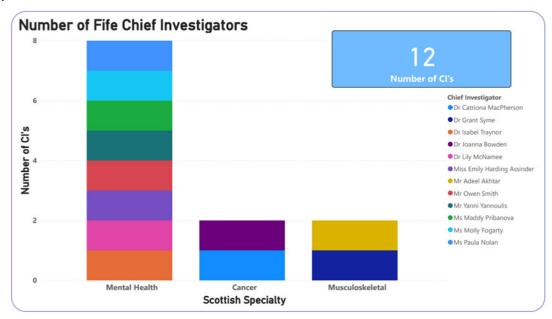


Fig 7

3.3.2 NHS Fife Principal Investigators

Eighty Three NHS Fife staff members acted as Principal Investigator for a research study from April 2023 - March 2024.

The top 6 research active Scottish Specialties with NHS Fife PIs (Principal Investigator) were Mental Health (14), Cancer (12), Neuroprogressive and Dementia (7), Musculoskeletal (6), Renal Disorders (5) and Respiratory Disorders (5).

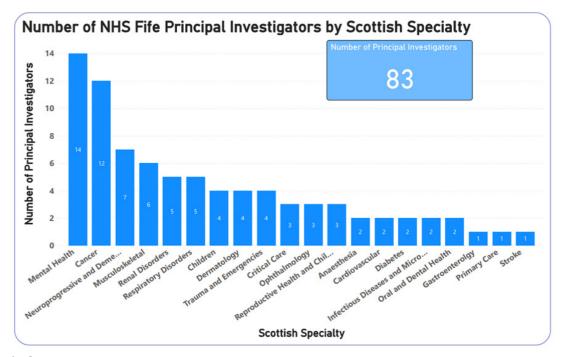


Fig 8

Most staff were Principal Investigator on a single study while 6 members of staff were Principal Investigator on 3 or more studies.

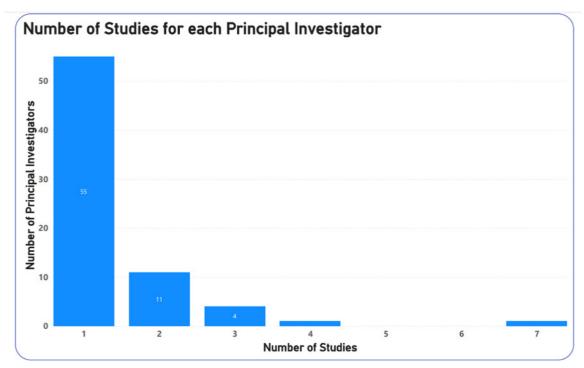


Fig 9

3.4 Trends in Research Activity

The following figures show the total recruitment and total number of studies for 2021-2022, 2022-2023 and 2023-2024.

Although the overall recruitment figure for Eligibly funded studies in 2023-2034 is significantly lower than the previous 2 years, in 2021-2022 a large part of the recruitment seen was from two large questionnaire/data only studies (CHOICE and ISARIC) which together accounted for 1033 participants, and in 2022-2023 a large part of the recruitment seen was from two large questionnaire/data only studies (CHOICE and DASHeD) which accounted for 820 participants.

The significant increase in total recruitment of participants for Commercial studies in 2023 was due mainly to one study (Investigative Clinical Study for Diabetes Rev A) which accounted for 380 participants.

Commercial studies accounted for 7% of the total number of studies that were recruiting in 2023-204, with non-eligibly funded studies accounting for 21%. These percentages were similar to those in previous years.

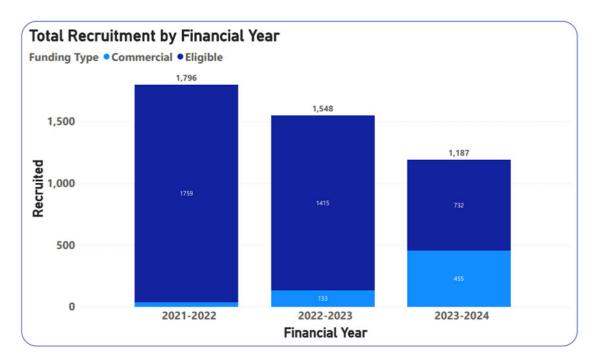


Fig 10

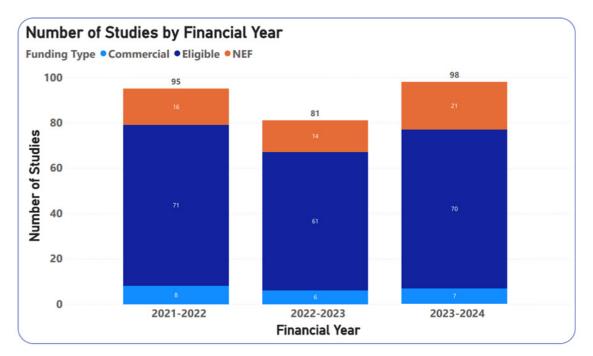


Fig 11

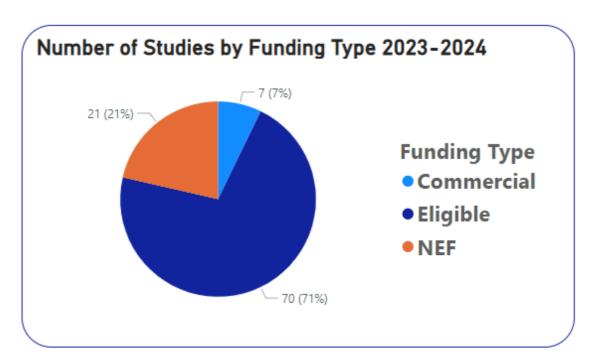


Fig 12

4. Research, Innovation and Knowledge Finance and Income



Grant McDonaldCapital Accountant

4.1 Funding

On an annual basis, NHS Fife RIK receives an allocation from the Chief Scientist Office (CSO) to support Non-commercial eligibly funded clinical research activity and general infrastructure. During the COVID-19 pandemic and initial recovery year, CSO were providing an allocation based on an average of activity over the years leading into the pandemic period due to the impact COVID-19 had on research. Now in the 2023-2024 Financial Year, CSO has returned to basing their annual allocations on the activity conducted within the Health Board. This activity mostly revolves around being the lead or supporting site in eligibly funded trials and recruiting participants to those trials.

Within Innovation, CSO also provides funding for the Health Innovation Southeast Scotland (HISES) hub through NHS Lothian as the lead Health Board, NHS Fife, along with NHS Borders, are member Boards of HISES. HISES is setup with the purpose of delivering "Government's vision to utilise the innovation process to deliver a healthier and wealthier nation for the future." HISES primarily support NHS Fife by contributing to funding our Innovation department with approximately 11% of the total SLA allocation from CSO to NHS Lothian. This is primarily applied to salary costs.

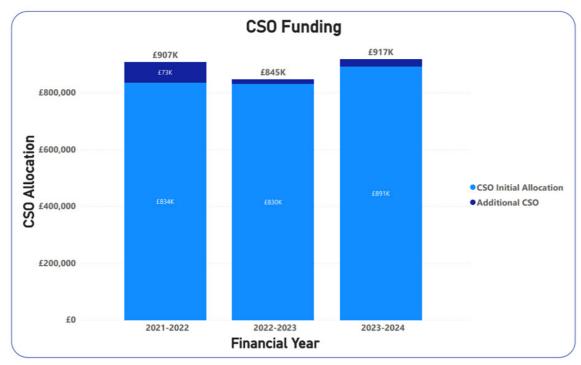
Additional funding to support Innovation activity is received from SLA's (Service Level Agreements) with CSO and NHS Golden Jubilee (on behalf of CSO and Office for Life Science) for local Project Management support and to support the administration of the UK wide Reducing Drug Deaths Catalyst Challenge.

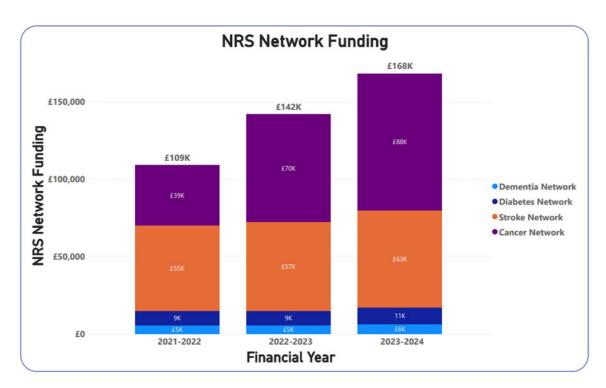
Along with HISES funding and general CSO allocation, NHS Fife is also involved in clinical research in various specialties such as Cancer, Dementia, Diabetes, and Stroke. Within these areas, NHS Fife receive Network funding from NHS Tayside as the nodal Health Board, NHS Lothian, and the University of Dundee as the holders of SLA's for the Networks.

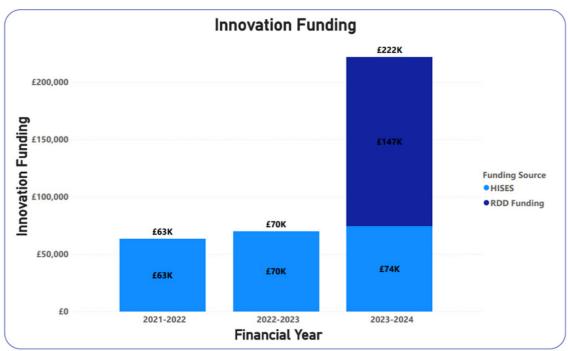
The following graphs show the total funding provided by CSO and other contributors over the previous 3 financial years, from 2020-2021 to 2023-2024. Key areas in funding movement are as follows:

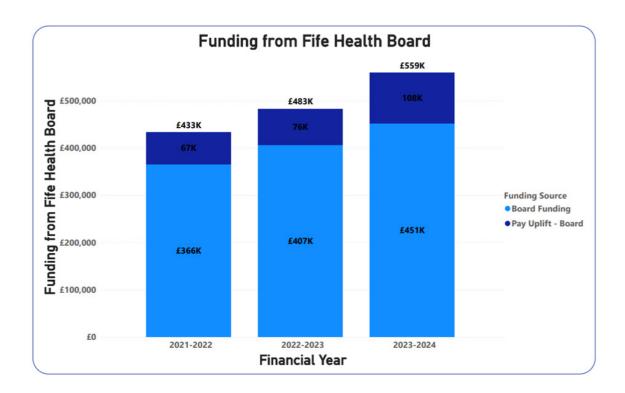
- Even though the initial CSO funding had dropped £4,000 between 2021-2022 and 2022-2023, there was a substantial increase of £61,000 between 2022-2023 & 2023-2024, leading to net increase in our initial allocation over the previous 3 years of £57,000, a total increase of 6.8% in initial funding.
- Additional funding of £26,350 was provided in 2023-2024 to employ an Innovation Project Manager to provide project development and management in the South-East Region and Scotland wide. This arrangement is expected to continue into the following year, and into 2025-2026.
- Funding from the Networks has remained stable over the past 3 years, with minimum movements except for the Cancer Network. Currently, the Cancer Network has seen the largest increase in funding, with an increase of £18,725 between 2022-2023 and 2023-2024, which is a 26.9% increase in funding.
- HISES Funding has been steadily increasing over the past 3 years, with an additional £6,830 provided in 2022/2023 and £4,542 in 2023/2024.
- Within Innovation, this the first full year of the Reducing Drugs Deaths (RDD) Project. As such, we have received funding of £147,398 from NHS Golden Jubilee to fund staff time in administering this project, which is expected to continue until the 2025-2026 Financial Year.

C









4.2 Income

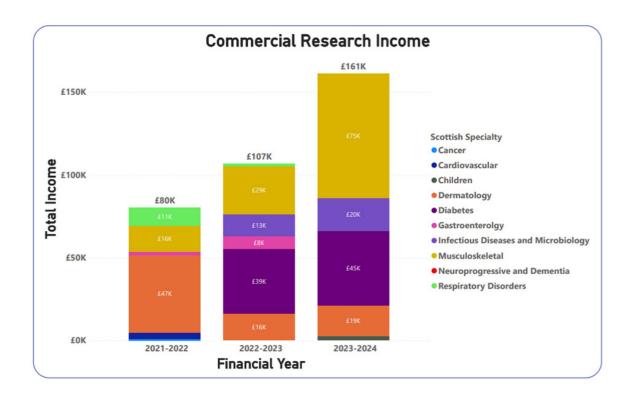
4.2.1 Commercial Income

Commercial Income for 2023-2024 was £161,000, an increase of £54,000 from 2022-2023. NHS Fife RIK commercial activity is still growing post-Covid-19 with the department looking to surpass pre-Covid levels of income soon.

Similarly to 2022-2023, the key clinical trials for commercial income are within the Musculoskeletal & Diabetes areas, with HP15-Mobile Link generating £71,000 and Lumira £45,000 in income. Other specific studies of note for 2023-2024 are Ensemble within the infectious Diseases and Microbiology specialty and the new study, Iconic Total within the Dermatology specialty which was unfortunately abandoned due the study reaching its competitive target recruitment.

In terms of specialties Musculoskeletal studies have seen the biggest increase in revenue generated over the past 3 years, with the amount of income increased by 368.75%, which is all relating to HP15-Mobile Link and will be recruiting new participants until July 2025.

The graph below provides a breakdown of the commercial income generated over the last 3 years, income is now increasing now that we are no longer in the Covid era and commercial studies are now a bigger part of NHS Fife's overall research portfolio.

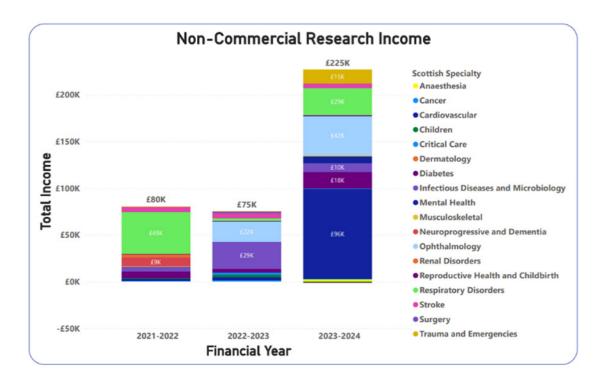


4.2.2 Non-Commercial Income

For Non-commercial research in 2023-2024, the overall research portfolio has become much more diverse, with 6 specialities generating a noticeable amount of income which are contributing to the £183,000 total income earned this financial year.

Of the £183,000 income generated, £121,000 of that was between 3 studies, Orion-4 with £84,000, Pneumo with £20,000, & Lens with £17,000. For Orion-4, it should be noted that much of this income does relate to work done in previous years and not previously invoiced.

Due to a change in calculating what is considered Research income, there was an increase of £21,000 income generated through non-commercial research due to the inclusion of the Stratifying Risk of Visual Loss from Glaucoma. This research trial had little involvement from RIK, but was work conducted by Digital and Information in developing a computational tool. This study also influenced the income generated through research in 2023-2024 of £42,000.



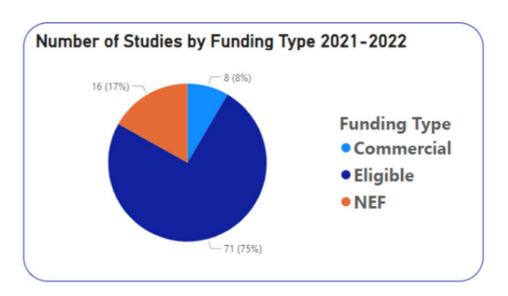
4.2.3 Research Portfolio

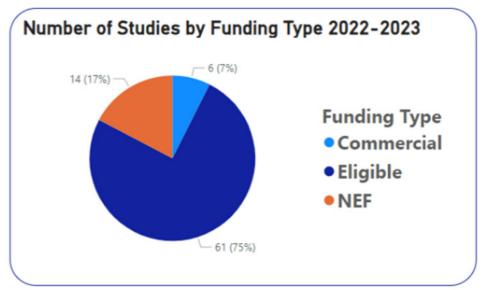
Unlike other departments within the NHS, which are generally given a budget and need to stick to that budget for the year, RIK is unique in that the department generates income through participation in various studies and clinical trials. This means that to ensure long-term sustainability for the department, we need to have a strong portfolio mix in the types of studies or trials the department participates in.

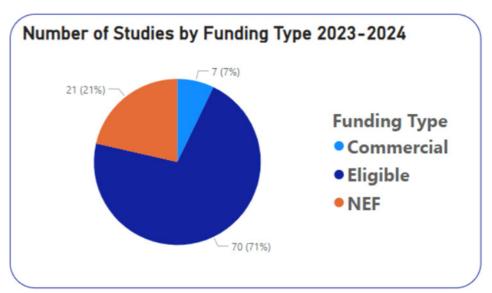
These trials come under 3 core headings, Eligibly Funded and Non-Eligibly Funded Non-Commercial studies or Commercial studies which provide different benefits to RIK.

For example, Commercial Studies will provide a short-term immediate benefit to RIK through the income that is generated, whereas eligibly funded Non-commercial studies provide a long-term benefit in that they affect our CSO allocation and may provide some short-term financial benefit if available.

Over the previous 3 years, our portfolio has remained stable per the graphs below. with little movement in commercial studies, with bigger changes in the portfolio revolving around eligibly and non-eligibly funded studies.







5. Innovation



Innovation Team

Dr Ramsay Khadeir, Senior Innovation Project Holly Jones, Innovation Admin Support Officer Neil Mitchell, Innovation Manager **Dr Angus Aitken,** Innovation Project Manager

NHS Fife is a member Health Board of Health Innovation South East Scotland (HISES), one of the three Regional Innovation Hubs, established by the Chief Scientist Office. HISES is a collaboration of three NHS Boards - NHS Fife, Lothian and Borders, with NHS Lothian taking the role of lead host board and receiving the funding from CSO. HISES forms part of a national network created to deliver the Government's vision to utilise Innovation to deliver a healthier and wealthier nation for the future. To date, most of the Innovation activity that RIK has supported has been focused on HISES hosted Small Business Research Initiatives (SBRIs) and the Reducing Drug Deaths program of work. NHS Fife has contributed to the review, discussion, and approval of projects to be hosted by HISES.

NHS Fife Innovation team has grown over 2023-2024 and the team now consists of Neil Mitchell, Innovation Manager, Dr Ramsay Khadeir, Senior Project Manager, Dr Angus Aitken, Innovation Project Manager, and an Innovation Support Officer. The Innovation team has further support from Clinical Innovation Champion, Dr Susanna Galea-Singer and supports HISES Clinical Innovation Fellow and NHS Fife Lead Advanced Physiotherapist Practitioner, Joyce Henderson, an associate member of the Innovation team. The Innovation team is led by Professor Frances Quirk, Innovation Champion and Associate Director of RIK.

Reducing Drug Deaths National Innovation Challenge

NHS Fife leads the administration and management of the Office for Life Sciences (OLS) and Chief Scientist Office (CSO) funded Catalyst Challenge aimed at Reducing Drug Deaths, on behalf of HISES. The total funding for this Challenge is £5.35 million. The central objective of this competition is to develop innovative technologies that help to reduce drug-related deaths by improving detection, response or intervention in potential drug-related deaths. Phase 1 of this SBRI had 11 companies awarded up to £100,000 to conduct a 4 month feasibility project from the start of September to the end of December 2023. Those involved in Phase 1 are detailed here £5 million fund to tackle fatal drug deaths across the UK - GOV.UK (www.gov.uk). Successful Phase 1 participants were invited to apply for Phase 2, a competitive process for up to £500,000 for a 12 month project. Phase 2 will commence in September 2024.

NHS Fife Clinical Innovation Champion, Dr Susanna Galea Singer, applied and was successful to support the Reducing Drug Deaths as a National Clinical Advisor, supporting the applications in Phase 1. This competitive process also saw 3 other experts in their fields join as National Clinical Advisors bringing expertise in their fields from across the UK.

Of the 11 successful applicants in Phase 1, HISES supported 3 Phase 1 projects. NHS Fife Addictions Service was vital in enabling the companies to access clinical expertise, lived and living experience members, and connection to relevant third-sector parties. The 3 companies working with NHS Fife were:

- MESOX Ltd: RescuePatch: a controlled-release combination patch for naloxone and flumazenil delivery - MESOX LTD in partnership with Health Innovation Southeast Scotland (HISES), Aston University, the National Physical Laboratory and On Target Pharma. This project will investigate a novel transdermal patch combination therapy called RescuePatch. The patch will contain a reservoir of antidotes to both opioid and benzodiazepine overdoses and is designed to be applied by a nonprofessional, which is expected to improve responder pathways and increase the chance of patient survival.
- eMoodie: Saving SAM: System for Alert and Monitoring of Potential Overdoses eMoodie in partnership with the University of Edinburgh and NHS Scotland Health Innovation South East Scotland (HISES). This project will design and develop Saving SAM: an AI-enabled drug overdose monitoring system to enable both self and responder digital alerts.
- ZioHealth: Improving Harm Reduction Strategies for Illicit Drug Use: A Handheld Device for self-monitoring Benzodiazepine use - ZiO Health Ltd working with Health Innovation South East Scotland (HISES). ZiO-Health's feasibility project is focused on improving harm reduction strategies for illicit drug use by developing a handheld therapeutic drug monitoring (TDM) device to notify users and responders of potential overdose.



Health Innovation South East Scotland (HISES) Projects

NHS Fife supported Phase I of the Mental Health SBRI which focused on the development of innovative solutions in several populations including young person's mental health, hard to reach populations, patient centered care pathways, treatment resistant conditions and prioritisation of backlog. NHS Fife provided stakeholder input to the successful companies selected to Phase 1 of this challenge with NHS Fife Children and Adolescent Mental Health (CAHMS) staff providing input and Digital and Information (D&I) staff providing guidance on implementation. In Phase 2, NHS Fife will support the implementation of a pilot to gather real world evidence of the innovative, digital products.

The national CAELUS drones project, which focuses on how drones may be utilised to rapidly transport blood products, medicines, pathology specimens between and within Board sites, has been progressing in HISES, with live flights planned between our partner Boards NHS Lothian and NHS Borders. NHS Fife signed the accession agreement for the CAELUS project to contribute valuable data to the project to feed into the Digital Twin. The Digital Twin, managed by the University of Strathclyde allows non-flying Boards to demonstrate how drones could be used in their Boards for the transport of blood, specimens and medicines. Live flights in flying Boards are planned for late summer 2024, depending on approval from Civil Aviation Authority (CAA).



Other SBRI's supported by HISES, with input from NHS Fife, include:

- Remote HbA1c Monitoring for Diabetes developing innovative solutions that address person-centred care, improve care pathway and optimise service delivery in HbA1c testing.
- Life After Stroke personalised information and support for patients' post-acute stroke in Lothian and Fife.

- Multi-Morbidity development of data-driven solutions that can improve and personalise care plans for patients with multimorbidity. This will use analytical clinical system models that could help with the risk assessment of patients.
- Delayed Discharge SBRI development of innovative technology- based solution to link statutory services to 3rd sector organisation providing services in the community.

CSO Innovation Fellowship

Joyce Henderson, Clinical Innovation Fellow and Advanced Physiotherapy Practitioner was awarded a highly competitive Innovation Fellowship which commenced in September 2022. The Fellowship focuses on Artificial Intelligence (AI) assisted screening of Developmental Dysplasia of the Hip (DDH). In order to progress the development and implementation of a handheld AI tool, UK Research and Innovation (UKRI) gap funding was sought to allow a research project comparing the current gold standard to the AI tool, as well as developing an integration module. This application was developed with Industry Partner Exo Inc, and Academic partner Professor Jacob Jeremko, University of Alberta, Canada. The application was submitted to UKRI in November 2023 with the submission being notified as successful in May 2024 for an award of £240,000. InnoScot Health have provided valuable insight and advice for this project, including development of the funding application through to agreement drafting and Intellectual Property advice.



Engagement

In October 2023, Innovation was highlighted at the second annual Joint Research and Innovation Symposium between the University of St Andrews and NHS Fife. This allowed for connections to be made with the wider Research and Innovation community in both Institutions, leading to a meeting of Strategic leaders from both the School of Medicine and NHS Fife RIK. Following this meeting an Innovation event was planned for May 2024. The aim of the event will be to bring together colleagues from St Andrews and NHS, along with industry and third sector groups to collaborate in identifying and developing creative and innovative solutions to proposed issues within the NHS, highlighted from NHS Fife's Reform, Transform, Perform (RTP) initiative.

NHS Fife Innovation has been involved in multiple engagement pieces over 2023-2024 to raise awareness of Innovation and the profile of the team. NHS Fife Innovation presented at the HISES Innovation Event online in 1Q 2024, presenting our work with the Reducing Drug Deaths projects. NHS Fife are members of the Southeast Academic Liaison Group, bringing together the 3 Health Boards of the Southeast and the 5 Higher Education Institutes in the region. NHS Fife continues to be represented at national Innovation meetings, as well as having regular attendance at external meetings and conferences such as the Digital Lifelines conference and the CSO at 50 event in Glasgow in October 2023.

6. Library and Knowledge Services



Alan Mill, Library Assistant Hannah Colston, Librarian Wendy Haynes, Librarian

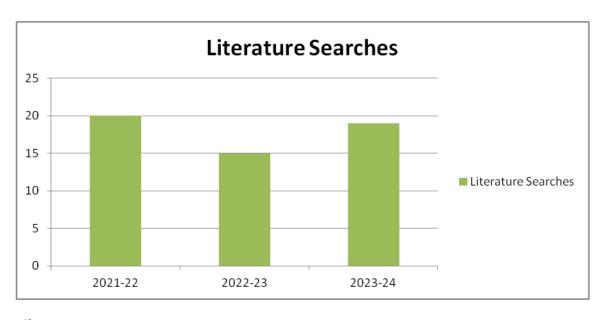
Introduction

This year the Library and Knowledge (LKS) Service continued to support staff and students by providing access to both online and physical resources, answering enquiries, carrying out literature reviews, and delivering user education sessions. Our main staffed site is the Victoria hospital. We also have locations at Queen Margaret and Stratheden hospitals.

This has been an exciting year for the library service, bringing in staffing changes. Our team currently consists of two part time librarians and our library assistant. Our Library services manager retired in 2022. Staff have been working hard to keep up to date with demand whilst this post is redesigned and readvertised. The LKS team are excited about the possibility of working with a new team manager and the ideas they may bring. Our long-standing librarian colleague also retired in March 2024, and we have welcomed our new librarian who has recently joined the team. We look forward to another year of working within the RIK team and developing the library service in line with our strategic priorities.

Literature searches

Encouragingly, demand for literature searches during 2023-24 have increased from the previous year (see Figure). Nineteen searches were completed compared to fifteen in the year 2022-23. Users of the LKS request literature searches for a variety of reasons. Some of which relate to direct patient care, reviewing medical guidelines and pathways, improvement reviews and general research around a topic. Examples of some of our work this year involved working with our Public Health colleagues. Areas looked at included the topics: young people and vaping, and hospital admissions related to adverse drug effects. Other areas of work involved looking at infant feeding and epilepsy to name a few. We collate feedback from colleagues who have requested literature searches. We appreciate all responses, and we can see the impact these searches can have, and how staff are able to utilise them when making decisions on patient care or other aspects of work.

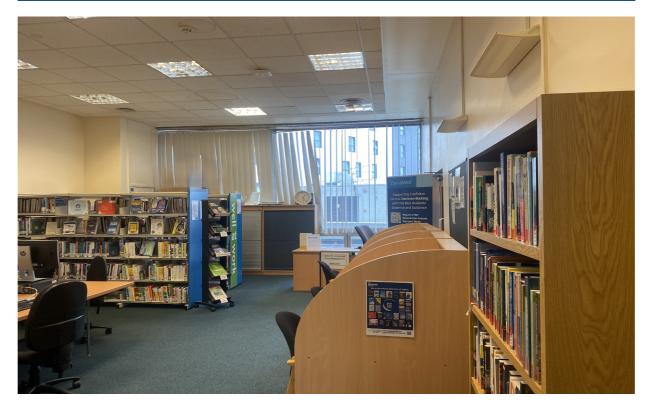


Library resource use

Activity	Numbers/data/quantity
Library Bookstock:	
Total number of books in stock	3699
Books added to stock	118
Book Loans:	
Book loans from own stock to NHS Fife staff	114
Book loans from own stock to external Boards' patrons	83
Book loans to NHS Fife staff supplied by external NHSS libraries	53
Resource Sharing Requests:	
Journal articles requested from the British Library or CLA Licence Plus	32
Books borrowed from the British Library	0

Other core activities

Activity	Numbers/data/quantity
Current Awareness Bulletin – Public Health	Produced Monthly
Local Authors Bulletin	Produced Monthly
Information Skills Training	5 individual sessions
Library Outreach	2 Events with display



Strategic priorities

Our strategic priorities are useful in focusing our efforts beyond LKS core activities and looking to further develop our services.

Stratheden Library

Since it was decided that the library at Stratheden would not be moving to alternative accommodation, we have improved the book collection by purchasing updated stock. As the library is based at Stratheden, the stock focuses mostly on psychology, psychiatry, and mental health. This library is unstaffed, but we have made more regular visits. This is because we made the books available on the Knowledge network catalogue, opening access to requests from other health boards. Visiting Stratheden more regularly to collect requested books for loan has given us more opportunity to check the physical space, making sure all is in order.

Queen Margaret Hospital Library

The book collection at Queen Maragret will be due for an update in the coming year. This Library is staffed one day per week. Giving us the opportunity to check the space, deal with loans and maintain the computer suite.

Public Health

With the upcoming closure of Haig house, we anticipate moving all the public health library stock to the Victoria Hospital. This stock will be updated in the coming year.

Increased student numbers

It is anticipated there will be an increase in student numbers from University of St Andrews with the establishment of the new full degree program ScotCOM in 2024. We have been working on training sessions to support students and Foundation year doctors and pharmacists. We hope this training on library services and literature search techniques will help them as they complete their training.

Right Decision Service

The Right Decision Service (RDS) will be a key priority for LKS staff in the coming year 2024-25. Staffing capacity has so far made this difficult, but we anticipate having more time to concentrate on this in the future. Staff have been familiarized with the Right Decision Service and have had some initial training.

LKS Promotion

Promotional efforts have been focused mainly on StaffLink. LKS staff also set up a popup stall in the hub area of the Victoria Hospital, and another stall at the NHS Fife and University of St Andrews Joint Research and Innovation Symposium in October 2023. This is a helpful tool as we can talk to staff face to face and display how the library service can assist with information and research. In the coming year we aim to post via the new RIK Linkedin account in a pre-set schedule.

Joint Research and Innovation Symposium

LKS staff attended the Second Joint Research and Innovation symposium in October 2023 to make contact with researchers in NHS Fife and the University of St Andrews, and to raise awareness of LKS and the support we offer to the research process.

7. Clinical Research Team

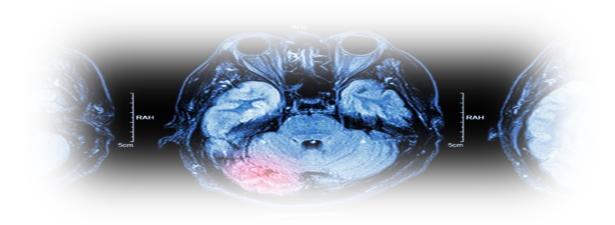


The clinical research team is led by Lead Clinical Research Nurse Karen Gray. It comprises 10 team leads for our most research active specialties in addition to research nurses, research practitioners and clinical research assistants who all work together to provide a comprehensive clinical research support service for our clinicians and researchers. The clinical team aims to support and advise researchers and staff from across the spectrum of specialties within NHS Fife and University of St Andrews with hands on expertise and support to manage their research projects and clinical trials within NHS Fife to the highest standards.

This is only possible with the enthusiasm and engagement of NHS Fife staff, our wonderful patients and the support and collaboration of the Health Board.



Diabetes/Critical Care/Stroke Team



Clinical Research Staff: Susan Fowler, Carol Cecen, Mandy Couser, Hannah Hughes and Samantha Balraj

Principal Investigators: Dr Cvoro, Dr McMahon, Dr Redfern, Dr Thompson, Dr Robertson, Dr Raman, Dr Patterson, Dr Bull

Recruiting studies- Stroke- TICH-3, MAPS-2 and ENRICH-AF, ABC, EVIS. COMMITTED, Genomicc, Lumira and INNODIA

Follow-up studies - TRIDENT, PANDOS

Studies in set-up – PhEAST, GEKO and CGM use in adults with type 2 diabetes on basal insulin.

Summary of activity

Within the last year we have had two new staff members welcomed to the team. A Research Nurse and Clinical Research Assistant, both are already making a positive impact within the team and adding to our success. We have recently changed and streamlined some current practices to enable more efficient and effective ways of working.

Highlights

- Stroke OPTIMAS study- Fife were 10th on the final recruitment board (out of 100 activated sites)
- ENRICH-AF- Fife is currently within the top 10 recruiting sites in the UK.
- Being top recruiters for EVIS
- 1st to recruit to COMITED in Scotland

Motivation

As a team we acknowledge the importance of research and how it plays a pivotal role in advancing medical knowledge and improving patient outcomes. Therefore, being part of this and enabling patients within Fife to access research gives us a great sense of achievement and is what motivates us within our jobs.



Cardiac Care Team



Clinical Research Staff: Sandra Pirie, Vasilika Ntoko, Tina Coventry

Principal Investigators: Dr Mark Francis, Dr Jagdeep Singh

Recruiting and follow up studies: Protect-HF and ORION-4

Summary of activity

Recruiting for Protect-HF and continuing to follow-up ORION-4 participants (2 routine monitoring visits a year).

Highlights

- Recruiting our first participant to Protect-HF. It has also been valuable working together with the pacing and Echo teams allowing over recruitment to the study.
- Attending the first ORION-4 nursing meeting allowed staff from NHS Fife to meet nurses taking part in this study from other sites. Finding out how they run the trial and discussing any issues they are having. As well as meeting the ORION-4 research team from Oxford. In addition, Vasilika and Sandra attended the heart and renal collaborators meeting where we heard about trials that are currently taking place and those planned that are taking place at Oxford University.

Achievements

Forming a brand-new Team since Valerie's retirement for cardiology research. Continuing to follow-up ORION-4 throughout this period without any issue (170 participants seen twice yearly at research clinic).

Motivation

Being involved in improving patient care through evidence-based research. Also working with enthusiastic and motivated cardiology participants.

8. Clinical Research and Innovation **Champions**

As an element of the enabling strategy to increase Clinical Research and Innovation activity and grow our Chief Investigator and Principal Investigator numbers a competitive call was launched in September 2023 for the second cohort of Clinical Research and Innovation Champion roles.

These roles are intended to support practitioners to take on a wider organisational contribution to enhancing culture, capacity and capability and provide for the equivalent of half a day a week for 2 years (reviewed after 12 months) to facilitate this engagement.

Three Clinical Research and Innovation Champions (Dr Rajendra Raman, Dr Joanna Bowden and Dr Sam Pattle) were appointed after this competitive selection process, commencing in January 2024.

In the following interviews Drs Raman, Bowden and Pattle provide their thoughts on their motivation to apply for a Clinical Research and Innovation Champion role and the benefits for NHS Fife patients and staff of these roles.



Dr Rajendra Raman **A&E Consultant**

1. What motivates you to fit research into your busy clinical life?

Until recently the evidence base for the specialty of Emergency Medicine was limited because it was felt to be too difficult to do research in our busy and sometimes chaotic environment. This situation has started to change thanks to a few pioneering academic Emergency Department clinicians, several of them in Scotland, who have been able to deliver large-scale, pragmatic, ED-based studies that have challenged dogma and changed practice. This is exciting for our specialty, and it is fantastic to be a part of this process.

2. Why did you apply for the Clinical Research Champion Award?

I was already involved in various research studies before I became aware of the Clinical Research Champion Award, and (like many of my ED colleagues) I was doing this work unpaid. The one session per week offered by the Award is therefore hugely beneficial. Beyond this, there had not previously been an ED-based Clinical Research Champion in NHS Fife, and it felt like a fantastic way to build new links between the very experienced and highly effective RIK department and the ED.

3. What will be the benefits of your role as Clinical Research Champion for NHS Fife and our patients and staff?

It feels like there is now a real buzz around research in the Emergency Department, with many ED medical and nursing staff delegated to a large number of studies, some undertaking the Associate PI programme, and a few starting to build their own study proposals. Without exception, the patients we approach for our studies seem delighted to be involved. Some have seen direct benefits to their own care, for example patients with pneumothorax (collapsed lung) avoiding invasive procedures which were previously routine but may be unnecessary. And all our patients seem pleased at the prospect of contributing to new knowledge that could help other patients in the future.

4. What advice would you give clinicians/Health professionals thinking about growing research capacity and capability within their area or service?

If your area or service is not yet engaged in research, reach out to other areas which are, and have a chat with the RIK team – I have found every single member of the team to be highly approachable and full of enthusiasm and encouragement. If your service is already engaged in research, look for opportunities to sign your staff up for the NIHR Associate PI scheme, which is an excellent way to get staff involved and engaged. And finally, if your team is receiving funds for taking part in studies, re-invest this directly into training and development opportunities for the team – as their skills and confidence increase, they will repay this investment many times over.



Dr Joanna Bowden Palliative Care Consultant

1. What motivates you to fit research into your busy clinical life?

I have worked in clinical research for the last 13 years, in a variety of roles and teams. I thoroughly enjoy research as a natural extension of my clinical role, and one which allows me and my colleagues (and our patients and families!) to bring new ideas to be examined and explored, as well as to support patients to access novel treatments and approaches to care through clinical trials. I relish having a working week that is varied and that stretches me in different ways. Research is fundamentally collaborative, and through research I have met and enjoy working with a huge range of people in all sorts of roles.

2. Why did you apply for the Clinical Research Champion Award?

During my two existing research sessions, I lead/co-lead a range of clinical studies and spend time developing research proposals and grant writing. The Clinical Research Champion session has allowed me to extend my role to connect with other clinical researchers coming from different departments in Fife and for us to join forces to promote a research culture more widely than in our own teams and to support more colleagues to learn about research and to get hands-on research experience. Our aim is that Fife becomes more well known nationally for its high quality, meaningful clinical research activities and outputs, and for us to attract medics, nurses and allied health professionals to our region because of this, as well as to grow more of our own talent locally.

3. What will be the benefits of your role as Clinical Research Champion for NHS Fife and our patients and staff?

It is well recognised that research active clinical teams offer the best quality care for patients and families. Promoting a research culture in Fife and developing more research capacity by supporting new clinicians into research roles and attracting more researchers to our region can only be good for clinical care. I benefit greatly from my dual clinical and research roles, in terms of job satisfaction and being challenged and kept on my toes, and I know that many others would benefit in these ways too. I am a positive role model for a combined clinical/academic career and can speak honestly and enthusiastically to anyone who wishes to know more.

4. What advice would you give clinicians/Health professionals thinking about growing research capacity and capability within their area or service?

Whether you have some research experience and qualifications or none, research can be for you. It is a common misconception that you have to have a PhD to be research active! A curious mind and a genuine interest in collaborating with others to develop and deliver research are both important. There are countless opportunities for any clinician or team to become research active, including: leading small-scale projects as part of a Master's or other Advanced Practice study, supporting patient recruitment to clinical trials and identifying gaps in our evidence base for practice and developing your own research questions and studies to address these. I would encourage anyone with any interest in learning more about research to get in touch with me and/or any of my Clinical Research Champion colleagues – we will always be pleased to find the time to talk and to discuss with you what might work for you. If you decide to get involved in clinical trials and/or to develop your own research proposals, the Fife Research, Innovation and Knowledge team is incredibly supportive and has a wealth of expertise to ensure that you make the progress you need.



Dr Samuel Pattle Consultant Pathologist

1. What motivates you to fit research into your busy clinical life?

As a diagnostic pathologist, working in a general hospital laboratory, I feel privileged to make observations across many different specialty areas of medicine as part of my routine practice. What really motivates me from that is the chance to translate those observations we are all making every day into an evidence base for real change and for the improvement in diagnostic accuracy and prognostic information for the benefit of patients. It is a constant challenge to balance the demands of near full-time clinical work with research engagement, but I would argue that this tension can only ever improve the relevance and robustness of the observations, questions, and hypotheses we work towards as clinical researchers. So, in a way, seeing so much and having a 'busy clinical life' is part of what motivates me to engage with research!

2. Why did you apply for the Clinical Research Champion Award?

Good quality clinical research relies on building teams of people with diverse backgrounds and skills, as no-one can work effectively in research on their own. Recognising this, and coming to the role from a laboratory background where highly specialised skill sets are essential to both clinical practice and research, I realised that the Clinical Research Champion Award was an opportunity to explore ways to help others within NHS Fife laboratories to get involved in research, and a way to promote what is and could be possible in pathology and lab-based research in NHS Fife, at present and with funding in future. I could also see the role empowering me to communicate more widely with the academic research community, giving me a platform for building a wider network of research contacts, thereby improving recognition of NHS Fife as a research hub, and opening further opportunities for funding and collaboration.

3. What will be the benefits of your role as Clinical Research Champion for NHS Fife and our patients and staff?

I think the benefits for staff are likely to be felt first from my involvement as a Clinical Research Champion, both in the laboratory and more widely amongst the clinical community, as I see part of the role as making pathology visible and engageable in research. We have projects that will be led by the pathology team, which will directly benefit lab-based staff who are keen to get involved in research but currently do not have the opportunity to do so. But we also want to open up pathology, and the wealth of laboratory expertise and archived patient material that can be accessed for research use, for those working in NHS Fife with research ideas and questions that would make use of patient material or histological methods. The benefits for the organisation will flow from this increased engagement, with what I hope will be a steady increase in both our internal infrastructure and our resource dedication to research activity (moving us beyond 'routine' clinical capabilities into more experimental techniques and technologies), consequent to securing funding both on our own standing, and through collaborations with research partners out with the organisation. Consequent with this will be an increased recognition and reputation of NHS Fife as a pathology research destination. As much of our planned work will be strongly focused on patient-derived material, and on methods and techniques that are (by default) employable within NHS laboratories, the benefits for our patients will follow from the research we are able to undertake through the demonstration of new diagnostic markers and techniques and the creation of new evidence bases in diagnostic research. All of this will be readily translatable and employable to routine clinical practice in future, thereby improving patient diagnosis and disease stratification through research in real world diagnostic samples and laboratories.

4. What advice would you give clinicians/Health professionals thinking about growing research capacity and capability within their area or service?

From the perspective of a pathologist who deals with diagnostic and surgical tissue specimens in both routine and research practice, I think some of the most effective ways to achieve scale and quality are to frame your research question from the perspective of what might already be out there and already collected. Some of the most illuminating and clinically impactful research studies I have had the privilege of working on have been based on well characterised patient cohorts, on existing material or data (therefore with no potential harm to the patient and no requirement for prospective data collection), and on relatively low-cost experimental investigations. If you can think about what is already available that could address your research question, and that wouldn't involve prospective collection, you are likely to find a less harmful, faster and cheaper way to engage with research. My second piece of advice would be to recognise and open up research engagement to a much more diverse group than the 'usual suspects' - expertise in data collection, coding, and technique expertise can be found at all levels of teams in NHS Fife, so harnessing that existing capacity can only ever be of benefit to improving research capacity, and growing research engagement within the organisation.

9. Clinical Researcher Career Spotlight



Karen Gray Lead Nurse, Research & Development

1. When did you first become interested in Clinical Research as a Nurse?

I first became interested in clinical research when I was working in ICU in my previous post. We had a study going on in the department looking at Activated Protein C in Sepsis patients and the research team would come down to recruit patients. The drugs were due to be given at different time points throughout the night shift, so some of the clinical nurses, including me volunteered to be trained in how to administer the medication and were added to the study team for this purpose. I found the whole thing fascinating and at the time I was also undertaking a Master's degree which also involved research. I helped on a basic level on other studies within the department and after investigated the role of the research nurse I decided then that is what I would like to do so when a post came up in Fife for a Diabetes research nurse, I was lucky enough to get it. I have now worked in research for the last 11 years and enjoyed every minute of it.

2. What drives you to be involved in Clinical Research?

I think it is a hugely underestimated role within the NHS. Seeing the impact it can have on various aspects of a patient's life and the improvements in their quality of life makes me extremely proud to work within this area. It is an area of nursing that allows a curious mind and can support continuous development every day, which I love. We have a fantastic clinical team in NHS Fife, with enthusiastic clinicians and extremely dedicated research nurses which makes working here rewarding but incredibly supportive within such an amazing work family. I think, this is, without exception the best job I have had over my career.

3. What's your Ambition?

I am happiest when I feel satisfaction at a job well done and when the team I work with are motivated and enthusiastic about their studies. I would like to see the Department develop and expand, giving us more space within the acute hospital at the VHK but also to encourage new and exciting roles within the department which helps give opportunities to our fantastic staff. I would also like to help develop the research nurse workforce within Scotland to be recognised for the specialty and expertise they have within the NHS.

4. What is your Career Highlight?

I think it was when I was nominated and appointed as an Honorary Teaching Fellow in the School of Medicine at St Andrews University. It was such an honour and lovely to be appreciated and recognised for the work I do. I really enjoy teaching the students and it allows me to diversify my skills within the department.

5. What does the Future look like for you?

I think the future for R&D and clinical research nursing in general is a very exciting specialty to be in now. There is so much going on to help develop and promote research nursing as a distinct workforce and more opportunities for non-registered research support staff. Within NHS Fife we have had a huge amount of support from other specialties and support departments, and I would hope to continue to build collaborations and develop the clinical team to continue delivering the valuable work that they do for the people of Fife.

6. What advice would you give to Future Aspiring Clinical Research **Nurses?**

I would suggest getting some clinical skills under your belt first and consolidating your learning within a specialty. Research is a fantastic way to develop your skills and knowledge, but it is a very autonomous role and very different from any other strand of nursing so having a good solid knowledge base and confidence with patients is essential. Investigating the role and finding out as much as possible about what being a clinical research nurse involves will help you decide if it is for you.

Spending some time with research nurses will also give you a greater understanding of the role and the variety of work we undertake.

10. Clinical Trials Pharmacy Team



Pharmacy Team: Maria Simpson, Senior Pharmacy Technician Clinical Trials, Sandee Beattie, Senior Pharmacist, Clinical Trials and Janine Ramsay Pharmacy Technician Clinical Trials.

Activity & Highlights:

We have had some personnel changes in the clinical trials team. Sandee Beattie joined the NHS Fife clinical trials team in March 2024 as Senior Clinical Trials Pharmacist, having previously held this position in the Queen Elizabeth University Hospital, NHS GG&C. Sandee replaces Alison Casey, Senior Pharmacist Cancer Services, who was on secondment with the team until Sandee came into post. Alison is no longer helping out with the team, as she left on maternity leave, but supported the team to facilitate opening Foxtrot, Refine Lung and Her2-radical. We would all like to thank Alison for her contribution to helping us open these studies. Sandee is enjoying getting to grips with the research portfolio in NHS Fife and embracing the full functionality of EDGE. Looking forward, Sandee is hoping to work with Maria and Janine to raise awareness within the wider pharmacy team of pharmacy's input into clinical trial delivery. Research forms one of the five pillars of the Royal Pharmaceutical Society's Core Advanced Pharmacy Framework, as such Sandee would like to engage more pharmacists, who are undertaking post-graduate training, in all aspects of trial delivery and aid in generating opportunities for more pharmacy staff involvement in research.

Janine Ramsay, Pharmacy Technician Clinical Trials has only been in post since 6th May 2024, and is proving to be a valuable team member. As many of you know, Janine has worked in clinical trials previously from 2021-22, she then left us to embark on the pharmacy technician training course. Having now qualified as pharmacy technician she has returned to the clinical trials team but also spends one day per week in a clinical capacity. With Maria and Sandee's support, Janine has completed her clinical trials training and is working towards taking an active role in study set-up activities and amendment review. Janine is also currently concentrating on training and developing others.

Maria is looking forward to the next 12 months, with a full team and the opportunity for further development in clinical trials with the support of both Sandee and Janine.

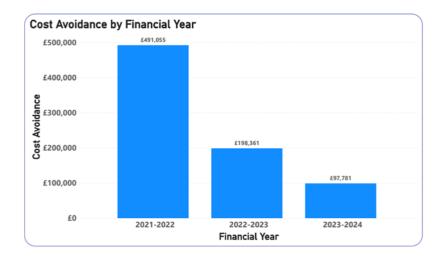
As ever the team continue to coordinate and oversee CTIMP studies in NHS Fife. We are passionate about maintaining a close relationship with the wider R&D team and enjoy working collaboratively to host studies throughout the board.

We have worked closely with the research teams to open several new CTIMP studies (including Cobalt, REFINE-Lung, HER2-Radical and Hi-Snap), and have processed amendments for the open CTIMP studies in a timely manner. Within pharmacy the clinical trials team is doing a great deal of work to streamline the in-house e-training provided to the wider pharmacy team. As studies are conducted across multiple sites in NHS Fife the wider pharmacy team are vital to processing clinical trial prescriptions at both QMH and VHK.

Motivation: Research is a key element of quality and improvement in healthcare systems and to be a part of that is something that the clinical trials pharmacy team feels very proud of.

COST AVOIDANCE 2023-2024

Study Name	Scottish Specialty	Cost Avoidance Figure
TEMPESTAS	Respiratory Disorders	£1,391.00
MYELOMA XI	Cancer	£13,608.00
FLAIR	Cancer	£82,782.00
Total		£97,781.00



11. Research Innovation and Knowledge **Approvals and Support Team**

RIK Approvals Team and Support



Catherine Kennedy R&D Approvals Coordinator



Penny Trotter R&D Approvals Coordinator

R&D Approvals Team

The R&D Approvals Team consisting of Aileen Yell, (R&D Research Coordinator) retired in June 2022 currently providing support to her replacement Dr Penny Trotter (R&D Research Coordinator) in post since June 2022, and Catherine Kennedy (R&D Research Coordinator) in post since November 2023 and Linzi Wilson, (Approvals Assistant).

Research Approvals

All research conducted within the NHS must have R&D Management Approval to ensure that the legal obligations of the Board are met. The Approvals Team ensures that such research studies are reviewed and approved within national timelines. This can include working with researchers and staff to provide advice and assistance for types of approval that are required, reviewing documentation, checking any implications around resource and costing, information governance, risk assessment, arranging contractual reviews, processing Research Passport applications, checking insurance/indemnity for research studies under the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) and dealing with any queries which arise during the process.

Between April 2023 and March 2024, the number of local management approvals was 50 studies as shown below in Figure 1. Figure 2 shows the NHS Fife Local Management Approvals by Financial Year 2021-2022, 2022-2023 and 2023-2024.

Figure 1 NHS Fife Local Management of Approvals by Month – April 2023 – March 2024

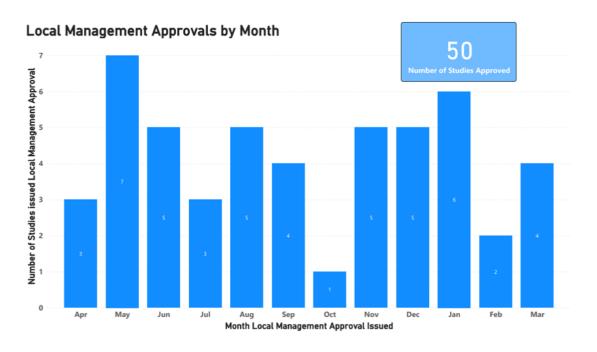
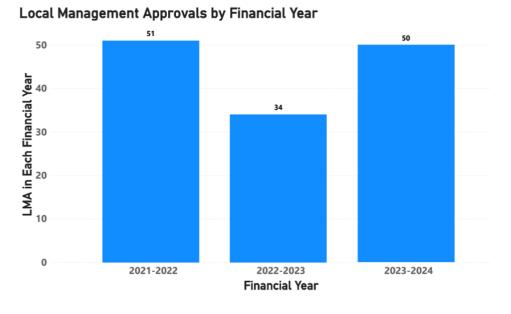


Figure 2 NHS Fife Local Management Approvals by Financial Year



Research Amendments

The majority of research projects which are approved will be subject to amendments during the period the studies are active or in follow up. The Approvals Team liaises with local study teams to ensure there are no issues around capacity or resources/costings and review and process the amendments timeously.

Between April 2023 and March 2024, the number of local management approvals was 210 study amendments approved as shown below in Figure 3. Figure 4 shows the NHS Fife approval of amendments by Financial Year 2021-2022, 2022-2023 and 2023-2024.

Figure 3 NHS Fife Approval of Amendments by Month – April 2023 – March 2024

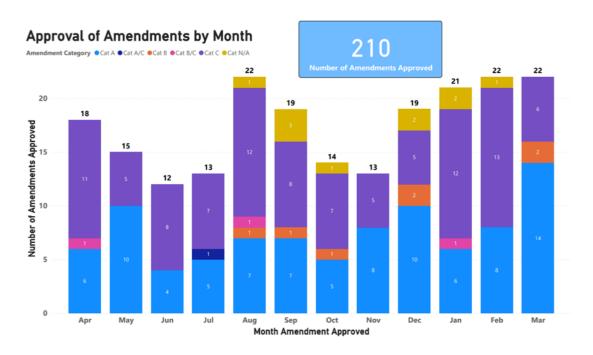
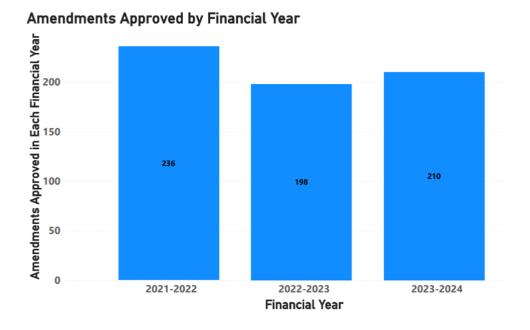


Figure 4 NHS Fife Amendments Approved by Financial Year



R&D Support



Roy Halliday **R&D Support Officer**

The R&D Support Officer Roy Halliday, provides overall administrative support to the R&D Department, including being a primary point of contact for the R&D Team, responding to all types of enquiries, organising and minuting of meetings, regular production of R&D Bulletin, providing support to the Assistant RIK Director and other team members where required. The R&D Support Officer is also responsible for processing of feasibility requests, ordering via the e-Procurement Scotland system (PECOS), Scottish Standard Time System (SSTS) and assisting with the delivery of the **R&D** Education Programme.

Highlights

The NHS R&D Forum Annual Conference May 2023 was attended by Professor Frances Quirk (Associate Director RIK), Dr Penny Trotter (R&D Research Coordinator).



12. Research, Innovation and Knowledge Quality and Performance



Julie Aitken - R&D Quality and Performance Lead.

Between April 2023 and March 2024, the R&D Quality & Performance Team consisted of Julie Aitken (R&D Quality and Performance Lead), Rachel Kuijpers and Isla McBain (R&D Quality and Performance Assistants).

The R&D Quality & Performance Team are responsible for several activities including:

Between April 2023 and March 2024, the R&D Quality & Performance Team consisted of Julie Aitken (R&D Quality and Performance Lead), Rachel Kuijpers (R&D Quality and Performance Assistant) and Isla McBain (R&D Quality and Performance Assistant).

The R&D Quality & Performance Team are responsible for several activities including:

Management of SOPs and Work Instructions

Standard Operating Procedures (SOPs) and Work Instructions (WIs) are vital to ensure efficient, controlled, and uniform conduct across all studies.

The R&D Quality and Performance Team ensures all SOPs and Work Instructions are constructed in accordance with the standard format, regularly reviewed, distributed, and made available to staff as appropriate. They work with the R&D Department admin and research staff to review the content of these documents and suggest improvements, as well as identifying gaps in the existing suite of documents where new procedures are required. This is an ongoing cycle and feeds into the continuous development of the department.

Between April 2023 and March 2024 6 SOPs and their associated forms and templates were reviewed, updated, and re-issued (Fig 1).

SOP/WI	Version	Active Date
SOP08 - Preparing and submitting progress reports for research studies	5	31 October 2023
SOP25 - Collection, processing, storage and transportation of biological samples for clinical research	4	09 November 2023
SOP35 - Archiving clinical research data	4	10 November 2023
SOP49 - Management of Suspected Research Misconduct	2	28 November 2023
SOP11 - The Process of Local Management Review and Approval of all Research undertaken in NHS Fife	4	04 March 2024
SOP40 - Local management review of amendments to studies	4	04 March 2024

Fig 1

Audit

The team are responsible for performing audits across all the clinical research conducted in NHS Fife. This covers a wide range of activities, looking at studies and their activities as well as procedures within the R&D Department itself. The audits are intended not only to ensure compliance to SOPs, WIs and study protocols but to assist those being audited by identifying and addressing issues and helping to improve and streamline study processes.

An Annual Governance Audit is conducted on all studies on the anniversary of them receiving Local Management Approval. Depending on the type of study, these audits cover a range of activities including a review of the study timelines, recruitment figures, safety reporting, implementation of study amendments and reporting of any deviations from the study protocol.

The team conducted 104 Annual Governance Audits between April 2023 and March 2024. A monthly breakdown is shown in Fig 2.

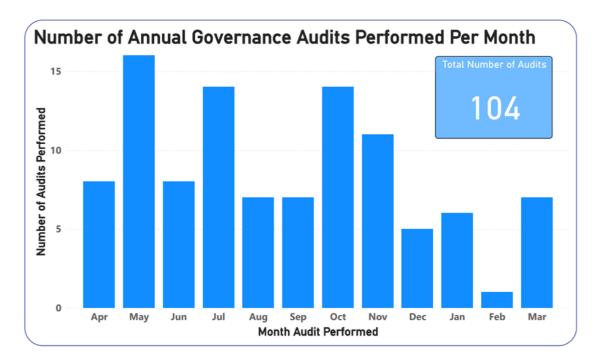


Fig 2

The Quality & Performance Team routinely audits the consent process for all studies, with the number of consent forms audited being determined by the complexity of each individual study. This audit ensures that the consent process complies with the study protocol, the correct documentation is being used and all activities are documented appropriately.

The team conducted consent audits on 18 studies with 53 individual consent forms reviewed. A monthly breakdown is shown in Fig 3.

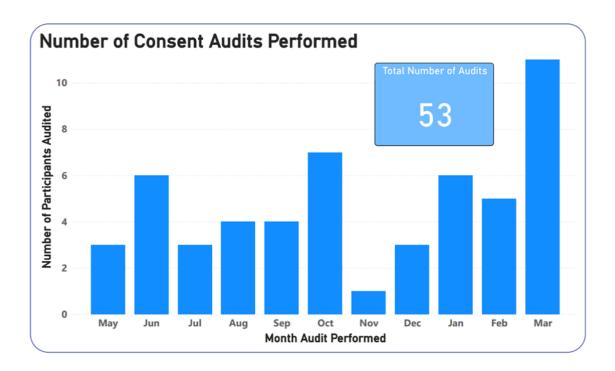


Fig 3

Tracking Research Activity and Performance

The team liaises with research teams to review study progress and timelines, collate recruitment figures and update local and national databases to track all research activity in NHS Fife.

Highlights

An updated version of EDGE (EDGE 3) was launched in May 2023 and the Quality & Performance Team delivered several training sessions to familiarise users with the changes that were introduced and offered guidance and support to ensure that the transition went smoothly.

The team has also been busy working with the R&D Approvals Team, Clinical Trials Pharmacy Team, and R&D Research Teams to further develop our use of EDGE for managing all aspects of the life cycle of a research project. We have continued to develop reports using the data collected in EDGE to track study approval and set-up processes and track the administrative tasks associated with participant recruitment and safety monitoring.

13. Research, Innovation and Knowledge Education and Training

Senior Research Advisors Activity 2023/24 - Dr David Chinn and Dr Fleur Davey

Education and Training

During the period April 2022 and 2023, there have been regular requests from NHS Fife and University of St Andrews staff and students to the Fife R&D Senior Research Advisor (SRA), covering a broad range of queries related to aspects of clinical research.

During the period covered by this Annual Report, 42 individuals made their first contact with a Senior Research Advisor (SRA), furthermore, there were several brief contacts not formally recorded. On the whole, the initial queries to the SRA were initiated by the clinical/academic member of staff, rather than the SRA, and the majority of these went first to the R&D generic e-mail illustrating that these queries were from individuals initially unsure who to approach in RIK, and what RIK could offer them.

Just under a third of the recorded contacts in this period (11) were from people who ultimately did not require the services of the R&D department but were signposted to other departments such as Innovation, Library services or the Quality Effectiveness team. The remainder of the people who contacted the SRA had clinical research related queries. At least 5 individuals had discussions around involving Patient and Public Involvement in their study design.

Most people who contacted the SRA were NHS Fife staff wishing to incorporate research into their clinical work, additionally there were 10 contacts from people who wanted to complete a higher educational project within NHS Fife, and a small number of clinical academics who wanted to complete clinical research projects. Requests from NHS Fife staff were from a range of professions including doctors, nurses and allied health professionals although staff from other roles within the organisation also contacted the SRA's.

Individuals looking for advice regarding clinical research were generally asking for help regarding; the varied aspects of study design, how to negotiate the approvals process, and the process of applying for NHS Fife sponsorship. To progress these queries each individual had ongoing discussions with an SRA over a period of time either by e-mail or face-to-face.

During this period the SRA's also met with colleagues from the University of St Andrews Research Governance and School of Medicine departments to discuss projects from the University that were being carried out within NHS Fife, this was to share understanding of the work and address any issues that arouse in a timely manner. Additionally, one of the SRA's is a member of the Scottish Health and Social Care Providers Research Leads Network, a group which meets quarterly to promote the building of research capacity and capability in nurses, midwives, allied health professionals, psychologists, and pharmacists by contributing to strategies for creating future clinical academic research opportunities.

Requests for help from Dr David Chinn were received from 8 staff with specific statistics enquiries, including data analysis. David provided 7 education sessions attended by 28 staff members and an ad-hoc teaching session to 20 trainee Clinical Psychologists

The Research, Capacity and Culture quantitative paper was published in April 2023 with the write up of the qualitative paper completed in February 2024.

GCP (Good Clinical Practice) Training- number of sessions, attendees

Date	Training	Trainers	Number of attendees
11 May 2023	GCP Update	Karen Gray and Dr Fleur Davey	5
10 August 2023	Introduction to GCP	Keith Boath and Dr Penny Trotter	5
16 August 2023	GCP Update	Karen Gray and Dr Fleur Davey	5
08 November 2023	GCP Update	Karen Gray and Dr Fleur Davey	6
15 November 2023	Introduction to GCP	Keith Boath and Dr Fleur Davey	3
07 February 2024	Introduction to GCP	Keith Boath and Dr Penny Trotter	3
14 February 2024	GCP Update	Karen Gray and Dr Fleur Davey	3

Principal Investigator training numbers of sessions, attendees

Date	Training	Trainers	Number of Attendees
04 Oct 2023	PI	Karen Gray and Dr Fleur Davey	5
28 Mar 2024	PI	Karen Gray and Dr Fleur Davey	2

Consent Training

Date	Training	Trainers	Number of Attendees
08 Feb 2024	Consent	Karen Gray and Dr Fleur Davey	6

14. Fife Health Charity Research and **Innovation Support**

Over the 23/24 period Fife Health Charity provided funding support for one research and innovation related project.

Al Assisted Developmental Dysplasia of the Hip-Data Manager-Pl Joyce Henderson, Award Value £33, 570

Support for trial to help new-born babies | Fife Health Charity

15. Fife Community Advisory Council

Patient and Public Involvement and Engagement in Research

NHS Fife Research, Innovation and Knowledge is committed to embedding Patient and Public Involvement and Engagement (PPIE) in research and research related activities. Whilst public and patient participants are recruited to clinical research studies and clinical trials we also aim to involve the public and patients more broadly in our program of work, providing input to the design of studies, supporting funding applications and working with clinical staff and researchers to develop clinical research studies and areas of priority. In partnership with the University of St Andrews we also support a generalised Patient and Public Involvement group called Fife Community Advisory Council (FCAC).



Fife Community Advisory Council (FCAC) was established in 2018 jointly by the University of St Andrews and NHS Fife Research, Innovation and Knowledge (RIK) to support health and social care research in Fife.

FCAC is made up of members of the public who through their knowledge and lived experiences can provide the "lay" perspective in research studies. They support Researchers, Clinicians and Scientists, contributing to the design, aims, delivery, and final recommendations of research studies. Working collaboratively, they share perspectives, skills, respecting and valuing knowledge and experience, reciprocity, and building and maintaining relationships.

FCAC governance is outlined in its Terms of Reference. It works within a published Scottish <u>framework</u> and follows guidance issued by the <u>National Institute for Health & Care Research</u> and <u>NHS Fife</u>.

FCAC provides a bespoke approach to PPI as no two projects are ever the same. Examples of responsibilities, though not limited to are:

- suggesting what health problems to study and how best to study these, looking at what resources are available or needed to improve on these.
- reviewing and contributing to grant applications, and in some cases acting as a grant Co-applicant

- reading and commenting on materials for research studies, such as participant information sheets and protocols.
- Joining PPI panels who contribute to the full lifecycle of a research project, often a 3 or 5 year project.

There are currently 20 members of FCAC who have collectively contributed to 15 research studies to date in 2024. FCAC aims to have an inclusive, diverse and as representative as possible group. Current membership statistics are:

70% fall within age bracket 60-79 years
85% identify as female
95% are of white ethnicity
50% do not consider themselves to have a disability

Further options to increase representation are currently being explored and developed.

One of the FCAC members, Anne Haddow, sits on the Research, Innovation and Knowledge Group (RIK-OG).

FCAC is co-ordinated by the PPI Co-ordinator in the School of Medicine, University of St Andrews. Contact <u>medfifecac@st-andrews.ac.uk</u>

16. Communications

The team utilise various platforms to advertise/promote our services and that of our collaborators.

Research, Innovation and Knowledge Bulletin

The bulletin is issued every two months and distributed via Stafflink and a mailing list, since August 2023 we have used Microsoft SWAY to produce this, which is easier for the viewer to read and includes live links, using SWAY also has the benefit of producing analytics for each issue.

August 2023 issue had 187 views Research, Innovation and Knowledge Bulletin August 2023 (cloud.microsoft)

October 2023 issue had 334 issues Research, Innovation and Knowledge Bulletin October 2023 (cloud.microsoft)

December 2023 issue had 365 views Research, Innovation and Knowledge Bulletin December 2023 (cloud.microsoft)

February 2024 issue had 221 views Research, Innovation and Knowledge Bulletin February 2024 (cloud.microsoft)

Research, Innovation and Knowledge Newsletter

Between April 2023 and March 2024 there were three editions of the RIK SWAY Newsletter created. The three specialities included Orthopaedics, Oncology and Diabetes.

An amazing ground breaking £33 million pound project, the Orthopaedic new National Treatment Centre (NTC) finally opened its doors on the 23rd of March 2023. The NTC has revolutionized treatment and care for patients in NHS Fife and beyond since opening. This edition also highlighted the R&D Orthopaedic nursing team with updates on some of their studies - CORE kids, CRAFFT & FAME. The 'Fife First' section featured the AFTER study. An enhancing rehabilitation study with the aim to find out if attending physiotherapy after an ankle fracture really does help improve recovery. NHS Fife was the first site in Scotland to open the study – a fantastic achievement!

https://sway.cloud.microsoft/uVcGmccBMQfW0s8u?ref=Link

The August edition was especially fun to create and I was proud to highlight the Oncology team studies and achievements. Our first platform study FOxTROT was featured along with PI, Dr Sally Clive as clinician for the clinical trial focus section. The new online cancer hub created by NHS Fife was noted, as it was set up to help patients and people affected by cancer to access the information they need to help navigate through their cancer journey. Another highlight was in innovation - NHS Fife, leading the national programme management and administration for the Reducing Drug Deaths National Innovation Challenge, on behalf of HISES.

https://sway.cloud.microsoft/D7V6fIAHnxXOjSlw?ref=Link

The Diabetic Network was featured in the November edition. The Network enables and supports efficient recruitment for diabetes-related research. Emphasis was placed on the current recruiting diabetic studies HbA1c (Lumira), INNODIA and LENS with an innovation update from Neil Mitchell, Innovation Manager. Innovation projects running in several areas for Diabetes care included Diabetes closed loop system, remote and in pharmacy HbA1c testing and utilising machine learning tools for clinical benefit. The second annual collaborative Research and Innovation Symposium was featured with highlights and photos taken on the day at the Balbirnie House hotel.

https://sway.cloud.microsoft/SCtixvByIxvDYjUH?ref=Link

Promotion and Advertising

The department also promotes Research and Innovation events, training and publications from internal and external collaborators again using Stafflink and a mailing list, during the period from 01st April 2023 – 31st March 2023, this was done 69 times.

Social Media

is a professional social networking platform that connects individuals and organizations across various industries. As a powerful tool for networking, knowledge sharing, and collaboration, and can greatly benefit the Research and Innovation Department of NHS Fife. https://twitter.com/NHSFifeResearch

17. Research, Innovation & Knowledge **User Experience**

R&D Participant Experience and Testimonies

"The Oncology research team was exceptional in providing expertise and emotional support throughout my participation in the FOXTROT3 trial for bowel cancer treatment. They consistently went above and beyond, dedicating additional time and effort to ensure clarity and advocacy. Their compassionate and friendly approach significantly eased the challenges of undergoing chemotherapy cycles, making a difficult experience much more manageable."

Anonymous 2023

Library and Knowledge Services User Feedback

Project progress and time efficiency:

"I am very grateful for the assistance! I work part time, and this allowed me to progress a project more timely than if I had not had help. Thank you!"

"This is incredibly useful – I really appreciate your help."

Information contributes to change:

"This impacted how recruitment / retention activities are conducted."

"Now aware of new clinical tests, and an informed background to a clinical pathway development."

"Informed practice for a niche area."

18. Opportunities and Challenges

To ensure the successful implementation of the NHS Fife Research, Innovation and Knowledge Strategy a series of annual 'priorities' have been selected to be progressed. An update on identified priorities /challenges to be taken forward within RIK in 2023 -24 were as follows:

- a. Participation in the development of medical and nursing clinical academic career development in Fife has been continued with discussion and actions about the Associate PI Scheme and Clinical Research Practitioners.
- b. Preparations for a potential inspection by the Medicines and Healthcare products Regulatory Agency (MHRA) have continued.
- c. Details of research-related academic degree programmes, short courses and bursaries, encouraging staff to apply, have been circulated.
- d. Liaising closely with universities and other academic institutions, particularly the University of St Andrews, to establish Research and Innovation projects, programmes and opportunities.
- e. We have continued to support and participate in the NHS Research Scotland (NRS) East Node, establishing joint documentation and actively participating in membership of groups and committees.
- f. We have continued to work with the Health Informatics Centre (HIC), consolidating and adding to the joint Tayside and Fife HIC Database to facilitate service-based evaluations/research. We have developed a relationship with the South-East Region data repository and asset, DataLoch.
- g. The infrastructure and processes required for NHS Fife to act as Sponsor for increasingly complex studies are being delivered.
- h. Greater activity and collaboration with academics, pharmaceutical and medical device companies are resulting in increased utilisation of the Clinical Research Facility.

Challenges for RIK in 2023-24

During 2023-2024 the Research, Innovation and Knowledge teams within NHS Fife continued to push for growth and improvement maintaining our diverse research profile, pipeline and priorities, maintaining compliance with the research governance framework, monitoring 100% of Fife Sponsored studies; the revision of the RIK Education Programme to focus more strongly on clinical research support, the adaptation of Library Services to staff changes and planning for increased medical student numbers. All teams have continued to perform extremely well in the context of multiple challenges and changes, but external pressures and the more challenging financial climate have had an impact on productivity, staff wellbeing and ability to progress some initiatives.

Opportunities for RIK in 2023-24

We have continued to look for ways to support protected time for our research active and interested staff, funding and implementing the second cohort of Clinical Research and Innovation Champion roles has been a significant step in supporting this. The legacy of the first cohort of Clinical Research and Innovation Champions (Dr's Susanna Galea-Singer, Devesh Dhasmana and Mr Phil Walmsley) has created a foundation for our new Champions (Dr's Rajendra Raman, Joanna Bowden and Samuel Pattle) to build upon.

We anticipate that they will all work together to help support research and innovation capacity and culture growth in 24/25.

The NHS Fife Innovation team have demonstrated leadership in their successful management of Phase 1 of the Reducing Drug Deaths program and this has led to NHS Fife being highlighted in the wider Innovation landscape.

RIK Strategy priorities (2023-24)

All activities detailed in the prioritised plan of the RIK Strategy for 2023-2024 are ongoing or have been achieved.

19. Conclusions

Each of the teams that make up the Research, Innovation and Knowledge Department demonstrably rose to the challenges and opportunities that presented themselves over 23/24. Staffing changes and recruitment demands in all teams has meant many have been without a full complement of staff for prolonged periods. This is particularly the case for our Library and Knowledge Services team who have spent most of 23/24 operating with reduced staffing, they are to be commended for maintaining a quality service in challenging circumstances.

We have continued to promote the research and innovation agenda, further developing the research and innovation culture and raising the profile of RIK within NHS Fife, whilst continuing to build on connections with colleagues at HISES, the University of St Andrews and with the wider research, innovation and knowledge community.

Innovation at NHS Fife has continued to develop over 2023/24 with new appointments and an increased profile from managing the large UK wide Reducing Drug Deaths program.

The Clinical Research team and support services of Approvals and Quality and Performance have provided outstanding support to our clinicians and research staff, whilst also contributing to national initiatives and demonstrating leadership for peers and colleagues in study management, processes and data management systems.

The NHS Fife Executive Lead for RIK and Associate RIK Director have worked together to ensure a significant raising of the profile of NHS Fife RIK and the promotion of Fife as an important, emerging player in the current, and future Scottish research and innovation agenda.

20. Publications

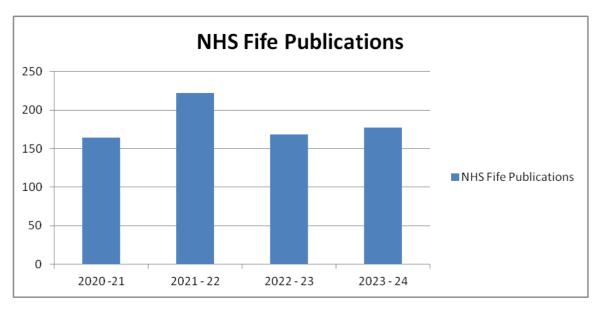
Research and related activity: publications by NHS Fife staff

Produced by NHS Fife Library and Knowledge Service Fife.libraries2@nhs.scot; 01592 643355 ext 28790 NHS Fife Library and Knowledge Service

Core databases were searched to retrieve articles where at least one author is an NHS Fife affiliated staff member. Research may have been done solely by NHS Fife staff or with colleagues from external institutions. Our search was supplemented by information supplied by the Pure team at St Andrew's University.

We searched for records added to the databases Medline, Embase, Psych Info and Cinahl between April 2023-March 2024. There were 177 publications found by NHS Fife affiliated staff. There may be other publications not included as they have not been published on the main databases. We included: articles, conference abstracts and letters. Articles contributed by NHS Fife are distributed worldwide. There is a vast range of collaborations with staff across institutions and sometimes continents, working together on their research.

This graph shows the yearly number of publications from the past four years. There is a consistent steady number of publications which have slowly increased since 2020.



List of Publications 2023 - 24

Abed Al Ahad, M., Demsar, U., <u>Sullivan, F.</u>, & Kulu, H. (2023). **Long-term exposure to air pollution and mortality in Scotland: a register-based individual-level longitudinal study.** Environmental Research, 238(2), Article 117223. Advance online publication.

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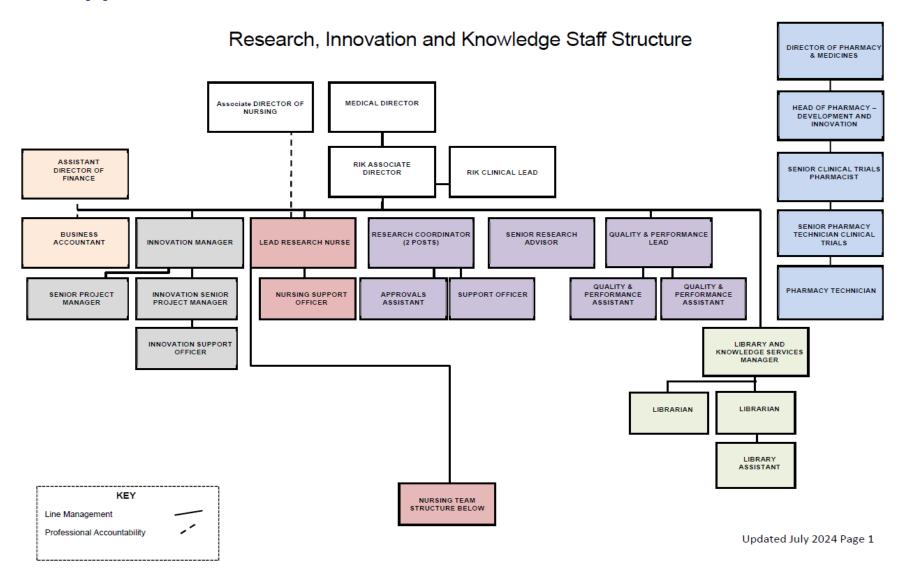
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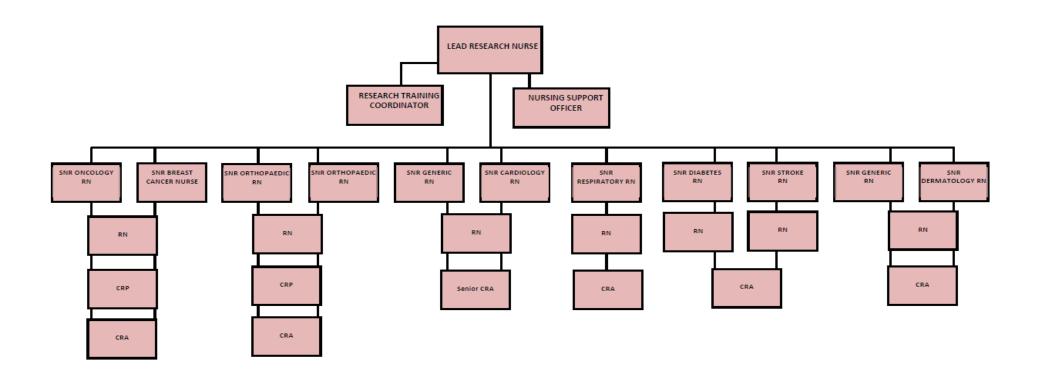
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21. Appendix 1 – RIK Structure





KEY

RN: Research Nurse

CRP: Clinical Research Practitioner

CRA: Clinical Research Assistant

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