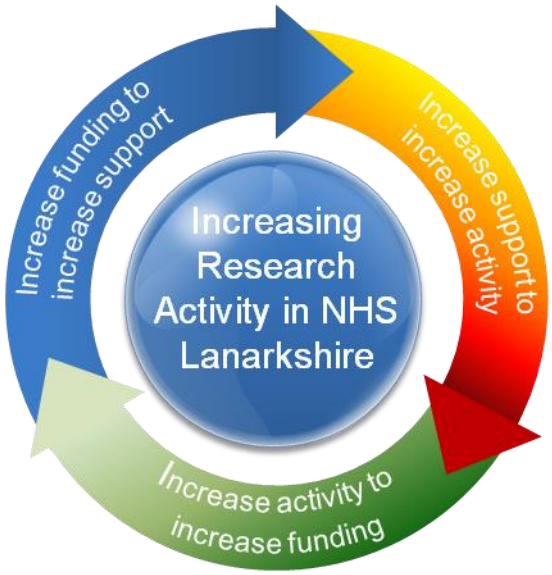
INCREASING RESEARCH ACTIVITY IN NHS LANARKSHIRE

Research & Development Strategy

April 2023 – March 2026



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08/03/2017	R Hamill	Issued to R&D Committee as new strategy	1.1
06/07/2017	R Hamill	Re-issued – reformatted following advice from R&D Committee	1.2
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18/05/2023	R Hamill	Revised following review / discussion within R&D Committee – a number changes to structure, minor changings in wording plus additional content re: Academic Partnerships and R&D Committee membership	2.2

Executive summary

The main national and local strategic drivers for NHS Lanarkshire's R&D Strategy are:

- The Scottish Government's most recently-published national *'Health and Social Care Research Strategy'* (*H&SC Research Strategy*)
    - The national H&SC Research Strategy was intended to cover the period from 2015-2020; its core aim was to support and increase the level of high-quality health research conducted in Scotland for the health and financial benefits of our population.
    - Notwithstanding the impact of the COVID-19 pandemic, that core aim remains entirely relevant; in fact, the pandemic brought the importance of health research into sharper focus than ever before.
    - During the pandemic, most non-COVID-19 research in the UK was suspended for a period as the research community across the globe focused on understanding and developing new vaccines against, and treatments for, the disease. Exceptions locally included research involving core patient treatments, such as in cancer clinical trials.
    - As part of national managed recovery planning, local non-COVID-19 research has largely recovered to pre-pandemic levels, and now runs alongside some of the major High Priority COVID-19 Public Health studies that continue to operate, such as the Oxford-led RECOVERY Platform Trial and the UK Health Security Agency-led SARS-CoV2 immunity and reinfection evaluation (SIREN).
    - While the existing national strategy continues to be the key driver for our local R&D Strategy, there is an expectation that a new national R&D Strategy will emerge under the direction of the Scottish Government's new Chief Scientist (Health) who took up post in July 2022. NHS Lanarkshire's R&D Strategy will be revised in light of the relevant new Scottish Government strategy when available.
- The UK and devolved governments' '*Future of Clinical Research Delivery: 2022 to 2025 implementation plan*'[1]
    - This was produced following publication of the UK government's strategic vision - '*Saving and Improving Lives: The Future of UK Clinical Research Delivery'*[2]*,* and will almost certainly be a key driver of any new Scottish national R&D Strategy.
- The Scottish Government's '*Health & Social Care Delivery Plan*' December 2016
    - This confirms that "…*research is central to all high-performing health systems, leading to better targeted and more personalised treatment and improved patient outcomes*…" and affirms that "…*Research and development (R&D) is a core activity for our health and social care services in Scotland*…"
- NHS Lanarkshire's 2016 Clinical Strategy – *'Achieving Excellence'*
    - Confirms NHS Lanarkshire's committed to delivering high-quality, person-centered innovative health and social care - participation high-quality research is in keeping with this overall ethos.

[1] https://www.nhsresearchscotland.org.uk/news/three-year-plan-for-implementing-the-vision-for-the-future-of-uk-clinical-research-delivery-published

[2] https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery/saving-and-improving-lives-the-future-of-uk-clinical-research-delivery

NHS Lanarkshire's previous R&D Strategy covered the period 2017-2022. Given the expectation that a new Scottish national R&D (*and possibly Innovation – so 'RD&I'*) strategy will emerge, the decision was taken by the Board's R&D Committee in 2022 to revise and extended the existing strategy on an interim basis.

This current R&D Strategy will cover the period 2023 – 2026; it is recognised, however, that it may be superseded within that period of time if and when a new Scottish national RD&I strategy is published.

'*Increasing Research Activity in NHS Lanarkshire' (the R&D Strategy)* mirrors the national *H&SC Research Strategy* vision of maximising the opportunities for our patients to participate in high-quality research and clinical trials. It is in harmony with the *Health & Social Care Delivery Plan* and also supports the commitments underpinning *Achieving Excellence*. It also, where relevant, supports some of the key activities outlined in the '*Future of Clinical Research Delivery: 2022 to 2025 implementation plan*'.

NHS Lanarkshire's Strategic R&D Aim mirrors the Scottish Government's vision for research; it can be summarised as follows:

NHS Lanarkshire's Strategic R&D Aim is to maximise the level of high-quality, NHS Ethics-approved research being carried out within NHS Lanarkshire for the benefit of our patients, staff and the organisation as a whole

We have identified eight Strategic Objectives that will support delivery of NHS Lanarkshire's Strategic R&D Aim. These are:

- Objective 1. Ensure R&D remains financially viable
- Objective 2. Enhance governance arrangements to improve GCP compliance
- Objective 3. Increase both eligibly-funded and commercial research activity
- Objective 4. Expand the provision of dedicated research sessions for clinicians
- Objective 5. Broaden the research base and the visibility of research
- Objective 6. Strengthen academic collaboration
- Objective 7. Improve access to research training for clinicians
- Objective 8. Secure dedicated accommodation for delivering research

The eight Strategic Objectives address some of the key factors that limit the opportunities for conducting research in NHS Lanarkshire. In each case, specific actions have been identified; the implementation of these actions will help attain the objectives and, in turn, will contribute to achieving the overall Strategic R&D Aim.

The actions necessary to achieve the Strategic Objectives, and therefore the overall Strategic Aim, are detailed within the R&D Strategy's accompanying Implementation Plan; the Plan is included at *Appendix 1*.

1. Introduction

In his preface to the Scottish Government's *Health and Social Care Research Strategy* 2015-2020, Professor Andrew Morris, the then Chief Scientist, stated that it aims to provide clarity and coherence on what we need to do to achieve the Scottish Government's vision "**…to support and increase the level of high-quality health research conducted in Scotland for the health and financial benefits of our population…**".

The Chief Scientist Office (CSO) - part of the Scottish Government Health Department (SGHD) - has a central role in overseeing the activities and performance of NHS Scotland Board Research & Development Offices in supporting achievement of the above vision, through the hosting and conduct of high-quality health research (R&D) within the NHS Boards. It promotes the increase of health-research within the NHS because it is generally recognised that:

- R&D is indispensable in the development of new treatments, and is therefore an essential component in modern and effective health services
- patient involvement in research leads to better quality of care and better outcomes
- clinical trials can offer early access to new, cutting edge treatment options that would otherwise be unavailable to patients

The Scottish Government's '*Health & Social Care Delivery Plan*' December 2016 also confirms that research is central in delivering the above benefits to our patients.

Further important organisational benefits are derived from involvement in research:

- opportunities to participate in research helps attract, engage and retain high caliber staff
- an active research portfolio yields reputational benefits for host organisations
- clinical research provides positive financial benefits
    - NHS Lothian researchers have estimated in one 2015 article[3] that clinical research may yield a return of a return of £147 for every £1 of public money that is invested in research. While we cannot verify the level of return described by NHS Lothian's researchers, NHS Lanarkshire has certainly been able to demonstrate financial benefits though its involvement in research and clinical trials in terms of commercial income, drug cost savings / avoidance.

The wide-ranging benefits that can be derived from an active research culture drive our Strategic R&D Aim, which is described below.

[3] Medical research in Edinburgh may save the NHS £300 / year (http://www.ed.ac.uk/news/2015/nhssavings-020415)

1.1. NHS Lanarkshire's Strategic R&D Aim

NHS Lanarkshire's Strategic R&D Aim is to maximise the level of high-quality, NHS Ethics-approved research being carried out within NHS Lanarkshire for the benefit of our patients, staff and the organisation as a whole

It is recognised that many of the benefits from research are not easily quantifiable or directly attributable – such as improvement in reputation, quality of care for individual patients, longer-term impact on treatment options for all patients. For the purposes of enabling progress to be measured empirically, the Board's R&D Committee will review a number of key metrics regularly throughout the lifetime of the strategy – these are discussed in more detail in the section - *Implementing the R&D Strategy*.

In addition to its alignment with the above universally-recognised drivers, the R&D Strategy also supports NHS Lanarkshire's Clinical Strategy – *Achieving Excellence*. This confirms that NHS Lanarkshire is "*…committed to delivering world-leading, high-quality, innovative health and social care that is person-centred* [and that] *our ambition is to be a quality-driven organisation that cares about people (patients, their relatives and carers, and our staff) and is focused on achieving a healthier life for all…*".

The R&D Strategy recognises that participation high-quality research and clinical trials is in keeping with this overall Board ethos. It therefore seeks to maximise the opportunities for our patients to participate in research, and supports the commitments expressed within Achieving Excellence as follows:

Achieving Excellence commitments	R&D Strategy will :
A caring and person-centred ethos that embeds high quality, safe and effective care	Focus on delivering safe, high-quality, NHS Ethics-approved research and clinical trials that provide care through structured protocols
That we continually strive to do the best individually and collectively	Increase opportunities for patients to access new, cutting-edge treatments within the context of clinical trials
That we accept individual accountability for delivering a service to the best of our ability	Ensure experienced Clinical Research Nursing and Pharmacy support is available to clinicians involved in conducting research studies
That we are responsive to changing culture, expectations and needs	Broaden the research culture by engaging with clinical groups and specialties to encourage and facilitate their involvement in research

The current R&D Strategy is planned to run for three years from 2023 to April 2026:

- This anticipates the production of a new Scottish national R&D (*or, more likely, Research, Development & Innovation – RD&I*) strategy at some point in the coming period. If and when that emerges, this R&D Strategy will be superseded by a new local strategy informed by that Scottish national strategy.
- Increasing Board engagement with Innovation – locally, regionally and nationally - will be a priority irrespective of publication of a new national strategy. See the section – *Out of scope: Innovation*.
- The Board's R&D Committee will maintain a watching brief on national developments.

1.1.1. In scope: Formal approved research

In considering the scope of this R&D Strategy it is important to be clear about the definition of '*approved research*' in the National Health Service, since the term itself can be interpreted differently in specific contexts or by non-NHS institutions.

- The *UK Policy Framework for Health and Social Care Research*[4] provides the following definition of '***research***' – this is the one that is commonly referenced across the NHS research community.

> …***research*** is defined as the attempt to derive generalisable or transferable…new knowledge to answer or refine relevant questions with scientifically sound methods. This ***excludes*** audits of practice and service evaluations…

- The UK Data Protection Act 2018 provides the definition of '***approved***' medical research in Part 2, Chapter 2, Section 19(4)[5] of the legislation. The full text is available in the reference provided, but is summarised here:

> …***approved*** medical research means medical research carried out by a person who has approval to carry out that research from—
>
> - a NHS Research Ethics Committee (NHS REC) recognised by the HRA, ***or***
> - another relevant NHS body (*as may be appointed for the purpose of assessing the ethics of research involving individuals*), ***or***
> - a research institution (*as defined in Income Tax Act 2003*)

For practical purposes, '*research institution*' refers to Universities, and approval of research by University Research Ethics Committees. In terms of legislation, the Income Tax (Earnings and Pensions) Act 2003 (section 457) defines a number of institutions and organisations that are research institutions, including: *"…any institution within the higher education sector for the purposes of the Further and Higher Education (Scotland) Act 1992, …"*

This definition is used as the basis for determining which activities can attract government research support funding and is therefore the definition accepted by all Scottish NHS Boards.

In the context of this R&D Strategy '***research projects***' therefore include only those projects that are:

- classified as **research** as defined in the UK Policy Framework ***AND***
- granted a favourable ethical opinion / approval by ***EITHER***:
    - a recognised NHS Research Ethics Committee (NHS REC) where the NHS REC guidance dictates (*e.g., when patients are involved as research participants*), ***OR***
    - a recognised Higher Education Institution (*e.g., academic research not involving patients*)

[4] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

[5] https://www.legislation.gov.uk/ukpga/2018/12/section/19

1.1.2. Out of scope: Audit and other clinical quality initiatives

It is important to clarify that, in line with the above definition, any other activities - such as clinical quality initiatives, patient safety initiatives, needs assessment, local service developments or their evaluation, clinical audit or service improvement initiatives – are out of scope of this R&D Strategy.

The CSO - in their Service Level Agreements (SLA) that govern the use of the funding they allocate to support approved research within NHS Lanarkshire, including all R&D staff salaries - explicitly requires that the Board:

> …*shall not* use the Funding provided under this Agreement for…clinical audit, patient surveys etc., local service developments including the introduction of new services into practice…

1.1.3. Out of scope: Innovation

The 2017-2022 R&D Strategy did not encompass the broad range of activities referred to as 'Innovation', other than where an innovation – such as a new medical device, drug, interventional treatment, care pathway – is being formally evaluated and assessed as part of an approved formal research study.

However, the move towards an integrated national Research, Development and Innovation Strategy (RD&I) has been signposted to an extent in the full title of the existing 2015-2020 national strategy: "…***Delivering Innovation through Research*** *- Scottish Government Health and Social Care Research Strategy*…".

Notwithstanding the name, the discussion of 'innovation' as a specific activity was restricted to only a small section within the Strategy, and only 1 of the 34 Actions listed in summary, i.e.:

> "…. *CSO will work with the SFC, Industry and the Innovation Centres – particularly the SMS IC and Digital Health Institute – with a view to ensuring that relevant outputs from these initiatives are suitably evaluated to warrant their adoption in the NHS*…"

The focus on 'Innovation' - the investment and the national infrastructure around it - has grown significantly since publication of the national strategy. In October 2018, the West of Scotland Regional Planning Board approved a paper - entitled "West of Scotland Healthcare Innovation" – which sought authority to "…*approve the establishment of the West of Scotland Regional Innovation Hub (the Hub) and recruitment to the posts*…"

Some £500K was allocated by the CSO for three years to each of three regional Hubs based in West of Scotland (NHS GG&C), East of Scotland (NHS Lothian) and North of Scotland (NHS Grampian).

The West Hub, with which NHS Lanarkshire is linked, was aligned to the West of Scotland Allied Health Science Network and Glasgow Health Science Partnership. The CSO funding was utilised to establish the central Innovation Hub Team, based in NHS GG&C – the central team comprises a mixture of clinical, management, project management and technical staff. NHS GG&C have supplemented the Hub Innovation Team with a Board-funded eHealth Innovation Programme Director post, and further project-funded posts.

Further elements of a national ecosystem for supporting innovation, and its adoption, have more recently emerged including, but not limited to, the Centre for Sustainable Delivery (CfSD)[6], the Scottish Health and Industry Partnership (SHIP)[7] and the Accelerated National Innovation Adoption (ANIA) Pathway[8].

[6] https://www.nhscfsd.co.uk/

[7] https://www.gov.scot/groups/scottish-health-and-industry-partnership-group

[8] https://www.nhscfsd.co.uk/media/euil5qvw/introducing-the-ania-pathway-booklet-a5-1.pdf

Given the vital importance of innovation in transforming health services for the future, and enabling them to be sustainable, NHS Lanarkshire – as with all NHS organisations – must be fully-engaged.

To that end, our local R&D Strategy, and the management and support arrangements necessary, will need to evolve to reflect this new and significant area of activity.

The intention is therefore to revise this R&D Strategy in due course, incorporating innovation in a more comprehensive RD&I Strategy. The precise timescale for this is dependent on some external factors, including the publication of the relevant national strategy and the availability of project management and technical support. However, this aspect of the strategy will be developed during the 2023-2024 fiscal year.

2. R&D Strategy, 2023-2026

The R&D Strategy has been developed by the Senior R&D Manager with input from the R&D Committee, the R&D team, and through informal discussions with other interested parties in Lanarkshire and with reference to the wider national and international context in which R&D operates.

It draws on, and supports the national strategic aims of, the most-recent national *Health and Social Care Research Strategy* for 2015-20. The national strategy is underpinned by six guiding principles and thirty-four specific actions which the CSO has defined to support its delivery. *Appendix 3* describes the steps that NHS Lanarkshire is taking in relation to these guiding principles and specific actions.

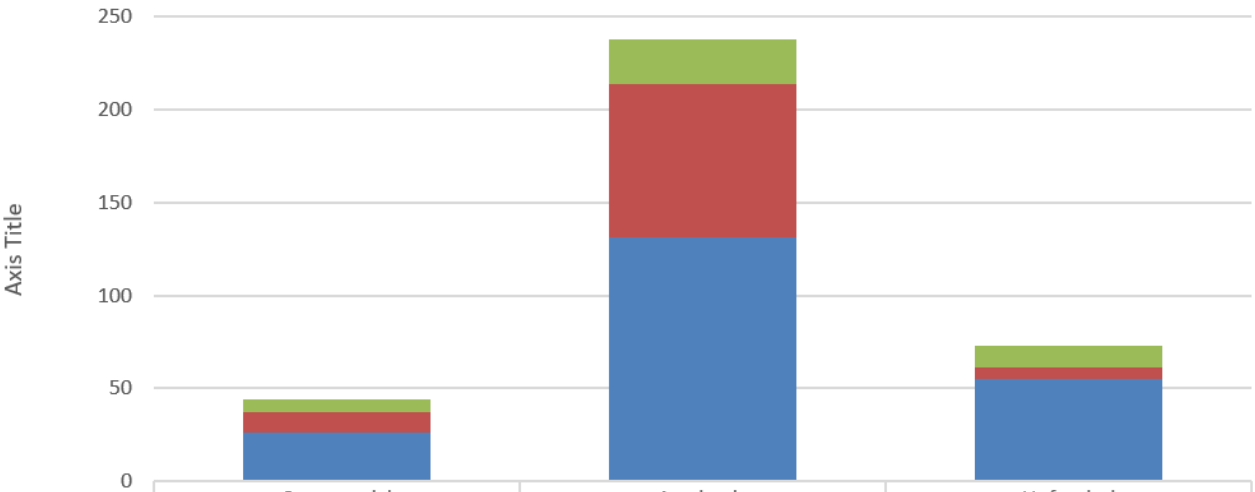
It also supports NHS Lanarkshire's own strategic priorities and plans, and in particular our Clinical Strategy – *Achieving Excellence* – and the Board's Local Delivery Plan.

Additional reference and background information is provided in Appendices 3, 4 and 5 – these are available on request from the R&D Office, and have not been updated as part of this R&D Strategy.

2.1. Brief summary of current activity

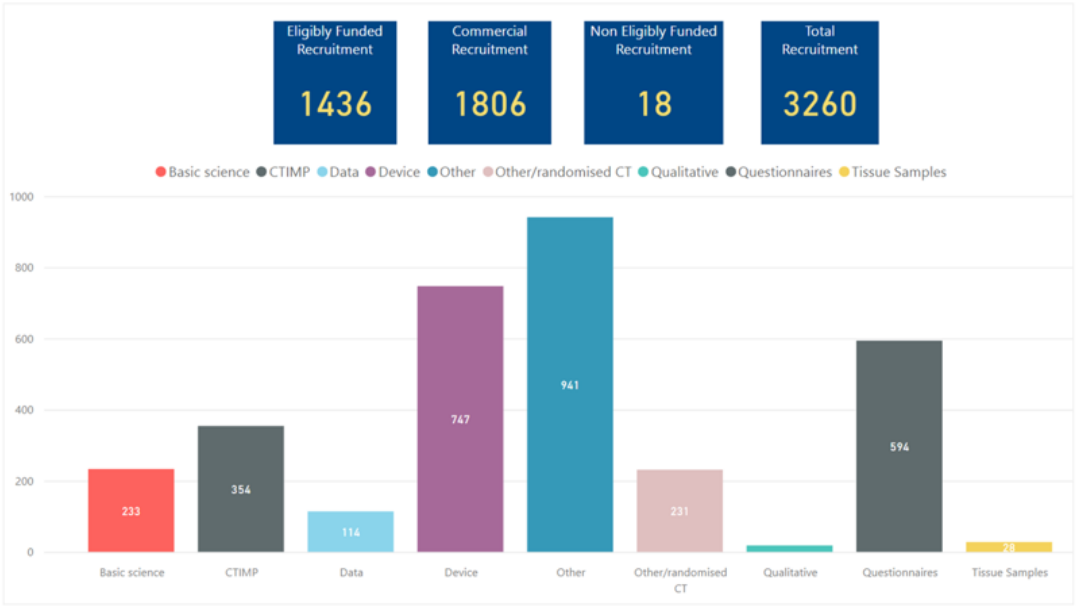
To provide some context for the growth-related aims and objectives of the R&D Strategy, the following charts offer a very brief overview of research activity in NHS Lanarkshire during the year 2022-2023.

Figure 1: Number of research studies (2022 – 2023)



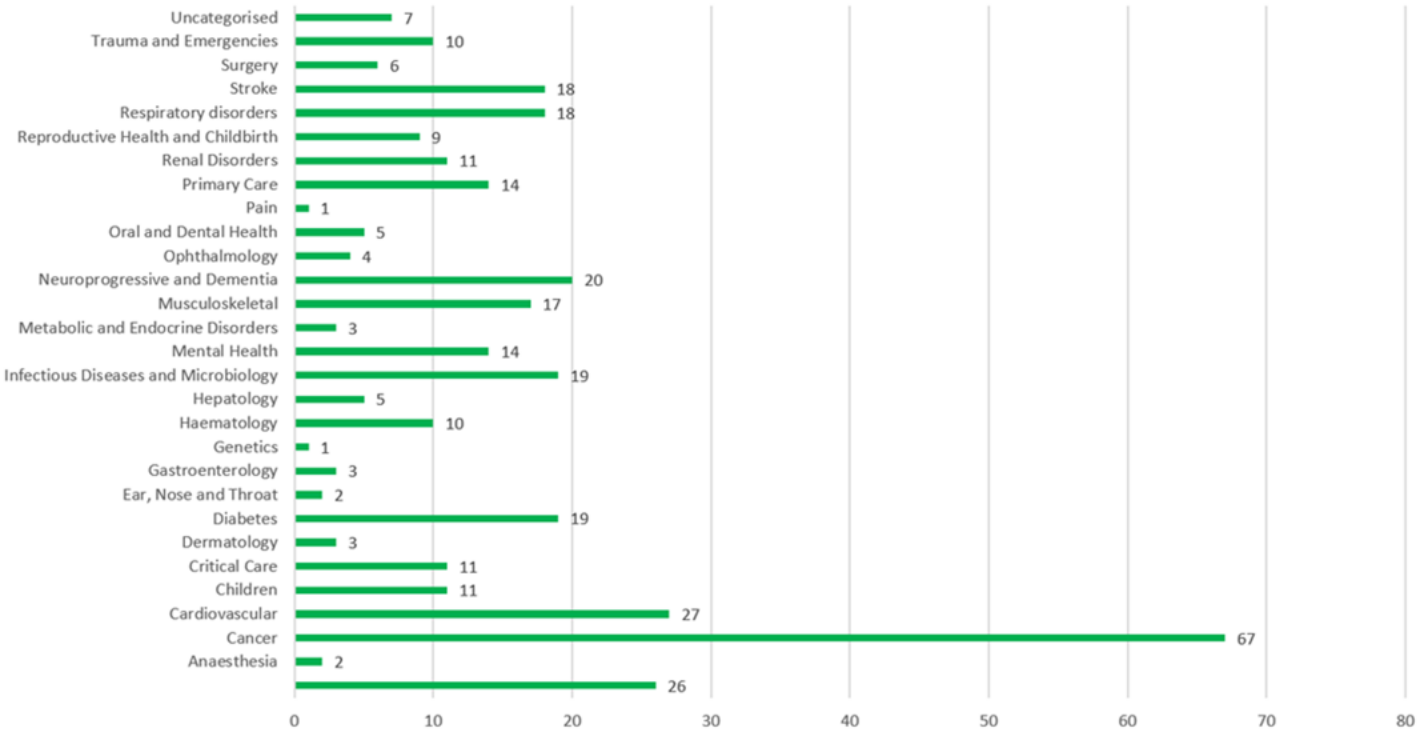
	Commercial	Academic	Unfunded
Proposed	7	24	12
In follow-up	11	83	6
Active	26	131	55

Figure 2: Recruitment to research studies by study type (2022-2023)



Scottish Specialty	Recruitment
Diabetes	811
Haem	653
Repro	497
Cardio	475
T &E	208
Cancer	138
NPD	99
Resp	68
Stroke	59
Mental Health	39
Crit Care	35
Musculo	34
Anaes	31
Children	28
Metabolic	22
Renal	16
	10
Hepato	10
IDM	10
Uncat	8
Ophthal	5
Surgery	2
Derma	1
Primary	1
Total	**3260**

Figure 3: Research studies by clinical specialty (2022-2023)



Whilst there is inevitable variability in the volume and breadth of research activities between years, the above provides a basic overview of the current size and scope of the Board's overall programmes of research. NHS Lanarkshire's research activities should be viewed in the context of the existing national and local research environments; these are explored in more detail in *Appendix 2: National and local research environment*.

2.2. SWAT analysis

An analysis of the current position in terms of our ability in to meet the aims of our own R&D Strategy and the Scottish Government's *'H&SC Research Strategy'* is summarised below; these have informed the development of our subsequently-described Strategic Objectives.

Strengths	**Weaknesses**
• Strong interest in participating in research in an increasing range of clinical specialties, including increasing requests for dedicated clinical time • Appreciation of importance of research at senior management / executive level • Experienced Clinical Trials Support Team (Trials Nurses and Pharmacy), and responsive R&D Office team • Expanding commercial research portfolio with reputation for positive, responsive R&D Office • The Board's structure and short internal lines of communication enable problems to be addressed quickly in many cases	• Lack of dedicated accommodation / space • Few clinical staff with dedicated time to lead research • Research funding not guaranteed year-on-year, and inability to grow and carry-over funding makes capacity-building difficult • NRS Research Network / Specialty Groups not all well-linked directly into specialties locally • Majority of activity focused on limited number of clinical specialties / local researchers • Few local research grant applications • Lack of clinical academic posts • Low rate of conversion of feasibilities to studies • Small R&D Department can limit support provided to researchers, and may hinder realisation of opportunities – e.g., via University collaborations
Opportunities	**Threats**
• Untapped clinical areas who may wish to participate in research • Redesign / redevelopment of Monklands presented opportunities which have manifested in the inclusion of plans for a dedicated Clinical Research Facility (CRF) in the new build • National NRS Research Network / Specialty Group structure • Large patient population who are generally supportive towards research • Formal Partnerships with Universities have increased opportunities for research collaboration	• Research seen as optional / competition for resources with 'standard care' delivery • UK-wide decline in industry-funded trials – particularly Phase III – threatens commercial income • National and local deficits in specialist clinical staffing in some areas where there are significant research opportunities • Significant, endemic capacity issues in key clinical support services • International competition for hosting clinical trials from larger markets (e.g. China, Eastern Europe) • Brexit has added complexity to national and international regulatory and financial landscape – UK arrangements for ongoing involvement in Horizon-Europe funding streams remains unsettled[9]

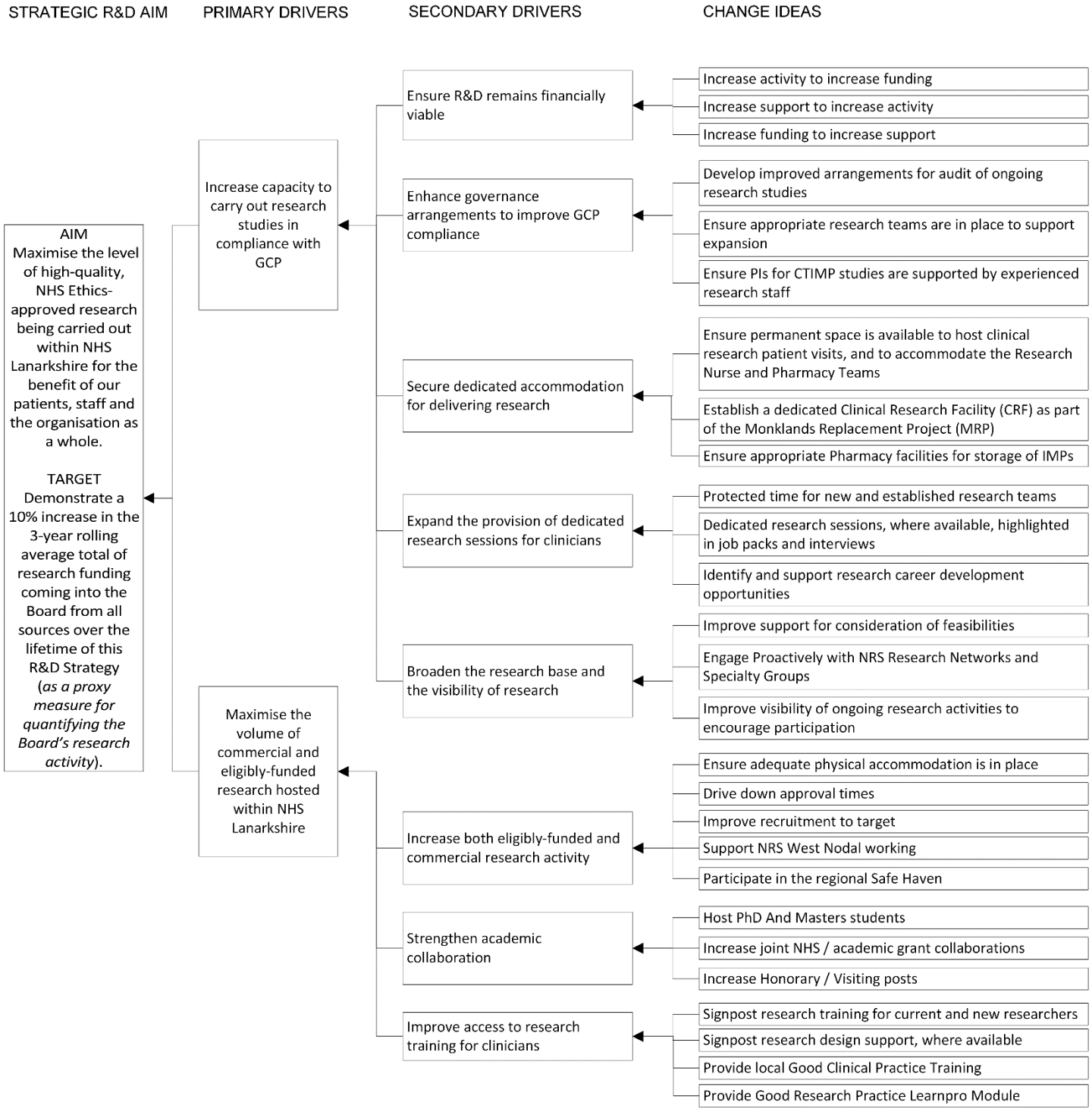
Some of the key factors that limit research activities locally, and how they may be addressed, are discussed in more detail within individual Strategic Objectives and in the R&D Strategy, 2023-2026: Implementation Plan.

[9] https://www.ukri.org/apply-for-funding/horizon-europe/

2.3. Driver diagram

The preceding SWOT analysis helped inform the construction of following Driver Diagram which identifies a series of change ideas, and associated primary and secondary drivers that will provide impetus for the delivery of the Strategic R&D Aim.

The secondary drivers have been transposed as eight Strategic Objectives which form the body of the R&D Strategy 2023-2026, as detailed in the next section.



2.4. Strategic Objectives

The Strategic Objectives are all closely interconnected, with the success of one objective being both dependent on *and* supporting the success of others.

For example, the expansion of commercially-funded clinical trials of new medicines is dependent on the availability of dedicated accommodation and the support of Consultants with sufficient dedicated time to take on the responsibilities of PI; in turn such expansion will provide funding to pay for Research Nurses and other R&D support staff, and will potentially support additional dedicated clinician time.

Our approach for delivering the objectives are detailed in the *R&D Strategy, 2023-2026: Implementation Plan*, which is included at *Appendix 1*.

Objective 1. Ensure R&D remains financially viable

Financial support for conducting research is almost exclusively self-generated as a result of the research activities carried out within the Board. Income is generated through participation in research studies, including recruitment, investigation, treatment and follow-up of research participants.

Research can be funded via a number of routes; these leads to a broad categorisation of research as either '*non-commercially-funded*' or '*commercially-funded*' research. However, irrespective of the funding source, it is generally true that the level of research income earned by the Board from all sources is directly related to the number of studies carried out, and the number of research participants who are enrolled.

The support provided for researchers – the R&D Office staff responsible for research governance, the Clinical Research Nursing and Pharmacy Teams, the limited number of dedicated programmed activity (PA) sessions for clinicians, research training provision, research equipment such as centrifuges and freezers, etc. – are all funded directly from this earned research income.

The Senior R&D Manager, supported by the R&D Finance Officer, ensures that expenditure does not exceed income, and therefore does not create an overall cost pressure for the Board.

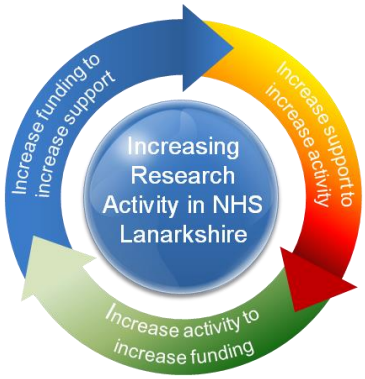
It is within this financial context that we will seek to meet the strategic objectives outlined in this document.

There are undoubted disadvantages in the funding model for research in the NHS:

- funding levels are not guaranteed as part of the core service funding for Boards, therefore long-term planning is difficult
- staff contracts can typically only be offered on a fixed term basis which creates problems in recruitment and retention
- funding allocated as a result of activities in a previous year do not reflect the support needs of any expansion of activity in a current year – that can inhibit growth.

Notwithstanding these disadvantages, the fact that 'funding-follows-activity' does provide opportunities for increasing research income, and therefore supporting expansion *if* the initial requirements for investment can be met from existing research funding.

The cycle of *'…Increasing funding → Increase support → Increase activity → Increase funding →…ad infinitum'* is therefore the model that provides the financial underpinning for this R&D Strategy.



The same model applied over the lifetime of the prior R&D Strategy.

This chart illustrates that income was growing steadily prior to the COVID-19 pandemic, and has begun recovering to pre-pandemic levels as the portfolio of research studies being carried out returns to a more broad-based mix of studies.

As mentioned, it is important to ensure that research income does not exceed expenditure, thus creating an overall cost pressure for the Board. However, it can also be the case that R&D activities can generate surplus revenues during any given financial year.

Indeed, one of the three key elements of the cycle underpinning the R&D Strategy is:

- ***Increase funding to increase support***

In the overall context of the R&D Strategy, the aim is therefore to generate sufficient *surplus* income – i.e., income not already required to meet existing commitments (*primarily existing staff salaries*) – to underpin investments in *new* areas so that the level of research activity can grow. This may be through additional Research Nurse posts, additional dedicated time for clinicians to enable them to act as Principal Investigators, or to fund specialised R&D equipment.

This is a key element that secures the success, or otherwise of the R&D Strategy – expansion and growth can only happen with investment in new areas of research activity.

This approach was proven to be successful during the first half of the lifespan of the prior R&D Strategy, where investments in, for example, dedicated Consultant research sessions and additional Research Nurses, enabled growth and expansion in research programmes in the specialties that were thus supported. Those research programmes in turn generate sufficient income such that the initial pump-priming investments have become more than self-sustaining.

Investments to grow new research programmes were primarily possible because of the presence of the R&D Capacity Building Fund. This Fund had been grown and maintained over a number of years through surplus income from, primarily, commercially-funded clinical trials. These include a contractual-payment called '*Capacity Building*' that is specifically intended "*…for maintaining, strengthening, and adapting and growing sustainable research capacity over the long-term…"* (*see the* **Note** *below for further details*).

A noteworthy issue arose following the implementation of the international accounting standard IFRS-15 '*Revenue from Contracts with Customers*' in 2018-2019. A consequence of IFRS-15 was that in-year surplus income – including the commercial funding designated as '*Capacity Building*' - could no longer be carried-over between years. As identified in the SWAT analysis – that inability to grow and carry-over funding makes capacity-building very difficult.

The demise of the R&D Capacity Building Fund has had a significant negative impact on the ability to invest to grow R&D in NHS Lanarkshire. It continues to be one of the substantial challenges in increasing research within the Board. As part of this objective we will explore alternative approaches to enable '*Capacity Building*' to underpin expansion.

Note: Payments to NHS Boards in respect of the conduct of commercially Sponsored and

Objective 2. Enhance governance arrangements to improve GCP compliance

The R&D Governance Sub-Group of the R&D Committee identified an objective to enhance support in relation to the start-up process for research studies and ongoing study conduct.

In particular, enhanced support is required for clinicians who are taking on the role of Principal Investigator for the first time to help them maintain adherence to Good Clinical Practice standards that apply to the conduct of research.

This objective includes supplementing the external, Sponsor-led formal Monitoring of studies with a locally-led system of audit, aimed at identifying local issues with study conduct, and ensuring they are appropriately addressed.

Objective 3. Increase both eligibly-funded and commercial research activity

All eight Strategic Objectives are ultimately aimed at enabling and supporting an increase in high-quality research activity in NHS Lanarkshire, for the benefit of our patients, staff and the organisation; this is in line with the national R&D Strategy, and with the funding agreements we enter into with the Scottish Government Chief Scientist Office.

In the context of both this local R&D strategy and Scottish National R&D strategy, the focus is on increasing 'Eligibly-Funded' and 'Commercial' research - these are defined below.

Eligibly-funded[10] research

The Chief Scientist Office, acting on behalf of the Scottish Government, provides an annual funding allocation to NHS Lanarkshire. This is the Board's primary source of research funding, and the associated and Service Level Agreement (SLA) is explicit in how it must be utilised:

> The Purpose of the Funding is to enable the Recipient to support research funded by an NRS Eligible Funder, and to increase Research being conducted under those arrangements and to also support the Recipient in meeting its obligations in supporting studies adopted to the Scottish portfolio that are NIHR Adopted.

'NRS Eligible Funders' are non-commercial organisations that fund high-quality research as part of their core mission, and maintain specific standards and governance criteria when doing so – the criteria are summarised below:

- Award research funds as a result of open competition across Scotland with high quality peer review; ***and***
- Fund research that is of clear value to NHS Scotland; ***and***
- Take appropriate account of the priorities, needs and realities of NHS Scotland in making decisions about the research that they fund.

The CSO maintains a list of non-commercial Eligible Funders – typically UK Charities, funding councils, Government. The SLA **requires** that the Board R&D Office **only** uses the research funding it receives to support and increase the volume of Eligibly-Funded research taking place within NHS Lanarkshire (*prohibitions on utilising the funding for other purposes are as previously described*).

Against a backdrop of ongoing service pressures and capacity issues, it can be difficult for some services to accommodate the additional investigations and other work that can be associated with the conduct of Eligibly-Funded research. The issues have been particularly evident on two areas – Radiology and Aseptic Pharmacy.

The limitations inherent in non-commercial research funding means that it is rare for funding to be provided for additional NHS activities, such as imaging investigations, pharmacy preparation and handling of novel medicines or additional research-driven laboratory tests. Lack of funding to, for example, pay for out-of-hours activity, can result in additional barriers to growth in non-commercial research.

[10] NRS Funding Guidance: Annex 2 details eligible non-commercial research funders – UK charities, government, research councils, etc. - https://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS%20Funding%20Guidance%20-%20Annex%202%20-%20Eligible%20Funders%20Working%20Document%20(4).pdf

Commercial research

These projects are commercially Sponsored and funded (*primarily by pharmaceutical companies*) and are essentially a contract between NHS Lanarkshire and the Sponsoring company to recruit participants according to a defined protocol. The aim is usually to determine the efficacy of a novel intervention with the information being used to support, for example, a drug licensing application. Costs are assessed using a national template which ensures full cost-recovery for the participating NHS Board at commercial rates.

A commercial research portfolio provides a number of significant benefits:

- Access to new medicines and treatment technologies that would otherwise be unavailable to our patients
- Generates significant cost avoidance or actual income for the Board (*prior examples of in excess of £25k / month cost avoidance realised over two through involvement in commercial studies where expensive medicines are provided free of charge during the conduct of the studies*)
- Increased opportunities to attract funding to help develop, test and deploy novel technologies as part of research studies

The key factors in attracting more commercial *and* Eligibly-funded Research to NHS Lanarkshire are:

- Appropriate support from an integrated, and appropriately qualified research team with time to carry out all protocol-directed tasks
- Suitable physical accommodation, equipment and facilities in which to safely deliver scheduled clinical Research treatment and assessments
- Demonstrable track record in approving studies quickly and recruiting to target

In what is an increasingly competitive UK and global research community, the ability to demonstrate excellent performance in the above key metrics to Sponsors will be vital in attracting commercial / Pharmaceutical Industry *and* academic research to NHS Lanarkshire, and winning competitively awarded research funding.

It is important to recognise and acknowledge that the UK is seeing a marked decline in industry-led commercial trials. In December 2022, the Association of the British Pharmaceutical Industry (ABPI), published their perspective on the UK's clinical research environment. Their conclusion was clear – industry-led, NHS-hosted clinical trial activity is on the decline in the UK.

A number of objective measures were presented that backed-up this conclusion:

- Over the five years from 2017 to 2022, the annual total of patients recruited fell from 50K pa to 28K pa.
- The level of recruitment to industry trials as a proportion of recruitment to all research in the NHS fell from 6% to 2%
- The number of new clinical trials initiated in the UK annually fell from 667 to 394
    - Within that, the number of new oncology clinical trials fell from 234 to 139
- The UK's ranking in terms of trials activity when compared to other nations globally has fallen sharply across trials of all Phases.
    - UK was ranked 3rd for Phase I trials in 2017 – now ranked 4th
    - UK was ranked 2nd for Phase II trials in 2017 – now ranked 6th
    - UK was ranked 4th for Phase III trials in 2017 – now ranked 10th

The ABPI has published a policy position paper outlining actions that, it suggests, can *Rescue Patient Access to Industry Clinical Trials in the UK*[11]. Many of the suggestions require action at a national level, and work on these will be ongoing in the UK administrations.

As noted, the drop in UK-initiated Phase III clinical trials was particularly stark. In terms of study numbers, that fall in ranking represented a reduction from 269 annually to only 140 – a drop of 48% in five years.

This is a particular issue for NHS Lanarkshire (*and all other Boards that are not co-located with a University Medical School*), since Phase III clinical trials are by far the most common - only a very small number of Phase II studies are hosted, and Phase I studies can only be hosted in accredited Clinical Trials Units.

Commercial trials activities are an important component of our portfolio, with income from commercial trials contributing around 25% of the Board's total research staffing budget in most years. This national decline in Phase III clinical trials therefore represents a particular challenge in delivering on this R&D Strategy.

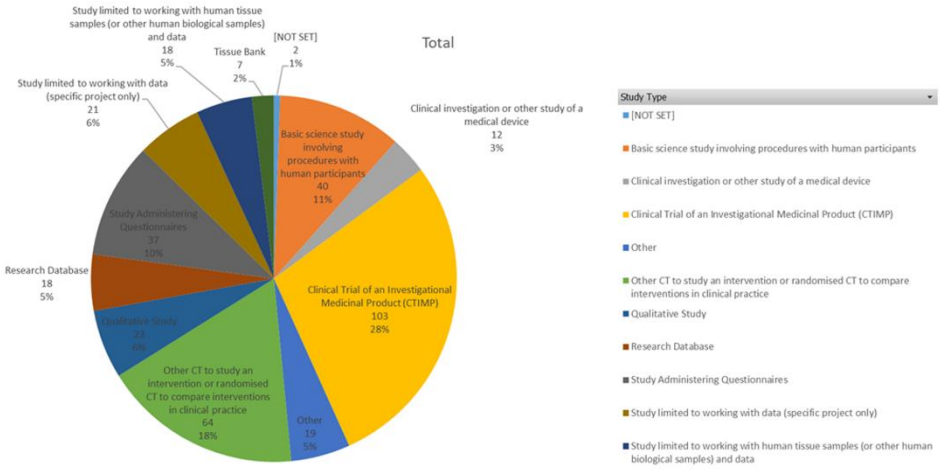
It is worth highlighting that, over the lifetime of previous Strategy and through the recovery period since the initial phase of the COVID-19 pandemic – and despite the severe downward trend nationally - NHS Lanarkshire has managed steady *increases* year-on-year in commercial research income.

However, the national decline, unless reversed, will inevitably be a limiting factor – and possibly a significant one – on our portfolio and associated income going forward.

Objective 4. Expand the provision of dedicated research sessions for clinicians

The *UK Policy Framework for Health and Social Care Research*[12] requires that research studies have a clearly identified clinical lead – a Principle Investigator (PI) - in each site where the research is taking place; increasing the number of active Principle Investigators will support an increase in research.

The largest group taking on the role of PI are doctors. That follows, in part, from the regulatory requirements related to clinical trials of new medicines as detailed in *The Medicines for Human Use (Clinical Trials) Regulations*, and from Principle 2.5 of the ICH GCP Guidelines (referenced in Schedule 1, Part 2 of the above legislation) which states that *"…A qualified physician…should have the overall responsibility for the medical care given to, and medical decisions made on behalf of, participants…"*



As illustrated here, Clinical Trials of Investigational Medicinal Products (*CTIMPS / drug studies*) are the largest single category of research activity in the Board's portfolio.

Other forms of research - basic science studies, interventional and non-interventional studies, tissue collections, student research, etc. – also require a PI, who may be from any clinical profession.

[11] https://www.abpi.org.uk/r-d-manufacturing/clinical-research/rescuing-patient-access-to-industry-clinical-trials-in-the-uk/

[12] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

While research is an important element of the role of clinical professions – as is made explicit in a range of national strategies and by professional bodies (see examples below) – the availability of, and funding for, dedicated / protected time to conduct research is currently limited.

The capacity of our clinical staff to take on the role of PI is a key factor in determining the limits of the Board's overall research portfolio and capacity.

Recommendations by professional / charity bodies re: dedicated research time

1. GMC statement on promoting research for all doctors[13] notes that:
    a. *all doctors…should have time protected in their job to carry out professional activities like leading research [and] should be encouraged to engage in the delivery of clinical research as part of direct clinical care*
    b. *research active environments save patient lives, and in the long term save money… retaining the medical workforce necessary for such environments requires resources. Therefore, there should be a requirement that all healthcare providers incorporate provisions for this aspect of medical practice in their budgets*
2. The Cancer Research UK (2021) report *Creating time for research*[14], notes:
    a. *dedicated research time is too inaccessible and inadequately supplied, meaning many staff conduct research in their own time and at their own expense.*
    b. *'high demands of clinical services' and 'no protected time for research' were the most cited barriers across all professions*

We will therefore explore what options may exist to meet the objective of expanding the amount of dedicated research-time available to clinicians in all professions, and to make it more straightforward for them to take on the role of Principal Investigator.

Objective 5. Broaden the research base and the visibility of research

The range of clinicians and clinical areas that are involved in research expanded somewhat over the period of the previous R&D Strategy. There are significant pockets of established activity, but sections of the clinical community are not engaged in supporting and participating in research for a variety of reasons, some of which we seek to address in this R&D Strategy. It must be recognised that not everyone is interested in research – some have other career interests – and, despite any support that this strategy can offer, there are some areas where other operational clinical priorities or staffing deficits makes participation in research very difficult.

One of the key strategic objectives, however, is to take steps to broaden the base of research in NHS Lanarkshire. Maximising the number of research-active clinicians will increase the volume of research and the benefits to our patient and organisation. It will also mitigate against the negative impacts felt when any individual researcher moves on from NHS Lanarkshire or when, as can happen, the research portfolio in an active specialty or other area of the organisation drops off temporarily.

[13] https://www.gmc-uk.org/education/standards-guidance-and-curricula/position-statements/normalising-research---promoting-research-for-all-doctors

[14] https://www.cancerresearchuk.org/sites/default/files/creating_time_for_research_february_2021_-_full_report-v2.pdf

Objective 6. Strengthen academic collaboration

Developing and exploiting academic collaborations is strategically important for the Board's future direction. To that end, it has, since 2016, entered into formal Academic Partnerships with three Universities – University of the West of Scotland, Glasgow Caledonian University and University of Strathclyde.

The Board's Strategic Academic Liaisons Workgroup oversees our academic collaborations at a strategic, organisational-level, and the Senior R&D Manager has a key role as part of that work. The benefits to be realised from such academic collaborations are wide-ranging and will continue to develop. They include enhanced clinical teaching and practice learning opportunities, development of advanced practice models, development of more defined clinical academic / research career pathways, opportunities for establishing jointly funded PhD studentships.

From the perspective of R&D, the main focus is on developing research collaborations. This may take many forms such as NHS-Hosted but University-led research, collaborative grant-funded projects, development of joint clinical / academic posts, hosting students to conduct research as part of postgraduate studies, etc.

It will be particularly important to understand how the Board's objectives and priorities align with the values and expertise of each of our University Partners. Specifically, a key goal will be to use this understanding to form NHS/University collaborations at individual, service and organisational level to evolve new programmes of research in areas of mutual interest and expertise.

The Academic Partnerships also play a key role in the Strategic Objective of broadening the research base, particularly through increasing engagement with delivery arms of the Board that have been less involved previously in formal research, such as the North and South Health & Social Care Partnerships (H&SCPs).

The Senior R&D Manager will also provide leadership and guidance for University partners to engage with and take advantage of NHS-funded research infrastructure, such as the West of Scotland Data Safe Haven and the NHS Tissue Biorepository. This work will underpin the establishment of new research programmes within the University Partnerships, such as in human-tissue-based research and Artificial Intelligence using NHS data.

Objective 7. Improve access to research training for clinicians

The UK Health Research Authority states that "*…Those conducting clinical trials of investigational medicinal products (CTIMPs) must comply with the high level conditions and principles of GCP, but there is no legal requirement for other types of research to do so.*

Such research should be conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data is reliable – but this can be achieved through means that are appropriate and proportionate to the activities being undertaken.

Different types of research may require different training, and some researchers are already well trained and competent in their area of expertise. Some researchers doing other types of clinical trials may also benefit from undertaking GCP training but other training may be more relevant..."

Lanarkshire clinicians who wish to be involved in, and support research activities, therefore need access to appropriate training to enable them to carry out their research roles. A wide range of free and fee-paying research training, covering a wide variety of scenarios, is available online and in-person across the UK.

In relation to this, we will ensure that NHS Lanarkshire staff have easy access to the core research training that they need. We will also ensure that the training that is provided or signposted is proportionate to the specific roles each individual carries out, and to the type of research study.

Objective 8. Secure dedicated accommodation for delivering research

Dedicated clinical accommodation in which to carry out research visits with patients is a basic pre-requisite for supporting a portfolio of health research. Facilities to host research were not, however, included in any of NHS Lanarkshire's three acute hospitals at the design stage.

There has been limited progress over the course of the previous R&D strategy in securing dedicated facilities for carrying out research study clinical visits; often these research needs can be in competition with operational services.

The lack of permanent dedicated clinical space – and space for research support staff - has been a consistent factor in inhibiting research activities, and has resulted in missed research opportunities, patient inconvenience and loss of research income.

If research is to continue to grow and flourish in NHS Lanarkshire, the maintenance of dedicated accommodation for research is a key objective.

The most significant advance in the longer term in relation to this Strategic Objective – beyond the lifetime of this R&D Strategy – will be the development of the dedicated Clinical Research Facility as part of the Monklands Replacement Project. That is currently expected to be commissioned around 2031 – the R&D team will continue to actively engage in the planning process in the meantime.

3. Implementing the R&D Strategy

3.1. Responsibilities for delivery and oversight

The Senior R&D Manager is responsible for implementing the Research & Development Strategy. Their authority is derived from the Executive Medical Director who, in turn, is the Executive with responsibility for R&D as detailed in the Board's Scheme of Delegation; the Medical Director Chairs the R&D Committee and the Senior R&D Manager is Vice Chair. The Executive Medical Director and R&D Committee will be responsible for providing the Senior R&D Manager with support for implementing the Strategy. They will provide advice, direction and, where necessary, the authority required for implementing individual elements.

Individual research activities and projects are delivered by the R&D team and the Board's research-active clinicians and clinical support departments as described previously.

The R&D Committee will ensure effective and appropriate implementation through receipt of regular updates from the Senior R&D Manager, through regular receipt of a series of metrics, and via the R&D Committee's Annual Report, which will also be provided to the Board's Healthcare Quality Assurance & Improvement Committee (HQAIC).

3.2. R&D Committee membership

Although its membership and Terms of Reference (ToR) are, strictly speaking, outwith the scope of the R&D Strategy, the R&D Committee felt it important to note the likelihood that changes to both membership and ToR may be required as a result of the implementation of the strategy.

Particular aspects of the R&D Strategy that may have implications for the R&D Committee include:

- publication of a new Scottish national Research, Development & ***Innovation*** strategy - and the Board's own engagement with Innovation.
    - The term 'Innovation' covers a broad spectrum of activities – from, at one end, primary research, prototyping and testing right through to operational implementation.
    - The governance frameworks for Innovation are evolving, with differing arrangements likely required at either end of the spectrum.
    - Some governance responsibilities may rest with the R&D Committee – if so, it is likely that representation from other areas, such as eHealth, will be required.
- continuing evolution of the Academic Partnerships to more explicitly recognise collaborations with the H&SCPs is likely to engender a growth in formal research in out-of-hospital settings – H&SCP representation to ensure appropriate governance will be crucial in these circumstances
- expanding the provision of dedicated research sessions / broadening the research base will stimulate a need for broader clinical representation on the R&D Committee
    - Taken together with the evolution of the Academic Partnerships, representation from the Board's growing cohort of clinical staff who have been awarded University 'visiting' positions may provide improved integration and insight into how the benefits of the Partnerships, from an R&D perspective, can be maximized.

3.3. External review

Research project activity, including levels of participant recruitment and other aspects of performance, are externally monitored annually by the Chief Scientist Office.

3.4. Metrics for indicating progress and delivery

NHS Lanarkshire's Strategic R&D Aim is to maximise the level of high-quality, NHS Ethics-approved research being carried out within NHS Lanarkshire for the benefit of our patients, staff and the organisation as a whole.

As noted previously, some of the many broader benefits from research are not easily quantifiable or directly attributable to specific research studies – such as improvement in reputation, quality of care for individual patients, longer-term impact on treatment options for all patients through input to new drug developments.

It is, however, possible to produce regular, simple process metrics describing the level of research activity within the Board. These will be used to measure our success in meeting the Strategic R&D Aim.

3.5. Single global measure of success

The previous R&D Strategy, when published, defined a single global measure of success as being able to demonstrate "*…an overall increase of 20% in the **number** of commercial and non-commercial research studies being conducted over the lifetime of the R&D Strategy*…"

It was subsequently recognised, however, that this single metric of **number of studies** was not a reliable measure of '*research activity*'. This was for a number of reasons, including not taking into account:

- the level of recruitment to those studies
- the level of complexity / work involved of individual studies
- national changes, such as a tendency towards small target, more complex studies

The R&D Committee subsequently agreed on a revision to the single global measure that would be used. This is also adopted into this R&D Strategy as follows:

Demonstrate a 10% increase in the 3-year rolling average total of research funding coming into the Board from all sources over the lifetime of this R&D Strategy (*as a proxy measure for quantifying the Board's research activity*)

**The level of funding allocated by the CSO and research funders for supporting non-commercial research projects, and the income derived from commercial companies and other research funders for supporting their clinical trials, is calculated using methods that take into account issues such as complexity, staff time commitment, number of patient visits and involvement of support services.*

Tracking funding growth therefore provides a more effective method for quantifying the growth of the Board's research portfolio than simply the number of studies. The rolling 3-year average is used to reduce the impact of excessive year-on-year variations (positive or negative), and provides a more balanced assessment of trend.

The above single global measure will be assessed as follows:

The average total income during the period April 2020-March 2023
(*i.e., the last three years of the previous R&D Strategy*)

versus

The average total income during the period April 2023-March 2026
(*i.e., the projected three-year lifetime this current R&D Strategy*)

3.6. Quarterly metrics

The Senior R&D Manager, supported by the R&D team, will produce a series of financial and performance metrics to the Board's R&D Committee every quarter. The R&D Committee will also have the discretion to request additional performance measures as required.

The undernoted examples are provided for illustrative purposes. This is, in-part, due to the fact that the Chief Scientist Office is currently reviewing the metrics that will be measured nationally, particularly around approval time performance and recruitment to target. In determining metrics, the R&D Committee will take account of any mandatory regular national metric reporting to avoid duplication.

- Approval times performance: Non-commercial studies / Commercial studies / Study amendments
- Finance allocation – annual trend
- Annual trend - Total research income by site
- Annual trend - Non-commercial / Commercial income by specialty
- Annual trend - Recruitment to Non-commercial, eligibly-funded studies / Commercial clinical trials
- Number of Non-commercial / Commercial and projects approved in the quarter
- Number of Feasibility requests considered by our clinicians
- Proportion of Feasibilities where we respond positively

The Senior R&D Manager will also provide a more general summary of progress against the eight Strategic Objectives to the R&D Committee, highlighting any issues that require support to aid progress.

The Executive Medical Director, in his role as Chair of the R&D Committee, will provide a summary of progress to the HQAIC on a quarterly basis, or as they require.

4. Equality and Diversity Impact Assessment

This policy meets NHS Lanarkshire's EDIA.

5. Appendices

Appendix 1: R&D Strategy, 2023-2026: Implementation Plan

Appendix 2: National and local research environment

The above Appendices 1 and 2 are included below, within this document.

The undernoted supplementary appendices are available from the R&D Office on request.

Appendix 3: Activities supporting the NHS National Research Scotland R&D Strategy, 2015-2020

Appendix 4: Local and national environment for supporting and delivering research

Appendix 5: Some additional factors that may influence our future vision for research

5.1. Appendix 1: R&D Strategy, 2023-2026: Implementation Plan

Objective 1: Ensure R&D remains financially viable	
Activity	**Actions**
Increase activity to increase funding	We will continue to proactively reinvest previously earned income in our research support infrastructure so we are in a position to support new research activities as they come on stream. In particular, we will maximise the availability of Research Nursing and Trials Pharmacy support – within our allocated budget – for clinicians so that they can participate in eligible and commercial studies. For non-commercial eligibly-funded research there is a time lag that can mean there is more than a year between research activities taking place and receipt of the CSO funding allocation earned as a result of those activities. For commercial studies, the income is more immediate – typically we invoice quarterly in arrears. In both cases, however, there is a lag between activity and funding received. This means that we must always be in a position to invest in support for specific research studies *prior* to the receipt of any earned income as a result of participation in those studies. To do that, we maximise, within financial constraints, a team of Research Nurses and Trials Pharmacy staff able to adopt new studies while also supporting ongoing research activity from prior years.
Increase support to increase activity	Clinicians rely on the support and advice they receive from the R&D Office and the Clinical Trials Nursing and Pharmacy Teams to allow them to act as Principle Investigators and conduct research studies. The Nursing and Pharmacy Teams have expanded since 2009. Following on from the appointment of the Lead Trials Pharmacist, the critical factor in the management and expansion of the Research Nurse Team was the appointment of a Lead Clinical Research Nurse in 2013. These developments resulted in a focused line management structure and a realistic assessment of capacity and support requirements for the overall research portfolio. The Lead Clinical Research Nurse will continue to work with her Research Nurse Managers to review the placement of Research Nurses so that they are able to provide targeted support where required, and to the best fit to support the strategy of expansion. The R&D Office staffing level has remained relatively static as research activity increased during the course of the previous R&D Strategy. Increasing R&D activity being managed the same level of staffing is difficult to maintain.

	We will continue to explore efficiencies in processes to enable R&D governance requirements to be accommodated. We will also, funding allowing, prioritise an expansion of the R&D Office function in line with any increase in activity and associated funding.
Increase funding to increase support	We will continue to reinvest all of our research income to increase and enhance our infrastructure so that we are in a position to provide the support necessary to underpin the expansion of research which will, in turn, generate increased income. We will also look at other options for increasing the funding available to R&D that can be deployed to augment the support available to researchers. The formal Partnerships that NHS Lanarkshire has with a number of local Universities will be a potential area for significant expansion for formal research. We will, as part of this, have a focus on collaborative grant applications that can increase the level of research support funding coming in to the Board. We will also explore what arrangements would enable us to improve capacity if more income is generated in any one year than is required to meet in-year costs.
Objective 2: Enhance governance arrangements to improve GCP compliance	
Activity	**Actions**
Ensure PIs for CTIMP studies are supported by experienced Research staff *PI – Principal Investigator* *CTIMP - Clinical Trial of an Investigational Medicinal Product*	It is recognised that the level of general input and support required from Research staff may be greater where the PI is *clinically* qualified, but inexperienced in terms of leading on the conduct of a CTIMP study. The level of support required will be agreed during the study set-up discussions between the PI / Research Nurse / Trials Pharmacists and any specific arrangements documented. The R&D Office and Lead Research Nurse and Lead Pharmacist Clinical Trials will continue to maintain a mandatory check to their pre-approval study assessment processes to ensure that appropriately experienced Clinical Research Nurse and Pharmacy staff are included as part of the study team supporting Principal Investigators in all Clinical Trials of Investigational Medicines. Such staff will be formally recorded on the Study Delegation Log.
Ensure appropriate research teams are in place to support expansion	The senior R&D management team will continue to ensure that research studies are only taken on when adequate support arrangements are confirmed, including Clinical Research Nurse and Clinical Trials Pharmacy support.

	We will continue to deploy integrated research teams in new clinical areas where dedicated research sessions have been agreed for individuals or clinical specialties by including the provision of Clinical Research support within applications for protected research sessions
Develop improved arrangements for audit of ongoing research studies	NHS Lanarkshire acts as Sponsor in only a limited range of research studies – typically non-interventional / qualitative research carried out as part of an educational qualification (*as a matter of policy, NHS Lanarkshire cannot Sponsor CTIMP studies*). Success in implementing this R&D Strategy is likely to result in an increase in the number and types of *non-CTIMP* research studies initiated by our own staff, and that this may include interventional non-CTIM studies. Although there is no legal requirement to conduct formal monitoring of non-CTIMP studies, it is vital that high standards of research conduct are maintained – we will therefore ensure that Sponsored, interventional non-CTIMP studies that involve changes in normal care are subject to audit by our Research and Research Nurse Teams. We will increase the regularity of audit by improving our arrangements peer-to-peer audit process within the Clinical Research Nurse team. In order to support this, we will develop and pilot a new role within the Research Nurse team, who will work closely with the R&D Office team.
Objective 3: Increase both eligibly-funded and commercial research activity	
Activity	**Actions**
Ensure adequate physical accommodation is in place	This is a key limiting factors in expanding research in NHS Lanarkshire. During the lifetime of the previous R&D Strategy, the situation has improved to an extent, with assistance from the hospital management teams on each of the three acute hospital sites. Limitation remain, both in terms of the amount of space available, and in terms of how secure that space is – R&D are asked to consider movements to other rooms from time to time – due to operational service pressures - and such moves do not always represent improvements. However, we will continue to work to maximise the efficient use of the space that we do have to enable us to host trials. The issue of accommodation is addressed as a separate objective.
Drive down approval times	We will continue to seek to improve already efficient processes within the R&D Office to reduce approval times for studies. This is of particular importance for commercial companies – they seek efficient approval times to shorten their overall time to market. This will involve ever-closer integration between the R&D Office and our research support teams.

	We will also continue to improve arrangements that involve other services and departments as components of the overall approval of research, such as Information Governance and Human Resources, including the development of shared processes and procedures.
Improve recruitment to target	In agreeing to act as a Host Site for a research study, the local study team – led by the Principal Investigator – estimates the number of people that they will recruit to the study. The delivery of recruitment to the targets estimated by Host Sites is crucial for the study Sponsor, as full recruitment is required to enable valid conclusions to be reached in relation to their study objectives. For the Host Site, maximising recruitment is also key in terms of determining research income to the Board – it is estimated that, for commercial research, more than 90% of the value of the study contracts are based around per-patient fees. Under-recruitment in commercial and non-commercial research therefore represents a real missed opportunity in terms of research income, cost-avoidance / savings, patient access to new treatment, improving reputation and attracting new research. The R&D Office and Research Teams will re-introduce arrangements – suspended during the pandemic - to maximise recruitment. The two main components will be: • Ensuring initial targets are realistic. This will be achieved through discussion with PIs, assessment of any existing clinical registers, etc., to ensure that the targets set are achievable • Regular review of recruitment, and action plans to address under-recruitment. The Research Nurse Managers will review recruitment-to-target based on the monthly RAG (Red, Amber, Green) reports that are issued by the NRS Scotland Network Managers, and will take actions where possible / necessary to improve recruitment.
Support NRS West Nodal working	Research thrives on collaboration, transfer of ideas and mutual support. Increasing *academic* collaboration is specifically addressed in a subsequent objective, but we will also reinvigorate collaborative working links within our own NRS West Node colleagues, and with the NRS Research Networks and Specialty Groups. We will work in collaboration with the NRS West Research Node – led from NHS GG&C - to enable our researchers to access regional and tertiary infrastructure and expertise. Among other benefits, this relationship will enable NHS Lanarkshire staff: • to access Glasgow Clinical Research Facility training free of charge • to participate in the Glasgow Biorepository for studies involving tissue collection

	• to collaborate more closely on research studies being led from tertiary service providers, such as carrying out cardiology studies in partnership with colleagues from the Golden Jubilee National Hospital We will proactively collaborate with the NRS Networks and Specialty Groups to identify research opportunities that can be hosted by NHS Lanarkshire, as is discussed in more detail below.
Participate in the regional Safe Haven	NHS Greater Glasgow & Clyde hosts one of NHS Scotland's five Safe Havens. NHS Lanarkshire does not currently provide data regularly to the regional Safe Haven, although discussions have been ongoing for some time. Some progress was made towards the end of the previous strategy when, with the agreement of the Board's IG Committee, a Data Sharing Agreement has been agreed as the initial agreement facilitating NHS Lanarkshire's involvement. The Senior R&D Manager will lead the programme of work to develop the necessary practical and governance arrangements between NHS Lanarkshire (*including Information Governance and eHealth and Digital teams*) and the Regional Safe Haven team to enable NHS Lanarkshire's involvement in the Safe Haven to progress. They will also work with colleagues in our Partner Universities to ensure that the Safe Haven arrangements support new programmes of research that they are developing – such as in the field of Artificial Intelligence – that utilise NHS Lanarkshire data in a safe and secure manner, and in compliance with best data protection practices.
Objective 4: Expand the provision of dedicated research sessions for clinicians	
Activity	**Actions**
Protected time for new and established research teams	The level at which we can support dedicated sessions for study teams with an active research portfolio of eligibly-funded studies is limited by the annually allocated CSO budget – although there is some *potential* to supplement this via commercial research income. The R&D Committee will therefore have to continue to make careful judgements as to how best to invest our limited funding, with the key considerations in their decision making being a demonstrable pre-existing track record in delivering research. We will seek, funding allowing, to extend the availability of research sessions to areas where there is a commitment to developing a new research portfolio. This is a crucial commitment in helping to broaden the base of research-active clinicians and aims to help remove some of the barriers that hold otherwise interested clinical teams from engaging in research. As above, the R&D Committee will make careful judgements about priorities for support. One of their key

	considerations in their decision making will be a commitment to take on identified, hosted eligibly-funded studies. The R&D Office will provide support for applicants, including liaising with the NRS Networks and Specialty Groups to identify potential studies that can be easily and quickly adopted. The Clinical Research Team will also provide support and experience in establishing new research portfolios. We will also pursue any other options or opportunities – internal or external, such as via funded Research Fellowships - that may arise to support the provision of dedicated time for research.
Dedicated research sessions, where available, highlighted in job packs and interviews	The ability to have dedicated time to pursue an interest and be involved in research is widely recognised as an important factor in attracting and retaining specialist clinical staff. National cooperative arrangements for filling senior clinical vacancies preclude advertising additional sessions to pursue research interests. This inhibits our ability to take advantage of a potentially important contributory factor in attracting staff, although it does recognise the likely reality that allowing this approach could introduce an 'arms-war' in advertising posts. As is the case in other Boards, NHS Lanarkshire exists in a highly competitive staffing environment. There are, however, examples where PA sessions have been allocated at interview, and this has been one of the key deciding factors in individuals choosing NHS Lanarkshire to build a career. We will therefore explore the potential for dedicated PA research sessions in job plans to be discussed routinely in interviews for clinicians in specialties where there is an established research portfolio, or a clear potential for developing one. In doing this, it is recognised that service / medical staffing funding may be the limiting factor.
Identify and support research career development opportunities	The R&D Office will proactively seek, internally advertise and support clinicians in applying for CSO Research Fellowships and other research career development awards. Our existing CSO Research Fellows and clinicians with dedicated research sessions will form a cadre, alongside the R&D Office, who will be available to offer advice at the application stage, and will also facilitate links via NRS West Research Node colleagues to utilise their experience. The R&D Office will liaise with medical / NMAHP / professional and technical leads to ensure such opportunities are appropriately targeted, and to help plan back-fill arrangements if required.

Objective 5: Broaden the research base and the visibility of research	
Activity	**Actions**
Engage proactively with NRS Research Networks and Specialty Groups[15]	From the National Research Scotland Website: "*…NHS Research Scotland supports delivery of a range of high quality studies across a spectrum of disease and clinical need. All research within Scotland lies within the remit of at least one Network or Specialty Group (SG). Topic Networks and Specialty Groups (SGs) are the key national bodies for supporting clinical research activity in Scotland. They act as the interface between the research community, the NHS and patients themselves, facilitating the development, set up and completion of clinical research studies across Scotland, improving the quantity and quality of research within their specific clinical area...*" Practically, in terms of increasing research, developing close working relationships with a number of the National Research Networks and Specialty Groups has been demonstrably beneficial in engaging local clinicians and raising awareness of new studies that may be of interest. A number of new studies have been awarded, and new investigators and specialties have become research-active, during the course of the previous strategy as a result of a proactive approach to engagement by the R&D Office. There are twenty-four national Networks / Specialty Groups in total – the Senior R&D Manager, supported by the wider R&D Office, will implement a systematic process of sustained re-engagement, the links having weakened somewhat during the pandemic. Named liaison staff will be identified within the R&D and / or Clinical Research Teams for each of the 24 groups. The local liaison staff will, with the help of the R&D Office, foster contact with local clinical teams to broaden involvement in research.
Improve visibility of ongoing research activities to encourage participation	The visibility and importance of research was highlighted throughout the pandemic, with a number of key, high-profile clinical trials being hosted in NHS Lanarkshire. There was a broadening of interest and support; through necessity a number of clinicians who were not previously involved in research became engaged with supporting these trials. Additionally, senior management at Board and site level were appraised on an ongoing basis about research that was highly-relevant to them, including trials that were helping develop new treatments for SARS_CoV-2. We will build on this improved profile by increasing visibility of the range of research that is taking place within the Board, so that staff have a better knowledge and understanding of what research is ongoing, and feel encouraged to become involved.

[15] https://www.nhsresearchscotland.org.uk/research-areas

	We will do this by developing an internal communication plan with the support of the Communication Team to make sure that all clinicians have access to information about the research infrastructure in NHS Lanarkshire, including access to this R&D Strategy, details of research training that can be provided, details of NRS Network research portfolios that could be accessed, details of the ongoing research studies across Lanarkshire, etc.
Improve support for consideration of feasibilities	Many opportunities to participate in research – and in particular, commercial clinical trials – are offered to the Board in the form of 'Feasibilities'. A 'Feasibility' is an approach by a research Sponsors to NHS organisations to determine if that they have the capacity, capability and interest in Hosting a study. The typical conversion rate – from an initial approach to a study eventually being opened in an NHS organisation – is very small – less than 10%. This can be for many valid reasons – lack of capacity, facilities, no interest, competing studies, clinical time, no patient population, etc. However, some steps can be taken to help maximise the conversion of approaches into studies. There is some evidence from some other NHS Boards that deploying an experienced Research Nurse to liaise with clinicians can improve engagement with Feasibility opportunities, and potential conversion. We will therefore pilot the above approach for a limited period of one year to assess whether this change in the management of Feasibilities is beneficial in increasing uptake.
Objective 6: Strengthen academic collaboration	
Activity	**Actions**
Increase joint NHS / academic grant collaborations	Over the course of the previous strategy there have been significant developments in relation to the work we do with our formal Academic Partners. As the relationships have developed, opportunities for collaborations across a range of activities have increasingly emerged, with some of these focussed on formal research. Research-active clinicians can be frustrated at the barriers that exist in initiating their own research ideas, such as - lack of experience in protocol structure and development; not being able to get their first grant and so establish a track record as a grant-holder. Similarly, academics may not have practical clinical experience that would prove useful in the operational clinical setting and would be attractive to research funders. NHS and academic collaborations can help both parties overcome these shortcomings. We will therefore continue to work with our Academic Partners to identify opportunities to undertake joint research activities, and in particular to increase the number of research grants that include funding for NHS activities.

	The Senior R&D Manager already provides advice and guidance on NHS process and procedures to University colleagues, such as arrangements related to the submission of applications to the NHS Research Ethics Service. We will work to improve operational cooperation in the relevant R&D office support functions that facilitate grant applications. As well as improving cooperative working, where funding allows the R&D Office will also explore the practicalities of establishing a Small Grants Scheme – funded via a combination of CSO and commercial research income - to support pilot work for collaborative research studies where there is a firm undertaking to seek external eligible-grant funding for full studies. It will be important for applicants to have a clear direction as to the potential external funding pathways that exist nationally.
Increase Honorary / Visiting posts	Developments in this area are led by through the NHS Lanarkshire Strategic Academic Liaisons Working Group, and the Joint Boards that we have with our formal Academic Partners. Increasing numbers of NHS Lanarkshire staff have been awarded 'Visiting' status at Partner Universities; similarly, an increasing number of academic colleagues have been awarded Honorary NHS contracts. It is expected academic colleagues will, in time, develop their own research teams through bringing in grant and commercial income to employ PhD students and post-doctoral researchers, and that a proportion of their research will be hosted in NHS Lanarkshire. We will ensure that the awarding of such Visiting/Honorary positions includes a focus on the development of new programmes of academic research in the areas of interest of the relevant clinicians/academics.
Host PhD and Masters students	The work of the NHS Lanarkshire Strategic Academic Liaisons Working Group has established a more recognised path for postgraduate students to both carry out their research and, potentially, to work within clinical services to gain work experience. We will continue to support the arrangements for PhD students which we expect may bring a number of benefits, such as: • The presence of postgraduate students embedded within departments represents, and should foster, an increase in academic engagement more generally - academically engaged departments will be more likely to adopt cutting edge and innovative ideas and treatment approaches, and will be well informed and better able to translate latest knowledge and research findings into practice, and therefore deliver direct benefits for patients. • The presence of postgraduate students will go hand in hand with increased researched activity focused, which should be focused on areas of research deemed to mutually beneficial to both the NHS and

	University; it is well recognised that involvement in research leads to improved quality of care, better outcomes and more cost-effective treatments through access to cutting edge treatment options, highly protocolised care and higher levels of personal attention. • There is the potential that students who have worked in NHS Lanarkshire during their postgraduate studies will be more likely to join NHS Lanarkshire permanently once qualified, than would otherwise be the case. • Success breeds success - in general terms, a recognised postgraduate-level career path that leads to demonstrable successful careers in NHS Lanarkshire will attract subsequent students and staff. • Postgraduate students will be able to collaborate with University and NHS colleagues in submitting research grant applications to seek answers to important clinical or therapeutic questions, and may potentially also fund additional research posts.
Objective 7: Improve access to research training for clinicians	
Activity	**Actions**
Signpost research design support, where available	The National Institute for Health and Care Research (NIHR) provides access for NHS staff and other researchers in England to their Research Design Service (RDS)[16]. Currently, no equivalent service exists in Scotland – that has been recognised as being disadvantageous to Scotland - and in particular to potential researchers who may not have a track record in converting a good research idea into a well-designed research study that can attract grant funding. We will continually review any opportunities that may develop in Scotland to support the design of research studies, and will signpost local clinicians to any resources that emerge during the lifetime of the strategy. We will also encourage local clinicians to engage with our Academic Partners to explore whether their research ideas can be taken forward as collaborative grant applications in partnership with University staff.
Signpost research training for current and new researchers	We will encourage NHS Lanarkshire staff, via our internal communication plan, to take advantage of the wide range of training for researchers that is currently on offer, at no or minimal cost, across NHS Scotland. The Welcome Trust Clinical Research Facility in the Western Infirmary, Edinburgh maintains the Clinical Research Training Scotland online register on behalf of NRS – the register includes details of all courses

[16] https://www.nihr.ac.uk/explore-nihr/support/research-design-service.htm

	provided by Scottish NHS Boards to support researchers. The courses listed are open to all NHS Scotland staff and can be booked online. They cover a wide range of topics including *'Helping you to submit a successful NHS Research Ethics Application', 'The Write Stuff: A Short Scientific Writing course', 'How to Interview Participants & Run Focus Groups', 'Blueprints: Protocol Writing Workshop'* as well as the core '*NRS Introduction to Good Clinical Practice (GCP)*' courses. In addition to promoting the availability of courses across Scotland, we will also review the range of courses available locally and, where practical, will seek to host courses specifically relevant to the development of research studies, grant applications and NHS Ethics submissions.
Provide local Good Clinical Practice Training	We will provide local clinicians with access to in-person certified Good Clinical Practice Training by supporting a number of our existing Research Support Staff to act as GCP Trainers
Provide Good Research Practice LearnPro Module	We will provide access to local on-line Good Research Practice Training via a LearnPro module – this will provide the training necessary for staff involved in non-drug studies, or with more limited roles in clinical trials
Objective 8: Secure dedicated accommodation for delivering research	
Activity	**Actions**
Establish a dedicated Clinical Research Facility (CRF) as part of the Monklands Replacement Project (MRP)	The Senior R&D Manager will continue to lead workstream of the Monklands Replacement Project to deliver on the strategic vision that will see two important new facilities created as part of the new hospital: • Research, Education and Conference Centre. The single Centre will incorporate NMAHP Practice Education; Medical Education; Knowledge Services/Library; R&D Office; conference and events facilities that will be able to host local, regional and national events • Clinical Research Facility. NHS Lanarkshire's first ever dedicated health research facility, incorporating modular clinical rooms, welcoming patient facilities, a clinical lab, research equipment storage, office base for the Research Nurse Team, space for regulatory inspections, etc. We will continue to work with the MRP team to ensure the vision of the creation of new, state of the art facilities is realised.
Ensure permanent space is available to host clinical research patient visits, and to accommodate the	Dedicated clinical accommodation in which to carry out research visits with patients is a basic pre-requisite for supporting a portfolio of research in any NHS organisation. Facilities to host research were not included in any of NHS Lanarkshire's three acute hospital at the design stage. That has mitigated against the growth of

Research Nurse and Pharmacy Teams	the Board's research portfolio, and will continue to do so to an extent at least until the delivery of the CRF as part of the Monklands Replacement Project. During the course of the previous strategy, and with the support of the senior management triumvirates in the three acute hospitals, some space was identified and allocated for research. This involved re-purposing a range of rooms – vacant 4-bedded ward areas, storage rooms, offices, etc. – to provide bases for the Research Nurses on all three sites, and to enable research patient visits to take place. This support – and the facilities provided – was crucial, and very welcome. Restrictions and limitations do continue to exists, particularly in terms of supporting clinical trials that may involve high patient volumes: • lack of suitable space was one factor that mitigated against NHS Lanarkshire's involvement in COVID-19 vaccine clinical trials • the permanence of the current arrangements is occasionally questioned, particularly when operational services are seeking space We will continue to liaise with hospital management to consolidate the advances that have been made, and to put research accommodation on a more secure basis.
Ensure appropriate Pharmacy facilities for storage of IMPs	Clinical trials of investigational medicinal products (CTIMPs) often require dedicated storage of investigational medicines away from normal Pharmacy stock. IMPs can potentially have 'blinded' labelling (i.e., the product within the box is not detailed on the packaging), there may be other study-specific storage, management and dispensing instructions. Storage away from normal stock is therefore an important safety and practical consideration. Current and future expansion in the volume of drug trials continues to create pressure within the existing hospital Pharmacy departments related to provision of adequate ambient and temperature controlled storage space. Additionally, some trials can require 'out of Pharmacy' drug storage – again, specialist facilities are required which cannot be provided in temporary accommodation. We will ensure that adequate facilities for any clinical trials that we undertake are available, and will invest in additional specialist storage - in and out of Pharmacy – as may be required. The Lead Pharmacist Clinical Trials will continue to liaise with his Pharmacy Heads of Department colleagues to ensure that the trials portfolio can be accommodated safely.

5.2. Appendix 2: National and local research environment

National environment

NHS Scotland consists of 14 regional NHS Boards and 6 additional Special Health Boards, and all Boards have legal responsibility any patients who consent to take part in research.

Each research-active Board has a Research & Development Office, primarily to take governance responsibility for all aspects of the research process, and to increase research activity; these operate within a national context under the direction of the Scottish Government Chief Scientist Office (CSO).

Each institution is part of a complex web of stakeholders and partners that includes Universities, Pharmaceutical and device industry partners, Contract Research Organisations (CROs), other Health Boards and their R&D Offices, UK and international research funders and other research organisations.

Chief Scientist Office (CSO)

The Chief Scientist Office (CSO) is part of the Scottish Government Health Department (SGHD) and has a central role in overseeing the activities and performance of NHS Scotland Board Research & Development Offices. Key activities of the CSO key include

- Developing and implementing a Health Research Strategy for NHS Scotland (the *Health and Social Care Research Strategy* 2015-2020)
- Allocating funding to NHS Boards to enable them to support eligibly-funded non-commercial research
- Encouraging strong research ethics appraisal and research governance
- Funding high quality research directly, or through contributions to National Institute for Health Research (NIHR) research funding programmes

With respect to funding, pre-pandemic the CSO allocated over £42million to research-active NHS Boards to support eligible research activities. The largest proportion of this funding was allocated to the lead Boards for the four regional NHS Scotland Research Nodes (NHS Greater Glasgow & Clyde, NHS Lothian, NHS Tayside, NHS Grampian).

Funding allocated to NHS Lanarkshire has averaged around £970,000 p.a. over the past five years. This is up from around £680,000 p.a. in the previous five years – an increase of around 40%. Funding is based on the level of research activity in terms of number of active eligible studies and recruitment to those studies. Achieving the strategic objectives detailed herein will typically result in an increase in CSO funding allocated to NHS Lanarkshire.

NHS Research Scotland (NRS)

From the NRS website - *"…NHS Research Scotland (NRS) is a partnership involving Scottish NHS Boards and the Chief Scientist Office (CSO). The overarching aim of NRS is to ensure that NHSScotland provides the best environment to support clinical research. This is achieved through the application of best practice and processes that can support efficient working, as well as providing the solid infrastructure that is need to support all research undertaken in the NHS for patient benefit..."*

NHS Lanarkshire's R&D Department is fully integrated with the national NHS Research Scotland (NRS) structure, and collaborates closely with other Health Boards, Universities and commercial and non-commercial research organisations.

NHS Research Scotland (West Node)

The NHS Boards are grouped into four national NHS NRS Research Nodes and operate within a hub and spoke model.

NHS Lanarkshire is a member of NHS Scotland's NRS Scotland West Node, alongside NHS Ayrshire & Arran, NHS Dumfries & Galloway, the Golden Jubilee National Hospital and the West Node Lead Board, which is NHS Greater Glasgow & Clyde.

NHS Lanarkshire environment

NHS Lanarkshire is a research-active Board, with commercial and academic research activity taking place in all three hospitals and in a number of General Practice and community-based locations.

The Board's Senior R&D Manager is the lead for all aspects of R&D within the Board, including developing, authoring and implementing the Research & Development Strategy, leading the multidisciplinary R&D support team, generating income to fund all research activities, and a range of other developmental and governance responsibilities including finance, information and staff. Their authority in developing and managing the delivery of the Board's R&D programme of activities is derived from the Executive Medical Director who has Executive responsibility for R&D as detailed in the Board's Scheme of Delegation. In that role, the Executive Medical Director Chairs the Board's R&D Committee; the Senior R&D Manager is Vice Chair. The R&D Committee, through its two officers, provide assurance reports to the Healthcare Quality Assurance and Improvement Committee (HQAIC).

In delivering the R&D Strategy, the Senior R&D Manager leads and directs the Research & Development Department (*commonly referred to as '**the R&D Department**' and taken to include both the R&D Office and Clinical Research Support functions*) – the department was established in 2009 to support and develop research activity in NHS Lanarkshire – the Clinical Research Support function in particular has expanded significantly since then.

Hosting a broad research portfolio is a complex exercise requiring four distinct groups of staff. These can be defined as listed below, and their roles are briefly summarised in the following sections:

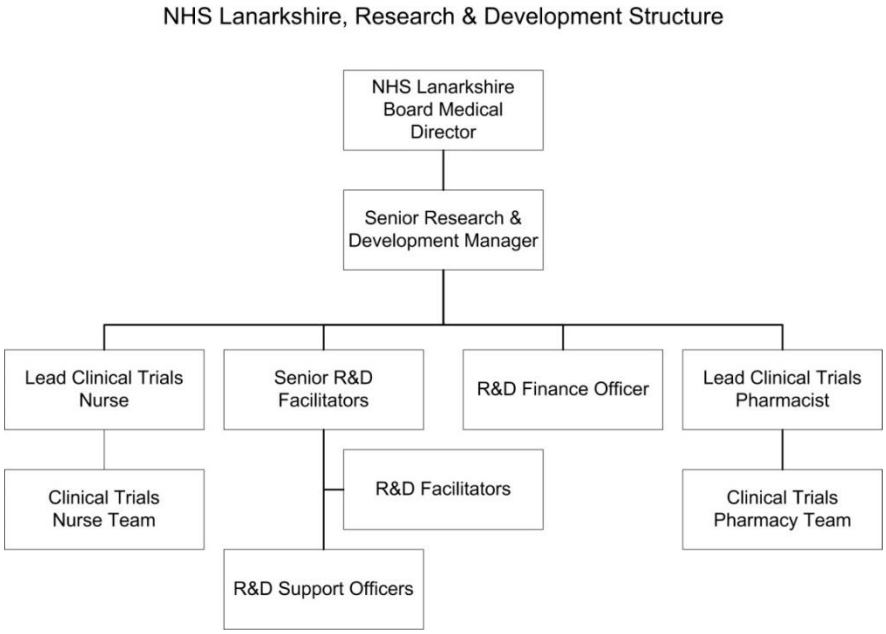
- Research & Development Office (Research governance)
- Research / Clinical Trials Support (Research project support)
- Principal, Chief and Co-Investigators / Research Team members (Local researchers)
- Supporting and enabling departments (Operational support departments)

Research & Development Office (Research governance)

The R&D Office is responsible for governance review and of healthcare research across all clinical settings in NHS Lanarkshire, and supports the Senior R&D Manager in fulfilling their responsibility for issuing R&D Management Approval for any formal research that takes place in NHS Lanarkshire.

Core R&D Office staffing levels have remained fairly static since 2009 despite increasing R&D activity, expanding research governance requirements and the need to enhance management of performance and delivery.

Research / Clinical Trials Support (Research project support)



This group comprises the Clinical Research Nursing and Clinical Trials Pharmacy Teams; they provide the essential support to our Principal Investigators (see below) and clinical teams enabling them to carry out research studies; they are an absolute pre-requisite to maintaining an active research portfolio.

The Lead Clinical Research Nurse is professionally responsible to the Director of NMAHP Practice Development, and manages the Clinical Research Nurses (~30 WTE) and Data Managers (1 WTE) in supporting the Board's portfolio efficiently.

The Lead Clinical Trials Pharmacist is professionally responsible to the Board's Chief Pharmacist, and manages a small team of site-based Clinical Trials Pharmacy Technicians (2.4 WTE) who support the pharmacy aspects of Clinical Trials of Investigational Medicinal Products (CTIMP studies). In 2022, two additional posts were created – a 0.5 WTE Aseptic Pharmacist and a 0.5 WTE Aseptic Pharmacy Technician.

Principal, Chief and Co-Investigators, researchers (Local researchers)

Each research project must have a clearly identified clinical lead - the Principal Investigator (PI). Where research involves medicines, the PI must be a medical doctor, usually a Consultant.

In most cases, PIs lead research studies as part of their normal clinical schedule with the support of the Clinical Trials Teams. Dedicated research time for PIs has, however, already proven to be successful in:

- enabling the establishment of a robust research portfolio
- attracting and retaining specialist clinical staff – in at least two specialties, this has been recognised by clinical services who have included research sessions in core job roles
- generating sufficient external income to make research PA sessions self-sustaining

The CSO provides a limited stream of funding as part of its annual allocation that organisations can use to provide dedicated research time for researchers, and NHS Lanarkshire has awarded a small number of time-limited job planned sessions to research-active medical staff as Programmed Activities (PAs) through a pilot process overseen by the R&D Committee.

This funding available is dependent on an annual allocation, and is not guaranteed. This approach can nevertheless be a small but useful element in supporting a continued expansion of the research portfolio, and is in line with the Scottish Government's *"Health and Social Care Research Strategy*" which has "Targeted Deployment of Resources" (i.e. to support dedicated clinical time) one of its key strategic aims.

The '*Future of Clinical Research Delivery: 2022 to 2025 implementation plan'* has a related aim of:

- continuing to support the UK's expert research workforce, and developing and contributing to workforce plans in order to enable strategic investment in capacity development

Supporting and enabling departments (Operational support departments)

The Operational support departments play a crucial role in supporting research by carrying out research-investigations as specified in study protocols.

The "*Attributing the costs of health and social care Research and Development (AcoRD)*" guidance[17] is agreed by all UK Health Departments; the guidance describes the arrangements for supporting activities related to non-commercial research. Support activities are attributed to one of three broad cost categories as follows:

- **Research Costs** - the costs of the R&D itself that end when the research ends – *costs met by non-commercial research funding bodies, UK Charities, etc.*
- **NHS Treatment Costs** - the patient care costs which would continue to be incurred if the service continued to be provided after the study ended – *costs met by the NHS Board*
- **NHS Support Costs** - the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided – *costs met via the CSO's research allocation to the NHS Board*

Notwithstanding the above nationally agreed arrangements, studies that incur NHS Treatment Costs can experience significant delays in gaining local approval due to the fact that costs have to be met by service budgets.

Commercial clinical trials provide a payment for any research activity that is required to be carried out, and this is paid to the relevant department.

[17] https://www.nhsresearchscotland.org.uk/uploads/tinymce/AcoRD-Guidance-Scotland.pdf