

NHS Greater Glasgow & Clyde Research & Innovation Strategy 2020-23

Vision: Our vision is for research and innovation to play a key role in delivering safe, effective and person-centered quality care within NHS GG&C, nationally and globally.

Mission: Our mission is to fully embed a research and innovation culture within NHS GG&C and maximise the opportunities and support for our researchers in order to increase the level of high quality world leading clinical research and innovation for the health and economic benefits of our population.

Purpose

It is well recognized that investment in clinical research and innovation leads to improved quality of care, better outcomes and more cost-effective treatments¹. Our patients expect to be offered the opportunity to take part in high quality research and access state of the art therapeutics, devices and new models of service delivery. Patients who take part in research and innovation generally enjoy better individual outcomes. Recent studies have also shown that survival rates are higher in research active hospitals^{3,4}.

Clinicians and members of the multi-disciplinary team who are research active are more attuned to contemporary ideas and treatment strategies and accordingly are better placed to translate research and innovation findings into benefits for patients in NHS GG&C and beyond. Studies have shown that staff who participate in research have reduced level of burnout and emotional exhaustion, improved morale and job satisfaction^{5,6,7}. Research active boards also find it easier to retain and recruit staff when academic components can be added to posts^{8,9}. Clinical research, also generates savings with a recent report estimating an average of £9,000 per patient income revenue for commercial research and significant additional savings due to the provision of pharmaceutical products¹⁰.

Increasing participation of teams in research, enables delivery of high quality clinical care and a willingness to embrace transformational change in health service delivery. Clinical research drives innovation and is an essential component in the Government's drive to increase growth in both the healthcare and life sciences sectors. Our focus will be to

address unmet clinical and healthcare needs and our approach will be open, transparent and collaborative.

1.1 Strategic Objectives

The strategy for research and innovation aims to contribute to realising the goals of NHS GG&C;

- NHS GG&C mission: To deliver “effective and high-quality health services, to act to improve the health of our population and do everything we can to address the wider social determinants of health which cause inequalities”
- NHS GG&C Moving Forward Together programme¹¹

1.2 The 5 core strategic objectives of the Research & Clinical Innovation Strategy are to;

- Deliver world leading quality research and innovation which will directly impact on and improve patient-centered care within Glasgow, Scotland and globally
- To fully embed a research and innovation culture within NHS GG&C
- Further promote patient and public engagement and participation in clinical research and innovation
- Optimise our use of informatics and real world data through collaboration regionally, Nationally and globally with NHS partners, industry and academia
- Actively support innovation and early adoption (or early rejection) of novel medicines and devices at scale, nationally and internationally

1.3 In order to achieve these objectives, NHS GGC recognises;

- The value of our strong academic partnership with University of Glasgow within the Glasgow Health Sciences Partnership (GHSP) and the important role of our clinical academics in delivering clinical research within NHS GG&C
- Our close academic collaboration with Strathclyde University, Glasgow Caledonian, West of Scotland and Stirling University within the West of Scotland Health Sciences Network and others across Scotland & Nationally
- The key role of research & innovation governance in ensuring that research and innovation areas conducted to high scientific, ethical & financial standards
- The expanding role of our nurses, pharmacists, allied health professionals, translational scientists and associated academic partnerships in clinical research and as principal investigators

- Our areas of current strength and research expertise
- Our close collaboration with other boards both within the NHS Research West Node, the West of Scotland Health Sciences Network and other NHS boards across Scotland
- Collaboration and close working with e-Health and Medical Physics within the West of Scotland
- The value of existing and new key research partnerships through NHS research Scotland, local and national charities, trusts and voluntary organisations
- The role of research and innovation to drive evidence based practice

1.4 Research & Clinical Innovation Strategy

1.4.1 Background

NHS research Scotland invests widely in pan-Scotland clinical research infrastructure, and encourages Clinical Research Organisations and researchers to bring studies to Scotland. The Scottish Government Health and Social Care Research Strategy “Delivering Innovation through Research” aims to “increase the level of high-quality research conducted in Scotland, for the health and financial benefits of our population”¹². In conjunction with this, NHS GG&C has developed and delivered our Research and Clinical Innovation Strategy (2016-19). Over the past 3 years, NHS GG&C has continued to expand its research portfolio. There have been increased opportunities for patients and clinicians to take part in high quality research, access state of the art therapeutics, devices and new models of service delivery. Both patients and clinicians benefit from innovative product use in the clinical trial setting knowing that, should the value be proven, the medicine or device will become more widely available. NHS GG&C continue to work closely with industry and academia to help drive the spread of these innovations at pace and scale, and as a result the revenue from commercial clinical trial activity has continued to grow.

1.4.2 National Developments

The 2017 Industry Strategy aims to ensure that the UK is at the forefront of the use of machine learning and data in enhanced prevention, decision support, early diagnosis, and new and improved treatment pathways¹³. Through the recently established Industrial Strategy Challenge Fund (ISCF) significant investment and funding has been made available in order to further expand the application of data for better, more innovative healthcare.

The value of the NHS in driving forward innovation is increasing recognised beyond its role as a purchaser of medical therapies and technologies. The NHS has the potential to act as a “test bed” to allow the evaluation and utility of innovation products within a healthcare system and their impact on pathways of care. A key NHS asset is the availability of data which if accessed at scale through collaboration with industry and academia can improve knowledge of how therapies work in the real world, and identify which patients are most likely to respond.

In order for an innovative-led healthcare system to succeed it is recognised that facilitated engagement and collaboration is required between the NHS, academia and industry. This is essential to enable the challenges of large data sets, storage and transfer and innovation at scale to be overcome. The UK Industry Life Sciences Strategy promotes the use of NHS infrastructure to run evaluative studies along with partnership with medtech and diagnostics companies to “reshape clinical pathways and improve efficiency”¹⁴. The aim is that the NHS will benefit sharing from proven innovative technologies and products, and improved patient outcomes. Industry will also benefit from uptake at a scale and pace of new innovations in the NHS where trial and early clinician and patient use has taken place¹³. It is recognised that this will require national streamlined procurement processes to overcome the current challenges that small medium enterprises and others currently experience.

The Life Sciences Strategy for Scotland 2025 Vision, recognises the expanding role of digital technologies in enabling “patient empowered healthcare management” and the realisation of precision medicine through the advances in genomics and big data¹⁵.

1.5 Global & National Challenges & Opportunities

The UK Industrial Strategy has detailed a number of challenges and opportunities which are detailed below.

1.4.3.1 Disruptive Technologies such as Artificial intelligence

The UK ranks in the top five in the Global Innovation Index¹⁵. New Technologies such as artificial Intelligence, robotic process automation and machine learning are already starting to transform the global economy¹⁵. The UK is already a world leader in AI, and it is estimated that it has the potential to add £232bn to the UK economy by 2030¹⁶. The UK industrial Strategy Challenge funds (ISCF) provide opportunities to accelerate medical research and AI in order to save lives, reduce costs and increase NHS efficiency as well as growing the economy through the development of new industries. This has led to the formation of 5 new

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centres of AI new centres of excellence for digital pathology and imaging, including radiology, using AI medical advances funded by the ISCF fund in November 2018. One of these ISCF centres, the “Industrial centre for Artificial Intelligence (AI) research in Digital Diagnostics” (ICAIRD) is based at the QEUH campus. This represents a collaboration between 15 partners including the NHS, Academia and Industry. The 5 centres form a key part of the precision medicine agenda and strategy.

1.4.3.2 Precision Medicine and Big Data

The ability to prevent and identify disease early, along with the development of treatments that are ‘precise’ and effective to the individual characteristics of each patient, is an area of significant strength within NHS GG&C and Glasgow university. This field has been a priority for the Department of Business, Energy & Industrial Strategy, and Scotland is now well positioned to capitalise on a growing precision market valued at \$43 billion in 2016 and by 2025 an estimated \$134¹⁷. A recent Government Science and Innovation Audit report concluded that “the combination of world class clinical research, high quality patient data, patient samples, a single healthcare provider (NHS Scotland), and large cohorts of patients with chronic disease, differentiates Scotland from other life science clusters”¹⁶. The Scottish ecosystem is underpinned by the quality of Scotland’s electronic health and care records and a unique patient identifiable number, which allows longitudinal data to be captured and facilitates the modelling and development of precision pathways of care. Precision Medicine Scotland Innovation Centre, based at the QEUH in Glasgow, represents “a platform for collaboration linking Scotland’s expertise, data assets and delivery infrastructure to accelerate the real world adoption of precision medicine”. The ISCF has also invested in large-scale genomics projects in order to further advance the knowledge of how complex diseases develop, with the aim of ensure that patients receive “the right treatment at the right time”. The NHS in Scotland is well placed to take forward advancements in genetic testing into routine clinical care through the 4 regional genetic centres and the National Genetics Management Committee.

1.4.3.4 Ageing population

The UK population is ageing, and thus UKRI aims to “harness the power of innovation to help meet the needs of an ageing society”¹⁴. Future funding calls will address pathways of healthcare delivery, new care technologies and mechanisms to further enable self-management of multi-morbidity and chronic disease.

1.4.3.5 Brexit and the UK The recently formed UKRI works in partnerships with research organisations, academia, industry and charities to promote and deliver an environment in research and innovation will flourish. It has been tasked with delivering specific aspects of the March 2020, J Brittenden R&I

governments planning for Brexit and ensuring ongoing research funding. Brexit represents a challenge in terms of funding, staff and legislative change which have been flagged in a number of key discussion papers. This is being addressed Nationally by the Scottish Government, and numerous other bodies such as UKRI, as well as through local contingency planning.

1.5 NHS GG&C Key Strengths & Opportunities in Research & Innovation

Efficient and effective use of our dedicated Glasgow Health Sciences Partnership research infrastructure and expertise is essential for further growth⁹. NHS GG&C aims to ensure that through increased collaboration it can capitalise on opportunities for funding, and deliver improved patient outcomes whilst benefitting the economy.

1.5.1. Expertise & Research Infrastructure

NHS GG&C R&I in collaboration with the two University of Glasgow Trial units support all of our multi-disciplinary researchers across the breadth of our clinical research portfolio. Jointly, we provide a wide range of services which ensure scientific and financial integrity, fast approvals, effective governance, active project management, and robust analytical and reporting processes. NHS GG&C also supports the West of Scotland Research Ethics Service which runs four fully accredited NHS research ethics committees. A total of 221 new clinical research studies were reviewed in 2017-18.

Research & Innovation is supported by state-of-the-art joint NHS GGC and University of Glasgow Clinical Research Facilities and research imaging capabilities including the only 7T MRI scanner to be based within an acute hospital setting within the UK. We have dedicated clinical research facilities at 4 of our sites, the Queen Elizabeth University Hospital, Glasgow Royal Infirmary, Gartnavel and the Beatson.

Our regional safehaven which encompasses the data of our 2.8million population (52% of the Scottish population) works closely with E-Health and the Robertson Centre for Biostatistics to provide a leading role in research and innovation as well as regional service planning. Our Biorepository also provides a regional role and works closely with the state of the art Regional Department of Pathology and safehaven to provide highly annotated tissue for researchers, academia and industry. In addition NHS GG&C has its own unique medical device unit. Our dedicated research and innovation infrastructure is shown in figure 3. At the QEUH, there is

also the University of Glasgow's Clinical Innovation Zone, which offers space for industry and is the location of the Precision Medicine Innovation Centre.

1.5:2 Track record in Research and Innovation

NHS GG&C is the largest NHS organisation in Scotland and one of the largest in the UK. It provides healthcare to 1.14 million people and regional services for 2.7 million, and employs 39,000 staff. Our population is relatively stable and has a high prevalence of chronic diseases.

NHS GG&C delivers complex, innovative and high impact clinical research and innovation, facilitated by our state of the art dedicated Glasgow Health Science Partnership research facilities (figure 1).

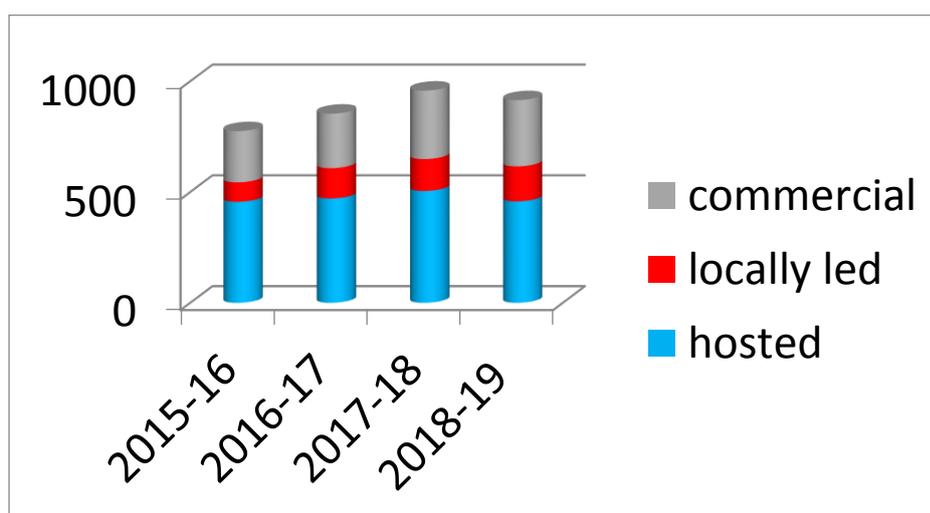
Figure 1: Research & Innovation Infrastructure



In 2018-19 GGC took part in over 1000 non-commercial and commercial studies, which involved approximately 10,000 new participants. Our broad and wide ranging portfolio ranges from observation to interventional, of which half involved clinical trials (phase I-IV) of investigational medicinal products. In addition we support a number of registry, tissue-based and non-eligibly funded studies. Currently within NHS GGC there are at least 34 high value active innovation projects involving, many involving the safehaven.

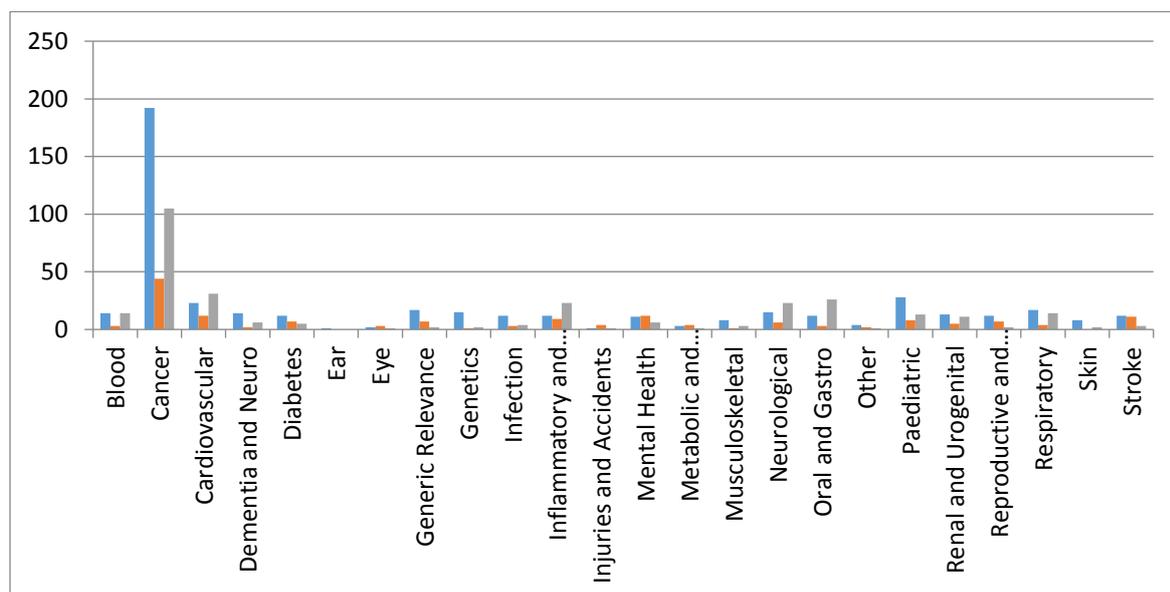
Successful delivery of our 2016-2019 Research & Innovation Strategy has led to a growth in the number of studies, both commercial and non-commercial and a rapid expansion in funding for innovation projects (figure 2). Of the non-commercial studies, we lead/sponsored a quarter of the studies and the remainder are sponsored by other health boards or universities.

Figure 2: Number and types of Clinical Research Studies



Over the past 3 years, our most active speciality areas for the sponsored studies within Glasgow Health Science Partnership are: cancer, cardiovascular, diabetes, stroke, mental health, and inflammation. These align with the strengths of the Glasgow Health Science Partnership, the Scottish Health & Social Care Delivery Plan and the UK's Life Science Industrial Strategy.

Approximately a third of our studies are commercial funded and involve novel therapies or devices. Figure 3 shows the disease speciality and type of studies (commercial, hosted and sponsored/Glasgow Led). Key new areas of growth have been in mental health, neurology, paediatrics and gastrointestinal research.

Figure 3 Number of studies according to disease speciality

Legend: Grey- commercial, blue eligible funded, orange - sponsored

1.6. Exemplars

Exemplars which illustrate R&Ds track record of excellent collaboration between the NHS, academia and industry are detailed below in Table 1. The ICAIRD project due to its scale is considered separately in Table 2.

Table 1: Research & Innovation Exemplars

<i>Precision Panc</i>
<p>In 2017 the Precision Panc Platform was founded bringing together expertise in pancreatic cancer in the NHS , University of Glasgow, CRUK Cancer Beatson and the CRUK institutes at Cambridge, Manchester, London & Oxford. There is a now a UK network of over 20 hospitals, with international sites due to come on board, which can offer novel treatments within clinical trials based on the genomics of the patient and tumour. This genome testing is performed within Glasgow and the PRIMUS study (Pancreatic cancer individualised multi-arm umbrella study) is co-sponsored by the NHS GG&C and Glasgow University.</p> <p>Study Sponsor NHS GG&C</p>

<p>Stage: The novel biomarker is under evaluation and validation will be complete by the end of 2019. It will then be evaluated in a device and Investigational medicinal compound</p>
<p>Outcome: Clinical outcomes will be improved by matching people with pancreatic cancer to the trial most likely to work for them via the evaluation of a new biomarker</p>
<p>Empower Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery (Phase 2) Study co-sponsor: NHS GG&C</p>
<p>A three year feasibility study which will develop and test a mobile phone application (app) to enhance detection of Early Warning Signs of psychosis for people with a diagnosis of schizophrenia, their carers and mental health staff. Relapse in schizophrenia is a major cause of distress and disability but through regular monitoring of thoughts and feelings it is possible to identify early warning signs which can support earlier intervention and improved outcomes.</p>
<p>Stage: a cluster randomised controlled trial. PHASE II Device study: randomised to App intervention or treatment as usual 6 community mental health teams NHS GG&C, Grampian and Melbourne</p>
<p>Outcome:</p> <ul style="list-style-type: none"> • Enhance self-management and empowerment for people in receipt of services. • Support detection of increased risk of relapse and improve the quality of information available on early warning signs. • Support relationships between people in receipt of services, informal carers and staff.
<p>SCOT trial</p> <p>3 versus 6 months of adjuvant combination chemotherapy for colorectal cancer</p> <p>Study co-sponsor: NHS GG&C, CRUK CTU</p>
<p>Colorectal cancer is the 4th most common cancer worldwide</p> <p>6 months of oxaliplatin containing chemotherapy is usually given to patients with stage 3 colorectal cancer</p> <p>Peripheral neuropathy is the main chronic side effect</p>
<p>Stage- completed</p> <ul style="list-style-type: none"> • International, randomised non-inferiority, 244 centres, involving 6088 patients • Main outcome: disease free survival

Outcome: 3 months treatment was as effective to 6 months in patient with high risk stage II or III colorectal cancer
Associated with reduced toxicity and improved QOI (NEJM April 2018)

Table 2 ICAIRD work streams involving the safehaven

ICAIRD the Industrial centre for Artificial Intelligence research in Digital Diagnostics WP2
Brings together 15 partners from NHS, industry and academia from across Scotland and beyond. This involves development of the Canon Safehaven AI platform (SHAIP) Clinical Cockpit within the NHS safehaven infrastructure and a HDRUK National Imaging Archive which includes Philips Pathology digitalisation images.
Stage: De-identification of text sources <ul style="list-style-type: none"> - fully anonymise the first 50 of each using the scrambled CHI register to enable DeepCognito to build the first prototype de-identification tool for each text source - Work in conjunction with DeepCognito on the NHS side to run the tool on a further 1000 records to enable refinement of the tools - Scoping of data availability, sources
Outcome: accelerate medical research and AI in order to save lives, reduce costs and increase NHS efficiency as well as growing the economy through the development of new industries
ICAIRD STROKE
Ultimate health outcome following stroke critically dependent on clinical care within first 1-2 hours <ul style="list-style-type: none"> ▪ Scotland's 65 min door to needle time well below international best practice ▪ Clinical portals inadequate for <i>timely</i> data review
Stage: Developing process to securely utilise patient data to enable technology and service improvement Develop software to enable rapid and accurate mining of Patients electronic record to flag key information e.g. thrombolytic therapy contraindications - subsequently provide access to 10,000 anonymised CTs within SHAIP
Desired Outcomes: Receive appropriate treatment more quickly, improving outcome

<p>Door to needle time reduced to <20 min</p> <p>Individualised risk-benefit scores</p>
<p>ICAIRD Chest X-ray</p>
<p>CXR is most common modality: 40,000 pa per hospital.</p> <ul style="list-style-type: none"> ▪ 30% interpretation error rate among junior doctors ▪ Insufficient radiologists, delayed reporting
<p>Stage/Aims: 500 expertly labelled CXR validation set</p> <p>AI powered app for real-time image classification to be developed and deployed in ED</p> <p>This requires identification of a baseline cohort of patients who have undergone chest X-Ray</p> <ul style="list-style-type: none"> - Provision of 100,000 radiology reports (GGC server pre SHAIP) once de-identified by safe haven for NLP analysis → normal/abnormal - Provide matched X-Ray within SHAIP once we can download at scale
<p>Desired Outcome: Reduced demand on acute radiology service</p> <p>Improve delivery of timely and safe care</p> <p>Enhanced training immediate feedback on XR</p>
<p>ICAIRD Pathology : Endometrial & Cervical</p>
<p>42% of gynaecological specimens are endometrial</p> <ul style="list-style-type: none"> ▪ Exclusion of neoplasia is key pivot, only 3% of endometrial biopsies show adenocarcinoma ▪ And 1.5% are atypical. Overall >95% of biopsies are benign <p>Develop AI to screen out non-malignant/atypical cases and reduce NHS workload</p> <p>26% of gynaecological specimens are cervical biopsies -assessment of cervical intra-epithelial neoplasia (CIN) and exclusion of invasive squamous or adenocarcinoma.</p> <p>Develop AI to identify invasive cancer, generate automated reports and reduce NHS workload</p>
<p>Stage/Aims: Provision of data linked and anonymised to be transferred with pathology images to EPCC and Phillips</p>
<p>Desired Outcome: Projected 85% time saving in consultant time across these specimen types. Saving of £185,650 per annum for NHS GGC, 54% of reporting time in gynaecological pathology. Extrapolated across the UK, equates to a saving of £9.3 M per annum</p>

1.7. Local Challenges and Opportunities

1.7.1 Challenges

Challenges exist at the national level and at the local level and accordingly will merit distinct strategies to be effectively addressed. The obvious barriers to performing clinical research and innovation are funding capacity and skills and these are not unique to NHS GG&C.

1.7.1.1 Funding

The current medical research funding landscape also imposes challenges with significantly less money being spent per head of the population in Scotland compared to England. Details of our funding streams from the CSO are shown in Appendix A. Obtaining funding from some research bodies such as the National Institute in Health Research (NIHR) which is static and in some areas decreased may also be a major challenge for our researchers. Nonetheless our competitiveness is evident by our success in attracting grant income, capitalising on newer funding streams such as Innovate UK and growing commercial income. Other areas of improvement, involving enhanced cost recovery and sustainability are currently being addressed.

NHS GG&Cs growing portfolio of complex trials involving devices, imaging, apps, technology as well as novel therapies has increased the demands on the R&D team leading to a case for change and organisational review. Many of these developments such as the 7T scanner available for use by research teams throughout Scotland, have not been met with additional funding.

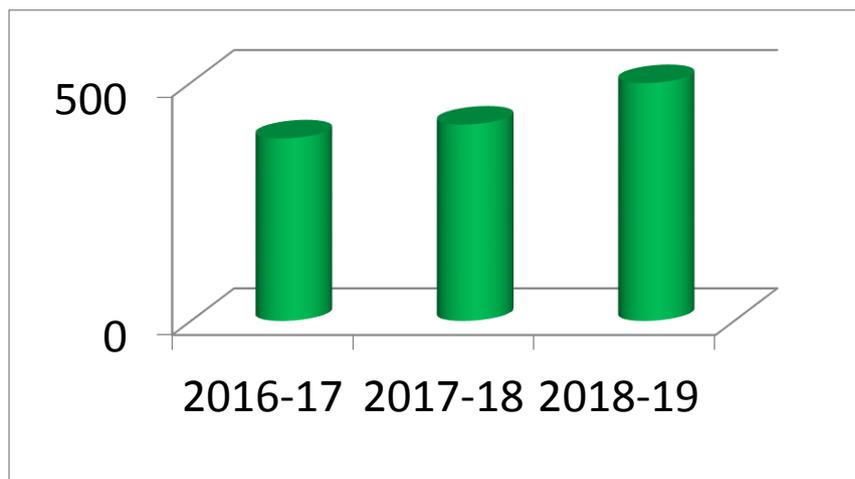
1.7.1.2 Capacity & Skills Clinical researchers and innovators in the consultant career track need to deliver and maintain clinical practice whilst also allocating and protecting sufficient sessions to prepare for, and perform research and innovation “in real-time”. Investigators need essential support with methodological design, protocol/trial literature preparation, trial and device evaluation procedures, informatics and statistics to optimise their competitiveness to secure eligibly funded grant income. Once funding is in place, investigators must navigate frequently changing regulatory hurdles and then deliver studies to timelines, demonstrating agility as problems arise. Recruiting patients to clinical trials in particular may be challenging and time consuming. Indeed National data show that in large multicentre studies only 55 % were found to have recruited to the original target sample size, 78 % recruited 80 % of the original target, and one third of trials required an extension to the projected recruitment time¹⁷. While R & I resources, including research nurses, administration support, use of our safe

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haven to identify potential patients and project management may all help, the rate limiting step is often lack of principal investigator's time to provide essential medical oversight and the complexity and multi-morbidity of many of our patients. We have developed an action plan that will help address these challenges (appendix B).

Within England, NHS trusts are now inspected on how clinical research is integrated within their organisation⁹. Within NHS GG&C measures and funding have been put in place to free up consultant time and provided support teams to drive forward research and innovation. As a result the number of research and innovative active Chief/principal investigators within NHS GG&C has increased year on year with a 20% increase in 2018-19 compared to the preceding year (figure 4). This increase in principal investigators does not only include doctors but also nurses, pharmacists and dentists and has been enabled through a number of initiatives which will be further expanded.

Figure 4: Number of Principal/chief investigators/innovators



The number of NRS fellows and senior fellows has also continued to grow, and some are mentored or work closely with clinical academics. However, a particular local challenge is a relative insufficiency of academic clinicians, nurses, dentists and pharmacists to provide the leadership and bridgehead to the funding agencies that can empower the growth in locally led studies.

1.7.1.3 Building future capacity

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It is important that Glasgow develops and delivers future research capacity, by ensuring that our students and clinical trainees are exposed to research and innovation⁹. In addition to the research specific expertise, the added benefits to trainees are well recognised and include the development of transferable skills such as critical appraisal, project management, team working and establishment of new networks. Currently Glasgow does not attract sufficient numbers of clinical trainees who are willing to embark on full time research and innovation training¹⁹. Exposing medical students and doctors to flexible research opportunities earlier may increase the numbers who wish to undertake full time research and future clinical academic careers. A recent survey of career intentions amongst clinical PhD students at two research intensive medical schools reassuringly found that at least half wanted to pursue a clinical academic career²⁰. Those that did wish to pursue a clinical academic career tended to have the most pre-doctoral research experience. Key reasons cited for not pursuing an academic career were: the small number of senior academic appointments available; work-life balance; competing pressures from service, teaching and research and the difficulty in securing research grants²⁰.

Only 5% of the UK medical consultant workforce are clinical academics who are employed by Universities and that this figure has been decreasing²¹. A survey by the UK Medical Schools Council, undertaken in 2017, found that the number of clinical academics has declined by 2.1% since 2015 and by 4.2% since 2010. The reduction has occurred predominantly at the Senior Lecturer level, with a 32.9% fall since 2000²². It is recognised that significant investment in academic training programmes are required to help reverse these trends. A number of local and national initiatives currently aim to promote early exposure of trainees to research and opportunities for training in clinical academia. These will ensure sustainability of translational research pathways enabling basic science discoveries to be evaluated in clinical trials, future medical practice and health care policies. Local initiatives aimed to promote training in academia for nurses, dentists and pharmacists are also in place and will be further developed and expanded.

It should be noted that translational of novel discoveries from laboratory to bedside is greatly facilitated through the Glasgow Health Sciences Partnership, the West of Scotland Health Science Partnership and the stakeholders detailed in section 1.3.

1.7.2 Future Local Opportunities

The key growth areas are in the application of precision medicine and data to provide early diagnosis, better prevention, and new and improved treatment pathways as detailed in section 1.5. The main drivers to change are the change in demographics with an ageing population, multi-morbidity, increasing healthcare costs and the potential for implementation of disruptive medical technologies. The local developments below will enable NHS GG&C to be at the forefront of these developments through collaboration with academia and industry and our NHS partners.

1.7.2.1 Innovation Hub: The recently established West of Scotland Innovation Hub acts as a “front door” for both innovators and industry. Promoting the West of Scotland as part of a “one Scotland “ approach is a core business priority of the Innovation Hub, which plays a key role in identifying innovations and developing a streamlined evaluation process to ensure that they are either adopted at pace and scale or undergo early rejection. The WoS Innovation Hub enables key assets to be harnessed whilst ensuring appropriate governance of the use of NHS resources (data, images and tissue) via the West of Scotland Innovation Governance Group. These are aligned to the National test bed governance group.

The single point of contact is designed to facilitate access to expert clinical and academic teams for industry partners. The newly formed innovation team based at the WoS Innovation Hub provide the services and expertise to enable innovations throughout all stages of the innovation pathway from discovery, selection, evaluation and deployment. The team includes project management, expertise in contracts, costings, regulatory approvals and evaluation, intellectual property and marketing. The route to procurement post successful evaluation remains a challenge which we will closely work with Scottish Government to streamline.

Innovative projects which have a research component will be continued to be managed through the R&I Good Clinical Practice and Quality Framework led by the Research Governance Manager and team. Innovation processes will mirror long standing R&D procedures within the board in relation to registration of projects, contracts, document management, cost-recovery and finance.

1.7.2.2 Analytical platforms and Clinical data cockpits

A number of clinical cockpits and analytical platforms are proposed and will be developed through close collaboration with the West of Scotland Safehaven and E-Health, academia and industry. The Safe-Haven Artificial Intelligence Platform (SHAIP) team are a subgroup of the i-CAIRD project, and consist of a growing team of software engineers and architects who collaborate with NHS GG&C safehaven, the Universities of Glasgow and Aberdeen, and

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Aberdeen Royal Infirmary. The aim is to develop and build useful tools for clinicians to select and annotate anonymised patient data for machine learning, together with infrastructure for data scientists to develop, train and validate algorithms within the NHS environment, whilst building the knowledge and capability within technical teams to further develop and support such infrastructure.

1.7.2.3 West of Scotland Health Sciences Network

The West of Scotland Health Science Network was established in 2019, and aims to build on the work previously undertaken by Glasgow Biomedicine on a regional scale with inclusion of all health boards and University in the West, including University of Stirling and Forth Valley. While this network is unique to Scotland, there are 15 Academic Health Science Networks in England which exist to “improve health and generate economic growth”. The West of Scotland Health Science Network has the opportunity to emulate the success of Oxford, UCL Partners or Health Innovation Manchester and spread health innovation at pace and scale.

1.7.2.4 Novel Advanced Therapies

NHS GG&C is a member of the Northern Alliance Advanced Therapy Treatment Centre (NAATTC), a consortium of twenty industry, NHS and academic organisations led by Newcastle Hospitals and the Scottish National Blood Transfusion Service (SNBTS). The purpose of the centre is to develop the systems and infrastructure required to support the delivery of cell and gene therapies with the ultimate aim of increasing patient access to advanced therapy medicinal products (ATMPs) on a national level. The Innovate UK award and NATTC initiative has allowed NHS GG&C to further build expertise, infrastructure, training and education for staff. As a result of this, we are now delivering advanced therapies both as part of standard care and within novel clinical trials.

1.7.2.5 Strength in places Fund

Glasgow University have submitted a 40 million stage 2 application to the Strength in places Fund. This project involves close collaboration with NHS GG&C with a proposed data laboratory and a “living laboratory” at the QEUH campus. Existing Precision Medicine diagnostics will be evaluated and implanted to improve safety and efficacy, whilst reducing costs to the NHS. It will also provide opportunities for SMEs as well as Pharmaceutical companies to develop and evaluate new technologies. It is anticipated that if awarded this project will be globally significant and have the potential to transform healthcare delivery, as well creating high value jobs locally within Govan.

1.8 Our Commitment

This strategy will build on the success of our 2016-19 strategy and focus on ways that we can further overcome challenges, build on our strengths and take advantage of opportunities both locally and nationally to become even better at high quality experimental and world leading translational innovative medicine. Our focus will be on patient-centered care enabled through advances in precision medicine and novel technologies which focuses on prevention as well as treatment. We have included actions and timelines in appendix B which address the operational aspects that will enable delivery of 5 key strategic objectives. We will ensure effective and efficient use of resources whilst working to the highest standards in order to enable NHS GG&Cs Research & Innovation ambitions to be realised.

1.8.1 Key outcome measures, over a 3 year average are to expand the research and innovation portfolio to deliver:

Target 1—10% increase in number of high quality, impactful research studies and innovation projects

Target 2 —10% increase in income for both research (non-commercial grants and commercial) and innovation.

Target 3- to offer more patients the opportunity to participate in research and innovation and increase recruitment numbers by 10%

Target 4: Increase the number of multi-disciplinary principal investigators and innovators by 15%

Target 5: Increase access to data for researchers, innovators, academia and industry through development of analytical platforms and clinical cock-pits

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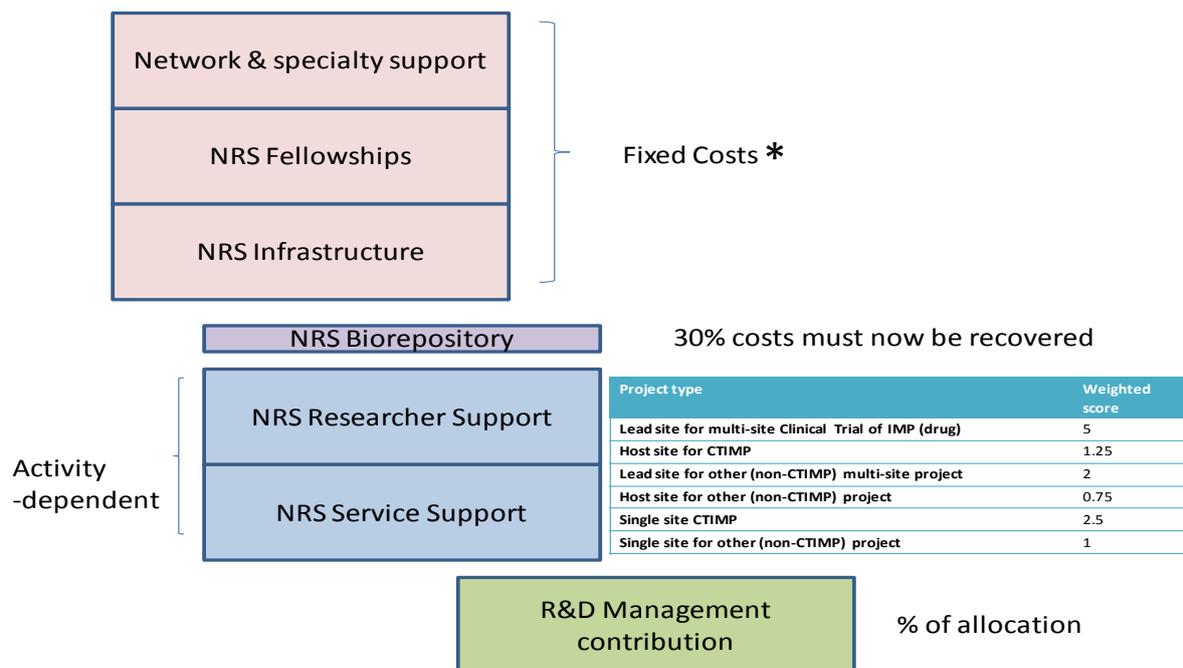
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Appendix B: Funding

The CSO through NHS Research Scotland (NRS) currently allocates over £42million to NHS Boards to support research. Funding by the CSO encompasses 7 funding streams, two of which, namely NRS service support & NRS Researcher support, are allocated according to research activity levels, which are based on 3 year cycles (Figure S1). NRS Service support is allocated depending on the number of patients recruited to a study and a “per-patient” cost. NRS Researcher support ensures protected time for research active consultants and is calculated based on the type of project (single or multicentre; led by the board or hosted; involvement of investigational medicinal compound) and recruitment premium. This is complemented by the NRS fellowship which affords junior consultants and allied health service professionals protected research time as part of a three year award. NRS infrastructure also has a very small component of activity based funding, which is capped by the CSO in order to avoid disruptive fluctuations in funding.

The other funding streams which part fund our shared Glasgow Health Science Partnership research infrastructure include: NRS management costs, NRS safehaven, NRS Biorepository, and network/speciality funding. NHS GG&C also supports the West of Scotland Research Ethics Service which runs four fully accredited NHS research ethics committees.

Figure 1: CSO Clinical Research Funding Allocations



*Minimal activity based funding model is assigned to infrastructure budget

Appendix B: Research & Innovation Operational Delivery plan

Objective	Action	Timescale
Objective 1: Deliver world leading quality research and innovation which will directly impact on and improve patient care within Glasgow, Scotland and globally		
1.1 Further enhance our Quality Improvement processes and systems		
1.1.1 Develop & deliver a Research & Innovation Quality Framework and Manual	Adapt our current quality manual to Include 5 levels, and provide overarching framework to include all our functional units: R &D, CRF, CRIF, ethics, safehaven & biorepository	December 2020
1.1.2 Fully utilise Q pulse as our data management system	Implement for all our SOPS, Corrective Actions and Preventive Actions, and non-compliances for R&D, CRF, CRIF, safehaven & Bio-repository	August 2020
1.1.3 Further expand our audit schedules to develop an integrated system based GCP approach	Develop, release & deliver new SOPs and training Draw together and review our schedules, findings, trends across teams.	December 2020
1.1.4 Provide an approved laboratory sample management system to allow ease of access, storage and tracking of all samples	Install a new fit for purpose online application system for researchers to access human tissue Install a new online STIMS into the Bio-Repository that allows staff to store samples with clearly identifiable tracking and auditable trails of accountability. Introduce new course within CRF Education/Training to provide researchers and laboratory staff with a clearer idea of how to engage with the Bio-Repository and facilitate access to human tissue.	April 2020
1.1.5 Continue to develop and expand our ability to perform Phase I & GMO studies in compliance with governance and accreditation requirements	Develop, release & deliver new SOPs and training including areas such as device legislation, and novel therapies. Audit progress	December 2020 2020

1.1.6 Further develop our expertise in regulatory process & evaluation of clinical devices	Develop, release & deliver new SOPs and training	2020
1.1.7 Develop and expand our infrastructure to perform studies involve novel medicines	Develop, release & deliver new SOPs and training for studies involving CarT cells	2020
1.1.8 Develop and expand our infrastructure to perform studies involve novel devices	We will develop a joint technology evaluation and development facility on the QEUH site. To enable the joint advancement of novel diagnostic technologies within a healthcare setting.	2021
<i>1.2 Increase the number of eligibly funded studies which are initiated and led by local chief investigators</i>		
1.2.1 Facilitate researcher access to support and advice	Establish Research Hubs at Glasgow Royal Infirmary, QEUH and Gatnavel within the CRFs	2021
1.2.2 Writing support	Work with GHSP to ensure that researchers have support to write study protocols and IRAS applications	2020
1.2.3 Increase awareness and provide ease of access for our researchers to GHSP research infrastructure	Workshops- promote methodological design service that is available through our CTUs Improve Website and develop joint GHSP website	2020-23
1.2.4 Actively seek and promote funding opportunities to our researchers	GHSP grant/funding Communication mechanisms & strategy	2019-23
1.2.5 Facilitate Pilot studies & Promoting funding for Pump priming	Continue to develop processes which facilitate access to our clinical research imaging facilities, biorepository & safehaven for developmental/pilot work Promote use of endowments and other local sources of funding for pump priming	2019-23
1.2.6 Actively promote studies which are locally led	Ensure resources are prioritised to support locally led studies and those in which the local principal investigator is a grant holder	2019-23

	Through the CRF speciality groups ensure that these studies are prioritised over potentially competing studies	
<i>1.3 Streamline sponsor processes and set up times</i>		
1.3.1 Sponsor approval times	streamline set up times through early bird project meetings in which patient pathways and processes will be established for all high value grants We will seek to jointly appoint clinical translational specialists to facilitate the set-up, management and successful delivery of strategic projects	2020
1.3.2 Regulatory Functions	separate sponsor team functions from R&D management approval processes	2020
1.3.3 Ensure that NHS research costs are provided in a timely and transparent manner	Ensure dedicated personnel within the sponsor team & one-stop for researchers	April 2020
1.3.4 Pro-active project management	All CTIMPS, Device & complex studies will have dedicated project management Part costing for project management time to be included at grant application wherever possible	2020-23
1.4 Increase the participation in high value hosted eligible funded & commercial studies		
Work with NRS networks and speciality groups to identify potential studies	Regular joint meetings within CRF	2020-23
Actively support commissioned and response mode NIHR funded multicentre studies by identifying and supporting local principal investigators	Speciality Operational Groups within the CRF	2020-23
actively facilitate study feasibility assessments	Secure funding for a dedicated feasibility officer	2020
facilitate access to and use of the clinical research facilities (CRF), staff and resources for	Newsletters & enhanced website Establish user groups	2020-23

our investigators involved in eligibly funded research		
increase capacity by seeking funding to provide medical cover	Provide medical cover through various fellowship models within our CRFs to work within our speciality teams Collaborate with NES to develop new funding streams	2020-23
1.5 Ensure that delivery and recruitment targets of eligibly funded and commercial studies are met		
Ensure rapid R & D approval times	Performance management meetings & targeted use of resource	2020-23
Establish closer working between R&D and ethics to streamline processes	Training & access to new document management systems Alignment of activity	2020
Performance management of studies within our key research active specialty teams within the CRFs	Quarterly activity, performance & finance reports Performance management of studies within CRF through the speciality operational groups Targeted use of the safehaven to direct efficient recruitment	2020-23
Role out the use of EDGE to ensure all research activity is accurately captured throughout NHS GG&C	Training of all R&D & research staff in order for activity to be captured on the EDGE IT system Undertake risk/ benefit appraisal of migrating from SReDa to EDGE	2020-23
<u>Objective 2: Fully embed a research and innovation culture within GG & C</u>		
2.1 Nest clinical research and innovation within clinical care pathways	Maximise the opportunities for patients to take part in research & innovation projects through routine care pathways	2020-23
2.2 Promote the multi-disciplinary participation in clinical research and innovation as a key quality indicator	Ensure robust processes for: awarding research protected sessions; setting targets; monitoring performance & evaluating outcome	2020-23
2.3 Work with NES, the dental and school of nursing to provide opportunities for junior doctors ,dentists and nurses to be involved with clinical research	Establish fellowships, secondments and research training modules	2020-23
2.4 Support newly appointed consultants, pharmacists, nurses and allied health professionals who may wish to become research active to apply for NRS	Advertise opportunities on website & newsletter	2020

fellowships and other funding sources		
2.5 Provide details of costing and financial management of research at a directorate level on an annual basis	Improve resources within R&D finance	2020
2.6 Further develop our processes for invoicing & reimbursement to enable cost recovery and capacity building	Further expand the use of EDGE throughout NHS GG&C Ensure adequate resource adequately for timely invoicing, disbursement and financial forecasting.	2020-23
2.7 Increase cost recovery through commercial and non-commercial research to enable increase in resource and improved service delivery of the Bio-repository	Review and streamline processes Adopt new National electronic IT system	2020

Objective	Action	Measurable
<u>Objective 3:</u> Promote patient & public engagement and participation in clinical research and innovation		
3.1 Establish patient focus groups aligned to our CRFs in our most active research speciality areas	Apply for funding Align NHS & GU resources to ensure unified policy & processes We will establish Glasgow CRF PPI training courses for all GHSP researchers	2020-21
3.2 Promote and encourage participation in the SHARE registry	promote SHARE to all screened and enrolled study participants include invitation letter with all new patient appointments.	2020-23

3.3 Actively increase public awareness of local research studies	Engage with science centre and local scientific outreach programmes, café scientifique, clinical research festivals	2020-23
3.4 Offer patients the opportunity to take part in all types of clinical research inform patients on the outcome of research studies that they participate in	Pilot an electronic “opt in “ option for patients to be contacted for future research Set up an annual half day conference for the public detailing involvement with clinical research.	2021 2020

Objective	Action	Measurable
Objective 4: Optimise our use of informatics and real world data through collaboration regionally, Nationally and globally with NHS partners, industry and academia		
4.1. Streamline our safehaven approval times	Develop metrics to drive forward delivery times	2020-23
4.2 Ensure efficient delivery of a quality assured research extract either for analysis on our secure analytical platform or through another NRS safe haven or Farr site	Develop a quality system including an audit program Named analyst as point of contact for high impact projects	2020
4.3 Actively promote the role of the safehaven in pharmacovigilance	Promote use of real life data	2020-23
4.4 promote the use of safehaven to support clinical trial activity	electronic eligibility searching for both accurate feasibility and patient identification as well as electronic follow up using health care records	2020-23
4.5 Promote use of safehaven for novel informatics and artificial intelligence	develop and expand our ability to provide safe access to linked, but scrambled and anonymised, patient-level data for both industry and researchers to stimulate innovative approaches to data interrogation	2020-23
4.6 Ensure sustainability through cost-recovery mechanisms	Recover costs for analysts time wherever possible to ensure effective delivery and future capacity building	2020-21

Objective	Action	Measurable

Objective 5: Actively support innovation and early adoption (or early rejection) of novel medicines and devices at scale, nationally and internationally		
5.1 Increase the number of commercially sponsored trials involving devices and novel therapies that are undertaken in NHS GG&C	Enhanced feasibility process	2020-23
5.2 We will work with the innovation Hub team to utilise R & D IT resources to capture all innovation projects and associated document sets within GGC and provide regular activity reports to innovative directorates and the board	Provision of templates for confidentiality, data sharing and material transfer agreements as well as standard commercial and academic contracts by R & D. Use of R&D database (SReDA) to capture all innovation projects Quarterly reporting of innovation activity to the Biomedicine board	2020-23
5.3 Continue to enable and facilitate increased collaboration with our academic partners and industry at an early stage to ensure that research innovation is driven through partnership to meet NHS needs	through governance procedures and transparent contracts	2020-23
5.4 Facilitate access to legal advice and appropriate contractual arrangements through Scottish Health Innovation Limited (SHIL)	Enhance prominence on website Update NHS GG&C IP policy	2020 2021