NHS Greater Glasgow and Clyde	**Paper No. 22/28**
Meeting:	**NHS Board Meeting**
Meeting Date:	**26 April 2022**
Title:	**Department of Research and Innovation: Board Report 2021 - Recovery, Resilience and Growth**
Sponsoring Director/Manager	**Dr Jennifer Armstrong, Medical Director**
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1. Purpose

The purpose of the attached paper is to:

Describe the breadth and diversity of innovative research undertaken within NHSGGC, enabled through successful collaboration with academia and industry.

2. Executive Summary

The paper can be summarised as follows:

- Recruitment to clinical research studies remains on course in 2021 to match that in 2019:
  - In particular recruitment to high intensity commercial clinical trials of investigational medicinal compounds has increased showing significant resilience.
- Over 1100 studies, paused due to the COVID pandemic have restarted.
- ~ 300 new studies have commenced.
- Leading role in the participation and delivery of 4 vaccine trials.
- Substantial growth in the number of novel advanced therapies trials
- Service adoption of key exemplar innovation projects, and ongoing collaboration with industry and academic partners to secure significant Innovation funding.
- A key priority is to promote patient and public engagement and opportunities to participate in high quality clinical research, access state of the art therapeutics, devices and new models of service delivery.
- Financial income generated through research is used for capacity building and the facilitation of further research and innovation. The overall reduction in

commercial recruitment is partially offset by the increase recruitment to high intensity drug studies.
- Clinicians 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 NHSGGC. There is a need to build future Research & Innovation workforce capacity

3. Recommendations

The CMT is asked to consider the following recommendations:

Note the research and innovation activity, exemplars and opportunities

4. Response Required

This paper is presented for **awareness**

5. Impact Assessment

The impact of this paper on NHSGGC's corporate aims, approach to equality and diversity and environmental impact are assessed as follows:

- **Better Health** **Positive**
- **Better Care** **Positive**
- **Better Value** **Positive**
- **Better Workplace** **Positive**
- **Equality & Diversity** **Positive**
- **Environment** **Neutral**

6. Engagement & Communications

The recovery plan reported in this paper have been shared, discussed and approved by the Glasgow Health Science Oversight board. The activity has been discussed at the R&I senior management team and shared with all staff at a town hall meeting.

7. Governance Route

Aspects of this paper (strengths and risks) have previously been considered by the Boards Clinical Governance committee and presented to the Corporate Management Team in March 2022

8. Date Prepared & Issued

Paper prepared on: 25 February 2022
Paper issued on: 19 April 2022

NHS Greater Glasgow and Clyde

Department of Research and innovation: Board Report 2021

Recovery, Resilience and growth

J Brittenden, 31-01-22

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Foreword

Research, innovation and the redesign of services are at the heart of the NHS Recovery plan. In 2021, the Directorate of R&I and wider research teams have worked tirelessly, to set up and deliver Key COVID -19 trials, restart studies paused during the first wave and take on new high impact non-COVID research & innovation projects. NHS GG&C are well placed to deliver the UK implementation plan for the restart, resilience and growth of NON-COVID clinical research and innovation as highlighted in this report.

The NHS GG&C research & innovation portfolio continues to expand with increased opportunities for patients and clinicians to take part in high quality research including accessing state of the art therapeutics, devices and testing new models of service delivery. NHS GG&C are proud to have been at the forefront of COVID-19 research, but also to have developed, evaluated and initiated new NON-COVID technologies, medicines and services as evident in the key exemplars detailed in this report. Both patients and clinicians benefit from innovative product use in clinical trials knowing that, should the value be proven, the medicine or device will become more widely available. This has been particularly evident throughout the pandemic, with the translation of research into guidelines and clinical practice occurring at remarkable and unprecedented speed. We now have an effective vaccine and booster programme, novel out-patient and in-patient treatment all of which have and will continue to ensure that we can effectively combat COVID-19 and improve outcomes. The new UK Life Sciences vision sets out a 10 year strategy to build on the success of the pandemic response with the aim of accelerating the delivery of life-changing treatment and innovations to patients.

In 2020-21, the NHS GG&C research & Innovation ecosystem continued to expand through collaboration with regional and National NHS partners, academia and industry. This has been facilitated through the establishment of the regional innovation hub and partnership with the Industrial centre for Artificial Intelligence (AI) Research in Digital Diagnostics (iCAIRD), both based at the Clinical Innovation Zone at the QEUH campus. Infrastructure, skills and expertise in data governance processes, clinical evaluation and validation and AI capability continue to develop and grow. In 2022 NHS GG&C aims to further expand its role as a powerful driver of

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research & innovation, with the development, testing & adoption of new technologies & medicines at scale.

Despite the pandemic, key highlights of 2021 include:

- Recruitment to clinical research studies remains on course in 2021 to equal that in 2019
    - In particular recruitment to high intensity commercial clinical trials of investigational medicinal compounds has increased showing significant resilience
- Over 1100 studies, paused due to the COVID pandemic have restarted
- ~ 300 new studies have commenced
- Leading role in the participation and delivery of 4 vaccine trials
- Substantial growth in the number of novel advanced therapies trials
- Service adoption of key exemplar innovation projects, and ongoing collaboration with industry and academic partners to secure significant Innovation funding

1.0 Introduction

This report provides a high level summary of Research and Innovation activity across NHS Greater Glasgow and Clyde (GG&C) in the context of the COVID-19 pandemic, compared to the preceding year, and the research recovery plan.

2.0 NHS GG&C Research Recovery Plan: Phase 1

In March 2020, the Research and Innovation (R&I) department re-configured based on the pandemic. All new patient recruitment to non-COVID-19 clinical trials, other than those which were categorised as providing "essential clinical care" within NHS GG&C were temporarily suspended. For patients already on drug studies, measures were introduced to ensure a continued of study medication, and participant safety. This action was mirrored across Scotland and the UK.

The R& I department established a COVID-19 Task force and Clinical Research Team to prioritise studies, oversee recruitment and efficient delivery of COVID-19 trials across NHS GG&C during the first wave of the pandemic. The COVID-19 taskforce has continued to meet throughout to ensure NHS GG&C participation in key public health studies such as those informing the UK booster program, third doses for immunocompromised patients and community based antiviral treatments.

2.1 Restarting research studies paused due to COVID-19

The NHS GG&C (non-COVID) Research Recovery plan became operational in July 2020. A short term working group and a sub-group of Cancer trials Executive Committee (CTEC) was set up to facilitate the recommencement of non-COVID clinical research which was temporary halted in March 2020. All researchers were required to complete a study specific checklist which are reviewed by these groups prior to approval. (https://www.nihr.ac.uk/documents/restart-framework/24886)

There were a number of pre-conditions (safety, capacity and readiness) that were required to be in place before studies were approved to re-start recruitment or for new studies to open. R&I have worked with sponsors, funders and researchers to overcome any barriers and ensure studies remain viable. For our sponsored and co-sponsored studies extensive work has been undertaken to ensure resilience, rapid approval of amendments, appropriate resources and funding.

Restart Progress: Out of 1146 eligibly funded studies, only 4 commercial studies have not restarted and 35 non-commercial hosted studies. All locally sponsored studies have restarted. Currently a further exercise is being undertaken to contact the sponsors and study teams of the studies which remain suspended.

2.2. UK Managed Recovery plan (phase 1)

In March 2021, the UK government published "Saving and Improving Lives: The Future of UK Clinical Research Delivery". This set out a vision to address health inequalities, enhance economic growth and aims to improve the lives of people through research.

From May 2021, a UK National process has identified interventional, multi-site clinical research studies that are both urgent and should benefit from the support of NIHR CRN, NHS research Scotland, and R&I to fully recruit and/or close in the next year. NHS GG&C R&I have worked with the NHS Research Scotland and the CSO to ensure that locally led Sponsored and co-sponsored studies which fulfilled this criteria were included in the managed recovery list of studies. Chief Investigators have been contacted directly if their projects have been selected for the managed recovery process. (https://www.nihr.ac.uk/documents/guidance-on-the-managed-recovery-of-the-uk-clinical-research-portfolio/27749).

3. NHS GG&C Research Recovery plan (phase 2)

3.1: Local initiatives

A NHS GG&C Research, regrowth and resilience short life working group has been established to drive forward local initiatives to increase capacity, take on board new studies, adapt and overcome some of the ongoing limitations to research activity imposed by the pandemic.

Existing key performance indicators and processes have been met thus ensuring streamlined and efficient R&D management approvals, throughout the pandemic. Sponsor timelines and measures to support and enable our locally led high impact studies are being established through a working group. Study pipelines have been reviewed and new studies identified.

Key to success, is investment in staff and their welfare. Capacity has also been increased through a number of COVID-19 project funded specific appointments. A number of staff have moved on to promoted posts and active recruitment is ongoing to address staff turnover as well as increase capacity. The nurse training scheme has been expanded, as has the number of joint research: service funded nurse specialist posts. The junior fellowship scheme has also been expanded to employ doctors in early career stages to work across portfolios in the Clinical research Facilities. Speciality groups which operate within the Clinical Research facilities have been reconvened and new clinical leads appointed.

3.2 National initiatives (phase 2)

In June, the 4 nations joined together to formulate an implementation plan for the restart, resilience and growth of clinical research The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan - GOV.UK (www.gov.uk). It is underpinned by 5 key themes:

1. Streamlined, efficient and innovative research – so the UK is seen as one of the best places in the world to conduct fast, efficient and cutting-edge clinical research
2. Clinical research embedded in the NHS – to create a research-positive culture in which all health and care staff feel empowered to support and participate in clinical research as part of their job
3. Patient-centred research – to make access to, and participation in, research as easy as possible for everyone across the UK, including rural, diverse and under-served populations
4. Research enabled by data and digital tools – to ensure the UK has the most advanced and data-enabled clinical research environment in the world, which capitalises on our unique data assets to improve the health and care of patients across the UK and beyond
5. A sustainable and supported research workforce – which offers rewarding opportunities and exciting careers for all healthcare and research staff of all professional backgrounds – across the length and breadth of commercial and non-commercial research.

Key aspects of the plan are described in Appendix A, along with NHS GG&C R&I response. This aims to ensure that NHS GG&C remains at the forefront of innovations, provides efficient and streamlined services and ensures patient and staff welfare.

4. Research Activity

4.1 Overall research activity

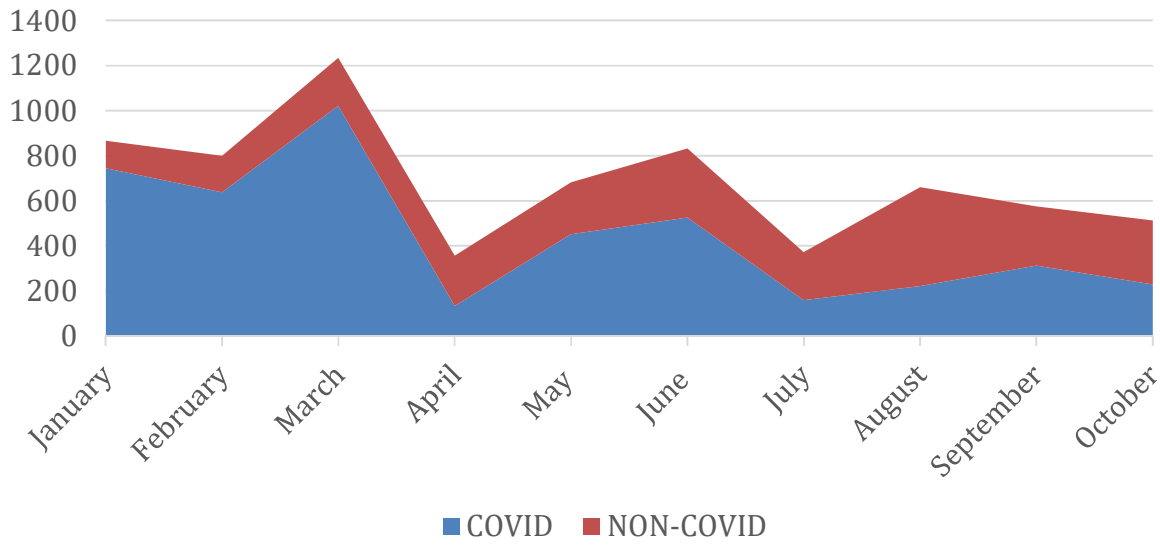
The 202O Board COVID-19 report highlighted that recruitment to clinical trials within NHS GG&C increased by increased by 47 % in April-June 2020 compared to April – end of June

2019 (1,752 compared to 1,185). The impact of the COVID-19 research and rapid translation to treatment guidelines, prevention via the vaccination program and wider understanding of the virus and immunity has been extraordinary.

Since January 2021, most recruitment has been in relation to COVID-19 research, although there are signs of a slow but steady recovery in non-COVID research especially for non-commercial activity (Figure 1).

The COVID clinical trials are however associated with a significant number of on-going follow-up appointments and activity, which is impacting on resources, space and staff availability for non-COVID research. Current service COVID-19 reconfiguration such as social distancing, remote clinics and reduced elective activity are also impacting on research activity.

Figure 1: NHS GG&C recruitment Activity (January 2021-october 2021)



In order to direct local efforts and resources R& I have prioritised

- NHS GGC locally sponsored/co-sponsored GU studies and in particular those involving early career researchers who have limited time to complete their funded clinical research.

- Studies that include " standard of care" as an option
- Ongoing "urgent public health COVID-19" studies (e.g., Oxford-Astra/Zeneca, Novavax, Valneva and COV-BOOST vaccine trials; OCTAVE, OCTAVE DUO and SIREN etc)
- Studies identified through the UK managed recovery process

4.2 Recruitment to non-commercial & Commercial studies

Overall, recruitment in 2020 was higher than in the preceding year, and so far it remains on course in 2021 to equal that in 2019 (table 1). Recruitment to non-commercial trials is higher than the year predating the pandemic.

The impact of COVID-19 is most apparent in terms of a reduction in recruitment to commercial studies, which is mirrored across Scotland and the UK. However, from table 1 it can be seen that recruitment to high intensity commercial clinical trials of investigational medicinal compounds was higher in 2020 and 2021 than pre-COVID (2019). This demonstrates ongoing resilience of chief investigators, principal investigators and wider study teams to undertake complex trial activity.

Table 1: Recruitment to all specialties studies^

All Specialties	2019 01.01.2019 - 31.12.2019	2020 01.01.2020 - 31.12.2020	2021 01.01.2021 - 30.09.2021
Non Commercial	6,587 (1698*)	7,226(1318*)	5,848(2,237*)
Commercial	1,509 (294*)	1322 (689*)	527 (340*)
Total	8,096(1992*)	8,545(2007*)	5,834 (2,615*)

*Number of patients recruited to CTIMPS – clinical trials of Investigative medicinal therapies

^Excludes studies involving tissue or data only

Cancer represents one of NHS GG&Cs key portfolios. The institute of Cancer Research has highlighted that in the UK the number of patients with cancer entering clinical trials fell by 60%

over the past 3 years. In NHS GG&C activity in 2021 has recovered, such that recruitment in the first three Quarters of 2021 exceeds that in 2019. It should also be noted that recruitment to trials involving medicines has increased 2.6 fold (table 2).
Commercial Cancer clinical trials are leading the way in precision medicine and have become tumour aberration driven, and thus require the presence of a specific tumour marker. This has led to a high volume of patient consents and screening to see if the patients which does not necessarily translate into patient recruitment. Thus the numbers in table 2 do not reflect the extent of research activity.

Table 2: Trends in Recruitment to cancer studies

Cancer	2019 01.01.2019 - 31.12.2019	2020 01.01.2020 - 31.12.2020	2021 01.01.2021 - 30.9.2021
Commercial	356 (136*)	69 (63*)	93 (77*)
Non-Commercial	772 (317*)	394 (112*)	1480 (1117*)
Total	1,128 (453*)	411 (175*)	1,573 (1,194*)

*Number of patients recruited to CTIMPS – clinical trials of Investigative medicinal therapies
^Excludes studies involving tissue or data only

NHS GG&C is a partner of the Northern Alliance Advanced therapy treatment centre, which aims to develop the systems and infrastructure required to support the delivery of advanced therapy medicinal products. Currently there are seventeen studies active in NHS GG&C (4 Viral ,3 gene, 10 cellular) and a further six in set-up. These predominantly involve cancer (Mesothelioma, cervical cancer, melanoma, leukaemia, lymphoma, Hepatocellular cancer) but also other specialities (Crohns, paediatric neurology)
Glasgow is also one of the top recruiting sites in the IMPACT network, a partnership of organisations committed to improving the outcomes of stem cell transplant patients through the delivery of clinical trials across the UK.

4.3 Number of studies

The number of studies open to recruitment at some point between the 3 time periods are shown in table 3. In addition, in 2021 there are 335 studies which are in follow-up. Overall, there has been a 12% fall in the number of overall studies in 2021 compared to 2019. New studies continue to open (table 3), despite the ongoing pandemic.

Table 3: Total number of studies open to recruitment (excludes studies in follow-up)

All specialties	2019 01.01.2019 - 31.12.2019	2020 01.01.2020 - 31.12.2020	2021 01.01.2021 - 30.9.2021
Commercial- recruiting	300	307	248
Non Commercial-recruiting	560	522	455
Total Actively recruiting	860	829	703

A number of new studies involving a large number of specialties have come on board in 2021, and are now actively recruiting (table 4). Many more studies are in the pipeline at earlier stages of development.

Table 4: New studies commencing in 2021

	Number of projects
Commercial	92
Non-commercial eligible	108
Other	80
Total	280

5. Key exemplars: Research

There are many examples of outstanding research over the past year. The 2020 board report highlighted key urgent Public Health studies highlighted studies such as those which included the generation of data to inform the SAGE and subsequent public health policy (ISARIC 4C,

GenOMICC, HOCI COG UK, SIREN), COVID-19 treatments studies (RECOVERY, REMAP CAP), evaluating tests and diagnostics (FALCON) and the vaccination research programme directed by the UK Government Vaccine Taskforce (VTF). In particular, NHS GG&C has played a leading role in Scotland in participating in vaccine trials: Oxford-Astra Zeneca, Novavax, Valneva, Octave-Duo.

The following studies provide some insight to the depth and variation of innovative research that is currently underway in NHS GG&C.

5.1 OCTAVE study **OCTAVE** Observational Cohorts Trial - T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2 **Chief Investigator** Prof. Iain McInnes **Principal Investigator** Prof. Stefan Siebert, Univeristy of Glasgow Dept of Infection, Immunity and Inflammation, Consultant Rheumatologist
Cohort clinically at-risk patients with specific immunocompromised or immunosuppressed conditions, cancer, inflammatory arthritis, diseases of the kidney or liver, a stem cell transplant. Just under 700 patients with rheumatoid conditions have been recruited to this study in NHSGGC
Aim: immune response after two doses of the same COVID-19 vaccine
Outcome The initial data show that 40% of people in the patient groups studied mounted a low serological immune response after two SARS-CoV-2 vaccines; approximately 11% of immunocompromised patients fail to generate any antibodies 4 weeks after two vaccines. Those who were in this group have been invited to take part in the Octave Duo Study.
Publication: pre-print Lancet

5.2 OCTAVE DUO A Phase III, Multicentre, Randomised Trial Comparing SARS-CoV-2 Re-Boost Vaccine Strategies in Immunocompromised Patients **Chief Investigator** Prof Iain McInnes **Principal Investigator** Prof Stefan Siebert
Participant Group: 158 immunosuppressed rheumatology patients
Intervention & comparator: patients receive a 3rd dose of either Pfizer or Moderna vaccines
Aim to determine the impact of this vaccinatination on antibody reponse and any subsequent COVID19 infection **Outcome:** awaited/imminent

5.3 COVBOOST

Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial

Chief Investigator: Prof Saul Faust (Southampton). Local PI, Prof Emma Thomson
(NHS GG&C is only Scottish site)

Participant group: 2878 (128 Glasgow)
aged > 30 years, > 70 days post two doses of AstraZeneca Oxford or > 84 days post two doses of Pfizer-BioNTech primary COVID-19 immunisation course
PCR- negative

Intervention: seven vaccines: AstraZeneca-Oxford, Pfizer-BioNTech; Moderna; Novavax; Valneva; Janssen; CureVac
Comparator: meningitis vaccine

Outcome: at 28 days all seven vaccines are safe to use, with acceptable levels of 'reactogenicity' – inflammatory side effects like injection site pain, muscle soreness, fatigue.
All 7 boosted levels of spike protein antibodies significantly after 2 doses of AstraZeneca, only 6 did so after 2 doses of Pfizer-BioNTech
large variations in response with different boosters

Impact: Informed national booster programme
Published Online December 2, 2021 https://doi.org/10.1016/ S0140-6736(21)02717-3

5.4 SUBCUT Trial

An open label, single dose study to assess safety and efficacy of a novel patch infusor device and novel SUBCUTaneous furosemide formulation combination in patients with Heart Failure: a phase I clinical trial

Chief Investigator Prof Mark Petrie **Principal Investigator** Dr Ross Campbell

Participant Group: 20 patients with cardiac failure

Intervention :novel patch infusor device and novel subcutaneous furosemide formulation combination

Aim: To investigate the safety, tolerability, efficacy and on-body performance of a novel patch infusor device and novel furosemide formulation combination
Outcome: Phase II trial

5.5 Renal

Anaesthesia **C**hoice for **C**reation of Art**e**riovenou**s** Fi**s**tulae (**ACCess** Study)

A multicentre observer-blinded randomised controlled trial

Chief Investigator: Miss Emma Aitken, NHS GG&C
Participant group: 566 adult patients with end stage renal disease (ESRD) who require primary radio- (RCF) or brachio-cephalic fistula (BCF) creation.
Intervention: regional anaesthesia (ultrasound-guided supraclavicular or axillary block 1:1 mixture of 0.5% L-bupivacaine and 1% lidocaine with epinephrine (final concentration 1 in 400,000) compared to **Comparator:** local anaesthesia (1:1 mixture of 0.5% L-bupivacaine and 1% lidocaine).
Outcome: 1-year primary unassisted patency of primary radio-/brachio-cephlic arteriovenous fistulae & Cost-effectiveness

5.6 Cancer **IMAGINE Integrating Medically Actionable Genomics INto Early-phase trials** Chief Investigator :Patricia Roxburgh
Participant Group: Eligible patients are those referred to the ECMC – supported "Phase I Clinic" (Evans, Wilson, Roxburgh) for an early-phase clinical trial and who are fit for systemic anti-cancer therapy and are able and potentially willing to have a tumour biopsy
Intervention: non-randomized, sample collection, feasibility study Next Generation Sequencing at the Glasgow Precision Oncology Laboratory (GPOL), NHS GG&C & University of Glasgow
Outcomes: establish a framework in which tumour samples can be obtained and molecular profiles generated in a clinically useful timeframe. Secondary: complication rate; proportion of patients where the biopsy contained adequate tumour; adequate DNA was isolated; an actionable aberration is identified; and the proportion of patients where an appropriate therapy is available

6. Safehaven

The West of Scotland Safe Haven has continued to support a diverse portfolio of data-driven research projects spanning a wide range of clinical areas and applications. Leveraging the Safe Haven's robust governance procedures and technical expertise has enabled unique data-informed approaches to rationalising trial recruitment for studies such as the Glasgow led COVID antiviral trial, GETAFIX.

Over 50 different data projects and feasibility studies have been initiated in the Safe Haven this year, from large-scale population linkages looking at cardiovascular disease and diabetes, to

smaller-scale, Glasgow-based service evaluations spanning cancer, orthopaedics, and unscheduled care.

The Safe Haven has worked closely with the Innovation team on high-profile studies such as OPERA, OPTIMAL, and DYNAMIC (see section 8) providing cohort builds, datasets, and data validation services to guarantee patient privacy. The team continues to develop expertise in the de-identification and management of clinical imaging data, and has lent expert support and capacity to deliver work packages across the iCAIRD collaboration.

7. NHS GG&C Biorepository

During this year the Biorepository has continued to support ongoing COVID-19 research and collections with a total of 42,000 samples being provided to the National Serology Surveillance Programme since it started in 2020. Our NHSGG&C COVID-19 Biobank now has ~65,000 aliquots of blood, sputum and urine samples from around 1200 patients which are available for research use along with supporting data from GG&C Safe Haven.

NHSGGC Biorepository continues to be involved with iCAIRD and have supported the generation and sharing of pathology digital images and stained sections with collaborators for multiple projects.

The safehaven is supporting two Cancer Research UK (CRUK) accelerator studies – PREDICTmeso and PANTHR-S. These involve Biorepository resource in coordinating multi-centre access to pathology archive material and data. PREDICTmeso is a multi-centre Biobank approved as a satellite of the NHSGG&C Biorepository. PANTHR-S is a cohort study aimed at developing a stratified medicine approach for personalised neoadjuvant chemotherapy in high-risk soft tissue sarcoma patients and comprises of both retrospective and prospective tissue collection.

One of the main areas of work in 2021 and going forwards into 2022 is the Scottish Transcriptomics Archive Resource (STAR) project under the Glasgow University Strength in Places UKRI award. This exemplar project involves identifying, processing and curating up to 30,000 samples from the Pathology archives for transcriptomic analysis and linking with the Safe

Haven to associate these profiles with clinical data to ultimately create a commercial database for research into precision medicine.

8. West of Scotland Innovation Hub

The WoS Innovation Hub acts as a "front door" and single point of contact for both innovators and industry and provides end-to-end support for innovation projects in the Region. The innovation team based at the WoS Innovation Hub include project management, proficiency in contracts, costings, regulatory approvals and evaluation, intellectual property and marketing, technical, communication and clinical expertise. The team includes staff aligned to the Directorate of Research & Innovation, E-health and Medical Device Unit.

The team aim to transform delivery of health and social care by driving forward the early adoption (or early rejection) of novel devices, products and services. Support for national test bed projects is provided in partnership with national networks and the National Innovation Hub. A number of projects have moved or are moving from development/testing through procurement to Business As Usual (vCreate; Trauma App; Opera Heart Failure: COPD digital service-see section 9).

In addition to the clear emphasis on quality and improved care, there is an expectation that healthcare Innovation can and should lead to economic growth and generate wealth. Improving Scotland's innovation performance is a top priority for Government, with Health and Social Care seeking to be at the forefront.

8.1 Evaluation of new Med-TECH devices

The value of the NHS in driving forward innovation goes well beyond its role as a purchaser of medical therapies and technologies. NHS GG&C is able to act as a "test bed" to allow the evaluation and utility of innovation products within the healthcare system and their impact on pathways of care. Critically NHS GG&C can partner with manufacturers of medical devices (sensors, software algorithms, point of care tests etc) to conduct a Clinical Investigation of an

unregulated device under the Medicines & Healthcare Regulatory Authority (MHRA) to demonstrate that the device does what it says it does and is safe. This is required for the device to get UKCA or CE marking. We have developed a partnership model where NHS GG&C (in some cases with the University of Glasgow) will act as Sponsor of the Clinical Investigation but with key defined roles for the manufacturer in terms of submission the MHRA. Benefit sharing (preferential licensing or Royalties) is a principle captured in the contracts.

8.2 Co-development of technology enabled services

NHS GG&C has created a live test environment to set up new service models. All pilot projects are evaluated to understand the patient, clinical and economic benefits. If encouraging an application will be made to the Technology Enabled Care (TEC) Board, part of Scottish Government. These proposals are evaluated by TEC and short term funding awarded on a test of change basis to roll out the technology enabled service across Scotland. NSS is responsible for procuring the company to conduct this work on behalf of TEC. The final step is national procurement of the service if on evaluation it has been shown to be effective and affordable.

Alongside these technology driven services there is usually an add-on project that utilises existing West of Scotland Safehaven data alongside the newly generated digital data to support machine learning. The development of Artificial Intelligence (AI) algorithms can potentially further improve care by risk stratification of patients and are classed as medical devices. These algorithms need to be evaluated to support regulatory approval prior to any procurement consideration.

8.3 Current Activity

In 2021, the WoS Innovation Hub team are currently supporting 57 Innovation projects. This includes large programmes of work such as iCAIRD, Strength in Places and the National Consortium of Intelligent Medical Imaging which have a number of large work packages running and more in the pipeline. In addition, 15 projects at the set up stage and 18 at the scoping stage. The total value of the active projects is £93m.

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8.4 Update on key projects

8.4.1 ICAIRD Industrial Centre for Artificial Intelligence Research in Digital

Radiology workstream Within NHSGGC, the Safe Haven AI Platform (SHAIP) is now functional and is hosted on a new West of Scotland supercomputing cluster, SHAIP is being actively used for machine learning for the stroke, chest X-Ray and COVID-19 exemplars. Currently 50-60 researchers are accessing the platform remotely using a new Nutanix Frame remote desktop environment. The images and data are held securely within GGC and all Machine learning outputs are checked by the safe haven before release.

A key success of the programme has been to secure the governance approval to download and anonymise images at scale from both local and national PACS (X-ray and CT). Currently > 10 million images are being used for Machine learning work. The pipeline to access images at scale has only been validated for X-Ray and CT so far. Further work is required to expand to other modalities,

Outputs include an X-Ray triage model several percentage points more accurate than a clinician, capable of separating COVID-potential from COVID negative X-Rays.

iCAIRD, led by NHSGGC, have been awarded £600k to act as technology-specific evaluation teams for two AI technology providers. University of Glasgow and NHSGGC will lead a health technology and economic assessment, study across 5 UK hospital sites to evaluate an AI-based chest x-ray triage and prioritisation tool focussed on detecting lung cancer and identifying normal chest x-rays with high confidence.

Pathology workstream 98.2% of all H&E pathology cases are now being reported using digital pathology. A new upgrade will allow the installation of a next-generation Philips scanner which will lead to 100% digitisation of H&E pathology. Work is near completion on the cancer AI classification algorithms for endometrial and cervical cancer.

8.4.2 Strength in Places Fund: Glasgow Living Laboratory for precision Medicine

Glasgow University and its partners which includes NHS GG&C and industry are recipients of a 38 million award from the UK research & Innovation strength and places fund. This forms part of a 90 million investment to create the Living Laboratory. The laboratory will include a Health Innovation Lab and a Digital Health Validation lab Key projects which are currently underway include:

Pharmacogenomics: this project will deliver a clinical decision support system that will use information from a patient's specific genetic characteristics to inform clinicians as to how an individual may respond to a medicine, thus improving outcomes, avoiding unnecessary side effects and potentially resulting in cost-savings to the NHS.

The Scottish Transcriptome Archive Resouce (STAR)project: which involves BioClavis, NHS GG&C and the precision medicine Scotland Innovation project will generate transcriptomic profiles of archive samples. These profiles shine a spotlight on DNA activity in cells and tissues, thus enabling academic clinical researchers and industry to understand more about a range of diseases.

Living Laboratory Coil development: this project aims to design, manufacture and clinically evaluate specialised coils to expand the imaging and diagnostic capabilities of the 7 Tesla MRI, located in the imaging Centre of Excellence on the QEUH campus. This is a collaboration between Glasgow based company MR CoilTech, Siemens Healthineers, researchers from the university of Glasgow and NHS.

9. Key Exemplars: Innovation

In response to COVID 19, a number of new exemplars have been developed, and existing projects have been adapted and rapidly implemented to address the COVID-19 Pandemic by the Innovation Hub team. These were described in the 2020 Board R&I report.

There are a growing number of Non-COVID projects currently supported by the Innovation Hub. Below are a details on a number of key exemplar projects. A number of these are at the stage of National roll out which will be undertaken by NSS and Centre for sustainable Recovery.

9.1 Chronic Obstructive Pulmonary Disease (COPD) DYNAMIC Project **Clinical Lead: Chris Carlin** **Integrated unscheduled care, Digital service, Artificial Intelligence**
Application: The DYNAMIC project involves patients with severe COPD and provides remote patient entered management through a patient facing web portal and the use of portable measurement devices.
Receiver Trial: outcomes: Proportion of enrolled high-risk COPD patients successfully engaged with remote-management in a digital service model -89.8%sustained use over time leading to **Admissions: 28% ↓Occupied bed days: 38% ↓**
Extension: In response to COVID 19, the service adopted this technology and it is now offered it to all patients with COPD in NHS GG&C and subsequently this will be expanded across Scotland. The information is fully integrated into the patient electronic health care record (via strorm LD Lenus platform)
Progress: **Recipient: Holyrood Connect's Technology Enabled Independent Living Award 2021**
Next stage: DYNAMIC-AI NIHR/AAC grant award - £1.2m 2021-2023 to develop live AI-model decision support to enhance COPD MDT care, with NHS GG&C sponsored implementation-effectiveness clinical investigation. DYNAMIC-SCOT-2 - Scottish Govt funding 2022-24 for multi-board adoption including support for further spread and scale of COPD digital service within NHS GG&C, as part of board recovery plan.

9.2 V CREATE & VCREATE NEURO **Clinical Lead: Neil Patel** **Industry Partner: VCREATE** **Preventive & Proactive care, Digital service**
Clinical need: at times when hospital attendances are limited, there has been an increased requirement for asynchronous communication between patients and clinicians to ensure the best standard of care continues to be delivered. Building on a previous successful project using video diaries within the Neonatal department in NHSGGC, the WoS Innovation Hub have worked with vCreate Ltd (Windsor, UK) to develop an asynchronous video services. Data is captured as part of the electronic patient record.
Aim: Patients with epilepsy or carers can upload videos for clinical review, and receive feedback asynchronously and securely from any smart device vCreate Neuro enableS remote management of patients within their department
Progress: expanded and now in use in all boards, adult & Paediatric
Recipient: **Holyrood Connect's Digital Health & COVID 19 award 2021**

9.3 Validation of an Artificial Intelligence Optimised Pathway for the Identification of Heart Failure in the Community (OPERA) Clinical lead: Dr Clare Murphy Industry Partner: AstraZeneca **Integrated planned Care, New Technology, Digital service, Artificial Intelligence**
Clinical Need: Involves patients with suspected heart failure. Echocardiography is the standard of care imaging modality used to confirm the diagnosis. Prompt diagnosis of heart failure is essential to allow effective treatment and reduce hospital admissions.
Opera Trial Outcomes: feasibility & accuracy of AI enabled point-of-care echo, non-specialist versus current standard of care echo performed by specialists operators Optimise future referrals to HF diagnostic pathway services and improve the efficiency of the service for managing people with suspected HF. (develop and evaluate the performance of a machine learning (ML) driven risk prediction model)
Progress: Trial: REC approved, NHS GG&C sponsored 800 Recruits, data analysis underway Digital dashboard developed (STORM ID) **Improved access to heart failure diagnostic services, reduced waiting times (12 months to 4 weeks)**
Planned Next Stage: Forth Valley is in set up currently and the Centre for sustainability is taking forward implementation across Scotland

9.4 National Trauma App **Clinical Lead: David Lowe Industry partner: Daysix** **Integrated Unscheduled care, Digital service**
Clinical Need: Trauma remains the fourth leading cause of death in western countries, and the leading cause of death for people under 40. In Scotland's four Major Trauma Centres, care is delivered by a clinical team, with a leader directing care, and a scribe documenting the case.
Aim: The Trauma App aims to replace existing paper forms; tracking the full trauma case and providing cognitive aides to assist clinicians with decision making. The app also automates reporting and reduces the amount of clinical paperwork, freeing up frontline staff's time for patient care
Progress: The West of Scotland Innovation Hub has worked collaboratively with Daysix, the Scottish Trauma Network and EMQUIRE through an Innovate UK project to co-design and develop the app, adhering to the ATLS standardised approach to trauma care, and ensuring it integrates seamlessly with other NHS clinical applications. User feedback through simulation tests and scenarios has been feedback from all 4 trauma centres
Next Stage: Live and integrated into WoS Major Trauma Centre (MTC) with national procurement being led by the Scottish Trauma Network supported by WoS Innovation Hub.

NHS GGC has procured the app through the Softcap framework till the national procurement is conducted

9.5 Patient Recorded Outcomes Measures (PROMS) Cancer Service **Service Lead: Debbie Provan; Industrial Partner: My clinical Outcomes** **Integrated planned care, Digital service**
Clinical Need: PROMs are transforming cancer care by providing patients with the ability to provide remote feedback on their physical and psychological symptoms.
Aim: to provide real time access to tis data to Clinicians and thus allow them to track patients' health and wellbeing.
Progress: The West of Scotland Innovation Hub team has worked with the industry partner, to support the project from the outset, providing guidance and governance assistance. Pilot has shown scalability across multiple cancer services and regional areas.
Next Stage: Funding has been secured from SG and a programme of implementation is underway in NHS GGC

9.6 OPTIMAL: Osteoporosis Treatment Identification using Machine Learning **Clinical lead: Chris Sainsbury Industry Partners: Storm ID, Zebra** **Artificial Intelligence Industry Partners: Zebra, Storm ID**
Clinical Need: Frailty is a multifaceted disease process of which optimal osteoporosis identification and treatment can significantly enhance healthy ageing. Ineffective management of osteoporosis leads to significant morbidity and mortality with associated healthcare costs. Early treatment of osteoporosis prevents fractures and reduces the risk of life limiting falls. Patients suffering osteoporosis related fractures require significant input of both hospital resource for surgical management of fractures but also additional social / community care input.
Aim: to create an optimised data driven pathway to osteoporosis risk stratification leveraging routinely collected electronic healthcare data and existing imaging with focus being on risk stratification for patients over 50 using a machine learning driven approach.
Progress: Development of AI risk stratification models to be applied to Glasgow and Israel data. Processing of routinely collected CT imaging to improve performance and co-design of clinical dashboard to support review initiated.

10. Feedback from families & Participants

We are very grateful to all the patients within GG&C who take part in clinical trials. Below are two case stories, and a selection of quotes from patients. These demonstrate the benefits that patients receive from taking part in research and their desire to help others.

10.1 ACCESS study: New Glasgow-led study aims to improve lives for those on kidney dialysis

Many patients with renal failure require to undergo dialysis until such time as they can receive a renal transplant. Dr Emma Aitken and colleagues, have launched a UK-wide study to try to maximise the success of fistulas (a connection between the artery and vein) which are required for connection to the dialysis machine (exemplar 5.5). The study aims to improve care for patients and, ultimately, increase life-expectancy. The importance of the study to patients are illustrated by the following quotes from Ewan

"I've had terrible times with my fistula and it's nobody's fault, it's just that they can fail," explains Ewan.

"They scan your arms to see where the veins are and see which ones are suitable. Once they find the right spot it takes anything from a few weeks to a few months for it to 'mature' and be of use. You are watching it constantly and praying that it won't stop working.

"As a new patient, you are constantly checking your arm to make sure the fistula is still working. You're careful not to lift anything too heavy with your fistula arm in case you damage it."

Ewan concludes "Getting a transplant is life and hope, but while you're on dialysis a fistula is the best option. Making them better will make a huge difference."

<u>10.2 NOVAVAX Vaccine trial</u>

A total of 15,000 people across the UK took part in the study including 517 people from the greater Glasgow area took part in this study, which has recently completed. These are the reflections from 1 participant in the trial.

Anni: "Last summer when I signed up for the trial, we all knew a vaccine was our way out of this but none had been approved yet. I'm a child of the 1950s and have benefited from vaccines all my life."

"Getting involved in the trial was part altruism, part self-interest".

"I felt fully informed during the process and supported by the research team."

On learning she was one of the participants in the study to receive the vaccine rather than placebo, Anni said:

"It was incredible news," she said. "It felt absolutely amazing, and I even felt retrospectively happy for myself all over the last few months knowing I had had protection and not realised it."

10.3 Heart Failure “Subcut” trial

Alex was among the patients who took part in the first phase of the novel device and drug formulation trial to treat heart failure (see exemplar 5.4).

He said: “It was painless, after 10 or 15 minutes I forgot it was even attached. It was non-intrusive, whereas previously it would take a lot of time and take up nurse’s times.

“The gadget did it all for me.”

11. Research, Resilience & Growth in 2022

Throughout the pandemic NHS GG&C Research & Innovation have embraced change, continued to innovate and strived to improve the available treatments and increase use of novel technology in order to enhance the care for patients. In 2022 we will build on this momentum for change, deliver our recovery plan, ensure support and resilience and growth in research and innovation within NHS GG&C. We will continue to work collaboratively with our partners in academia and industry to advance our knowledge and practices and play our part in delivering the UK life sciences vision. This builds on the success of the vaccine program and focuses on key healthcare challenges. The vision is to make the NHS the country’s most powerful driver of innovation, through the development, testing and adoption of new technologies and treatments at scale.

Key areas of focus in 2022 in the NHS GG&C R & I recovery plan and strategy will be to improve speed and efficiency of study start up, build upon digital platforms to deliver research, and increase our participation in trials which are innovative in design. We will also strengthen the public, patient and service user involvement in the shaping of research and innovation including the evaluation of A-I in areas such as radiology.

Appendix A Recovery Plan for the restart, resilience and growth of clinical research The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan - GOV.UK (www.gov.uk).

Improved speed and efficiency of study set-up – particularly for costing, contracting and approvals			NHS GG&C response
1.1	NHSEI, NIHR and HRA will work with devolved administrations to design and implement a national contract value review process for commercial contract research. This will work with existing support available in Scotland with the aim of creating an aligned UK service.	By reducing variation and time spent negotiating costs for commercial research across the UK, we will make study set-up more efficient and predictable.	NHS GG&C R&I will implement new National contract
1.2	HRA, through the UK contracts group, will expand the range of model UK contracts agreed with Industry and the NHS. This will include templates to support innovative trial delivery through hub and spoke models.	By increasing the model contract offering we will make research contracting faster and simpler for decentralised trials and other innovative models	Ongoing engagement & implantation of new model contracts
1.3	HRA, working with relevant partners, will streamline and accelerate the UK ethics review service including offering rapid REC review as an option for clinical trials across the UK, including Phase I trials in healthy volunteers.	By ensuring REC review is not a barrier to fast and efficient research set-up, we will support faster approval of new research studies in the NHS and across the UK, whilst maintaining high ethical standards for research.	P/T Secondment of NHS GG&C Ethical Scientific Office to NRS/CSO Phase I volunteer studies not performed in Glasgow
1.4	HRA will continue work on developing IRAS as a UK portal for research approvals and ongoing study oversight, streamlining approval processes, improving communication with digital interfaces and workflow tools.	By improving the processes and systems which support research, we can make study set-up more efficient and transparent.	R&I to consider changes to the system with operational impact on current teams/structures
1.5	NIHR, working with the devolved administrations, will ensure development of digital solutions that link research approvals portals with delivery management systems where linked systems are not already in place.	By supporting greater digitalisation of the research ecosystem we will remove red tape and make it easier to track progress of studies and research portfolios.	Already aligned
1.6	The UK government and devolved administrations will ensure late phase commercial clinical research is delivered through efficient and responsive models.	By making delivery of late-phase commercial clinical research easier and more efficient, we will provide people across the UK with the opportunity to access research opportunities that	Promotion of Glasgow Clinical research facilities and building on recent successes

		are of relevance to them and increase the UK's attractiveness as a destination for late-stage research investment.	Appointment of Director to Beatson WoS CRF Expand number of principal investigators & NRS fellows as per R&I strategy Key outcome measures
1.7	The Innovative Licencing and Access Pathway (ILAP) will continue to provide an integrated UK approach to accelerate the time to market. ILAP will also facilitate patient access to medicines by delivering tools and advice for companies on clinical trial design to ensure optimal data is generated for both regulatory approval and health technology appraisal from its partners across the UK.	By implementing ILAP we will ensure speedier UK-wide approval processes and easier access to support along the development pathway for new treatments. This will provide increased clarity for innovators and companies regarding the data and evidence they need for licencing and health technology assessment.	SMC is Scottish link to ILAP. Updates via NRS management R&I Directors group
1.8	MHRA will continue to develop proposals to improve and update the regulation of clinical trials, while maintaining alignment with global standards. This includes legislative changes to the Medicines for Human Use (Clinical Trials) Regulations 2004, using powers under the Medicines and Medical Devices Act 2021.	By improving clinical trial regulations we can ensure better research transparency, risk proportionate safety requirements, greater accessibility for patients, and streamlined approvals for faster research delivery. In addition, this will help drive more effective delivery of trials, informed by global best practice and harmonisation of regulatory requirements in key areas such as terminology.	Staff participation in workshops- i.e. Medicines and Medical Devices Act 2021 Develop and expand Infrastructure and processes as per R&I strategy

1.9	MHRA will further develop combined review with HRA and devolved administrations on research for both medicines and medical devices, through established and defined collaborative clinical trial (medicine) and clinical investigation (devices) reviews.	By introducing greater combined working, we can streamline UK-wide processes and reduce bureaucracy for researchers conducting research with medicines and medical devices. This will also benefit UK companies conducting phase I trials in healthy volunteers for global sponsors.	Covered IN NHS GG&C R&I strategy NHS GG&C R&I sole/co-sponsor innovative device and drug trials including recent combined phase I drug & device trial Develop & implement joint NHS GG&C And GU co-sponsorship agreement for devices
1. 10	The Experimental Cancer Medicine Centre (ECMC) Network, with support from MHRA and HRA, will deliver a pilot to set-up Phase I oncology trials within 80 days of IRAS submission.	By expediting recruitment to phase 1 experimental cancer trials, we will help ensure the UK remains a globally competitive location to bring trials of innovative, new and experimental treatments - particularly for ground-breaking cancer research.	Beatson ECMC &R&I to participate in CR-UK project to rapidly accelerate clinical trial set-up/ The project involves a number of phases starting with a series of site visits and workshops. Key personnel include MD, ECMC director, R&I Director & managers/co-ordinators, chair CTEC, chair of Phase I committees, clinical staff and investigators Review of phase I committee timelines will be undertaken to determine any potential impact
1. 11	The RRG Programme will ensure strategic coordination of work to improve the speed and efficiency of the UK clinical research ecosystem, supporting progress and ensuring alignment of current initiatives, as well as identifying key areas for improvement and investment necessary to fully realise the overarching vision.	By continuing to work together in partnership the RRG members will coordinate activity across the UK, ensure we remain on track to deliver on our overarching vision and communicate a clear and consistent message to commercial and non-commercial researchers.	Coordination not governance No specific action
Build upon digital platforms to deliver clinical research			

2.1	The RRG programme will work across the UK to develop a seamless UK-wide system of digital platforms for research sponsors, ensuring they can bring research, particularly those with a digital component, to any part of the UK effectively.	By joining up the UK systems we will bring increased diversity in research sponsors and research sites. This will ensure patients and researchers across different parts of the UK are not disadvantaged by location, especially for digitally enabled trials	Sponsor team to adopt UK digital platforms once available
2.2	The RRG programme will work with funders, researchers and volunteers to understand the various registries across the UK that allow for people to register their interest in being part of research, these include the COVID Vaccine Registry, other condition specific registries and more generic registries like Our Future Health.	By understanding the UK registry landscape we will identify ways to make the ecosystem more efficient whilst developing better links and interdependencies that will reduce confusion for researchers and volunteers resulting in increased opportunities for people to be part of research.	NHS GG&C has access to vaccination data and test & protect dataset via the safe haven. Appropriate approvals including Caldicott are in place to enable recruitment to clinical trials. This model will be expanded going forward Also collaboration with NHS Digital on the design, user interface and the specification for invitations for NHS GGC citizens to participate in for vaccine trials
2.3	HRA and NIHR CRN, working with the devolved administrations, will establish guidance and support services that support data-enabled recruitment and help researchers understand, navigate and use data services as part of effective study delivery. Initially, this will focus on mature, large-scale data and digital infrastructure and expand in future years.	By making it easier to navigate and access our NHS data and digital platforms as well as offering guidance on effective and appropriate use, we will increase researcher confidence, support more efficient study delivery and enable more innovative study design.	Data enabled recruitment is promoted through safehaven. Consent to use data being built into innovative projects such as Dynamic Scot. Further expansion planned. Digital infrastructure will be considered by the proposed Clinical Trials Centre SLWGs
2.4	We will further develop the capabilities of specific data and digital services in order to enhance UK capability for clinical research delivery, including: CPRD, working across the UK, will fully launch SPRINT (Speedy Patient Recruitment Into Trials) - a data-enabled patient find and recruit service for commercial studies in any setting.	By ensuring secure and appropriate use of national data sets we can speed up set-up, recruitment and follow-up further enabling innovative trial designs. This will lay the foundations to connect services across the UK in future years and also support increased access	Limited number of GPs registered with CPRD-need to promote Further investigation and consideration of impact/links with other systems required

	NHS DigiTrials in England will automate and develop the sophistication of their feasibility, recruitment and outcomes services to increase both capacity and speed.	to research and improved diversity of study participants.	
Increase the use of innovative trial designs through innovative regulation, investments in data and infrastructure, and by expanding the evidence base on innovative trial designs.			
3.1	MHRA will further enhance their early engagement support for researchers. This includes joined-up advice from NICE, SMC and HRA alongside a robust 'pre-assessment service' and establishment of guidance from MHRA/NICE on innovative trial designs, as an ILAP tool.	By bolstering early regulatory engagement we can help more researchers with their study designs, to ensure they align with the UK-wide regulatory review processes for faster decisions and the use of more innovative designs.	Sponsor(s) to work with researchers to support early engagement with MHRA
3.2	NIHR and HRA, working with the devolved administrations, will undertake a programme of work to assess and develop capability to support virtual and decentralised trials, including delivery of pilot projects.	By boosting our capacity to support novel study designs we will increase future system resilience and widen access to research amongst a broader range of prospective participants to increase access for patients with the greatest health need.	Actively promote decentralised trials and support PIs/Cis (ROCHE study planned) NIHR RTD event in planning for 29/30 Nov
3.3	NIHR and devolved administrations will continue work to share examples and learning from the implementation of innovative design and delivery of clinical research, to help these approaches to become business as usual.	By building awareness and confidence across the clinical research ecosystem we will increase the use of innovative research designs and delivery methods.	Collaborate & support Glasgow CTUs Participate in proposed Glasgow Clinical Trials Centre SLWG
3.4	The RRG Programme will lead work to understand the barriers and enablers facing researchers in delivering patient centred, innovative research designs as standard, and use this as a basis for the design of interventions that will enable a step change in practice.	By continuing to work together RRG members will develop an informed and evidence-based approach to enable sustainable change across the UK research, health and care communities.	Address locally through Glasgow Clinical trials Centre SLWGs
Aligning our research programmes and processes with the needs of the UK health and care systems			
4.1	NIHR, on behalf of the UK, will develop the professional identity, standards and regulatory accountability for Clinical Research Practitioners and further develop the Associate PI role.	By building and securing a sustainable research workforce and by ensuring more people within the NHS are able to support research, we will bolster overall system capacity. In addition, by making research roles more	Adopt and expand associate PI role within Glasgow CRFs Deliver enhanced SCREDS and gateway research programme

		appealing the NHS will be better able to attract and retain the best talent and to open research to all healthcare staff.	Advertised the Associate PI scheme launch/virtual event on 3rd November amongst our investigators
4.2	The use of flexible workforce and delivery models will be increased - particularly to support research delivery in primary and community care. Further strategies to boost capacity and expand to other research settings will be explored across the whole of the UK.	By using more flexible workforce models and boosting capacity in non-traditional research settings we will increase system capacity across the wider NHS and support wider access to research amongst all prospective participants.	Outreach recruitment through Living lab pharmacogenomics collaboration
4.3	The RRG Programme will provide strategic coordination of initiatives around embedding research in the NHS and workforce, ensuring alignment across initiatives and identifying areas which require improvement and investment to fully realise our overarching vision.	By continuing to work together in partnership the RRG members will coordinate activity across the UK, ensure we remain on track to deliver on our overarching vision and communicate a clear and consistent message to commercial and non-commercial researchers.	See NHS GG&C R&I strategy – objective 2
Improving visibility and making research matter to the NHS			
5.1	Across the UK the NHS will facilitate recognition of the professional contribution of nurses, midwives, allied health professions, pharmacists and healthcare scientists to the research workforce, and the value of research and innovation amongst NHS leaders, making clear to these professions the different ways they can get involved in research	By acknowledging the important role of nurses, midwives and allied health professionals in research delivery and by embedding research within these professions we can help to ensure all health and care staff are supported to get involved in research and further boost overall system capacity.	Ongoing activity, through R&I reports. Expand number of nurse, pharmacy and allied health professionals principal investigators
5.2	Across the UK we will make clear to all staff the different ways they can get involved in research and increase awareness of the value of research and innovation amongst staff and NHS Leaders. This includes promoting evidence that research active settings have lower mortality rates and increased staff retention.	By promoting the benefits of research and having this acknowledged by senior NHS leaders, we will increase staff engagement in research delivery and bolster overall system capacity.	Via R&I strategy, annual reports to NHS GG&C Board, communication via Press officer
5.3	NIHR, on behalf of the UK, will engage with regulatory bodies for registered professionals around the inclusion of research delivery activity in standards and revalidation requirements.	By ensuring research becomes embedded within the role of registered professionals across the UK we will increase participation and embed	Locally promote inclusion of research activity within job plans

		research as a core part of the job for all health and care staff.	Effective use of researcher support funding
5.4	Based on the outputs of the RRG programme's work, we will explore ways in which metrics and reporting can increase the visibility of research across the NHS and strengthen the NHS mandate for trusts and boards to support clinical research.	By increasing research visibility and providing NHS leaders with detailed insights into health and social care research performance, we will be able to effectively demonstrate the positive impact research has on patient outcomes, improvements in patient care and as a source of NHS revenue	Achieved by Annual board report, new programme of seminars, presentations to study teams, Clinical senate and departments
5.5	Based on the outputs of the RRG programme's work, we will review and amend existing performance reporting requirements, including the UK's Performance in Initiating and Delivering (PID) research metrics for clinical trials, high level objectives and other metrics used across the UK.	By transforming the way we capture research activity we will increase the visibility of a range of research delivery within the NHS enabling all staff and leaders to recognise its value. This will reinforce the value of research and support further delivery across the NHS, leading to better overall outcomes for researchers, sponsors, delivery teams, participants and all patients.	Ensure recruitment activity is captured efficiently and in a timely manner on research databases (EDGE/SCRED) R&I set up times and delivery of KPIs are performance managed via weekly meetings Participate in the ECMC CR-UK rapid study acceleration start up project
5.6	The RRG Programme will lead work to review and refine the package of metrics, measures and incentives to drive the behaviours and ultimately the performance needed to realise the vision. This will include recognition and promotion of the range of activities which enable effective research delivery in addition to recruitment, and workforce involvement in research across multidisciplinary teams.	By adopting an informed and evidence-based approach across the UK we can enable sustainable change across the NHS and wider research community to support clinical research delivery across all phases, settings and specialties.	Ensuring robust processes for awarding research protected sessions, monitoring performance & outcome Study recruitment Performance management through CRF speciality groups
Making research more diverse and more relevant to the whole of the UK			
6.1	NIHR, on behalf of the UK, will work with existing centres of excellence and other partners to develop systems and processes that enable health research to be directed to and supported within areas and communities traditionally under-served by research (e.g. by	By enabling under-served communities to access research, we will help to broaden recruitment, ensuring that people with the greatest health need can be supported through research.	Consider establishing mobile community units. Participate in CSO Diversity SLWG Work with researchers and CTUs to Include

	deprivation, ethnicity or geography) to tackle health inequalities.	Helping researchers to drive improvement in the diversity of research cohorts will lead to more inclusive research and address disparities between research activity and the prevalence of certain diseases, leading to better healthcare provision for all.	diversity within protocols & grant applications Aim to ensure diversity within study and CTU PPI groups
6.2	NIHR, NHS Digital and the devolved administrations will scope the use of national datasets to analyse the diversity of research participants.	By gathering this data, we will improve our understanding of the diversity of participants in research, including in underserved groups. Research designs, methodologies and support can then be adapted appropriately to ensure all prospective participants have the opportunity to get involved.	Work with CTUs to capture diversity of NHS GG&C sole and GU co-sponsored studies. Address in proposed Glasgow CTU/ Clinical Trials Centre SLWGs
6.3	MHRA and HRA will lead the development of guidance to increase diversity in studies.	By creating clearer guidelines, regulators will increase confidence within the research community and enable researchers to take action to address the current imbalance for under-served communities and groups.	Guidelines will be implemented
6.4	HRA will automatically register clinical trials in a public registry, unless the sponsor has permission to delay this to a later stage, starting with trials of medicines.	A single source of information for all UK clinical trials supports work to increase participation in research. By removing the need for registration, this reduces the burden on sponsors and trial managers.	Sponsor(s) will continue to ensure compliance with registering trials and outcomes on public databases/registries (currently 100%)
6.5	Where not already in place, the UK will work to develop and strengthen the ecosystem that will allow people to indicate their interest in taking part in research and explore ways to sustain high quality engagement over time.	By providing people a range of options to participate in research, we can increase the number and diversity of potential participants by ensuring that different options meet the needs of different groups in different contexts.	Establish local process to enable patients to indicate willingness to be contacted for future research Expand support for SHARE. Agreement now in place for spare blood to be collected
6.6	The RRG programme will map activity aimed at increasing the diversity of people taking part in research across	By reducing duplication of efforts across research organisations we will enable coordinated and	NIHR have established a Race Equality Public

	the sector and facilitate joint working in this area.	targeted interventions to increase diversity of people taking part in research.	Action Group (REPAG) – outputs awaited
6.7	The RRG Programme will lead work in addressing the barriers and enablers of behaviour change needed to deliver patient centred, innovative research designs.	By supporting a sustainable change towards diversity in clinical research, researchers will be empowered to carry out more representative participant cohorts as standard practice, resulting in improved health outcomes.	Staff participation in CSO RRG workshops
Strengthening public, patient and service user involvement in the shaping of research.			
7.1	NIHR and devolved administrations will build on their local and regional capacity to work on community engagement with patients and communities to shape priorities and study designs for research.	By working with local communities we can help to ensure patients and the public across the UK feel empowered to get involved in research and that they have a voice in the research that affects them.	Key component of NHS GG&C R&I strategy
7.2	The UK will increase opportunities for researchers to access patient expertise by further developing services connecting researchers with patients.	By helping sponsors to easily access patient groups across the UK who can support development of their studies we can ensure publicly funded research demonstrates the highest standards of public, patient and service user involvement.	Close collaboration with Glasgow CTUs Signpost of current PPI groups Proposed joint interactive website to increase access to PPI support for staff, and PPI members. Promote PPI opportunities for public and patients.
7.3	The UK will work to address practical barriers to enable increased and easy-to-administer involvement of the public, working with key partner organisations.	By working with the public involvement and engagement community and organisations across the UK we can address and overcome barriers, such as pragmatic processes for payment for public involvement activities, resulting in increased public engagement in research.	Key component of NHS GG&C R&I strategy New process have been introduced to fund PPI activities
7.4	The RRG Programme will draw on this work to address the barriers and enablers of behaviour change needed to deliver patient centred, innovative research designs.	By furthering progress towards public, patient and service user involvement in clinical research delivery, researchers will be empowered to carry out	Key component of NHS GG&C R&I strategy

		more patient-centred innovative research designs resulting in improved efficiency, costs and relevance of studies.	