BOARD OFFICIAL

NHS Greater Glasgow and Clyde	**Paper 23/21**
Meeting:	**Board meeting**
Meeting Date:	**25 April 2023**
Title:	**Department of Research and innovation: Board Report 2022** **Recovery, Resilience and growth**
Sponsoring Director/Manager	**Professor Julie Brittenden - Director of Research and Innovation** **Dr Jennifer Armstrong- Board Medical Director**
Report Author:	**Julie Brittenden/Roma Armstrong**

1. Purpose

To describe the breadth and diversity of innovative research undertaken within NHS GG&C, enabled through successful collaboration with academia and industry.

2. Executive Summary

Key achievements of 2022 include:

- ~ Over 400 new studies have commenced
- Leading role in delivering complex early phase trials (I-II)
- Impact of Research experience with advanced medicinal therapies on ability to deliver licensed products within the clinical service
- Award of 2.2 Million(over 5 years) to Experimental Cancer Medicine Centre
- Overall recruitment to Cancer trials has now recovered and is on par with 2019
- Leading role in the participation of COVID-19 Booster trial
- Establishment of a near-clinical digital pathology research environment
- Digitalisation of Pathology & Growth in AI evaluation
- Collaboration with industry to develop a licensed (Class I) CXR A-I algorithm
- Service adoption of key exemplar innovation projects, and others under assessment by the centre for Sustainability for national scale-up

3. Recommendations

The Board is asked to note the research and innovation activity, exemplars and opportunities.

4. Response Required

The Board is asked to note the research and innovation activity, exemplars and opportunities.

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** **Neutral**
- **Environment** **Neutral**

6. Engagement & Communications

Input & review by R&I Senior Management team.

7. Governance Route

The report has been reviewed by the Board Clinical Governance Forum and Clinical and Care Governance Committee. It was submitted for awareness to the Corporate Management Team (6th April), prior to the NHSGG&C Board Meeting (25th April), for Assurance.

8. Date Prepared & Issued

17/04/23

NHS
Greater Glasgow and Clyde

Department of Research and innovation: Board Report 2022

Recovery, Resilience and growth

Contents

Foreword

Research, innovation and the redesign of services are at the heart of the NHS Recovery plan. It was well known that Research & Innovation active Health boards have lower mortality rates and increased staff retention. The 2021 Campbell report has highlighted the importance of innovation not only for the economy but also the benefit of our population's health and care needs. Innovation has the potential to significantly enhance disease prevention, further enable patient centered pathways, cost-saving and efficiencies and a more resilient and higher skilled workforce.

Throughout the pandemic NHS GGC Research & Innovation have embraced change, continued to innovate and strived to evaluate novel therapies and technologies in order to enhance care for patients. In 2022 we have built on this momentum for change, delivered our phase I recovery plan, supported and ensured resilience of the clinical research & Innovation workforce. Local initiates have aimed to give as many studies, as possible the chance of completing and yielding results, whilst increasing capacity to initiate new studies. The phase II recovery plan aims to ensure not only the restoration of clinical research activity that was underway pre-COVID but to improve on our processes. The focus is on streamlined & efficient study set-up and delivering studies & projects to target and time. These measures are designed to further develop and build on our outstanding research & Innovation ecosystem, allowing Glasgow to play a key role in making the UK the leading Hub for life sciences.

Within NHS GGC innovation continues to expand at pace, along with the infrastructure, skills and expertise in data governance processes, clinical evaluation and validation and AI capability. A number of West of Scotland Innovation Hub projects are being taken forward through the newly established Accelerated National Innovation Adoption (ANIA) collaborative. This forms part of a national end to end pathway which aims to enable rapid scaling of innovation adoption to deliver wider improvement in patient care.

In 2023, NHS GGC is well placed to play a key role in the proposed Scotland Health Innovation Life Science Cluster and build upon the recovery evident over the past year and highlighted in the exemplars included in this report.

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1.0 Introduction

This report provides a high level summary of the implementation of the Phase 2 Research Recovery plan and Research and Innovation activity across NHS Greater Glasgow and Clyde (GGC) in 2022, compared to pandemic and pre-pandemic.

2.0 UK Research Recovery Plan (Phase 2)

2.1 Impact of COVID-19 Pandemic on UK Clinical Research

Previous NHS GGC board reports have highlighted the increased recruitment to COVID-19 clinical trials in 2020 compared to recruitment pre-pandemic (2019) as a success.

Furthermore, the impact of the research and rapid translation to treatment guidelines, prevention via the vaccination Programme and wider understanding of the virus and immunity has been extraordinary. However, across the UK, the need to complete existing COVID-19 research along with the ongoing impact of the pandemic, service recovery plans and workforce pressures had resulted in delays in the completion of non-COVID studies. Furthermore, the majority of non-COVID-19 studies were closed during the pandemic across all UK centers. These factors have resulted in a substantial reduction in the number of non-COVID studies able to recruit effectively and close on time across the UK. In order to address this, throughout 2022 the UK Research Reset and Recovery programme have introduced a number of initiatives designed to increase capacity in the NIHR and NHS Research Scotland (NRS) portfolios (see section 2.2 and 2.3 below). These aim to give as many studies, as possible the chance of completing and yielding results, close studies which are considered to be non-viable, and increased capacity to initiate new studies.

2.2 The future of Clinical Research Delivery: 2022 to 2025 implementation plan

In June 2021, 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). This has now been updated with a 2022-2025 implementation plan The Future of UK Clinical Research Delivery: 2022 to 2025 implementation plan - GOV.UK (www.gov.uk).

The plan is underpinned by 5 key themes:

1. A sustainable and supported research workforce to ensure that healthcare staff of all backgrounds and roles are given the right to deliver clinical research as an essential part of care
2. Clinical research embedded in the NHS, so that research is increasingly seen as an essential part of healthcare to generate evidence about effective diagnosis, treatment and prevention

3. People-centered research to make It easier for patients, service users and members of the public across the UK to access research and be involved in the design of research, and to have the opportunity to participate
4. Streamlined, efficient and innovative research so the UK is seen as one of the best places in the world to undertake cutting-edge clinical research, driving innovation in healthcare
5. Research enabled by data and digital tools to ensure best use of resources, leveraging the strength of UK health data assets to allow for more high quality research to be delivered

The delivery of the action plan described is being coordinated by the UK Clinical Research Recovery, Resilience and Growth Programme (RRG).

2.3 UK Clinical Research Recovery, Resilience and Growth Programme (RRG)

The main aims of the UK RRG Programme are to:

- Ensure the restoration of clinical research activity that was underway pre-COVID
- Maximise opportunities to build back a better research ecosystem
- Deliver on the commitment to make the UK the leading global hub for life sciences

The Phase 2 Research Recovery, Resilience & Recovery plan encompass the support, processes and infrastructure that enable clinical research delivery, and aspects of research design, management and oversight. A key focus of the plan is re-establish the volume and performance of industry interventional studies to that delivered pre-pandemic.

Details of the recovery plan which are relevant to Glasgow and Scotland are included in appendix A, along with NHS GGC R&I response. This plan includes significant changes which will simplify and streamline R&I processes, including costing, contracting and regulatory approvals.

3. NHS GGC Research Recovery plan (phase 2)

3.1 NHS GGC Research Recovery, Resilience and Growth Plan

The NHS GGC Research, regrowth and resilience short life working group was established in 2021 with the aim of driving 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 and oversee the recovery plan. The phase I recovery plan focused on restarting non-COVID studies, along with measures to ensure staff welfare and increase capacity. All studies have restated, new studies are coming on board (see section 4.1) and vacancies due to staff turnover have been filled. We now have a new Glasgow CRF manager, there has been expansion of joint CRF: service funded nurse specialist posts and nurse training posts and new initiatives such as the appointment of a Director of the Beatson CRF. The number of principal investigators has increased from 449 just before thee pandemic to 463 at the end of 2022. Long term initiatives to increase capacity are also underway and detailed within the NHS GGC Research & innovation strategy document.

The junior fellowship scheme has also been expanded to employ doctors in early career stages to work across portfolios in the Clinical research Facilities, in addition to the matched funding scheme of fellows who are undertaking a higher degree.

Exposure to research has been actively promoted through the NIHR associate Principal Investigator training. To date 35 staff, from medical, nursing, pharmacy and physiotherapy specialties have completed the scheme and a further 30 have registered. R&I currently fund 4 CRF fellows in the CRF and provide 50% of funding for 6 trainees undertaking a higher degree involving studies active within the CRF.

3.2 NHS GGC R&I Phase 2 Recovery plan

The Phase 2 recovery plan (see Appendix A), is focused on the adoption of R&I processes aimed to reduce delays and speed up study set-up along with delivery of studies to time and target. The team including network & specialty leads currently meet bi-monthly to

review the portfolio, study pipeline, oversee trial performance metrics, and address capacity issues.

In order to direct local efforts and resources criteria for study prioritisation have been in place throughout the pandemic and into the recovery phase. The following studies have been prioritised during 2022:

- Eligibly funded NHS GGC locally led sponsored/co-sponsored GU studies
- Commercial trials
- Eligibly funded hosted studies, which have a Glasgow grant holder

In addition, the Clinical Research Facility (CRF) specialty groups have been reconvened. These are attended by chief and principle investigators, CRF staff, Pharmacy and R&D portfolio staff. As part of the portfolio review, principal investigators of hosted studies which do not include rare diseases that have not recruited in 2022 are now being contacted directly to determine recruitment strategy.

The aims of the CRF specialty groups are to oversee:

- study delivery -recruitment to target (RAG: Red, amber, green metrics)
- Review of pipeline -ensuring capacity, avoidance of competing studies, high impact studies

3.3 Glasgow Led Multi-Centre Studies

As part of the NIHR "Research Reset" all sponsors and funders have been instructed to review and appraise all of their *multicentre s*ponsored and co-sponsored trials which were behind in recruitment or timelines on the central portfolio management system. This exercise has taken place as part of a rolling review process at three time points throughout 2022. Senior members of the NHS GGC and Glasgow University co-sponsors team met with chief investigators and study teams to provide support, and liaised with the CTU Directors. The small number of Glasgow Led studies with a "red" RAG outcome on the portfolio have been supported to develop and implement recovery plans which are overseen by the respective Trial management and steering groups.

4. Research Activity

4.1 Number of studies

Currently, there are 1040 studies active in NHS GGC (recruiting and in follow-up) overall which compares favourably to the last two years (2021, n=1056; 2020, n=1,107). Thus there is no evidence of a bulging portfolio as exists elsewhere in the UK. Of these 394 (38%) are commercial, 126 (12%) sponsored eligibly funded, 458 (44%) hosted eligibly funded and 62 come under the category of others. Safehaven and Biorepository activity is considered separately below.

New studies continue to come on board at a much faster pace, with the total number so far this year totaling 402 (table 1). Only 9 of these are COVID-19 related. A further 85 commercial trials are currently in the pipeline. Measures to reduce timelines for R&D management approval and study start up are being implemented and monitored as described under phase II recovery plan above. Delivery is managed through the Clinical Research Facility.

The Association of British Pharmaceutical Industries in their October 2022 report "Rescuing patient access to industry clinical trials in the UK" have highlighted a 41% reduction in number of industry clinical trials initiated in the UK between 2017 and 2021. This has not been evident in Glasgow, where there has been significant increase noted in the number of commercial trials, from 246 in 2017/18 to 394 in 2022.

Table 1: Recovery: New studies commencing in 2021 & 2022

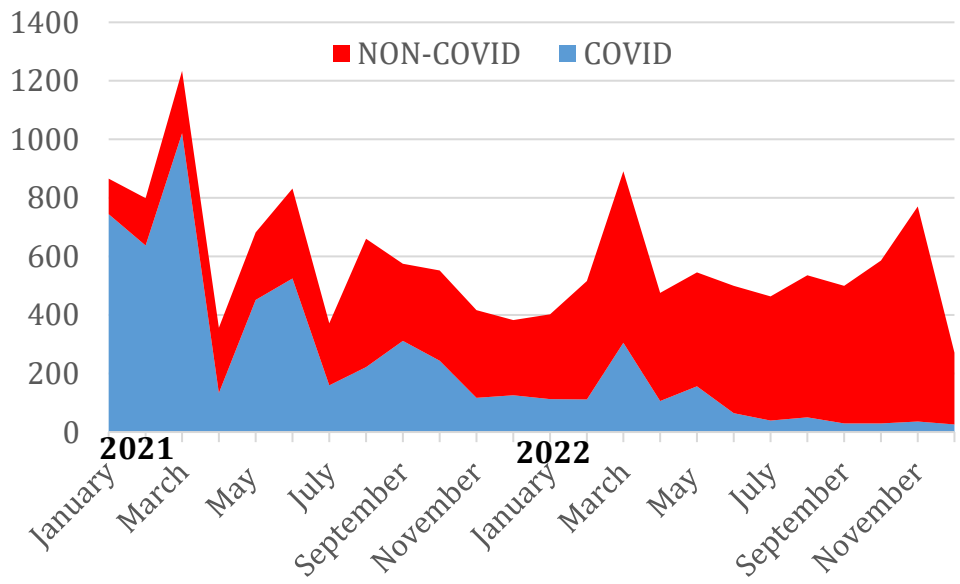
New studies	2021 Number of studies	2022 Number of studies
Commercial	111	124
Non-commercial eligible	122: (36 Sponsored and 86 Hosted)	158 (26 Sponsored 132 Hosted)
Other ∞	89	128
Total	322	410

Other ∞ – Mainly student projects

4.2 Non COVID/COVID-19 research activity: Recruitment

Throughout 2022, the focus has been to increase recruitment to our non-COVID trials which had been paused during the pandemic and to take on new studies. Recruitment to Covid-19 trials has fallen from 28% of all activity at the beginning of 2022 to 5% by the end of the year (figure 1).

Figure 1: NHS GGC recruitment Activity (January 2021-December 2022)



The peaks in recruitment to COVID trials during the 2022 Omicron wave (Figure 1) relate to recruitment to GenOMICC, Recovery, and locally led studies such as GETAFIX, CHARISMA (Clinical Characterisation of Respiratory Viral Infections among Patients with Hospitalised Severe Acute Respiratory Illness using Point-of-Care Multiplex Assays). NHS GGC also took part in the COVBOOST trial -Evaluating COVID-19 Vaccine Boosters which informed which vaccines were deployed in the 2022 autumn booster programme.

A number of others COVID studies continued with long term follow-up in order to generate data to inform the SAGE and subsequent public health policy such as SIREN. In addition we

have a number of ongoing long COVID trials such as Heal COVID and the locally led CISCO 19, CISCO 21, and Lochinver trials.

4.3 Overall research activity: Recruitment

The main impact of the pandemic has been a reduction in recruitment to commercial studies, which is mirrored across Scotland and the UK. The Association of British Pharmaceutical Industries have requested that high-priority interventional clinical trials are prioritised.

In NHS GGC, the significant recruitment to commercial COVID-19 vaccine trials had led to an increase in recruitment to commercial interventional clinical trials. A key priority in 2022 has been to increase recruitment to non-COVID commercial clinical trials of Investigative medicinal therapies (CTIMPS) across our specialty portfolios. There are signs of significant recovery although activity still lags behind 2019 figures for CTIMPS (table 2). Interestingly, it can be seen from table 4 that almost half of the recruitment to CTIMPs is occurring in the more complex early phase trials (I-II) (table 3). This demonstrates significant resilience and recovery.

With the focus moving from COVID trials, it is reassuring to note that across the various specialties, non-commercial recruitment has bounced back to that seen in 2019 (table 2). Furthermore the significant contribution of locally lead CTIMP trials can be seen in Table 3.

Table 2: Overall Recruitment activity

Recruitment All Specialties	**2019 01.01 - 31.12**	**2020 01.01 - 31.12**	**2021 01.01 - 31.12**	**2022 01.01- 31.12**
Commercial	1,509 (294*)	1322 (689*)	679 (384*)	764 (208*)
Non Commercial	6,587(1698*)	7,226(1318*)	7,847(2,591*)	6,763(722*)
Total	8,096(1992*)	8,545(2007*)	8,526(2,974*)	7,527(930*)

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

^Excludes studies involving tissue or data only

NHS GGC has a balanced portfolio of studies ranging from observational to complex Interventional studies across a variety of specialties. In 2022, the top 3 recruiting specialties were Cardiovascular, cancer and trauma& Emergencies. Cancer is considered further below.

Table 3: Recruitment to Clinical trials of Investigational Medicinal Therapies by Phase

CTIMPs - Trial Phase	I	I/II	II	II/III	III	III/IV	IV	Total
Eligible Sponsored	0	6	53	159	70	7	14	309
Eligible Hosted	4	2	71	86	225	0	25	413
Commercial	9	41	42	5	111	0	0	208
Total	13	49	166	250	406	7	39	930

4.4 Cancer portfolio research activity

The 2021 R&I Board Report highlighted that in the UK the number of patients with cancer entering clinical trials had fallen by 60% over the preceding 3 years. Within NHS GGC restarting cancer research post-pandemic has been a key priority and measures have been implemented to increase capacity and address workforce shortages. These have taken a while to implement, but staffing capacity is now at full complement. It is reassuring to see activity recovering (see table 4) such that overall recruitment now exceeds that achieved in 2019. However, as mirrored across the UK, recruitment to commercial trials is not yet at pre-COVID 19 levels and this has been prioritised with a focus on clinical trials of

Investigative medicinal therapies. It can be seen that recruitment to these trials is now almost on par with recruitment pre-pandemic.

Table 4: Recruitment to Cancer studies

Cancer Recruitment	2019 01.01- 31.12	2020 01.01- 31.12	2021 01.01-31.12	2022 01.01-31.12
Commercial	**356 (136*)**	**69 (63*)**	**124 (108*)**	**131 (121*)**
Non-Commercial	**772 (317*)**	**394 (112*)**	**1,071 (382*)**	**1,249 (133*)**
Total	**1,128 (453*)**	**463 (175*)**	**1,195 (490*)**	**1,380 (254*)**

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

^Excludes studies involving tissue or data only

Glasgow is fortunate to have an Experimental Cancer Medicine Centre, led by Professor Jeff Evans which is funded by Cancer Research UK and the Chief Scientist Office, Scotland. In 2022 In 2022 Glasgow took art in the Experimental Cancer Medicine Centre (ECMC) Network initial intelligence gathering phase of a project which aims to radically accelerate the set-up of phase 1 oncology trials. GGC will participate in the 'Improve' phase, which will facilitate the co-creation and testing of approaches to overcome identified challenges (appendix A). The ECMC underwent a quinquennial review in 2022, and has been awarded 2.2 M over the next 5 years. The award panel "*were impressed by Glasgow's trial portfolio which it noted included a number of high quality investigator lead trials"* and that "*patient recruitment had recovered well following COVID" and "approximately half of trial activity was early phase".*

4.5 Commercial income

A key recommendation of the ABPI report (see Appendix B) is that revenue generated via industry clinical research is reinvested into increasing the provision of dedicated research time and research training, especially for nurses and other staff critical to delivering clinical trials. In NHS GGC the Glasgow Biomedicine model enables revenue generated by industry funded clinical research to be re-invested into research, enabling capacity building.

Net Commercial income over the past 5 financial years is detailed in table 5 below. The COVID-19 vaccine trails has ensured that income has been maintained over the past 2 years. This will compensate in the short term for the reduction in overall recruitment in 2022 and allow the recovery to progress.

Potential cost savings relating to innovation are illustrated in the case study detailed in section 8.4

Table 5: Net commercial income

Summary		**2022/23**		**2021/22**		**2020/21**		**2019/20**
Duration		**M1-9**		**M 1-12**		**M 1-12**		**M 1-12**
Net Commercial Income		**-£6,667,726**		**-£7,338,575**		**-£5,584,744**		**-£5,967,057**

4.6 Research Pharmacy Cost savings

In addition to the visible income from Research there is an added benefit of potential savings to the drug budget. The Pharmacy Clinical Trials team track Phase III projects to calculate both projected and real savings where standard care therapy may be replaced by experimental study treatment (saving NHSGG&C standard spend) or where the standard care therapy is funded by Sponsors in addition to provision of the experimental arm.

Since last reported in 2019 the actual cost savings achieved in this period are ~£3.3M. CTIMP trials have continued to open during 2020-2022 with the potential total cost savings relating to the supply IMPs from Sponsors of approximately £5.1M (assuming

recruitment targets are met and all participants achieve their full number of treatments on trial). These will be tracked to visualize what real saving is achieved versus contracted patients and projected figures. In addition to allowing patients access to novel therapies, the saving is used for the benefits of other patients.

Particular cost saving opportunities have been realised in our commitment to deliver clinical trials with Advanced Therapy Investigational Medicinal Products (ATIMPs), where the trials offer offset of the costs of particularly high cost CAR-T products on occasion. Since 2018, the number of ATIMP clinical trials hosted within NHS GGC has grown and we have participated in 22 trials over this period including gene therapy and cellular therapy products. Two of these trials have met primary endpoints enabling the commercial Sponsor to have discussions with regulatory authorities regarding progressing the products further towards marketing (see Exemplar 5.6). There are 11 ATIMP trials open currently with 5 others in set-up. Research experience with ATIMP products also supports the delivery of licensed ATMP products within the clinical services and NHS GGC are the only center in Scotland administering licensed CAR-T products and the onasemnogene abeparvovec (Zolgensma™) gene therapy product.

5. Key exemplars: Research

The 2020 & 2021 board reports highlighted key urgent Public Health studies highlighted studies some of which continued to recruit and follow up participants throughout 2022. There are many examples of outstanding non-COVID 19 research over the past year, which are briefly described below. These provide some insight to the depth and variation of innovative research that is currently underway in NHS GG&C.

5.1 Ironman
Chief Investigator: Paul Karla, Prof Ian Ford
(NHS GG&C & GU co-sponsored trial) BHF funded

Background: Iron deficiency is an important comorbidity in patients with heart failure, occurring in around 40% of patients with chronic heart failure. Iron deficiency is associated with a reduction in both quality of life and exercise capacity, and an increase in hospital admissions for heart failure and mortality, irrespective of the presence of anaemia.

Aim: Safety and efficacy of ferric derisomaltose on cardiovascular outcomes
Participant group: 1,137 patients with heart failure & iron deficiency
Intervention: ferric derisomaltose **Comparator:** usual care, open label, 72 sites
Outcome: cardiovascular death or HF hospitalization, for ferric derisomaltose vs. usual care: 22.4 vs. 27.5 events/100 patient-years (p = 0.07) Primary outcome when censored September 2020 due to COVID-19: relative risk 0.76, 95% confidence interval 0.58-1.00 (p = 0.047)
Impact 1st Prospective outcome study with any iron preparation in patients with chronic heart failure. New treatment Published https://www.thelancet.com/journals/lancet/article/PIIS0140-6736

5.2 CISCO 21 A multisystem, cardio-renal investigation of post-COVID-19 illness Chief Investigator: Prof Colin Berry (NHS GG&C sponsored trial) Funder: CSO Background: pathophysiology and trajectory of post-Coronavirus Disease 2019 (COVID-19) syndrome is uncertain
Aim: determine impact of severe COVID-19 using multisystem imaging, biomarkers and changes over the short (<3 months) and medium (12–18 months)
Participant group: 159 patients hospitalised with COVID 19 (pre-vaccination) **Comparator:** controls
Design : Prospective, observational, longitudinal cohort
Outcome: Myocarditis was "very likely in 13%(21) patients; probable in 41% (65) During Follow up(mean 450 days) : 15% (24) patients died or rehospitalied, and 68% (108) received outpatient secondary care
Impact: illness trajectory, includes persisting multisystem abnormalities that could lead to substantial demand on health services in the future Published :Nature medicine, 23rd May 2022

5.3 SUBCUT PHASE 2 Trial An open label, single dose study to assess safety and efficacy of a novel patch infuser device and novel SUBCUTaneous furosemide formulation combination in patients with Heart Failure: a phase I clinical trial Industry Funded, (NHS GG&C & GU co-sponsored trial) **Chief Investigator** Prof Mark Petrie **Principal Investigator** Dr Ross Campbell

Aim: To investigate the safety, tolerability, efficacy and on-body performance of a novel patch infuser device and novel furosemide formulation combination
Participant Group: 20 patients with cardiac failure
Intervention :novel patch infuser device and novel subcutaneous furosemide formulation combination
Outcome: Phase I – successful outcome Phase II trial now underway – Patients now being treated at home

5.4 TRUCK

Explanatory comparative study of conventional Total Knee Arthroplasty versus Robotic assisted Bi-UniCompartmental Knee Arthroplasty

CI: Mark Blyth, EME Funded

Sponsor: NHS GGC, NIHR funded

Background: Osteoarthritis (OA) is the most common form of joint disease. It causes pain and stiffness and affects at least 8 million people in the UK imposing a considerable economic and personal burden. The knee is one of the most common sites affected by OA. Knee Replacement, or Arthroplasty, is the current surgical treatment of choice for end stage OA of the knee.

Aim: to compare a novel robotic assisted knee replacement surgery, for Osteoarthritis of the Knee, with traditional Total Knee Replacement (TKR)
Participant group: 80 Patients with OA of medial & lateral Knee compartments
Intervention Robotic Assisted Bi-Unicompartmental Knee Replacement **Control** traditional Total Knee replacement
Primary Outcome: Gait No differences at 1 year, longer term follow up underway

5.5 Cancer

Phase I Commercially sponsored trial (Lovance Biotherapeutics)

PI: Prof Jeff Evans

Background: Tumor infiltrating lymphocytes (TIL) are naturally occurring immune cells that fight cancer. A patient's naturally occurring TIL are collected and grown outside the body so they can be administered back to the patient as a one-time treatment.

Participant Group: patients with advanced metastatic melanoma
Intervention: **Active:** open label
Outcome: results have led to the potential for the first FDA-approved TIL cell therapy for the treatment of melanoma rolling biologics license application (BLA)

5.6 EVIS study Early Vasopressor in Sepsis study,
CI : Prof Alasdair Corfield
Sponsor: NHS GGC, NIHR Funded, commenced 2022

Background: Sepsis is a life-threatening reaction to an infection.

The aim of this research study is to compare the two different ways to treat sepsis, in the early phase of treatment immediately after the participants arrive in hospital.

AIM: to determine whether early peripheral vasopressor infusion, targeted to MAP>65 , improves clinical effectiveness in hospitalised adult patients with septic shock compared with usual care, in the first 48 hours.

Participant Group: 3286 patients with sepsis, multi-center

Intervention:
Active: open label, peripheral vasopressor infusion of norepinephrine
Comparator: usual care as per UK national Sepsis guidelines

Outcomes: Primary –all cause mortality at 30 days
Secondary: length of hospital stay, admission rates to critical care; Acute kidney injury; renal & respiratory support

5.7 Biologics and Partial Enteral Nutrition Study (BIOPIC)

CI: Dr Jonathan MacDonald
Funder: $2.1m from The Leona M. and Harry B. Helmsley Charitable Trust
Sponsor: NHS GGC

Background: Crohn's disease (CD) is a chronic condition which currently affects more than 115,000 people in the UK and causes inflammation of the lining of the digestive system. Crohn's is incurable, though it can be managed with treatments: currently either biologic medication, a type of drug that can slow or stop damaging inflammation, or a liquid-only diet which uses prepared formulas for 6-8 weeks.

Primary Aim: improve remission rates at 12 weeks in adult patients with active ileo colonic CD treated with first-line biologics (TNFα antagonists, adalimumab) as their standard treatment of care.

Participant group: 80 Patients with Active ileocolonic Crohns Disease on first line biologics (TNF antagonists, adalimumab)

Intervention biologics plus Partial (50%) enteral nutrition for 6 weeks.
Control standard treatment with Biologics

Primary Outcome: awaited

6. Safehaven

In 2022 the Safe Haven successfully renewed its REC approval for another five years and will continue to offer data linkage services and hosting for data projects within the local Trusted Research Environment, as part of this ethical approval as a research database. The West of Scotland Safe Haven has delivered 59 new projects, datasets, and feasibility studies over the last year, and continues to work closely with the West of Scotland Innovation Hub to deliver novel data-driven proofs-of-concept to improve local clinical services.
The Safe Haven portfolio for this year has included linked datasets to support consented studies such as ASSIST (A Surveillance Study in Illicit Substance Toxicity) and Early Heart Failure Optimisation Pathways (OPERA). ASSIST aims to assess the feasibility of prospective surveillance of patients attending the Emergency department due to acute illicit drug toxicity.

The safehaven has also been involved in computationally-intensive efforts to synthesise large artificial datasets such as MRC Generative Adversial Networks, and new collaborations with the National Consortium of intelligent Medical Engineering in Oxford to provide de-identified radiology imaging datasets for studies on COVID and other respiratory conditions.

New developments has included federated data project tests between regional Safe Haven nodes in Scotland, and initiation of a new Research Data Scotland grant-funded collaboration with Dataloch in Edinburgh on the topic of synthetic data. Support for the iCAIRD programme has delivered the latest version of the Safe Haven AI Platform in collaboration with our industry partners. The Safe Haven is also extensively involved in planning and delivery of data-centric work packages for the Living Lab initiative in cooperation with the University of Glasgow. Engagement activities over the past year include a 'Date with Data' session at the University of Glasgow's summer ARCadia science festival, outreach with the MVLS Public and Patient Involvement and Engagement (PPIE) group, and the recruitment of new lay members to our local ethics committee via Volunteer Glasgow.

7. NHS GG&C Biorepository

Over the past year the Biorepository has supported an increase in new tissue based studies whilst also working to deliver the backlog of projects that were restarted during 2022.

It has been involved in over 90 research projects, which involved consenting more than 800 patients and the collection of over 3000 samples. In addition the biorepository approved 77 new research application to enable access to stored tissue.

To continue providing an efficient service and meeting high quality standards this year the Biorepository has successfully had its NRS Tissue Bank accreditation renewed and is due to have final assessment in 2023 for accreditation under ISO 20387:2018 Biobanking standards as one of the first sites in the UK to do so.

Key successes this year included the completion of a research feasibility study into the ability to extract research data from dried blood spots for predictive medicine. As custodians of the 3 million blood spot cards the NHS GGC Biorepository reviewed and collated contents of Newborn Screening archives ranging from 1965 to present day. Newborn blood spots from consented Generation Scotland volunteers were retrieved, anonymised and sent samples to Edinburgh for DNA analysis. The study has established the potential value of the 3 million Scottish newborn blood spots archive for epidemiological and DNA-based biomarker studies. Further public and stakeholder consultation is now planned to assess whether it will be possible to use the blood spots for future research with appropriate governance oversight (Feasibility and ethics of using data from the Scottish newborn blood spot archive for research | Communications Medicine (nature.com)).

The Biorepository continues to support two Cancer Research UK (CRUK) accelerator studies – PREDICTmeso and PANTHR-S. These involve Biorepository resource in coordinating multi-center access to study specific fresh tissue and annotated pathology archive material.

NHSGGC Biorepository continues to be involved with iCAIRD as it nears the end of the current UKRI funding and will build on infrastructure created to utilise digital pathology data for research and innovation.

8. West of Scotland Innovation Hub

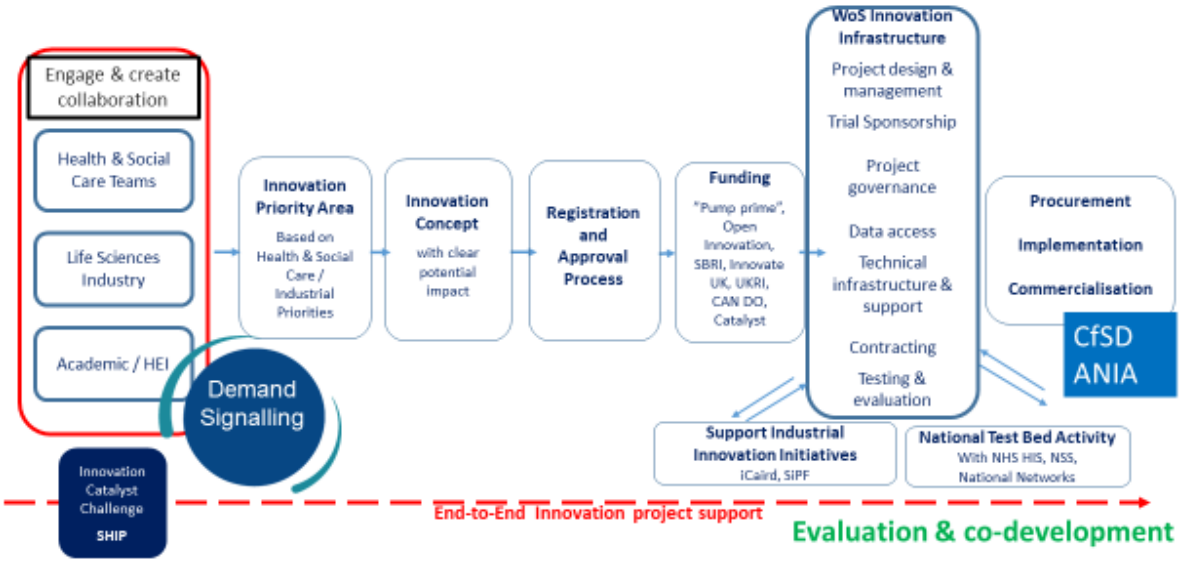
8.1 End to End Innovation Pathway

The WoS Innovation Hub established in 2019 supports delivery of the national Health and Social Care innovation objectives set by the Chief Scientists Office (CSO) and Scottish Health and Industry Partnership (SHIP) and works in collaboration with NHS Scotland innovation partners including the Centre for Sustainable Delivery, NHS National Services Scotland and the Innovation Test Beds of the North and East regions.

As described in previous board reports, 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 aim to transform delivery of health and social care by driving forward the early adoption, or early rejection of novel devices, products and services through an end to end pathway (figure 2).

New to 2022 has been the development of the Accelerated National Innovation Adoption (ANIA) collaborative which is led by the national Centre for Sustainable Delivery.

Figure 2: End to End Innovation Project Support



Previous Board reports have detailed the expertise, infrastructure and service provided by the Innovation team which underpin this pathway. In 2022, the team has expanded to include innovation leads for mental health (Dr Nagore Penades) and Cancer (Dr Ioanna Nixon). We also welcomed three Innovation fellows to the team, two of whom are consultants within NHS GGC and lead on exemplar projects (see section 9.1 and 9.2). SHIP have developed this new scheme which aims to develop capacity and capability to engage and lead in the development of Innovation for Scotland. NHS GGC R&I also part fund two additional innovation fellows for doctors in training.

8.2 Engagement Activities

There have been a number of engagements activities throughout 2022, with two key developments involving Women's & Children & Cancer. The WoS Innovation Hub in collaboration with SHIP, led two Women's' and Children's Innovation Workshops. These events attracted over 100 nursing, medical and allied health clinicians from across Scotland to share their challenges and identify potential areas to develop innovation-based solutions. These were followed by the Scottish Health Industry Partnership (SHIP) Women's and Children's Open Innovation Challenge, the outcome of which will be announced in 2023.

The newly appointed Lead for the Cancer Theme, has launched the "Inspiring Innovation in Cancer Care" webinar series. The webinars aim to increase awareness of the role of innovation in cancer care and services, through showcasing exemplary projects, and knowledge exchange from keynote speakers. The first event of the series took place on the 4th October and was attended by over 100 delegates, a further webinar is planned for the 7th February. At this meeting, the results of a top-level survey for staff, patients, and carers canvassing their views on innovation priorities in cancer care will be presented. In addition a patient focus group on cancer innovation has been established.

8.3 Current Activity

In 2022, the WoS Innovation Hub team are currently supporting 42 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 5 at the scoping stage. The total value of the active projects is greater than £83m.

A number of NHS GGC led digitally supported pathways which have been developed by the WoS innovation Hub are currently being assessed by the centre for Sustainability for national scale-up: COPD, Early Diagnostic Heart Failure. The early Diagnostic Heart failure pathway is also proceeding to NHSGGC adoption via a service led Business-case. Other projects have moved from development to business as usual at a number of health boards across Scotland: Lenus asynchronous appointments; TraumaApp; and vCreate.

8.4: Assessing the Impact of Digitally Enabled Pathways

In order to assess the potential impact of technology and novel devices, it is important to determine a number of outcomes including: user acceptance; impact on patients; efficacy; cost-effectiveness and environmental impact. This involves both quantitative and qualitative evaluation and is illustrated in the case study below.

8.4.1 Case study: VCREATE Neurology

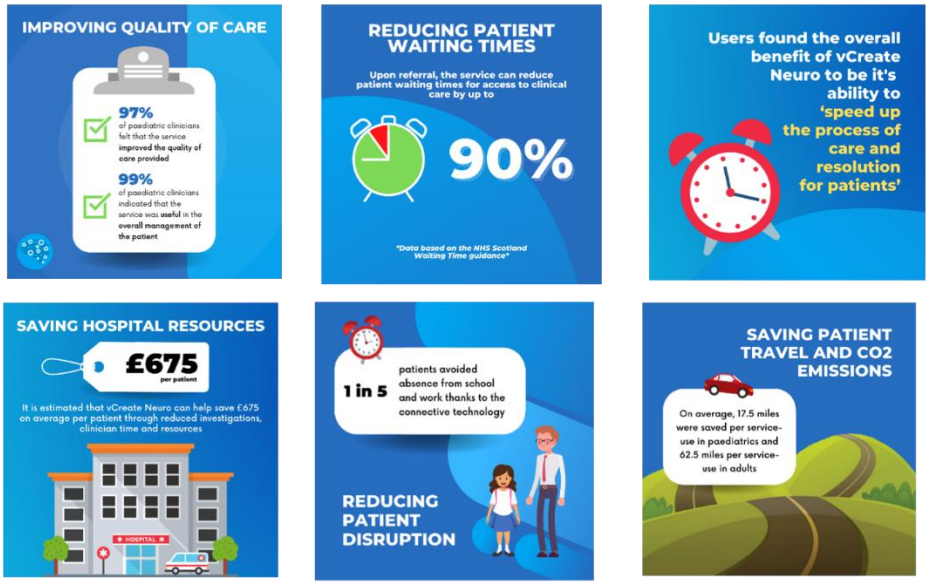
At times when hospital attendances are limited, there has been an increased requirement for asynchronous communication between patients and clinicians to ensure the best standard of care continues to be delivered. Building on a previous successful project using video diaries within the Neonatal department in NHSGGC (leads Neil Patel, Sameer Zuberi), the WoS Innovation Hub have worked with vCreate Ltd (Windsor, UK) to develop an asynchronous video services. vCreate Neuro enables patients or careers to send videos of seizures that have been recorded on smartphones, and associated data, to their clinical team for remote clinical interpretation and management advice.

The Scottish Health Technologies Group (SHTG) have assessed the value of using vCreate Neuro and have undertaken a rapid review of 1)the published literature 2) Quantitative and qualitative data from a user experience survey (service users & clinicians) and 3) an economic analysis conducted using the survey responses.

Key findings (August 2022 report) : vCreate Neuro may add value to the delivery of care for people (adults and children) who have epilepsy and other neurological disorders by reducing people's waiting times, more efficient triage and improving information available for diagnosis and treatment (Figure 3). Furthermore, using vCreate Neuro within the existing pathway to deliver care for patients with epilepsy and other neurological disorders is likely to be resource saving and therefore cost effective for NHS Scotland, with gross savings of £441,000. Scaled up nationally these savings equates to in excess of £1.9 million. The precise extent of cost savings remain uncertain due to the survey data upon which the analyses are based, and is sensitive to the finding that the use of vCreate Neuro reduces inpatient admissions.

These findings have led to additional information gathering, test of change pilots and procurement of vCreate by the Scottish Government for all tertiary adult and paediatric neurology services in NHS Scotland. Further analysis has shown that within NHSGGC alone, there have been approximately 6000 clinical interactions with an estimated cost savings to date of £3,997,350 (based on SHTG health economic analysis data, £675/interaction).

Figure 3: Outcomes of Digitally Enabled pathway vCreate Neuro



8.5 Update on key projects: ICAIRD Industrial Centre for Artificial Intelligence Research in Digital

The Industrial Centre for Artificial Intelligence Research in digital Diagnostics was established in 2018 following the competitive award of a 5 year 10m grant from Innovate UK. This was matched by an additional 6M of funding from the 15 founding partners. Since then, the number of partners from across industry, the NHS, and academia has grown to 40, with over 41 research projects across radiology and pathology.

Pathology work stream: This was the recipient of the 2022 Holyrood Connects Data Driven Innovation Award 2022. Currently, 98.2% of all H&E pathology cases are now reported using digital pathology. Post iCAIRD NHS GG&C will work with industrial partner (Philips) to transition to a fully digital workflow, staged over the next two years.

The digitalisation has enabled a number of industry collaborative AI projects evaluating the safety and precision of automated reporting of lymph node status in colorectal cancer; prostate cancer detection and automated reporting of endometrial and cervical biopsies. In 2022 a near-clinical digital pathology research environment with dedicated scanning capability has been established, enabling on going AI research and 5 evaluation studies.

Radiology work stream: Key achievements of this work stream include the establishment of a trusted research environment for artificial intelligence development (SHAIP). Integration of the SHAIP platform with PACS, National PACS has enabled secure access to over 60m radiology images and linked safehaven datasets. In 2022, testing of an evaluation environment with the potential to allow the performance of an AI model to be evaluated in a near-clinical setting with live clinical data was successfully piloted. A federated machine learning environment has also been developed which allows artificial intelligence models to be trained in different health boards without having to move the data.

In collaboration with iCAIRD, Bering has developed an AI algorithm (BRAVE CX) which in pre-clinical studies, detected normal CXRs with over 95% accuracy and achieved 97% concordance in radiological sign identification with three Consultant Radiologists. The software has achieved UKCA Class I accreditation in 2022. It is able to interface with Radiology Information Systems and outputs the probability of CXRs being normal or abnormal, identifies the likelihood of abnormal radiological signs, and highlights them on

an image. This information following further clinical trial evaluation could allow health professionals to prioritise their CXR reviews.

iCAIRD comes to an end in March 2023, with A-I research activity and evaluation occurring through externally funded projects such as Dynamic –AI COPD and others in breast cancer, osteoporosis, heart failure and integrated cancer care (see exemplars below)

9. Key Exemplars: Innovation

The exemplars below illustrate and depth of the innovation projects currently led by NHS GGC.

9.1 Chronic Obstructive Pulmonary Disease (COPD) DYNAMIC Project **Clinical Lead: Chris Carlin** **Industry partner: Lenus Health** **£1.2m funding award from NHSX** **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.
DYNAMIC-AI NIHR/AAC grant award - £1.2m 2021-2023 to develop live AI-model decision support to enhance COPD Multi-disciplinary team care, with NHS GG&C sponsored implementation-effectiveness clinical investigation
The purpose of the modelling is to give real time predictions of how likely a patient is to have an exacerbation in the next 72 hours, their risk of readmission to hospital in the next 3 months and their 12-month mortality risk. As well as giving a measure of risk, the machine learning predictive modelling categorises the user of the web app as either high or low priority for these three outcomes, alerting a clinician to a negative change in condition and allowing them to act proactively. **Recipient: Holyrood Connects Industry Collaboration Award 2022**
Progress: The Clinical Investigation documents have received ethical approval and are currently under review by the MHRA. The MHRA has already asked for changes to the electronic consent process and to provide evidence that the requirement for patients to use a novel IT system does not introduce bias through digital exclusion. There was a strong focus on our patient engagement activities in early feedback.

9.2 A feasibility study assessing the impact of at-home infrared temperature monitoring (AITM) with telemedicine support in the management of patients with potential for diabetes foot ulceration. **Clinical Lead: Professor Brian Kennon** **Industry Partner: Thermidas**

Investigator-initiated feasibility study (£190,376) **Remote disease monitoring, telemedicine**
Background: The lifetime prevalence of diabetes foot ulceration (DFU) is 19-34% and ulcers are associated with significant morbidity, including amputation, and mortality. In addition, diabetes related foot ulceration is the commonest cause of diabetes related admission to hospital. Therefore, the individual and socioeconomic impact of DFU is enormous. Despite improvement in the multidisciplinary management of DFUs the recurrence rate is up to 70% at 2 years and effective strategies to prevent recurrent ulceration is limited. There is increasing evidence that home monitoring of foot temperatures, for early recognition and treatment of pre-signs of ulceration may be a promising approach. The approach to be tested allows At home Infrared Temperature Monitoring (AITM) of both the dorsal and plantar aspects of the foot using a CEM AI-202DK IRT camera, Samsung smart phone, Thermidas Vista Telehealth App and a camera tripod. The App interprets temperature difference in bilateral feet to detect hotspots and flags this to the Healthcare Professionals (HCP).
AIM: This is a feasibility study to assess the acceptability and sustainability of AITM by HCP and patients with diabetes (PWD) in managing diabetes foot disease using validated outcome measures. To monitor the proportion of PWD deemed at 'high-risk' of developing an incident foot ulcer in those who have never ulcerated before or a recurrent ulcer in those with a previous DFU during a 3-month follow-up.
Progress: The study has received ethics and MHRA approval. Waiting for eHealth support prior to R&I approval. The Site Initiation visit and staff training have taken place. Patient recruitment will start mid-February.
Next Stage: Patient and staff feedback will determine any changes to the device that are required for a larger efficacy study

9.3 OPTIMAL: Osteoporosis Treatment Identification using Machine Learning **Clinical lead: Chris Sainsbury** **£194,278 funding from Innovate UK & Nanox costs from Israeli Government** **Artificial Intelligence** **Industry Partners: Nanox, Lenus Health**
Clinical Need Osteoporosis is a significant cause of morbidity and economic burden (fractures costing an estimated £4 billion per year). Current guidance for initiating treatment is based on a combination of imaging and fracture risk scores, which are an insensitive tool for prediction of major fracture
Aim: To create a data-driven pathway to osteoporosis risk stratification, using models trained on routinely collected data and existing imaging (where available). The uniquely large cohort of individuals within the NHSGGC within whom longitudinal routinely collected laboratory, demographic and DXA (radiological bone density measurement) is available makes this an ideal population in which to perform this study
Phase 1 progress: Lenus has been developing a machine learning osteoporosis risk stratifcation tool using routinely collected EHR data for the NHS GGC population. A validation cohort was generated which excluded patients with a diagnosis of oseteoporosis, a DEXA scan within the last 3 years and those that contributed to the training cohort.

Lenus has run their osteoporosis risk stratification algorithm on the refreshed dataset to identify the following cohorts: 1) 250 highest risk people aged 50-59 at prediction time, 2) 250 highest risk people aged 60-69 at prediction time, 3) 250 highest risk people aged 70-79 at prediction time, 4) 5000 highest risk people according to model score (not age stratified) and 5) A subset population of cohort 4 who had at least one appropriate chest/abdomen CT examination during their model data window (likely to be 600-1000 people)

Cohorts 1-3 relate to the clinical study. Once re-identified by the safe haven, the Study team will screen the population comprising cohorts 1-3 (the three age stratified cohorts of 250 people, 750 people in total,) to identify a cohort of 250 people to be invited to take part in the study. Consent will be obtained by the study team.

Cohorts 4 and 5 relate to the Nanox work. Lenus will deliver the full 5000 highest risk cohort to the SafeHaven and the subpopulation of patients with relevant CT scans in their data window. Nanox will retrieve the pseudonymised images, upload these to their Cloud environment and read the images using their HealthOST AI software.

Phase 2 progress: The aim of the clinical study is to assess the performance of developed bone mineral density and osteoporosis prediction models when compared with the gold standard clinical investigation (DXA). The study has received ethical and R&I approval. Cohorts 1-3 have been screened and letters of invitation have been sent to possible study participants. The CT images (cohort 4-5) have been downloaded and sent to Nanox for analysis.

9.4 Development & Implementation of a comprehensive multidisciplinary heart failure service at Glasgow Royal Infirmary and Stobhill Hospital for patients with heart failure and preserved ejection fraction (HFpEF)

Clinical Lead: Karen Hogg **Industry partner: Boehringer Ingelheim (BI)**

Joint Working Agreement - £688,077 from BI and £579,445 from GGC

New clinical service

Background: The current clinical service is focused on patients with Heart failure with reduced ejection fraction. Due to a lack of evidence based therapies, the HFpEF population is currently not well quantified. The increase in use of NT-proBNP in primary care has highlighted a previous unidentified large cohort of patients with HFpEF who are currently managed in primary care. The OPERA (Optimising a Digital Diagnostic Pathway for Heart Failure in the Community) study investigated 870 patients with elevated NT-proBNP and suspected HF referred from primary care. It was found that approximately 40% of patients had HFpEF with no formal service available for ongoing care.

Aim: This new service will capture HFpEF patients from both primary and secondary care with referrals from the existing HF diagnostic pathway, outpatient clinics, care home and hospital inpatient settings. The service will be multi-disciplinary and will adopt a home first approach which includes clinic, home, care home and inpatient comprehensive reviews to support early supported discharge and admission avoidance strategies.

The complex needs of the HFpEF population will require the service to encompass and describe;

- Development of new pathways for HFpEF and capture the flow of patients
- HFpEF patient characteristics
- Investigation of the multiple causes of HFpEF and describe what investigations are performed
- Development of best practice management and support guidance
- Establishing what management and support strategies are received by patients with HFpEF. Adjustment of cardiovascular and non-cardiovascular drug therapies, Interventions to meet social & psychological needs, educational interventions to empower self-care, management of numerous co-morbidities, palliative and end of life care as appropriate and cohesive working with other specialties and service providers.

Progress: The JWA is signed off. Payment has been received for planning phase. Service to open in April. Electronic Data Capture and data flows are being agreed.

9.5 Advanced Respiratory Monitoring Events in drug toxicity

Clinical Lead: David Lowe **Commercial Partner: PneumoWave**

Investigator initiated study £218,326

Remote monitoring / digital therapeutic solutions Unscheduled care

Clinical need: The ability to continuously monitor the breathing of patients and detect problems in real time, both in hospital and at home, is an enormous unmet need. This is crucial work as we strive to reduce the impact of unnecessary deaths which is a priority in Scotland and worldwide.

Aim: The TARS trial (Toxicology Advance Respiratory System), will study patients at risk of death from respiratory depression presenting to the Emergency Department following ingestion of an illicit substance.

Progress: The study opened in June 2022 and is actively recruiting. There were 2 groups in the study – 1) patients undergoing procedural sedation and anaesthesia in ED and 2) patients presenting at ED due to presumed overdose of drug with potential for respiratory depression. Recruited 46 patients from total of 100 – split of 29/17. However there has been a problem that for some patients no usable data was being provided. The Company analysed the data and confirmed that when patients are sleeping/ sedated/ co-operative, the device returns good data. They only need 3-4 minutes of usable data and so the nurses have been asked to stress to the patient the requirement to keep still and not talk during this 3-4minute period.

Next steps: Paediatric equivalent is being worked up. Chief Investigator Ross Langley**.** Costs are with R&I finance but Pneumowave has agreed in principle to fund the study. The ethics application is nearly ready for submission.

Pneumowave has received £7.5m of funding to accelerate clinical validation and regulatory approval of their respiratory change diagnosis and monitoring platform.

9.6 Development of a virtual reality (VR) based tool for theoretical and practical training in dialysis modalities for patients, families and staff

Clinical Lead: Ben Reynolds **Glasgow Caledonian University**

Kidney Research UK funded £50k

Virtual Reality; Education

Clinical need: End-stage kidney disease is rare, affecting 8-9 children per million per year. About 100 children will start on dialysis in the UK each year. Some families will choose to do peritoneal dialysis (PD) which is usually done at home. Learning how to do PD typically requires either an admission to hospital lasting 1-2 weeks, or sometimes daily attendance at an outpatient clinic for the same time. Very few families have any experience of PD before starting training. Training covers the practical aspects of doing a dialysis session, and includes some theoretical aspects for troubleshooting – but this cannot be taught practically unless the patient develops that issue during their admission. Learning how to do dialysis is also needed for new staff nurses that join the kidney team. Similarly to patients and families, much of the practical training requires an in-patient to be present on the ward, and a nurse educator/nurse specialist to be present to provide training. Training on clinical problems/'troubleshooting' can only occur if those problems arise.
Aim: To develop an application for VR which provides the basics of dialysis training. Initially we are developing an application for PD education, though if successful we could then extend the application to include haemodialysis, home haemodialysis, and even other medical technologies. Though it will not replace face to face training with educators, we hope that use of the application will reduce the duration of the inpatient admission. Including troubleshooting scenarios also allows 'practical' experience of commonly occurring issues without the patient being at risk.
Progress: The pilot study is complete. Patient and family feedback has been incredibly positive. In addition the VR solution was showcased to the British Association for Paediatric Nephrology, and also the Paediatric Nephrology Nurses Group. Feedback was almost universally extremely positive with several units really keen to test it asap. There are also 3 groups interested in the potential to use the tool for training. KRUK is mediating a call with Baxter about potential exploitation – but other companies are interested too. InnoScotHealth is also involved with these discussions.
Next steps: A second grant has been funded by KRUK (Assessment of a VR application for peritoneal dialysis training; £88,733).

10. Patient stories & Feedback

We are very grateful to all the patients within GG&C who take part in clinical trials. Below are two case stories which demonstrate the feedback from patients.

10.1 Pembrolizumab for treatment in patients with renal carcinoma

A recent multicentre trial has shown that patients with renal carcinoma who received treatment with the immunomodulatory pembrolizumab for a year after surgery have a significantly lower risk of recurrence.

William was one of the patients who took part in the trial and attended Glasgow's Beatson Cancer Centre (local investigator, Dr Venugopal), "*The doctor explained that after getting kidney cancer you can be totally free or it can come back. My GP told me if it did return it would likely be in my lungs.*"

After going through the year-long programme, William said: "*It's helped me because I'm getting constant checks. The staff were brilliant. And so far I'm clear*."

The positive outcome of the trial has led to the Scottish Medicine Consortium approving Pembrolizumab monotherapy for the adjuvant treatment of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

10.2 Holoportation trials

Paul has been taking part in the Holoportation trails and has been delighted with his experience. He said: "*About two years ago I discovered a lump on the back of my leg and I was diagnosed with a sarcoma cancer. Professor Lo asked me if I would be interested in taking part in the Holoportation technology trial and I was able to come and see a demonstration of how it would work*."

"*The benefits it gives you as a patient are great. You don't have to move around, the cameras give the consultant a full view of you and I found that it gave me a better understanding of my situation as I could see everything on the screen. I think it helps inform patients, without upsetting them and without the need for loads of different meetings.*

"*Although you're not in the same room, you still get a full and in-depth consultation*."

11. Research & Innovation, Resilience & Growth in 2023

In 2023, R&I 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 and Scotland's Health Innovation Life Science Cluster. The vision is for NHS GGC to play our part in making the NHS the country's most powerful driver of innovation through the development, testing and adoption of new technologies and treatments at scale. R&I will work with our colleagues in e-Health to develop a NHS GGC A-I strategy and build on the success of iCAIRD. A key deliverable will be to undertake later phase evaluation trials to enable the transition of A-I to business as usual particularly in diagnostics.

In 2023 R&I continue to deliver our phase II Research recovery plan, establish the clinical research activity that was underway pre-COVID whilst continuing to develop and improve the ecosystem. In this difficult financial climate, it is crucial that measures are in place to maximize income generation and cost-recovery, enabling a sustainable and supported R&I workforce. These will include processes to increase grant income as well as expansion and further development of collaborative models with academia and industry. R&I will update the 2020-2023 strategy to ensure that it maximizes on the opportunities afforded in the post-pandemic era. The focus is on delivering research & innovation which impacts significantly on patients care & experiences, addresses national public health priorities and results in cost-savings and greater efficiencies in the NHS.

Appendix A: Research Recovery, resilience and Growth plan: Phase 2

1. A sustainable and supported research workforce			NHS GGC Response
1.1	Cross sector workforce planning in support of our vision a cross-sector research workforce plan will be developed over 2022 to 2023, and guide additional investment in workforce from 2024	Aims to ensure workforce plans developed by key healthcare organisations include research requirements, particularly noting the knowledge and skills needed across the wider workforce to deliver research as an essential part of high-quality care. CSO new research strategy awaited Scottish Research Academy proposed- further details awaited	Building future workforce : promotion & facilitation of enhanced SCREDS, SHIP Innovation & NRS Research fellowship programmes Promotion of Clinical Research Academic Partnership (CARP) awards On-going joint investment in PhD programmes, CRF fellows, ECMC fellow R&I work force plan succession planning
1.2	Normalising research - Promoting research for all doctors In April 2021, the General Medical Council released a position statement	Aims to enable a culture in the workplace where doctors are encouraged to be research-aware and research-active. In addition, the General Medical Council updated their Good medical practice guidance to include emphasis on the importance of clinicians promoting potential research opportunities for patients.	Continue to locally promote inclusion of research activity within job plans Continue to ensuring robust processes for awarding research protected sessions, monitoring performance & outcome

1.3	Research in Integrated Care Boards	NHS England and the Devolved Administrations will use existing legal duties and planning frameworks to promote and facilitate research. NHS research Scotland: CSO are Updating Strategy	Promoted through R&I strategy, presentations to Board, seminar Programme & workshops
1.4	Professional accreditation scheme for Clinical Research Practitioners (CRP)	In June 2021, NIHR launched a new UK-wide professional accreditation scheme for Clinical Research Practitioners (CRP) as part of efforts to double the number over the next few years.	Develop through the Glasgow CRF training team
1.5	NIHR Associate Principal Investigator Scheme	In November 2021, the NIHR Associate Principal Investigator Scheme was launched. Aim: to make research a routine part of clinical training, to develop health and care professionals to be the PIs of the future and to recognise and promote health professionals' engagement in NIHR portfolio research in a consistent manner.	Promote associate PI role within Glasgow CRFs and for all eligible sponsor/Co-sponsor studies via collaboration with CTUs

2.Clinical research embedded in the NHS **Aligning programmes with current and future demands for UK health services**			**NHS GGC Response**
2.1	Demand signaling prioritising and articulating the most important research questions horizon scanning the process of identifying and better understanding emerging of transformational technologies	Work on demand signalling will be accelerated to improve identification of the most needed treatments and technologies and rapidly bring these into clinical use. AMRC is in talks with NIHR Will be addressed in Chief scientist Office, Scotland updated Research Strategy	Studies prioritised via funders and through CRF speciality portfolio meetings Key component of R&I strategy 20-23

2.2	The Scottish Health and Industry Partnership Scientist Office (CSO) Enterprise and Innovation Division of the Economic Development Directorate	Aims to strengthen Scotland's innovation activities in health and social care -solve real problems and improve quality, efficiency and sustainability of healthcare.	Via the WoS Innovation Hub, hosted by NHS GGC NHS GGG&C Staff :R&I, E-Health, Finance, information governance
2.3	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.	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. **Research active settings have lower mortality rates and increased staff retention.**	Via R&I strategy, annual reports to NHS GGC Board, communication via Press officer Measures to expand number of nurse, pharmacy and allied health professionals principal investigators
2.4	Supporting delivery of the UK Rare Diseases Framework	In January 2021, the UK Government published the UK Rare Diseases Framework	Improve access to trials involving rare diseases Ongoing support for Glasgow's Office for Rare conditions in children

3.People centered research			**NHS GGC response**
3.4	Shared commitment to public involvement NIHR and devolved administrations will build on their local and regional capacity to work on community engagement with patients and communities to shape	Findings from NHS Research Scotland patient and public involvement workshops and the Scottish Patient Public Involvement Survey are informing work to support greater visibility and connectivity, increased diversity and representation and a review of the current mechanisms for pre-award funding.	Key component of NHS GGC R&I strategy Close collaboration with Glasgow CTUs Signpost of current PPI groups Proposed joint interactive website to increase access to PPI support for staff, and PPI

	priorities and study designs for research.		members. Promote PPI opportunities for public and patients
3.1	Think Ethics The HRA, working with partners in Northern Ireland, Scotland and Wales, wants to make ethics review more innovative and efficient, whilst retaining public trust.	Consultation about how ethics review could change to make sure that people and ethics really are at the heart of research.	NHS GGC R&I have responded to the consultation WoS REC committee will adopt the changes Chief investigators will submit final lay summaries of their clinical study results to be uploaded on HRA website
3.2	Removing barriers to payment for public contributors UK project on removing administrative barriers for payment to public contributors	The guidance was launched in June 2022 and will be released as 'consultation in use'.	R&I will use the guide to support payments for public contributors and provide feedback. This will apply to studies with appropriate funding and relevant REC committee approvals.
3.3	NIHR's PPIE Strategy	NIHR updated its 'Going the Extra Mile' strategy and reaffirmed its commitment to PPIE. To further inform this work, NIHR carried out a series of workshops with public contributors and the research community, these generated 16 priority actions.	R&I will work with Glasgow CTU and chief investigators to ensure adherence to NIHR PPI funding requirements

4. Simplifying and streamlining the route to study set up, incorporating greater transparency and consistency in research approvals and by expediting the processes for costing and contracting: reduce delays and speed up all aspects of study set-up			NHS GGC response
4.1	Joining up research approvals across the UK A new pan UK approvals service will simplify the arrangements for set-up of studies taking place in the health and care service, especially projects taking place across more than one UK nation.	The single UK approvals service will be supported through IRAS to provide a predictable, consistent, transparent and proportionate study-specific journey from idea to close-down. The existing systems for HRA approvals as well as site permission/confirmation processes across the UK, will be replaced by a single service delivered through all four nations.	NHS GGC is working with NRS to establish and implement this new approval service This may impact on teams/structures
4.2	Integrated Research Application System (IRAS) and combined review	**Combined review** offers a single application submission and coordinated review leading to a single UK decision for Clinical Trials of Investigational Medicinal Products (CTIMPs). **This has resulted in approval times for clinical trials being halved.** For studies involving investigation of both a medicine and a medical device The MHRA are piloting a combined regulatory assessment scheme. New functionality allows trial sponsors to manage their complete Clinical Trials of Investigational Medicinal Products (CTIMPs) lifecycle via combined review using IRAS – from initial application through to amendments, safety reporting, end of trial notification and submission of summary results,	WoS REC & R&I piloted the new combined review process enabling a rapid transition NHS GGC and GU as co-sponsors are involved in 1 of the 4 applications that have piloted by the MHRA Adoption of new functionality by NHS GGC sponsor team

		to submitting their amendments online rather than via email.	
4.5	Accelerated set-up of Phase I oncology trials pilot	The Experimental Cancer Medicine Centre (ECMC) Network has completed the initial intelligence gathering phase of a project to **radically accelerate the set-up of phase 1 oncology trials**. The 'Improve' phase- will facilitate co-creation and testing of approaches to overcome identified challenges **Experimental Cancer Trial Finder**, the ECMC network's tool to support trial recruitment, will shortly be available to any NHS clinician to assist in matching patients to trials.	The Beatson ECMC team led By Prof Evans and R&I have participated in the consultation and will be involved in the "Improve phase" The Beatson ECMC is one of only 8 ECMC centers in the UK. It is currently undergoing its 5 yearly review, and is supported through funding from R&I, CSO and CRUK
4.6	National Contract Value Review	Implementation of the UK-wide National Contract Value Review (NCVR) is beginning, with the aim to expedite the speed of the costing elements of the contracting process across NHS sites NCVR will replace the current time-consuming process whereby each NHS organisation negotiates with each commercial sponsor for every study in order to agree bespoke contract value	R&I will pilot the NCVE and participate in the quality assurance programme which is being led by NRS
4.7	Excess Treatment Costs	Within England the model for managing ETCs has changed – from 1 April 2022 the organisational ETC threshold was lowered from 0.01% of operating budget to 0.001%.	NHS GGC R&I are in consultation with NHS Research Scotland to request changes to ETC in Scotland

		This significant reduction in the payment threshold will provide additional funding of £4m per annum to secondary care providers in England only. The decision to reset thresholds will significantly reduce the average threshold levels for secondary care providers from an average of £40,000, to £4,000 per annum.	
4.8	Model contracts	The range of model UK contracts agreed with industry and the NHS has been expanded. Hub and spoke: A model agreement to support hub and spoke arrangements where the PI is not located at the trial site but where PI oversight is needed. A draft of this model has been shared with companies for studies in set-up to facilitate development of hub and spoke models.	To simplify and speed up the approval process R&I have adopted the use of model contracts R&I are in contact with companies to discuss participation in these hub and spoke trials
4.9	New UK clinical trial legislation	The MHRA has run a public consultation on proposals for legislative changes for clinical research, designed to make the UK the best place to do research and develop safe and innovative medicines. Following public consultation on proposals for legislative changes for clinical research the MHRA are now carefully analysing the responses received and preparing a Government response.	R&I have participated in this consultation R&I has representation on the device stakeholder reference group
4.10	Innovative Licensing and Access Pathway (ILAP)	By implementing ILAP we will ensure speedier UK-wide approval processes and easier access to support along the	SMC is Scottish link to ILAP. Updates via NRS management

	ILAP will 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.	development pathway for new treatments. This will provide increased clarity for innovators and companies regarding the data and evidence they need for licensing and health technology assessment.	R&I Directors group

5.Build upon digital platforms to deliver clinical research & Increasing use of Innovative Research design			**NHS GGC Response**
5.1	Scotland's Digital Health and Care Strategy	Enabling, Connecting and Empowering: Care in the Digital Age published on 21 October 2021 sets out commitments to promote and facilitate appropriate, safe and secure access to clinical, biomedical, care and other data for approved research, development and innovation.	Participation in a short life working group on Data and Digitally enabled approaches to ensuring recruitment and retention in clinical trials has been set up in Scotland.
5.2	Health data for research in Scotland	Functionality of **The Scottish Health Research Register and Biobank (SHARE)** has been expanded to provide researchers more options to identify potential research participants. This includes health board, age range and condition. Over 286,000 people (about 5% of the Scottish population), aged 11 years and over have consented to be contacted for medical research.	Recruitment to SHARE continues to increase across NHS GGC A letter of support from Medical Director is included in new OP appointment letters SHARE seminar held in 2022 The Biorepository the blood collection arm of SHARE

5.3	Trusted Research Environments (TREs)	In Scotland, work will continue to support the already established regional NHS controlled Trusted Research Environments (data safe havens) and their collaboration with the newly established Research Data Scotland to support use of data in research.	Glasgow Safehaven is an active member of the confederation of safehavens Data enabled recruitment is promoted through safehaven. Consent to use data has been built into a number of research studies. Planned. Digital infrastructure will be considered by the proposed Clinical Trials Centre SLWGs
5.4	Democratising access to research through 'Be Part of Research'	The website "Be Part of Research" (BPoR) has been updated to include the devolved administration alongside NIHR More Functionality has been added whereby patients, carers and the public can find out about health and social care research taking place in their area and ask to take part.	Complement by developing website for locally led trials involving Glasgow CTUs
5.5	Real-world data to support research	Advances in capture of Real-world data (RWD) can be translated into promising opportunities for patients to improve clinical practice, guidance and drug safety. MHRA has published guidance on points to consider for sponsors planning to conduct clinical research using RWD to support regulatory decision making.	Considerable potential which needs to be piloted through clinical trials Work with Clinical Trial methodology Hub to pilot

5.6	Increasing Trial Recruitment Speed through CPRD SPRINT Clinical practice Research Datalink (CPRD) collects anonymised patient data across the UK	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.	Limited number of GPs registered with CPRD- need to promote Further investigation and consideration of impact/links with other systems required Aim to expand safehaven datasets to include primary care
5.7	New UK clinical trial legislation	The MHRA has run a public consultation on proposals for legislative changes for clinical research, designed to make the UK the best place to do research and develop safe and innovative medicines. Following public consultation on proposals for legislative changes for clinical research the MHRA are now carefully analysing the responses received and preparing a Government response.	R&I have participated in this consultation R&I has representation on the device stakeholder reference group
5.8	Innovative Licensing and Access Pathway (ILAP) ILAP will facilitate patient access to medicines by delivering tools & advice for companies on clinical trial design to ensure optimal data is generated for both regulatory approval & health technology appraisal	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 licensing and health technology assessment.	SMC is Scottish link to ILAP. Updates via NRS management R&I Directors group

Appendix B: ABPI report recommendation & GGC response

		Recommendation	NHS GGC response
Prioritisation	1.	The Research Reset initiative should accelerate prioritisation of the set-up and delivery of interventional clinical trials of new medicines and vaccines, especially global studies where the UK is competing for participation.	Actively managed through Glasgow RRG group and CRF speciality Groups. CTIMP trials are prioritised.
	2.	NHSE and the devolved administrations – in coordination with the ABPI and other life sciences sector stakeholders – should establish mechanisms to improve coordination between companies and study sites. These mechanisms should be designed with the aim of:	Capacity, & avoidance of competing studies is managed through the CRF groups. A formal review of the timeline to set-up studies will be undertaken
		Ensuring companies are well informed when seeking study sites with available capacity to deliver their planned clinical trial;	
		Ensuring study sites are well informed when deciding whether to agree to deliver industry clinical trials;	
		Ensuring companies have visibility of where their clinical trial sits in a site's queue of studies, which will help inform decisions on whether to continue trials struggling to meet set-up milestones or recruitment targets.	R&I Review of set up and Site initiation visits to be undertaken. A list will be complied for all specialties, and timelines will be actively managed.
Set-up	3.	NHSE and the devolved administrations should introduce a 60-day maximum timeframe, with	Costing and contracting timeframes. Approval time metrics are reviewed weekly by the GGC R&I systems group.

		limited negotiation, for costing and contracting of industry clinical research.	Adherence to new National SOP will be audited.
	4.	NHSE and the devolved administrations should commit to achieving UK-wide use of unmodified model contracts for industry clinical research, which should be aligned across all four nations and periodically reviewed in consultation with industry.	R&I is committed to use the unmodified model contracts for industry clinical research
	5.	NHSE should work at pace to ensure all NHS Trusts in England are committed to adhering to prices generated by the interactive Costing Tool for industry clinical research.	R&I has committed to use the UK standard Tariff as generated from the interactive Costing Tool
	6.	NHSE should develop hub-and-spoke model contracts for ICSs that cover all providers in an ICS's catchment in a single contract.	Scottish Health Boards have operated as single regional entities since 2004, requiring one contract for each Board Pilot models for wider hub and spoke working allowing cross-Board working were developed during the COVID pandemic.
Capacity & Culture	**7.**	NHSE and its devolved equivalents should reinvest revenue generated by industry clinical research into increasing the provision of dedicated research time and research training, especially for nurses and other staff critical to delivering clinical trials.	Glasgow Biomedicine model enables revenue generated by industry clinical research to be re-invested into research, enabling capacity building. Review local model for use and reinvestment of Board commercial income
	8.	NHSE and the devolved administrations should mandate rapid invoicing for all research costs, as current delays in invoicing deprive the NHS of much-needed research revenue.	Local review of boards invoicing models as part of proposed SLWG

	9.	NHSE and the devolved administrations should consistently incorporate research leadership (ownership and championing of one's research function) into the role descriptions for NHS R&D Directors, Medical Directors, Directors of Nursing, and Chief Executives.	Research leadership is a key function of the R&I Director role & SMT roles. Promoted through annual reports to Board, seminars, and local departmental meetings Board Senior Management are fully supported & committed to R&I
	10	NHSE should incorporate best practices in research finance into its upcoming research guidance for ICSs. This guidance should help increase the visibility of revenue generated by industry clinical research and set an expectation that the majority of that revenue is reinvested into the NHS's research workforce and infrastructure.	Integrated Care Systems (ICS) are new structures in England, so guidance is not applicable to Scotland. R&I finance oversee revenue generated by industry clinical research – see response to 7
	11	NHSE should work with the pharmaceutical industry to co-develop research guidance and research performance metrics for ICSs.	Metrics are reviewed by R&I RRG group, CRF speciality groups and reported to GHSP oversight & Board.