NHS Greater Glasgow & Clyde	**Paper No. 19/48**
Meeting:	**NHSGG&C Board Meeting**
Date of Meeting:	**Tuesday 22nd October 2019**
Purpose of Paper:	**For Noting**
Classification:	**Board Official**
Sponsoring Director:	**Dr Jennifer Armstrong**

Research and Development (R&D) Annual Report 2018/2019

Recommendation

The Board is asked to note the Research and Development Annual Report which provides an overview of innovative research activity within NHSGG&C in 2018/2019 and provides details on key clinical trials, and developments within the safehaven and biorepository programmes of work.

Purpose of Paper

To describe the breadth and diversity of innovative research/ development undertaken within NHSGG&C

Key Issues to be considered

- The scale and breadth of clinical research underway
- Expansion of data-driven funded innovative research
- The potential impact of Clinical & Innovation Exemplars
- Patient experience and feedback

Any Patient Safety /Patient Experience Issues

Patients desire to help others and their appreciation to be given the opportunity to take part in high quality research and access state of the art therapeutics is reflected in the quotes and feedback included.

Any Financial Implications from this Paper

Financial income generated through research is used for capacity building and the facilitation of further research and innovation.

Any Staffing Implications from this Paper

There is an increase in the number of research active clinicians. 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 NHSGG&C.

Any Equality Implications from this Paper

None

Any Health Inequalities Implications from this Paper

None

Has a Risk Assessment been carried out for this issue? If yes, please detail the outcome.

N/A

Highlight the Corporate Plan priorities to which your paper relates

Better Health

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Date: 22/10/2019

NHS Greater Glasgow and Clyde

Research and Development (R&D) Annual Report 2018/2019

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Executive Summary:

In 2018-19, NHSGG&C has continued to expand its research portfolio and increased the 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.

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. NHSGG&C continues to work closely with industry to help drive the spread of these innovations at pace and scale, and as a result the revenue from commercial clinical trial activity has continued to grow.

The 2017 Industry Strategy aims to ensure that the UK is at the forefront of the use of machine learning and data in the early diagnosis, better prevention and new and improved treatment pathways. In response to the focus on data-driven innovation, NHSGG&C has worked with a range of NHS partners to establish a regional Safehaven which encompasses anonymised patient data of our 2.8million population (52% of the Scottish population). The Safehaven team works closely with e-Health to provide a leading role in research and innovation as well as regional service planning.

The NHSGG&C Biorepository also provides a regional role and works closely with the Regional Pathology Service, MRC Pathology node and the safehaven to provide highly annotated tissue for researchers, academia and industry.

NHSGG&C has worked with collaborators to secure funding for innovation projects both through Scottish Government initiatives and the UK Industrial Strategy Challenge Fund (ISCF). In November 2018, the ISCF announced the funding of 5 new centres of excellence for digital pathology and imaging, including radiology, using artificial intelligence medical advances. One of these centres, the Industrial centre for Artificial Intelligence (AI) Research in Digital Diagnostics (iCAIRD) is led by Glasgow University and is based at the Clinical Innovation Zone at the QEUH campus. This centre will act as a catalyst to accelerate medical research and the use of AI in order to save lives, reduce costs and increase NHS efficiency as well as growing the economy through the development of new industries.

In 2019-20, we wish to build on our success and further develop our processes and expertise to work with industry and academia in order to deliver evaluative studies of new devices and technology and take advantage of growing opportunities in this area. Further strategic priorities include the need to further expand our ability to utilise real world-data in order to assess clinical and cost-effectiveness

and develop processes so that we can offer our patients' novel advanced therapies. Enhanced interaction with industry will be facilitated through the establishment of a regional innovation hub and team based at the QEUH. In 2018/ 2019 we have

- Recruited over 9,000 new participants to clinical research studies;
- Delivered over 900 clinical trials;
- Increased the number of research staff (principal and chief investigators) by 20%;
- Brought in over 3 million pounds in commercial research activity;
- Collaboration with industry and academic partners to secure £19 million worth of Innovation funding.

1.0 Research & Innovation Activity: Clinical Trials

The NHSGG&C Research & Development Department provides a wide range of services which ensure scientific and financial integrity, fast approvals, effective governance, active project management and delivery of clinical trials. For locally led studies the sponsor team take responsibility for the initiation and management of the trial. Depending on who is the chief investigator, studies can either be sole sponsored by NHS GG&C or co-sponsored with the University of Glasgow (UoG) through the Glasgow Health Science Partnership. This research activity is underpinned by joint NHSGG&C and UoG state of the art dedicated clinical research infrastructure, including imaging and close working across NHS departments, industry and academia.

The following R&D activity summary includes the Studies and trials open to recruitment and in follow-up within NHSGG&C at some point within the 2018-19 financial year. Data has been obtained from two databases (SReDa, and the National NIHR Open Data Platform (ODP). Studies involving data or tissues are not included in this section (please refer to sections 4 and 5).

1.1 Number of studies

In 2018-19, there were 915 eligibly funded studies, compared to 958 in 2017-18, which represents a 5% decrease. In 2017-18 the overall number of studies increased by 18% compared to the previous year. The type of studies were:

- 299 (32%) commercial studies,
- 458 (50%) hosted [led by a chief investigator out with Glasgow and local principal investigator]
- 158 (17%) studies led locally by a NHSGG&C or UoG Chief Investigator

This year, the number of commercial studies has decreased by 3%, non-commercial eligibly funded by 10% and locally led studies has increased by 10% compared to the previous year. Trends over the past 4 years are shown in Table 1. The fall in the past year has occurred mainly due to a large increase in patients in follow-up due to the 18% increase in number of studies in the preceding year. Measures have been introduced to capacity build through enhanced cost recovery. In terms of study numbers, NHSGG&C is responsible for performing 50% of the commercial research activity in Scotland.

Table 1: Number of eligibly funded and commercial studies

	Hosted*	Locally Led	Commercial studies
2015-16	456	88	231
2016-17	471	137	246
2017-18	505	144	309
2018-19	458	158	299

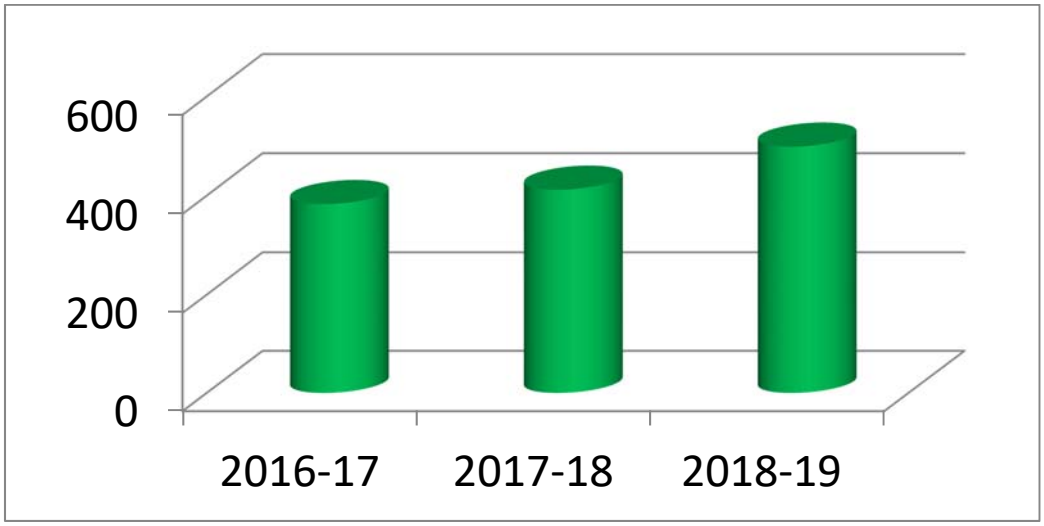
***** led by a chief investigator out with GG&C with a local principal investigator

Exclusions: In addition there were a further 207 non-eligibly funded studies in 2018-19, which have not been included in the above figures or detailed within this report. These non-eligibly funded studies represent activity for which we are not reimbursed by our funder and include student projects and other pilot studies which increase our ability to secure eligibly funded grants.

1.2 Chief/Principal investigators

The number of chief and principal investigators involved in commercial and eligibly funded studies has increased by 20% (499) compared to 2017-18 compared to the previous year (2016-17 n=383, 2017-18 n= 415).

Figure 1: Number of Principal Investigators



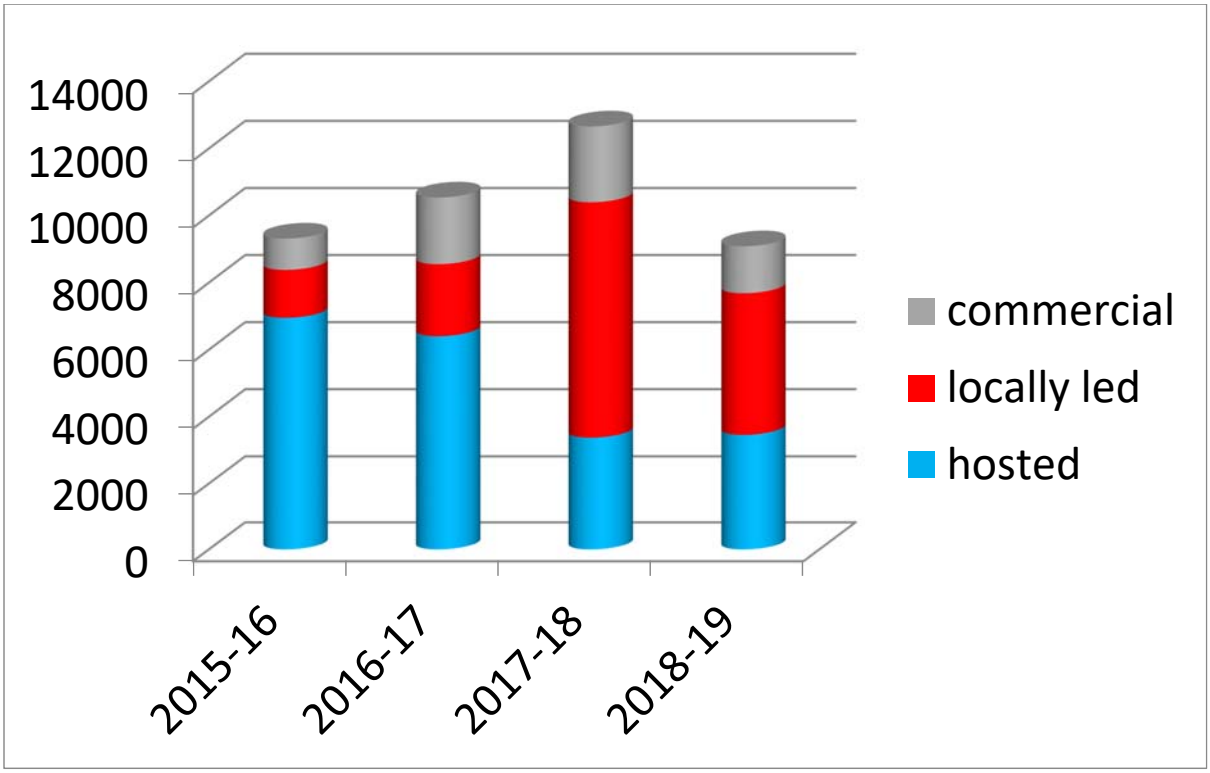
1.3 Number of study participants

In 2018-19, a total of 9,085 new participants were recruited, which compares to a figure of 12,658 the preceding year (29% decrease). However, the number of participants who are being followed-up in

studies has increased, so activity within the clinical research facilities is continuing to expand. The number of participants recruited to hosted studies has increased slightly from 3381 to 3462, whilst the number of participants recruited to locally led studies has decreased. The later is due to the completion in 2019 of three large low complexity questionnaire studies which in 2017-18 accounted for over 5000 recruits.

Commercial recruitment: In 2018/19, we have recruited 1399 participants to commercial studies, which represents a 38% decrease in commercial recruitment. This is due to the closure of a small number of high recruiting, low intensity (blood sampling) studies during the past year. The top 5 recruiting studies in 2018-19 accounted for 947 recruits, whereas in 2017-18 the top 5 recruiters accounted for 1747. The pattern of recruitment over the last 3 years is shown in Figure 3.

Figure 2: Number of new participants recruited to eligibly funded and commercial studies



1.4 Type of Studies

We have a balanced portfolio of studies ranging from observational to complex interventional studies. The study type and phase of studies involving investigation medicinal products are shown in **table 2a** and **2b,** respectively. NHS GG&C along with UoG sponsored/ co-sponsored 136 of these studies of which there were 22 clinical trials involving investigational medicinal products (CTIMPs) and one involving a novel medical device. Overall, the number of studies involving Investigational Medicinal products has remained stable, following an increase of 7% in 2017-18, and a 14% increase in the preceding year.

Table 2a: Study Type (excluding trials of Investigational Medicinal compounds)

Non-CTIMP Q1-4 2018-19	Eligible Hosted	Locally Led/Sponsored	Commercial	Total
Interventional	166	78	23	267
Observational	114	58	31	203
Total	280	136	54	470

Table 2b: Study Type of trials involving investigational Medicinal Products

CTIMP 2018-19 Q1-4	Eligible Hosted	Locally Led/Sponsored	Commercial	Total
Phase I	6	1	19	26
Phase I/II	15	4	17	36
Phase II	44	3	62	109
Phase II/III	23	4	10	37
Phase III	65	5	131	201
Phase IV	24	5	6	35
NA/Pilot	1	0	0	1
TOTAL	178	22	245	445

1.5 Overview of Disease Speciality and Research Activity

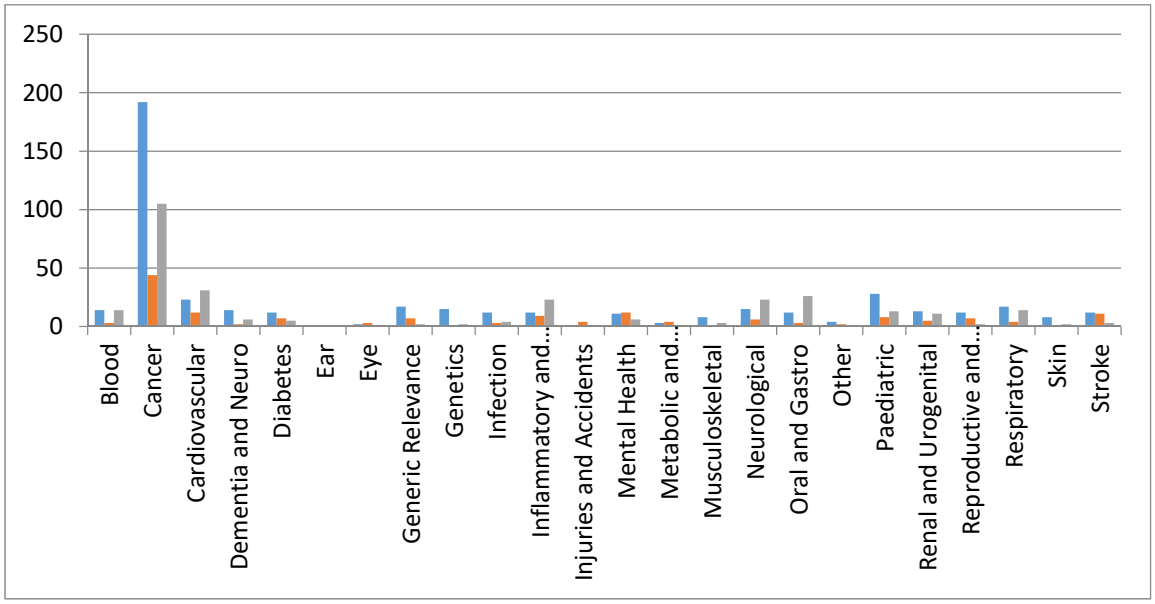
The number of studies according to disease specialty as listed on the National database which are commercial, and non-commercial (hosted or locally led) is shown in Figure 3.

The specialities which have the highest number of commercial studies are: cancer (35%), cardiovascular (10%), gastrointestinal and hepatology (9%), neuroprogressive (8%) and Inflammatory & immunity (8%)

The top 5 *non-commercial hosted* research active areas in terms of study numbers are: cancer (41%), paediatrics (6%), cardiovascular (5%), respiratory (4%) and generic reference (4%).

For the *locally led studies*, the most active speciality areas in terms of study numbers are: cancer (28%), cardiovascular (8%), mental health (8%), and stroke (7%).

Figure 3: Number of studies by disease speciality



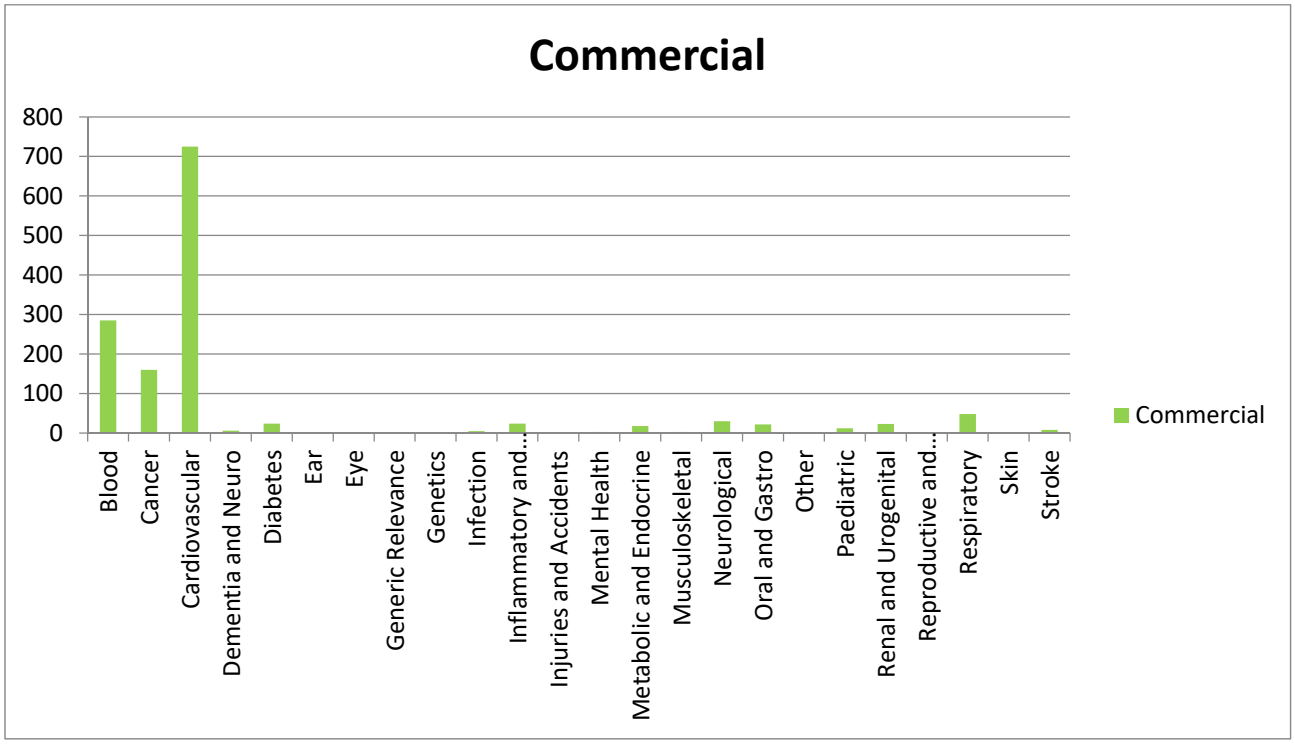
Legend: Grey- commercial, blue eligibly funded, orange – locally led

1.6 Commercial Recruitment by Disease Speciality

The top recruiting specialities for commercial trials are: cardiovascular (50%), blood (20%) and cancer (11%). The high number of participants recruited in haematology is due to two commercial medical device studies, as is the case in cardiovascular. Please see Figure 4 for commercial recruitment. The Cancer portfolio tends to have complex studies, with small recruitment targets targeting specific biomarkers.

An audit of non-recruiting commercial studies is currently underway across all specialties and performance management of all commercial studies is undertaken in the Clinical Research Facilities.

Figure 4: Commercial recruitment by disease speciality



1.7 Commercial income

Despite the fall in recruitment to commercial studies, the income to the board has increased, indicating the increasing complexity of these studies and also the impact of the introduction of an enhanced cost-recovery system in 2017-18. This income is returned to the relevant departments by R&D Finance and re-invested in staff and resources to support further research.

Table 3: Commercial income to Board

Commercial studies	2015/16	2016/17	2017/18	2018/19
Income (£)	£1,398,303	£2,517,982	£2,689,752	£3,068,878
3 years average	**n/a**	£1,903,388	£2,202,012	£2,758,871
% change on 3 years average	**n/a**	**n/a**	16%	25%

1.8 Pharmacy Cost savings arising from clinical trial activity

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. Many projects offer small savings in this arena, but

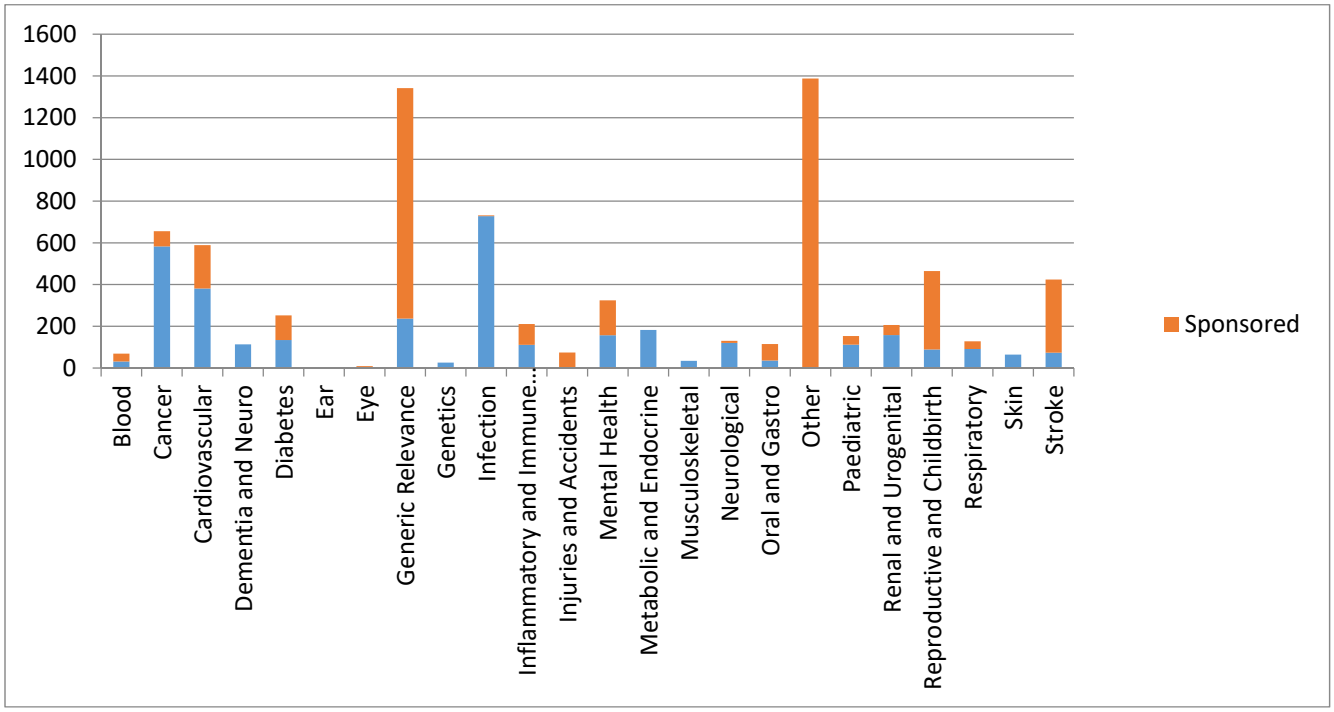
currently there are 6 projects which have projected saving of ~£1.8M to GGC drug budget if all patients are recruited as planned and complete all treatment. These will be tracked to visualise what real saving is achieved versus contracted patients and projected figures. In addition to allowing patients access to novel therapies, the saving is used for the benefits of other patients.

1.9 Non-commercial Recruitment by Speciality

The highest recruiting specialties *for hosted studies* are cancer (17%), infection (21%), cardiovascular (11%), Metabolic & endocrine (5%), renal & urogenital (5%) and mental health (5%) (Figure 5).

For the *locally led studies*, the most active speciality areas in terms of study numbers are: cancer (28%), reproductive and childbirth (9%), cardiovascular (8%), mental health (8%), and stroke (7%) (Figure 5). Performance management of non-commercial studies in our key portfolios is undertaken within the clinical research facilities.

Figure 5: Non- commercial recruitment by speciality



Legend: orange is locally led, blue is hosted

2.0 Research Governance

The key role of Research Governance is to ensure patient safety and the highest standards of quality in research. Processes and procedures are in place to ensure that our researchers adhere to the

Principles of Good Clinical Practice, that all studies are risk assessed, any non-compliance or safety issue are reported and reviewed. Monitoring and audit is undertaken to ensure that our excellent safety record is maintained. In 2018-19 NHS GG&C underwent two routine MHRA (Medical Healthcare Regulatory Authority) inspections involving:

- NHSGG&C Laboratories held in June 2018,
- Good Clinical practice (GCP) inspection involving Clinical Trials of Investigational Medicinal products (CTIMPS) which are sponsored- solely by NHS GG&C or co-sponsored with Glasgow University.

The NHSGG&C Laboratories inspection was the first NHS Laboratory inspection to be held within Scotland and the second within the UK. In addition to the Biorepository service, the inspection involved both NHSGG&C Pathology, Haematology & Clinical Biochemistry Laboratories in the North & South Sector. A task force, comprising key NHS laboratory and NHS R&D was established to prepare for the inspection and address the findings. There were two major findings, which have been addressed through the Corrective and Preventive Action Plan which is overseen by the newly established Sponsor Laboratory Oversight Group. Progress is reported and overseen by the Board Clinical Governance Committee and Glasgow Health Science Partnership Regulatory Affairs Group.

The MHRA GCP sponsor inspection, took place over 5 days in January 2019, with a supplementary site visit to the Golden Jubilee Hospital in March 2019 to review a study carried out at this site in participants undergoing percutaneous coronary intervention. There were no major findings, but a number of other findings which are being addressed through the SOP committees. The full report of this inspection has not yet been received from the MHRA.

In 2018-19, there were three potential serious breaches reported to the MHRA. One breach, involved a patient safety issue in a study NHSGG&C co-sponsored with UoG. This led to a serious critical incident investigation within another health board. The remaining two breaches were classified as relating to potential system failures and did not involve patient safety or data integrity of the clinical trial. These have now been closed out following completion of corrective and preventive action plans. In addition NHSGG&C led a SCI for a hosted study in which imaging scans had been misreported. This was considered a breach by the sponsor.

3.0 Exemplar Research & Innovation Studies

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

Table 4: Research & Innovation Exemplars

Cancer: SCOT trial 3 versus 6 months of adjuvant combination chemotherapy for colorectal cancer Study co-sponsored: NHSGG&C, CRUK CTU
Colorectal cancer is the 4th most common cancer worldwide 6 months of oxaliplatin containing chemotherapy is usually given to patients with stage 3 colorectal cancer Peripheral neuropathy is the main chronic side effect
Stage • International, randomised non-inferiority, 244 centres, involving 6088 patients • Main outcome: disease free survival
Outcome: 3 months treatment was as effective to 6 months in patient with high risk stage II aor III colorectal cancer Associated with reduced toxicity and improved Quality of Life (NEJM April 2018)

Cancer: Precision Panc
In 2017 the Precision Panc Platform was founded bringing together expertise in pancreatic cancer in the NHS , University of Glasgow, CRUK Cancer Beatson and the CRUK institutes at Cambridge, Manchester, London & Oxford. There is a now a UK network of over 20 hospitals, with international sites due to come on board, which can offer novel treatments within clinical trials based on the genomics of the patient and tumour. This genome testing is performed within Glasgow and the PRIMUS study (Pancreatic cancer individualised multi-arm umbrella study) is co-sponsored by NHSGGC & UoG
Stage: The novel biomarker is under evaluation and initial validation will be complete by the end of 2019
Outcome: Clinical outcomes will be improved by matching people with pancreatic cancer to the trial most likely to work for them via the evaluation of a new biomarker

Mental Health

Empower Early signs Monitoring to Prevent relapse in psychosis and prOmote Wellbeing, Engagement and Recovery (Phase 2) Study sponsor: NHS GG&C
A three year feasibility study which will develop and test a mobile phone application (app) to enhance detection of Early Warning Signs of psychosis for people with a diagnosis of schizophrenia, their carers and mental health staff. Relapse in schizophrenia is a major cause of distress and disability but through regular monitoring of thoughts and feelings it is possible to identify early warning signs which can support earlier intervention and improved outcomes.
Stage: a cluster randomised controlled trial. PHASE II Device study: randomised to App intervention or treatment as usual 6 community mental health teams NHS GG&C, Grampian and Melbourne
Outcome: • Enhance self-management and empowerment for people in receipt of services. • Support detection of increased risk of relapse and improve the quality of information available on early warning signs. • Support relationships between people in receipt of services, their informal carers and mental health staff.

Cardiovascular
DAPA Heart failure study – industry sponsored
• international, multicentre, randomized, double-blind, placebo-controlled study in patients with chronic heart failure with reduced ejection fraction evaluating the effect of dapagliflozin versus placebo. • Outcomes: cardiovascular (CV) death or reduction of heart failure (HF) events.
Stage: study completed, accepted for publication in NEJM
Outcome: Treatment with dapagliflozin reduces worsening heart failure events, particularly hospital admissions :cardiovascular deaths and improves symptoms

4.0 Patient Stories

We are very grateful to all the patients within NHSGG&C who take part in clinical trials. Below are two case stories involving a patient with cancer and cystic fibrosis. These demonstrate the benefits that patients receive from taking part in research and their desire to help others.

4.1 CUPISCO Trial

Around 8,800 people are diagnosed with cancer of unknown primary (CUP) in the UK each year, accounting for around 2% of cancer diagnoses (Cancer Research UK). CUPISCO is a first of its kind Phase II clinical trial which aims to find out whether personalised therapy is more effective than chemotherapy for people diagnosed with CUP.

This trial has been embedded into the CUP service at the Beatson West of Scotland Cancer Centre (BWoSCC). As the only site in Scotland, Principle Investigator Dr Anne McKillop is proud to support the CUPISCO trial and be able to offer participants the opportunity to potentially access personalised therapies which would not otherwise available to this patient group.

"Carcinoma of unknown primary is a relatively rare but highly aggressive cancer. Patients have often had a difficult pathway to diagnosis and can struggle to understand and accept the label of being "unknown". The diagnosis of CUP is all the more devastating for patients and families as the prognosis is so poor. This is only made worse by the relative lack of good treatment options. In the last 2 years we have been able to open a dedicated CUP service including a MDT and clinic to diagnose and treat patients. Having the opportunity to enrol into a clinical trial specifically designed for CUP not only gives them hope for their own treatment but also treatment of future patients. "

(Dr Anne McKillop, Principle Investigator, BWoSCC)

The trial has been well received by patients and one participant has shared their motivations and experience of participating in the CUPISCO trial:

"When I received the diagnosis of cancer of unknown primary, and I realised that the prognosis was so dismal, I immediately decided that I was going to throw everything I could at this dreadful disease. I had never considered taking part in a clinical trial before but when I was approached by my Consultant to consider participating in the CUPISCO trial it felt like the right decision for me.

As part of the trial I am monitored closely by the research team which I find very reassuring and I have found participating in the trial to be a positive experience. The only way to beat cancer is to keep conducting new research and I hope my participation in the CUPISCO trial helps people with CUP in the future." (CUPISCO participant, Glasgow)

4.2 Drug study involving patients with cystic fibrosis

Below is the quote of a Mum who's teenage son has taken part in this study

"We have been lucky enough to be involved in a new clinical trial for cystic fibrosis and it has been simply life changing...I don't use that expression lightly! My son has gone from having 2 weeks of intravenous antibiotics every 3 months for the past 7 years and since started the new drug over a year ago, he has not needed to be admitted to hospital, he is attending school full time and enjoying life as a "normal 15 year old" . In Jamie's own words "mum, I don't worry anymore"
Research and new drugs are not just about fixing the physical problem, Jamie's mental health and all round attitude to life has changed dramatically! He is a young boy now living life as he should.
As a family being part of research in Glasgow we can't thank everyone involved enough, please continue and hopefully more families will have the same positive outcome we have had".

4.3 Drug study involving patients with Schzophrenia

Below are some quotes of participants and relatives of participants who have taking part in this study:

T: "*It is good to help and feel useful". "I am definitely coming for the next one*".

A: "*It feels great to be part of something bigger" "It's really good, thank you I am really enjoying this" "Please let me know when you have more of these studies"*

A's Mum: "*Thank you very much for thinking of xxxx for the study. He is really happy to have been approached and very happy to be able to help. And so are we."*

L's Grandmother: "*To be able to come here and meet you all and help others in the future it is great for such a young boy. He is really enjoying it and I enjoy my wee cup of tea!"*

5.0 Research & Innovation Activity involving Safehaven

The NHSGG&C Safehaven currently holds 14 national and 68 local datasets, and all data is completely anonymised and accessed within a secure environment. The safehaven collaborates with a number of partners including the Health Data Research UK, Stratified Medicine Scotland Innovation Centre and with other NRS safe havens on SCI store data for the SHARE cohort. Details of the safehaven research and Innovation high value collaborative projects active within 2018-19 are summarised in Table 5.

Table 5: 2018-19 Safehaven Research & Innovation projects

Exemplar Lead	Title	Funding
1 – Dr Iain Findlay (NHSGG&C) Professor Colin Berry (UoG)	Acute Coronary Syndrome e-Registry and Dashboard	**Joint Working Agreement (£160k)** NHS GGC, GJ AstraZeneca UoG Data Lab
2 –Dr Jennifer Logue (UoG)	Small talk, big difference (STBD) –personalised care for patients with type 2 diabetes who are overweight or obese	**Joint Working Agreement (£270k)** NHS GGC UoG AstraZeneca
3 –Jonathan Fallowfield (UoE)	SteatoSITE - An integrated gene-to-patient data commons for NAFLD research)	**Innovate UK** (£1.7m) Eagle Genomics SMS-IC
4 -Colin Palmer (UoD)	EPIC Study - Extreme Phenotypes in COPD study	AstraZeneca (£800k) SMS-IC
5-James Boyle (NHSGG&C)	Transform Type 1 Education and monitoring	**Small Business Research Initiatives** (£500k over 2 phases; all companies)
6 –David Lowe (NHSGG&C)	Emergency Care COPD challenge	**Small Business Research Initiatives** **(£75k)** TrustMarque & KenSCi
7 –Chris Carllin (NHSGG&C)	DYNAMIC – A Digitally-enabled continuous research & Innovation programme for sleep and NIV care	**Innovate UK** (£750k) NHSGGC KenSci StormID **ResMed £480k**
8 –Finlay Craig (NHSGG&C)	iCAIRD WP2 and 3 relate to building the SHAIP and cockpit infrastructure within NHSGGC	**Innovate UK** (£15.5m) Cross Scotland partners
9 – Prof Keith Muir (UoG)	iCAIRD WP2 & 4	**Innovate UK** (£15.5m) Cross Scotland partners

10 –David Lowe (NHSGG&C)	iCAIRD WP6	**Innovate UK** (£15.5m) Cross Scotland partners
11 – Gareth Bryson (NHSGG&C)	iCAIRD WP 7-10	**Innovate UK** (£15.5m) Cross Scotland partners
12 –Dr Jennifer Laskey / Prof Marion Bennie	Cancer Medicines Outcome Programme (CMOP)	**Scottish Government** (£1m)
13-Chris Sainsbury (NHSGG&C)	Predicting Clinical Events using NLP analysis of clinical notes in Diabetes Patients	**Innovate UK** feasibility (£71k) RedStar Consulting
14 – Keith Muir (NHSGG&C)	Evaluation of acute ischemic stroke signs and ASPECTS scoring algorithm	**Canon** (£6k)
15 –Kevin Blyth (NHSGG&C)	Automatic RECIST reporting in Mesothelioma using Deep Learning AI: Phase 2	**Small Business Research Initiatives Cancer Challenge** (£200k phases 1 &2) Data Lab Canon
16 –Prof Nick Mills (UoE)	HighSTEACS	**BHF**
17 – Prof Nick Mills (UoE)	HISTORIC	**BHF**
18 – Emily Jefferson (NHSGG&C)	SCI-store SHARE	No funding to local safe havens
20 –Dr Emily Tweed (NHSGG&C)	Homelessness linkage project	Development
21 Deborah Wake(UoE Chris Sainsbury (NHSGG&C)	Digital Health Catalyst; MyDiabetesMyWay	**Innovate UK (£1m)** MYWAY Digital Health Ltd

6.0 Research & Innovation Exemplars involving Safehaven

Table 6 Research & Innovation Exemplars involving safehaven

ICAIRD the Industrial centre for Artificial Intelligence research in Digital Diagnostics **WP2**
Brings together 15 partners from NHS, industry and academia from across Scotland and beyond. This involves development of the Canon Safehaven AI platform (SHAIP) Clinical Cockpit within the NHS safehaven infrastructure and a HDRUK National Imaging Archive which includes Philips Pathology digitalisation images. Project is led by Glasgow University
Stage: De-identification of text sources - fully anonymise the first 50 of each using the scrambled CHI register to enable DeepCognito to build the first prototype de-identification tool for each text source - Work in conjunction with DeepCognito on the NHS side to run the tool on a further 1000 records to enable refinement of the tools - Scoping of data availability, sources
Outcome: accelerate medical research and AI in order to save lives, reduce costs and increase NHS efficiency as well as growing the economy through the development of new industries
ICAIRD **STROKE**
Ultimate health outcome following stroke critically dependent on clinical care within first 1-2 hours ▪ Scotland's 65 min door to needle time well below international best practice ▪ Clinical portals inadequate for *timely* data review
Stage: Developing process to securely utilise patient data to enable technology and service improvement Develop software to enable rapid and accurate mining of Patients electronic record to flag key information e.g. thrombolytic therapy contraindications - subsequently provide access to 10,000 anonymised CTs within SHAIP
Desired Outcomes: Receive appropriate treatment more quickly, improving outcome Door to needle time reduced to <20 min Individualised risk-benefit scores
ICAIRD **Chest X-ray**
CXR is most common modality: 40,000 pa per hospital. ▪ 30% interpretation error rate among junior doctors ▪ Insufficient radiologists, delayed reporting
Stage/Aims: 500 expertly labelled CXR validation set

AI powered app for real-time image classification to be developed and deployed in Emergency Department

This requires identification of a baseline cohort of patients who have undergone chest X-Ray

- Provision of 100,000 radiology reports (NHSGGC server pre SHAIP) once de-identified by safe haven for analysis → normal/abnormal
- Provide matched X-Ray within SHAIP once we can download at scale

Desired Outcome: Reduced demand on acute radiology service

Improve delivery of timely and safe care

Enhanced training with immediate feedback on Chest X-Rays

***ICAIRD* Pathology : Endometrial & Cervical**

42% of gynaecological specimens are endometrial

- Exclusion of neoplasia is key aim, only 3% of endometrial biopsies show adenocarcinoma
- And 1.5% are atypical. Overall >95% of biopsies are benign

Develop AI to screen out non-malignant/atypical cases and reduce NHS workload

26% of gynaecological specimens are cervical biopsies -assessment of cervical intra-epithelial neoplasia (CIN) and exclusion of invasive squamous or adenocarcinoma.

Develop AI to identify invasive cancer, generate automated reports and reduce NHS workload

Stage/Aims: Provision of data linked and anonymised to be transferred with pathology images to EPCC and Phillips

Desired Outcome: Projected 85% time saving in consultant time across these specimen types.

Saving of £185,650 per annum for NHS GGC, 54% of reporting time in gynaecological pathology.

Extrapolated across the UK, equates to a saving of £9.3 M per annum

Acute Coronary Syndrome e-Registry and Dashboard

Joint Working Agreement (£160k) involving NHS GGC, GJ, AstraZeneca, UoG

First NHS Scotland comprehensive linked data collection & analysis for patients linked vis NHS GG&C safehaven

(i) a patient administration system

ii) invasive cardiovascular procedure referrals

(iii) a catheter laboratory record

- Episodes of care categorized into care pathways, outcomes &service delivery

Extract, link and anonymise required electronic data to replicate MINAP dataset - Expand to cover multi-morbidity. - Create a dash boards for clinicians
• Outcome: Data shown to reflect changes in service delivery and reduced hospital save • Projected savings of >£1m Now extending to NHS Lanarkshire

7.0 Biorepository: Research Activity involving Human Tissues

The Biorepository, located within the Department of Pathology, enables access to surplus tissues for researchers, academia and industry and also plays a key role in clinical trials involving tissues. The biorepository underwent a successful routine three yearly re-accreditation process in 2018-19.Table 7 details the number of applications to request surplus tissue submitted during 2018-19 and the approval times. The number of applications have marginally reduced compared to 2016-17 (100 versus 107) and the approval times have increased. This will be addressed by a new National IT system which will be introduced in 2019-20. The new system will facilitate access for researchers and industry via a web portal and streamline access to tissues both locally and nationally within the Biorepositories.
Further details of funding of surplus tissues projects are shown in table 8. It can be seen that of the 86 projects, 32 are commercially funded and some of these involve the supply of fresh surplus tissue to companies such as Charles River, Reprocell and BioClavis.

The number of clinical trials supported by the biorepository continues to grow and currently sits at 119. A large number of these involve the department of Pathology and are facilitated by the Biorepository.

Table 7. Biorepository project activity in reporting year: number of applications for tissue received and approved and number of active projects

	Applications for tissue received in reporting year (excluding requests for information or governance advice only)	**Number of projects active before reporting year requiring on-going biorepository**	**Total number of projects requiring biorepository activity in reporting year**

				activity in reporting year	
	Number of applications	**Number applications approved**	**Number applications rejected/withdrawn**		
Requests for samples from Biorepository managed collections *other than pathology archive	*79*	*54*	25 – pending/with management group[1]	*14*	*68*
Requests for samples from pathology archive	*32*	*32*	*0*	0	32
Time from application to approval/rejection decision in reporting year mean number of days (range)	*Mean[2] – 20.3 Median[2] - 16*				

[1] – We have a larger than satisfactory number of projects pending for 2018/19. This was largely due to management staff shortage during the middle of the reporting period and consequent time pressures on senior staff to fulfil additional roles.

[2] - We do not currently record the time from application to approval/rejection on our application system and this metric is not easily extracted from our database. To provide this information we carried out an audit of ~10% of 2018/19 approved cases. We are aware that this is above an acceptable length of time but this was largely due to circumstances described above.

Table 8. Biorepository project activity in reporting year by project funder

Nature of funder	**Active (approved) projects**				
	Number of projects			**Status at year end**	
	Projects started in reporting year	***Active projects that started before reporting year***		**Number of projects completed during reporting year**	**Number of projects remaining active into year**

					following reporting year
Eligible funder*	23	6		15	24
Commercial funder	32	4		2	*30*
Other funding**	31	4		15	14
Total for all types of funding	86	14		32	68

**Health research studies (i.e. research for the promotion and protection of human health and modern, safe and effective health services) funded by an NRS Eligible Funder and studies adopted to the Scottish portfolio that are NIHR adopted. NRS eligible funders list at: http://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS-Funding-Guidance-Annex-2-Eligible-funders-v4.pdf **Other includes departmental funding, endowments e.g. for pilot or feasibility projects*

8.0 Key Future Developments 2019-20

8.1 West of Scotland Innovation Hub

The WoS Innovation Hub which is due to open in October 2019 will act as a “front door” for both innovators and industry. Promoting the West of Scotland on a national and international stage will be a core business priority of the Innovation Hub. It will play a key role in identifying innovations and developing a streamlined evaluation process to ensure that they are either adopted at pace and scale or undergo early rejection. The WoS Innovation Hub will enable us to harness our key assets whilst ensuring appropriate governance of the use of NHS resources (data, images and tissue). The single point of contact will facilitate access to relevant clinical teams and experts for industry partners.

The innovation team based at the WoS Innovation Hub will provide the services and expertise to enable innovations throughout all stages of the innovation pathway from discovery, selection, evaluation and deployment. The team will include project management, expertise in contracts, costings, regulatory approvals and evaluation, intellectual property and marketing. For innovative projects which have a research component these will be continued to be managed through the R&D Quality Framework led by the Research Governance Manager and Sponsor team. Where possible Innovation processes will mirror long standing R&D procedures within the board in relation to registration of projects, contracts, document management, cost-recovery and finance. Funding for this new team is via a SLA from the Scottish Government of 0.5M, recurring on an annual basis.

8.2 Governance of WoS Innovation team

The established NHSGG&C Innovation Governance Group (IGG) will be amended to also include a regional element to support transparency and ownership. It is expected that the group will meet formally twice yearly, Group agenda will be devoted to Regional Innovation matters. It is anticipated that the WoS IGG will bring together representation from WoS Boards and ensure that regular updates are made available around existing projects on a monthly basis. The WoS IGG will be accountable for reporting to CSO on innovation funding and taking direction from and to existing NHS Board governance structures.

8.3 Novel Advanced Therapies

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

8.4 Strength in Places Fund

The University of Glasgow have submitted a £40 million Stage 2 application to the Strength in places Fund. This project involves close collaboration with NHSGG&C with a proposed datalab and a “living laboratory” at the QEUH campus. This aims to implement existing Precision Medicine diagnostics to improve safety and efficacy, whilst reducing costs to the NHS. It will also provide opportunities for SMEs as well as big Pharma to develop and evaluate new technologies. It is anticipated that if awarded this project will be globally significant and will have the potential to transform healthcare delivery.