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### **Meeting: NHS Golden Jubilee Board**

### **Meeting date: 30 May 2024**

### **Title: Golden Jubilee Research Institute (GJRI) Quarterly Report**

### **Responsible Executive/Non-Executive: Mark MacGregor, Medical Director**

### **Report Author: Dr Catherine Sinclair, Head of Research**

## 1 Purpose

### This is presented to NHS Golden Jubilee Board for:

### Approval

### This report relates to a:

* Operational / Finance Performance Review

### This aligns to the following NHS Scotland quality ambition(s):

* Safe
* Effective
* Person Centred

**This aligns to the following NHSGJ Corporate Objectives:**

* Research

## 2 Report summary

## 2.1 Situation

The Finance and Performance Committee and the Clinical Governance Committee request a quarterly report from the Golden Jubilee Research Institute. The report is included as Appendix 1. The report details the GJRI Key Performance Indicators, including targets and progress to date.

## 2.2 Background

Research Management is the review and approval of each research project that NHS Golden Jubilee is either asked to host, or to sponsor and host. At any one time, there are approximately 50 projects at this stage. The complex and specialist work relating to the project set up process is carried out by the Head of Research, supported by a Research Facilitator. A Deputy Head of Research has recently started which should resolve issues around approval timelines, particularly with respect to non-commercial research and project sponsorship.

In the reporting period, 10 projects were approved. More information is provided for each of these projects in the appended report.

Ongoing research delivery is supported by nine specialist research delivery groups who have the responsibility for the day to day running of each research project. Extensive support is provided by the pharmacy department, labs, imaging, theatres, cath labs etc.

## 2.3 Assessment

### 2.3.1 Quality/ Patient Care

Patient Care - Research positively impacts on patient care because 1. Patients have access to new devices and drugs and other treatment options; 2. Patients receive enhanced care in that follow-up visits can include imaging, physical examinations, quality of life questionnaires etc. Research Delivery Teams will let Care Teams know if anything is identified that may affect the patient e.g. concerning blood results, imaging anomalies that might indicate an underlying condition etc.; 3. Patients tend to be more involved in their own care and will contact the Research Delivery Team if they have any concerns. Research Delivery Teams will then signpost the patient appropriately.

Service – Research positively impacts on the service departments because: 1. Staff have the opportunity to work on specialist protocols e.g. MRI, echo etc.; 2. Research staff contribute to clinical care both as described above and more directly e.g. University of Glasgow employed staff working in the cath lab. There is an argument that research negatively impacts on services because imaging, labs, theatres etc. carry out work specifically for research projects. This can range from additional time required during the primary intervention (e.g. in the cath lab) to additional lab analyses and imaging requirements.

### 2.3.2 Workforce

The Research Institute workforce is made up of Research Delivery Teams and Research Administration. Both give a career option to Healthcare Workers. Research active NHS Organisations tend to be more attractive to Healthcare Professionals who will sometimes move to an organisation because it is involved in research.

### 2.3.3 Financial

KPI 3 (Appendix 1) lists the income received through the various sources which include per patient fees and the CSO allocation. The target is £1.5 million and income generated for 23/24 was £1,145,161 which is below target. The introduction of EDGE in 24/25 (a research patient management system) will support invoicing for all projects.

In terms of the support departments, research funding is allocated as follows:

Pharmacy £10,000 (plus set up fees)

Echocardiography £5,000

Radiology £36,000 (0.6WTE, Band 6)

Respiratory £14,288 (0.2WTE, Band 7)

The procedures carried out by radiology are detailed below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **22/23 (research)** | 22/23 (Board) | 22/23 (% research) | **23/24** **(research)** |
| MRI | **273** | 15437 | 1.77% | **228** |
| X-ray | **122** | 24596 | 0.50% | **111** |
| CT | **8** | 14864 | 0.05% | **6** |
| TTE | **20** | 6353 | 0.31% | **18** |

Note that research procedure numbers are provided by the radiology department (RIS system).

There are less tangible positive financial implications which include University of Glasgow staff working in the cath labs, and drugs and devices that are provided free of charge for patients recruited to research projects. These will often replace the drug or device that the patient would have received as part of standard care and therefore is a saving.

There are also less tangible negative financial implications which include additional time in the cath lab in order to obtain a specific measurement, additional time in theatres for a specific procedure etc. It is likely that this is offset by the positives as detailed above.

### 2.3.4 Risk Assessment/Management

The Research & Development Steering Group reviews and updates the research risk assessment document at each meeting. The document is available on request.

### 2.3.5 Equality and Diversity, including health inequalities

### 2.3.6 Other impacts

**Climate Emergency and Sustainability**

### Communication, involvement, engagement and consultation

### Route to the Meeting

This report is requested by the Committees and is provided on a quarterly basis.

## 2.4 Recommendation

* **Decision** – NHS Golden Jubilee Board is asked to approve this report

## List of appendices

The following appendices are included with this report:

Appendix 1 – Golden Jubilee Research Institute Performance Report

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**Research Institute**

**Performance Report**

**Reporting Period: 01 January 2024 – 31 March 2024**

**Report prepared April 2024**

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## Section 1 – Key Performance Indicators

### Summary

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| KPI | Quarterly reported  | Target 2023/24 | Target(Q4) | Actual(Q4) | Total Q1-Q4 |
| 1 | Number of approved research projects | 40 | 10 | 10 | 38 |
| 2 | Participant recruitment (exclude blood sampling studies) | 800 | 200 | 224 | 794 |
| 3 | Income is maintained close to target | £1,500,000 | £375,000 | £379,395 | £1,145,161 |
| 4 | The number of research project audits is in line with target | 4-5 | 2 | 3 | 8 |
| KPI | **Annually reported**  | **Actual 22/23** | **Actual 23/24** |  |  |
| 5 | Number of journal publications with NHS Golden Jubilee quoted | 119 | 114 |  |  |
| 6 | Number of projects sponsored by NHS Golden Jubilee  | 11 | 4 |  |  |
| 7 | The number of Principal Investigators | 30 | 29 |  |  |

### KPI 1: Research project approvals

The target for Q4, 23/24 was 10; 10 projects were approved in the period. This section provides details for each project. Note that the information is from the lay summary section of each ethics application.

**23/CARD/06 – RePHIRE -** A Phase IIb Randomised, Double-blind, Placebo-controlled, Multi-centre, Dose-ranging Study of AZD3427 in Participants with Heart Failure and Pulmonary Hypertension due to Left Heart Disease (WHO Group 2).

PI – Roy Gardner; Advanced Heart Failure Research Delivery Team; site target recruitment is 5.

Sponsor - AstraZeneca.

This study is being conducted in patients with heart failure and pulmonary hypertension due to underlying heart disease (known as Group 2 pulmonary hypertension). Pulmonary hypertension Group 2 increases mortality and reduces exercise capacity. These patients live with significantly limited physical activity and quality of life despite optimal guideline-directed management. Currently, there is no dedicated treatment for this group of patients.

The study intervention AZD3427 consists of human hormone relaxin and immunoglobulin and is expected to mimic beneficial effects of relaxin on the circulatory system, which are observed in pregnant women. AZD3427 is designed to work by relaxing the blood vessels, making it easier for blood to flow. Researchers think that by relaxing the blood vessels in the lungs, the pulmonary vascular resistance (PVR) will go down. PVR is a way to measure how hard the heart has to work to pump blood through the lungs. Decreased PVR could lead to decreased pulmonary hypertension and improved heart function as well.

220 participants will be randomised to AZD3427 or placebo, such that approximately 188 evaluable participants complete the study. The study will be conducted in approximately 60 study centres across an estimated 15 countries.

**21/CARD/31** – **FAST III Trial** - Fractional Flow Reserve or 3D-Quantitative-Coronary-Angiography Based Vessel-FFR guided revascularization.

PI – Damien Collison; Interventional Cardiology Research Delivery Team; site target recruitment target is 65.

Sponsor - European Cardiovascular Research Institute (ECRI)

The study is being conducted in patients exhibiting obstruction in one or more of the vessels that supply the heart with blood and require coronary angiography (procedure using X-ray imaging to see the heart’s blood vessels) or a coronary revascularization (widening of coronary arteries). There are different methods to determine the severity of the obstruction. The two methods that will be compared in this study are: Vessel fractional flow reserve (vFFR) guided revascularization. vFFR utilizes a commercially available computer program to calculate the portion of flow that goes through an obstruction based on images acquired during routine diagnostic angiography. Fractional flow reserve (FFR) guided revascularization FFR utilizes a commercially available computer program to calculate the portion of blood flow that goes through an obstruction based on pressures obtained with dedicated pressure wires that are inserted into the coronary arteries The adoption of FFR into daily practice has not been universal. FFR assessment requires the use of a dedicated pressure wires along with the administration of a hyperemic agent associated with temporary patient discomfort. Additionally, there is the perceived issue of additional time and cost needed to perform FFR. Technological developments allow to estimate this fractional flow reserve (portion of blood flow that goes through an obstruction) without using additional pressure wires, and it is important to determine if the benefits of both options are comparable.

**23/CARD/12 – Librexia** - A Phase 3, Randomized, Double-Blind, Double-Dummy, Parallel Group, Active-Controlled Study to Evaluate the Efficacy and Safety of Milvexian, an Oral Factor XIa Inhibitor, Versus Apixaban in Participants with Atrial Fibrillation.

PI – Roy Gardner; Advanced Heart Failure Research Delivery Team; site recruitment target is 16.

Sponsor - Janssen-Cilag Limited

This is a Phase 3 Active-Controlled study of a study drug called Milvexian for the prevention of cardioembolic (blood clots) events in patients with Atrial Fibrillation (AF). The study will compare the efficacy and safety of milvexian to apixaban for the prevention of strokes and embolism in patients with AF.

AF is a condition whereby the upper chambers of the heartbeat rapidly and irregularly and out of sync with the lower chambers of the heart. This condition increases the risks of developing strokes, blood clots, heart failures and other cardiac related complications.

Milvexian is a part of a new class of anti-coagulants (blood thinners) that may have clinical benefits in patients with AF. Milvexian will act as an inhibitor of activated human coagulation Factor X1 which is a specialised protein involved in the pathway of coagulation in the human body. This mechanism will have the potential to reduce thrombin generation (a protein that activates platelets) to prevent thromboembolism (blood clots). Preliminary results show that Milvexian may meet an unmet need due to its safer mechanism

compared to other therapies. Apixaban was chosen as the active comparator due to its efficacy and safety profile.

The study will include 3 periods: Screening /randomization, treatment period, and follow-up period. Study duration will be approximately 4 years. This is to ensure an adequate data is collected in order to perform a more robust primary analysis, drawing definitive conclusions and obtaining sufficient safety information on the drug. Study participants will be randomly assigned on a 1:1 ratio to receive either milvexian or apixaban. This means there will be a 50% chance to receive either milvexian +placebo or apixaban+placebo during this study. Globally, the expected number of participants for this study is approximately 15,500.

**22/CARD/34 –** An Open-Label Extension Study to Assess the Safety, Tolerability, and Effectiveness of the Long-Term use of Treprostinil Palmitil Inhalation Powder in Participants with Pulmonary Arterial Hypertension.

PI – Colin Church; SPVU Research Delivery Group; site recruitment target is 2.

Sponsor - Insmed Incorporated

Pulmonary arterial hypertension (PAH) is a debilitating progressive disease that causes a wide range of non-specific symptoms including, dyspnoea, shortness of breath, chest pain, fatigue, generalized weakness, and exertional syncope, severely affecting the patient’s physical mobility, emotional and social well-being, ability to perform activities of daily living and overall quality of life. Pharmacological treatments are available to mitigate disease symptoms and slow disease progression, but treatment-related adverse events (AEs), inconvenience, and side effects can be treatment limiting and negatively influence the patient’s daily life.

The purpose of this study is to evaluate treprostinil palmitil inhalation powder (TPIP), an experimental drug being tested for treatment of PAH, for the following reasons: (1) to learn how safe TPIP is for people with PAH to take for a long time and to learn if TPIP helps PAH to get better (or makes it worse), (2) find out if TPIP is well tolerated (has few side effects), (3) learn more about TPIP and how it works in the human body and the substances it produces (“biomarkers”), and (4) to measure the amount of TPIP in the body (pharmacokinetics) and to learn more about how the body reacts to the study drug. This is the same drug that was studied in the previous original/main study, INS1009-202.

There are six research sites, and six participants are planned to be involved in the UK. All participants in the study will complete the same study procedures. The overall treatment period is up to 24 months followed by a 4-week follow-up period.

**23/CARD/19 –** Randomised, double-blind, placebo-controlled study to investigate a single administration of BI 765845 on top of standard of care in patients with acute myocardial infarction.

PI – Colin Berry; Interventional Cardiology Research Deliver Group; site recruitment target is 5.

Sponsor - Boehringer Ingelheim Ltd

This study is open to adults aged 18 and over who have just had a heart attack. The purpose of this study is to find out whether a medicine called BI 765845 helps people who have had a heart attack. The investigators also want to test how well different doses of BI 765845 work and how they are tolerated by people who have had a heart attack. Participants are randomly assigned to receive either BI 765845 or placebo. Placebo treatments look like BI 765845 treatments but do not contain any medicine. Participants are about 4 times as likely to receive BI 765845 than placebo. Participants are in the study for 3 months. During this time, they visit the study site 7 times and get 3 phone calls from the site staff. At the visits, the doctors use clinical tests to check the health of the heart.

The results are compared between the BI 765845 and placebo groups to see whether the treatment works. The doctors also regularly check participants’ health and take note of any unwanted effects.

**23/CARD/29** – The TROPOS study - A Randomized, Phase 2, Double-blind, Placebo-controlled Study to Investigate the Safety and Efficacy of KER-012 in Combination with Background Therapy in Adult Participants with Pulmonary Arterial Hypertension.

PI – Colin Church; SPVU Research Delivery Team; site recruitment target is 3.

Sponsor - Keros Therapeutics, Inc.

Pulmonary arterial hypertension (PAH) results from the blood vessels in the lungs becoming thickened, narrowed, or blocked which make it harder for the blood to flow. This can cause the blood pressure in the lungs to increase making the heart to work harder to pump the blood to the lungs which eventually can lead to a heart failure.

The study drug (called KER-012) binds to proteins involved in unusual thickening of the blood vessels in the lungs. It is hoped that the study drug may restore the normal function of these proteins and thus delay or reverse disease progression.

About 90 participants in approximately 60 study sites worldwide will take part in this study. Patients will be randomly assigned to 1 of 4 groups. In each group, a different dose of the study drug or placebo will be looked at. Participant will receive KER-012 or Placebo as an injection under the skin every 4 weeks and will continue to take their other current PAH treatments. The study treatment will take 24 weeks and the study participants may be able to take part in the extension period of 72 weeks which allows them to continue to receive the study drug or gives the opportunity to take the study drug if they received placebo in the study treatment period. Study assessments include physical examinations, vital signs, blood/urine samples, right heart catheterisation, lung scan, lung functions tests, ECGs, breathing tests and health questionnaires.

**23/CARD/26 –** Severe mental illness and receipt of acute cardiac care and mortality following myocardial infarction.

PI – Elizabeth Boyd – Interventional Cardiology Research Delivery Team; site recruitment is 3.

Severe mental illness (SMI), which includes conditions such as schizophrenia, bipolar disorder and major

depression, affects about one in ten people. People with SMI die 10-20 years sooner than the general population. This is mainly due to poorer physical health, in particular a higher risk of cardiovascular disease (CVD), which includes conditions such as heart attack. After a heart attack, people with SMI are more likely to die than those without SMI. The reasons for this are not well understood, but differences in delivery of clinical care may contribute. We also do not know whether any differences in delivery of care and risk of dying after a heart attack have been affected by the COVID-19 pandemic. In this project, we will use data from electronic patient records to study links between SMI and (1) care provided in hospitals after a heart attack and (2) death following a heart attack and (3) whether these have been affected by the COVID-19 pandemic. To help us to understand our findings from this work and to provide insight into experiences of the care pathway we will interview patients with SMI who have had a heart attack and a family member/carer, as well as relevant health care workers involved with hospital care for patients with a heart attack. Our project will identify points in the care pathway where patients with SMI may be disadvantaged and/or where healthcare workers could be better supported to deliver the best possible care for these vulnerable patients.

**23/CARD/10 –The Euro-CRAFT Registry.** Prospective evaluation of the impact of coronary themodilution on clinical outcomes in chronic coronary syndromes.

PI – Colin Berry; Interventional Cardiology Research Delivery Team; site recruitment is 50.

Sponsor – CoreAalst and Mid and South Essex NHS Hospitals Trust.

Ischemic heart disease is the disease of reduced blood flow to the heart muscle. The heart muscles are supplied with blood by the coronary arteries. The arterial coronary circulation can be subdivided into the epicardial arteries and the microcirculation. The epicardial arteries are the larger arteries that run along the surface of the heart, and are the arteries that are visible on a standardard coronary angiogram. They are also the arteries in which stents can be placed in order to dilate narrowings and improve the flow.

The microcirculation is comprised of smaller vessels that are not visible to the eye on coronary angiograms. Their main purpose is to increase and decrease blood flow to the heart muscle in order to match the oxygen demands. A sizeable portion of patients will have symptoms of chest pain, however no significant narrowing of the epicardial arteries. This is defined as ischemia with no obstructive coronary arteries (INOCA). In addition, patients with acute coronary syndromes (heart attacks) sometimes do not have any significant narrowing of the epicardial arteries as well. This condition is now known as myocardial infarction with no obstructive coronary arteries (MINOCA). The European Society of Cardiology (ESC) guidelines has now assigned a class 2a recommendation to invasive microciculation coronary function testing in patients with INOCA, as has American guidelines. Microvascular dysfunction can be measured using the principle of continuous thermodilution to derive an absolute flow (Q) and mircovascular resistance (R). It can also be used to derive the Mircovascular Resistance Reserve (MRR) which is a novel microcirculation specific index. This method has already been assessed as safe and feasible in prior studies. This study aims to investigate the basic characteristics of these indices, compare them to existing metrics,and correlate MRR with clinical outcome data.

**23/CARD/03 –** Quantification of coronary artery calcification in contrast enhanced, un-gated, non-cardiac CT imaging: a comparison with the Agatston score derived from dedicated CT coronary calcium imaging.

PI – Richard Good – Interventional Cardiology Research Delivery Team; site recruitment target is 200.

Sponsor – NHS Golden Jubilee.

Coronary artery calcification is indicative of atherosclerotic coronary artery disease and is a major determinant of cardiovascular events and all cause mortality for patients. Coronary calcification can be detected on commuted tomography (CT) scans, the "gold standard" investigation is a gated non-contrast cardiac CT. We have identified that coronary calcification can also be detected on ungated CT that include the heart in the field of view. These scans are performed for a number of non-cardiac indications including sepsis, cancer and lung disease. This ‘incidental’ finding is often not reported and patients may remain undertreated for the prevention of cardiovascular events. In addition, coronary calcification may be a harbinger of risk for patients undergoing treatments including surgery, chemotherapy or radiotherapy.

Artificial intelligence applied to the analysis of medical imaging is a rapidly evolving field with the potential to transform the way we detect and manage many conditions. Together with Canon Medical Europe Ltd and University of Glasgow, our team in GJNH have developed a number of projects to assess the presence and extent of coronary calcification on ungated CT scans that include the heart in the field of view. In particular, we are developing an artificial intelligence algorithm to automatically detect and report this finding. As previous mentioned the "gold standard" investigation for coronary calcification is CT-CA. Calcification on these scans is quantified using a threshold level previously determined by Agatston et al, providing an overall Agatston score.

The aim of this project is to compare the manual and AI quantification of calcification via coronary calcium score (CCS) on ungated, contrast enhanced CT scans with the historic Agatston score derived from a dedicated, non-contrast, cardiac gated CT scan. To our knowledge contrast enhanced CT scans have not be assessed for the ability to detect and quantify coronary calcification.

**23/ORTH/05 –** Design and validation of novel socket concept and synthetic residual limb replica using MRI data.

PI – Jon Clarke; Orthopaedic Surgery Research Delivery Team; site recruitment is 3.

Sponsor – the University of Strathclyde.

The objective of this research project is to design, validate, and perform user testing of a novel transtibial prosthetic socket. Prosthetic sockets form the connection between the residual limb and prosthetic device. Residual limb discomfort and injury, caused by force transmitted via the prosthetic socket, is commonly experience by people living with amputation. This can lead to reduced device use and device rejection, severely impacting on users' ability to complete activities of daily living. With prosthetic socket comfort consistently highlighted by users as an area requiring improvement, further research into socket design is warranted.

The novel socket in this study aims to more uniformly load the residual limb than currently clinically utilised designs, therefore reducing mechanical stresses within the soft tissues and minimising the danger to users. The novel socket utilises a fluid filled chamber and elastomeric interface to facilitate improved load redistribution. This study seeks to recruit three people with transtibial amputation who are regular prostheses users and who do not suffer from chronic residual limb complications. MRI scans will be taken of each user’s residual limb; wearing no socket and while wearing two clinically utilised designs. The MRI scans will be used to manufacture a synthetic replica of each residual limb, and to manufacture the novel socket. The synthetic replica will allow benchtop testing, including ensuring the socket meets appropriate elements of ISO-22675:2016, before undergoing user testing. The novel socket will then be tested against two clinically utilised designs using a range of outcome measures including pressure distribution, user feedback, and a further set of MRI scans to investigate soft tissue deformation. The study duration will be 24 months. MRI Scans will be taken at the Golden Jubilee University National Hospital. The rest of the

study will be conducted at the department for biomedical engineering, University of Strathclyde.

### KPI 2: Participant recruitment (excluding blood sampling studies)

The target for Q4, 23/24 was 200, Recruitment was over target for this quarter with 224 participants recruited (this excludes the NOVEL project which is a blood sampling project).

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | AHF | Anaes/ CC | Cardiac Surgery | Colorectal  | Int Cardiol | Ortho Surgery | SACCS | SPVU | Thoracic Surgery | Total |
| Apr-23 | 0 | 11 | 0 | 3 | 26 | 1 | 3 | 0 | 1 | 45 |
| May-23 | 0 | 15 | 0 | 9 | 36 | 0 | 4 | 1 | 0 | 65 |
| Jun-23 | 1 | 16 | 0 | 19 | 28 | 0 | 4 | 1 | 0 | 69 |
| July – 23 | 1 | 12 | 3 | 9 | 38 | 1 | 3 | 1 | 1 | 69 |
| August-23 | 0 | 20 | 3 | 8 | 33 | 0 | 2 | 0 | 0 | 66 |
| Sept-23 | 0 | 14 | 2 | 8 | 34 | 3 | 4 | 0 | 0 | 65 |
| Oct-23 | 1 | 16 | 3 | 9 | 21 | 1 | 5 | 2 | 0 | 58 |
| Nov-23 | 1 | 18 | 3 | 9 | 42 | 4 | 3 | 2 | 0 | 82 |
| Dec-23 | 0 | 12 | 0 | 6 | 31 | 1 | 1 | 0 | 0 | 51 |
| Jan-24 | 2 | 47 | 0 | 6 | 34 | 6 | 1 | 1 | 0 | 97 |
| Feb-24 | 1 | 19 | 0 | 8 | 42 | 2 | 2 | 0 | 0 | 74 |
| Mar-24 | 2 | 14 | 0 | 5 | 25 | 4 | 0 | 0 | 3 | 53 |
| Total | 9 | 214 | 14 | 99 | 390 | 23 | 32 | 8 | 5 | 794 |

### KPI 3: Income is maintained close to target

The income target is £1.5M. This includes invoiced income from commercial research, non-commercial research and the Chief Scientist Office (CSO) allocation. The total invoiced income for Q4 23/24 was £379,395 which is slightly above the target of £375,000. The table below shows the summary of income to the Golden Jubilee Research Institute for 2023/2024.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **2023/24** | **Q1** | **Q2** | **Q3** | **Q4** | **Total** |
| **Invoiced income - commercial research** | £31,000 | £152,950 | £67,065 | £140,277 | £391,292 |
| **Invoiced income for non-commercial research** | £27,613 | £65,171 | £58,977 | £52,054 | £203,815 |
| **invoiced income (non-commercial research – other)** | £0 | £0 | £0 | £66,064 | £66,054 |
| **CSO Research Support fund**  | £121,000 | £121,000 | £121,000 | £121,000 | £484,000 |
|  |   |   |   |   |   |
| **Total invoiced income** | £179,613 | £339,121 | £247,042 | £379,395 | £1,145,161 |

##

## Note that the CSO Research Support fund stated value excludes funding for the NRS Cardiovascular Speciality Group.

## The table below shows trends in GJRI income for this and the past four financial years.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Source of income** | **Explanation** | **2019/20** | **2020/21** | **2021/22** | **2022/23** | **2023/24** |
| **Commercial research** | **Per patient fees** | £557,374 | £285,820 | £373,961 | £558,035 | £391,292 |
| **Non-commercial research** | **Per patient fees** | £154,205 | £394,754 | £158,583 | £222,369 | £203,815 |
| **Non-commercial research (other)** | **Income for directly funded research posts, grant income** | £451,318 | £199,226 | £173,102 | £197,182 | £66,054 |
| **CSO income** |  | £482,000 | £363,785 | £475,000 | £475,000 | £484,000 |
|
|  |  |   |   |   |   |   |
| **Total**  |  | **£1,644,897** | **£1,243,585** | **£1,180,646** | **£1,452,586** | **£1,145,161** |

### KPI 4: The number of research project audits is in line with target

As of 01 February 2024 there were 143 projects in the portfolio - 44 in proposed status and 9 non-consenting projects. Removing these leaves 90 actively recruiting / follow-up projects. The Research & Development Steering Group agreed that at least 5% of active/follow-up projects should be audited which means that a minimum of 4-5 projects should be audited in this financial year.

In the 23/24 financial year, 8 research project audits were carried out. Audit reports are available on request.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| GJ Ref Number | Study Title | Risk Score (assessed at study approval) | Date of audit | Status |
| 21/CARD/31 | FAST III  | 10 | 17/04/2023 | Complete |
| 21/CARD/15 | Integrated Flow Reserve in the Heart and End-organs of ACHD patients | 8 | 19/05/2023 | Complete |
| 21/CARD/12 | CONGEST HF | 9 | 31/07/2023 | Complete |
| 20/CARD/18 | I Cormica | 8 | 28/08/2023 | Complete |
| 19/CARD/15 | Tight K Trial | 8 | 09/02/2024 | Complete |
| 22/CARD/03 | EMPRESS-MI | 7 | 12/01/2024 | Complete |
| 21/CARD/32 | INVEST CTO | 7 | 05/10/2023 | Complete |
| 21/ORTH/01 | PJI Test Bundle | 3 | 08/03/2024 | Complete |

### KPI 5: Number of journal publications with NHS Golden Jubilee quoted

This is an annual KPI, which records the number of publications on PubMed that quote the NHS Golden Jubilee / Golden Jubilee National Hospital. The KPI relates to the number of publications however, it is also possible to look at the impact factor for each publication. Impact factors are used to evaluate the relative importance of a journal within its field and to measure the frequency with which the “average article” in a journal has been cited in a particular time. Higher impact factors are associated with journals that are more impactful.

The number of journals remain steady with 119 in 22/23 and 116 in 23/34 however; the average impact factor has increased from 8.01 in 22/23 to 11.3 in 23/24. This indicates that the impact of research carried out at the Jubilee is increasing. The highest number of journals published originates from the Interventional Cardiology research group that also has the highest impact factor.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|   | AHF | Anaes/ CC | Cardiac Surgery | Colorectal Surgery | Interventional Cardiology | Orthopaedic Surgery | SACCS | SPVU | Thoracic Surgery | **Total** |
| Publications 2022/23 | 3 | 14 | 13 | 3 | 45 | 18 | 12 | 7 | 4 | **119** |
| Publications 2023/24 | 7 | 11 | 13 | 4 | 42 | 20 | 8 | 7 | 4 | **116** |
| Combined impact factor 2022/23 | 16.7 | 138.8 | 97.5 | 23.6 | 407.6 | 69.2 | 96.7 | 89.7 | 13.2 | **953.2** |
| Combined impact factor 2023/24 | 74.5 | 45.4 | 117.9 | 30.3 | 777.6 | 63 | 66.9 | 71.7 | 63.1 | **1310.4** |
| Average impact factor per publication 2022/23 | 5.58 | 9.92 | 7.50 | 7.86 | 9.06 | 3.84 | 8.06 | 12.82 | 3.30 | **8.01** |
| Average impact factor per publication 2023/24 | 10.6 | 4.1 | 9.1 | 7.6 | 18.5 | 3.2 | 8.4 | 10.2 | 15.8 | **11.3** |

### KPI 6: Number of projects sponsored by NHS Golden Jubilee

The definition of a sponsor in the context of research within a UK NHS Organisation is as follows: **The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project**. In order for an organisation to take on this responsibly, a robust system of auditing, monitoring, and financial management needs to be in place. This creates additional work for research administration, which is amplified if there are sites out with the NHS Golden Jubilee.

The organisation sponsored fewer projects in 2023/24. Research administration processes are in place however, staff capacity has meant that sponsoring projects is challenging. The introduction of the Deputy Head of Research role will support the sponsor process and the management of external sites.

|  |  |  |  |
| --- | --- | --- | --- |
| **Project ID** | **Short Title** | **Start date** | **Multisite?** |
| 21/CARD/29 | StratMed-MINOCA | 06/04/2022 | Yes |
| 21/CARD/23 | Incidental Coronary Calcification on CT imaging | 02/08/2022 | No |
| 21/CARD/15 | Integrated Flow Reserve in the Heart and End-organs of ACHD patients | 02/09/2022 | No |
| 22/RD/01 | Cardiovascular Research Database | 02/09/2022 | No |
| 21/CARD/28 | RV – PA coupling in Tetralogy of Fallot | 27/09/2022 | Yes |
| 22/COLO/01 | LAMA: Laparoscopy or antibiotics for appendicitis. Version 1.0 | 03/10/2022 | Yes |
| 22/CARD/09 | DSP as a Predictor in Pulmonary Hypertension | 21/12/2022 | No |
| 22/CARD/28 | MRC Dyspnoea to predict survival in PH | 06/01/2023 | No |
| 22/CARD/11 | Ambulatory Oxygen in Pulmonary Hypertension | 20/01/2023 | No |
| 22/CARD/21 | CorVasc Science Study | 16/02/2023 | No |
| 23/ANAES/01 | SEARCH-IV | 21/02/2023 | No |
| 22/ANAES/06 | IMPRoVE  | 26/04/2023 | Yes |
| 22/CARD/35 | A Modelling Study of Right Ventricular Function in Fallot's Tetralogy  | 08/06/2023 | No |
| 21/CARD/32 | INVEST CTO | 06/07/2023 | Yes |
| 23/CARD/03 | Quantification of coronary calcification in non-gated CT imaging. | 26/02/2024 | No |

### KPI 7: The number of Principal Investigators

Given the nature of the clinical service and the resulting complex nature of the majority of research projects hosted by the Jubilee, most Principal Investigators (PIs) are consultants. Out of the 29 PI’s noted below, 27 were consultants. The other PIs were the Team Lead for HLD research, and the Head of Research.

The number of PIs is slightly below the 22/23 number but remains relatively stable.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|   | AHF | Anaes/ CC | Cardiac Surgery | Colorectal Surgery | Interventional Cardiology | Orthopaedic Surgery | SACCS | SPVU | Thoracic Surgery | MISC | **Total** |
| PIs 2024 | 4 | 2 | 1 | 1 | 10 | 3 | 2 | 2 | 3 | 1 | **29** |
| Projects 2024 | 10 | 12 | 7 | 2 | 28 | 9 | 3 | 19 | 8 | 1 | **99** |
| PIs 2023 | 3 | 1 | 1 | 1 | 11 | 4 | 1 | 2 | 2 | 4 | **30** |
| Projects 2023 | 8 | 12 | 2 | 3 | 29 | 8 | 2 | 18 | 9 | 4 | **95** |

## Section 2. Research Governance

|  |  |  |  |
| --- | --- | --- | --- |
| GJRI Reference | Document name | Version | Review date |
| GJRI 000 | Research Quality Framework  | 3.0 | August 2024 |
| GJRI 001 | Informed Consent  | 2.0 | July 2024 |
| GJRI 002 | Research Project Protocol Peer Review  | 4.0 | November 2026 |
| GJRI 003 | Review and Approval of Amendments | 3.0 | September 2026 |
| GJRI 004 | Delegation Log - Guidance | 3.0 | July 2025 |
| GJRI 006 | Monitoring and Audit of Clinical Research Projects - Policy  | 3.0 | May 2026 |
| GJRI008 | Guidance for setting up and maintaining a Research Site File. | 2.0 | July 2025 |
| GJR I009 | Serious Adverse Event Reporting  | 3.0 | April 2025 |
| GJRI 010 | Research Archiving Policy  | 2.0 | March 2024 (in work plan) |
| GJRI 011 | Training for staff engaged in Research | 2.0 | November 2026 |
| GJRI 012 | Management of Intellectual Property | 4.1 | December 2024 |
| GJRI 013 | Research Fraud and Misconduct Policy  | 4.0 | November 2026 |
| GJRI 014 | Honorary Research Contract / Letter of Access for researchers | 2.0 | June 2023 (draft with HR for review) |
| GJRI 015 | Research Project Indemnity Guidance Document | 2.0 | November 2026  |
| GJRI 016 | Medical Emergency in the CRF | 2.0 | November 2026 |
| GJRI 017 | Management of Source data  | 2.0 | December 2026 |
| GJRI 022  | Management of Policies, guidance documents and SOPs  | 1.0 | September 2025 |
| GJRI 024 | Principal Investigator – role and responsibilities | 1.0 | May 2025 |

## Section 3. Staff Governance

**Sickness/absence**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Research admin/ governance (Headcount = 7) | Research Support (Headcount = 23) | Average for Board |
| January 2023 | 0.0% | 5.2% | 6.1% |
| February 2023 | 0.8% | 7.2% | 5.6% |
| March 2023 | 4% | 1.9% | 6.6% |
| April 2023 | 0 | 1.8% | 5.8% |
| May 2023 | 0 | 1.1 | 6.2% |
| June 2023 |  |  |  |
| July 2023 | 0.8% | 1.1% | 5.5% |
| August 2023 | 0 | 7.9% | 5.9% |
| September 2023 | 0.9% | 8.6% | 6% |
| October 2023 | 2.1% | 7.4% | 5.9% |
| November 2023 | 9.8% | 9.9% | 6.6% |
| December 2023 | 11.6% | 4.4% | 6.3% |
| January 2024 | 0.8% | 3.3% | 6.3% |
| February 2024 | 0 | 2.9% | 6.3% |
| March 2024 | 5.4% | 3.2% | 6.1% |

**TURAS completion rate**

|  |  |  |
| --- | --- | --- |
|  | Research admin/ governance (Headcount = 7) | Research Support (Headcount = 23) |
| January 2023 | 86% | 72% |
| February 2023 | 100% | 74% |
| March 2023 | 100% | 64% |
| April 2023 | 100% | 75% |
| May 2023 | 86% | 73% |
| June 2023 | 86% | 77% |
| July 2023 | 86% | 81% |
| August 2023 | 80% | 80% |
| September 2023 | 57% | 61% |
| October 2023 | 43% | 48% |
| November 2023 | 43% | 43% |
| December 2023 |  |  |
| January 2024 | 50% | 57% |
| February 2024 | 33% | 57% |
| March 2024 | 50% | 61% |

## Section 4. Risks & Incidents

Two incidents were reported in the time frame. Both are currently being reviewed.