

# Research and Development

## Summer 2024 newsletter



Welcome to summer edition of the Royal Papworth Hospital R&D newsletter.

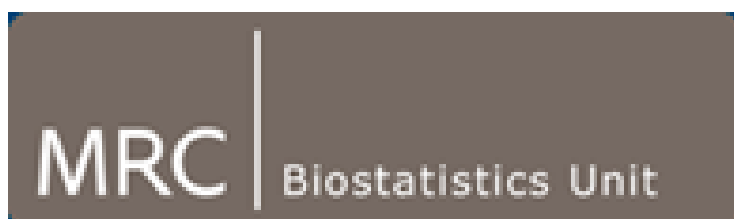
Please circulate this to colleagues who may be interested in receiving it. If you wish to be removed from the mailing list please email [Katrina Hobson-Frohock](mailto:Katrina.Hobson-Frohock).

# Papworth Trials Unit Collaboration

Royal Papworth Hospital collaborates with the MRC Biostatistics Unit, University of Cambridge and King's College London to form the Papworth Trials Unit Collaboration which works closely with our research and development department.

Our project management service, which is available to investigators throughout the UK, includes:

- Clinical trial / protocol design
- Sponsorship
- Health economics
- Support with grant applications
- Data management
- Data base provision and eCRF design
- Randomisation
- Trial set up and coordination
- Trial closure
- Monitoring
- Statistics (including analysis)
- Dissemination of results (writing for publications)
- Archiving



# Latest news

## New study opened

### SENTINEL

A new trial, SENTINEL, is set to investigate if skin patches can be used as an early warning system to identify if lung transplants are being rejected, so treatment can begin sooner, reducing the chance of longer lasting organ damage.

Rejection may show as a rash on the donated skin patch, often before the body has started to reject the lungs. If such a rash is seen, a tiny biopsy from the skin will be taken, as a step to confirm the presence of rejection.

If the trial is a success and the approach can be rolled out to all lung transplant recipients, the research team believe it could cut rejection by up to 50%.

The SENTINEL trial started this month and will recruit 152 patients over three years. The £2million trial is run by the Surgical Trials Units at the University of Oxford in collaboration with NHS Blood and Transplant and the five UK lung transplant centres and funded by a Medical Research Council (MRC) and National Institute for Health and Care Research (NIHR) partnership.

## New study opened

### Anticoagulation for New-Onset Post-Operative Atrial Fibrillation after CABG (PACeS)

A coronary artery bypass graft (CABG) is a surgical procedure used to treat coronary heart disease. It involves taking a blood vessel from another part of the body (usually chest, leg or arm) and attaching it to the coronary artery to improve blood flow to the heart.

Some patients will develop an irregular heartbeat (atrial fibrillation (AF)) after CABG surgery. Patients who have AF are at higher risk of developing blood clots that can lead to conditions like stroke and result in death. To prevent blood clots there are two classes of drugs: anti-platelets (like aspirin) and anti-coagulants (blood thinners). Anti-platelets work by preventing clots from forming and growing by stopping blood cell fragments, called platelets, from clumping together.

Patients undergoing CABG surgery will normally receive these drugs anyway to help stop clots forming in the grafts and keep them working. Anti-coagulants work differently. They affect the reaction of the clotting proteins in the blood, so that the blood is 'thinner' and less likely to form a clot. These drugs can increase the risk of bleeding, which can have serious consequences. Both anti-platelet and anti-coagulant drugs are well-used in current practice, but guidelines from different international bodies are based on weak evidence.

This study aims to determine whether the addition of blood thinners to anti-platelet drugs improves treatment outcomes in patients who develop AF after CABG surgery. The study has already started in the US, and will also take place in Canada, Germany, Brazil as well as in the UK.

Overall, the study aims to involve 3,200 patients over a five year period, 400 in the UK until the end of 2024. Participants will be assigned on a random basis to either receiving anti-platelet drugs only or anti-platelet drugs plus blood thinners and followed-up for six months. In February Royal Papworth Hospital was the highest global recruiting site in the UK. Well done Moh and the team!

# Latest news

## New study opened

### StratosPHere 2

Pulmonary Arterial Hypertension (PAH) is a progressive condition in which a narrowing of blood vessels, carrying blood through the lungs puts an increased workload on the heart. This results in the heart working harder to pump blood through the lungs. Current treatments help to manage the symptoms of the disease but do not treat its underlying cause.

The purpose of this study is to test two drug therapies and to improve our understanding of increasing BMPR2 as a treatment for patients with PAH. We know there are different types of BMPR2 and we want to investigate how these different drugs work on two of the main types. Drug repurposing is the process of finding new uses for existing drugs. In this study we will be testing two repurposed drugs; hydroxychloroquine and glycerol phenylbutyrate, which are currently used to treat other conditions. Previous studies have shown that both drugs have an effect on BMPR2 but in different ways. We are using a simple blood test to measure BMPR2 function.

Currently only Royal Papworth is open to recruitment but we are close to opening Imperial and Glasgow Golden Jubilee.

## Results from XVIVO's clinical trial NIHP2019 for heart preservation presented at ISHLT in Prague

The results showed that the primary endpoint, representing severe complications after heart transplantation, was registered in 18.8% of the subjects who received a donor heart preserved with the XVIVO Heart Assist Transport and in 30.1% of subjects in the control group who received a donor heart transported on ice, the current gold standard. The rates of severe primary graft dysfunction (PGD) after heart transplantation were also lower for patients who received a donor heart preserved with the XVIVO Heart Assist Transport (11% compared to 28%).

The NIHP2019 trial is a randomized, controlled, open label, multicentre clinical investigation of the XVIVO Heart Assist Transport to collect the safety and performance data to support CE marking. The NIHP2019 trial enrolled 203 patients in 15 institutions across eight European countries between November 2020 and May 2023.

"This trial represents a significant evolution in donor heart preservation," says Filip Rega, Professor of Cardiac Surgery and Transplantation at the University Hospitals Leuven, Belgium, and coordinating investigator of the trial. "Primary graft dysfunction is a feared complication after heart transplantation associated with serious morbidity and mortality. The study outcomes reveal an important and clinically relevant reduction in primary graft dysfunction for patients who were transplanted with a donor heart preserved using this novel technology."

# Latest news

## ACNAP 2024, Wrocław (Poland), 14 - 15 June

A truly international congress to discover and share the latest science from across all core specialties within cardiology.

The ACNAP Congress is organised by the [Association of Cardiovascular Nursing and Allied Professions](#).

Jo Oliveira's abstract on 'Exercise-based cardiac rehabilitation effects on severity of angina, HRQoL and exercise capacity in patients with microvascular angina: systematic review and meta-analysis', has been accepted for presentation. After the congress Jo's abstract will be published in the online abstract supplement of the European Journal of Cardiovascular Nursing; and both the abstract and the presentation will be available on ESC365, the cardiology knowledge hub.



## ACE-CF

An app that uses artificial intelligence (AI) could be "revolutionary" for patients with chronic lung conditions such as cystic fibrosis, with the technology able to predict when a patient will fall ill up to 10 days in advance.

It is hoped Breathe RM will allow patients with cystic fibrosis (CF) to be monitored remotely, removing the need for regular wellness checks in clinics.

The technology can also predict when patients are likely to get a major infection – known as an exacerbation – which can lead to weeks in hospital.

Read the full article [here](#).

## IQM update

### (New system for R&D SOP compliance)

Staff working on current CTIMPs and our super users have received the web link and training materials to go live with IQM.

We have received positive feedback regarding our training guides, we are focusing on R&D staff initially and will then move on to Trust staff that are research active.

We hope to roll out the training to all staff by mid-June. Until you receive the web link and training email, please ignore any automated emails from IQM/QPulse and keep your login details (these are being sent separately). You can still read the SOPs on our website in the interim – please keep a note of those that you have read.

# Papworth Trial Unit Collaboration PTUC

## – latest news

### Get involved in research atrium stand Thanks for popping by

On Tuesday 23 January the R&D team were in the atrium alongside the library discussing grant development workshops and how to develop an idea.



R&D run regular sessions for staff who wish to come and discuss their research project and ideas to gain advice and input from a team of statisticians, health economists, data managers and clinical project managers. For an application form to request an appointment, please contact Stacey Hattingh. Or, if you simply want to ask some questions, please contact Sarah Fielding. an appointment, please contact Stacey Hattingh. Or, if you simply want to ask some questions, please contact Sarah Fielding.

### Celebration of Research Poster event

Thank you to everyone that took the time to attend the Celebration of Research Poster event. The event was a great success, and it was a great opportunity for staff to showcase their work, and to see what research is taking place across the campus.

### Diversity in research

On Monday 29 April, members of the EDI network, R&D, Dr Patrick Calvert, and Chair Dr Jag Ahluwalia met to discuss understanding barriers to communities becoming involved in research and how we can make research more accessible. It was inspiring to see active engagement and valuable perspectives shared. Together, we have developed actions moving forward and we are now in the process of setting up a working group.

Thank you to all who came!



## BIOPATTERN

The BIOPATTERN study is a clinical investigation of a medical device designed and funded by PlaqueTec Ltd and co-ordinated by Papworth Trials Unit Collaboration. The device, the 'LiquidBiopsy System' (LBS) is uniquely capable of measuring local biomarker release at the site of an inflamed plaque within coronary arteries. This enables the characterisation of disease that could inform patient care and aid targeting of patient-specific precision medicines.

The aim of the study is to demonstrate the performance of the LBS. Alongside key endpoint analysis, extensive site-of-disease biomarker data will be generated that will close a knowledge gap and facilitate the development of tailored treatments.

Patients with coronary artery disease who are already scheduled for a coronary procedure at specialist NHS cardiac centres across England are offered information about the study. If they choose to participate and if during their planned procedure, they meet inclusion/exclusion criteria they will be enrolled and undergo intra-coronary imaging and LBS blood sampling.

The total recruitment target is 300 patients.

Royal Papworth opened to recruitment in September 2023 with Dr Stephen Hoole as Chief Investigator. Norfolk & Norwich, Royal Bournemouth and Bristol Royal Infirmary hospitals opened soon after.

The study reached its Interim Analysis target of 34 patients recruited on 15 March 2024. From 19 April 2024 at 37 patients recruited the study is now in a temporary 'pause to recruitment' due to a delay in device manufacture. During this time the Interim Analysis will be undertaken. The team are looking forward to the readiness of a new batch of devices and therefore a restart to recruitment at our four original sites (and opening of four new sites) from September 2024.

Thanks to all the hard work of our participating hospitals and research teams! We couldn't do it without you.

### Dr Joe Newman interview - The one minute walk test: the future of exercise testing in PH.

Pulmonary hypertension (PH) is a rare and serious condition that causes high blood pressure in the blood vessels connecting the heart and lungs (the pulmonary arteries). A study involving PHA UK members has shown that a one-minute walk test is just as effective as a six-minute walk test when it comes to assessing pulmonary hypertension. But how soon could we see a change in clinical practice? Watch the interview [here](#).



## NOTACS - Clinical trial coordinator update

‘Hi’ from the Royal Papworth Hospital NOTACS operational team. I’m Liz, the clinical trial coordinator. I’ve worked at Royal Papworth since February 2017. I’ve been working on the study since April 2022, along with other research studies, and fulltime since December 2022. The R&D Department is very active, with approximately 220 studies currently. I work alongside the NOTACS trial manager and the data team, as well as the NOTACS follow up team. This is very convenient if I need to ask a quick NOTACS question or get a patient moved over to the unblinded OpenClinica side! The photo below shows the team – Liz, Jamie, Karen, Georgia and Carmen - some with Costa Coffees, as we were lucky enough to win the Costa prize for the 1200th patient into the study. The NOTACS Papworth Team have been full steam ahead with recruitment. We are the highest recruiting site at the time of writing, although The Prince Charles Hospital is hot on our heels!



On a day-to-day basis, I (Liz) usually call the elective patients about a week or so prior to their admission to see if they are interested in receiving the participant information sheet. If they are then I agree to see them, or one of the team will if they are covering that day, on the patient’s admission. It’s all been about teamwork and putting the patient at the heart of the research process, giving them every opportunity to take part in research if they wish to. In house urgent patients are continually screened for on an almost daily basis too, although the majority of our NOTACS patients are elective patients. Now that we are all nearing the end of the recruitment phase of the study, I’m busy making sure that all the data is as up to date as it can be so that, once recruitment ends, I’m well placed to move onto new research projects.

Dr Guillermo Martinez is the NOTACS principal investigator(PI) for the Royal Papworth Hospital site. He has always been interested in enhanced recovery after cardiac and thoracic surgery, and high flow oxygen (HFO) has been a key intervention in his previous research on perioperative pathways. Dr Martinez’s research experience in patients undergoing lung cancer surgery, where HFO showed a faster recovery and significantly reduced length of stay, paved the way for further studies. His personal challenge is to make Royal Papworth Hospital the highest recruitment centre for NOTACS, and he cannot wait to see the trial results to disseminate the practice and improve patient care for as many patients as possible.





# Studies closed to recruitment

## **Pain and Opioids after Surgery (PANDOS)**

After surgery, many people are prescribed pain relief medication, but the use of such medication in the year after surgery is not well understood.

In this study, we will investigate people's use of pain relief in the month before they have surgery, while they are in hospital after surgery, and up to one year after they have had surgery. We are specifically interested in pain relievers of the morphine family (sometimes called opioids) and any unwanted effects they may have on people who take them.

Royal Papworth Hospital recruited 36 patients to the PANDOS study, they recruited over the course of one week and is now in follow up.

## **Nasal Oxygen Therapy After Cardiac Surgery (NOTACS)**

NOTACS is an international, multicentre study that completed recruitment of 1280 patients in June 2024, from 17 hospitals across the UK, Australia and New Zealand. Royal Papworth Hospital were the second highest recruiting hospital, enrolling 199 patients over almost four years.

The NOTACS study is investigating the role of high-flow nasal oxygen therapy in reducing pulmonary complications in patients who have undergone cardiac surgery. High-flow nasal therapy is a non-invasive form of respiratory support which provides a higher flow of air and oxygen gas mixture to patients than standard oxygen therapy.

The study is exploring whether patients spend fewer days in hospital post-surgery and if it reduces readmissions to hospital by preventing patients from developing chest infections and other respiratory complications. It is also looking at the cost effectiveness of the use of high-flow nasal therapy against standard oxygen therapy, from the perspective of the patient as well as the health service.

The study is now in follow-up which is expected to be completed by the end of September 2024.



# The Victor Phillip Dahdaleh Heart and Lung Research Institute Clinical Research Facility

## Heart Failure Study: Now open to recruitment at the HLRI Clinical Research Facility

Over a million people in the UK suffer with heart failure. Many of these patients develop pulmonary hypertension as a consequence of heart failure. This is associated with an increased risk of mortality. These patients also live with significantly limited physical activity and quality of life despite optimal guideline-directed treatment.

Sponsored by AstraZeneca, the Re-PHIRE study will test a new drug treatment called AZD3427 for the treatment of patients with heart failure and group 2 pulmonary hypertension. The drug mimics the action of the naturally-occurring hormone Relaxin, which reduces vascular resistance in women during pregnancy. The objective of the study is to discover whether AZD3427 is safe, tolerable and effective in patients with heart failure. We also hope to gain a better understanding of heart failure and group 2 pulmonary hypertension.

Around 220 patients will be involved in this Phase IIb trial of different doses of AZD3427. The study will be conducted in approximately 60 centres across 15 countries in Europe, North America, and Asia. Royal Papworth Hospital (RPH) is the first site opened in the UK.

Dr Stephen Pettit, Consultant Cardiologist at RPH, is principal investigator and Dr Dolores Taboada Buasso the co-principal Investigator of this major international study. Research nurse Ana Bueno and the CRF nursing team are supporting recruitment and delivery of the study at Royal Papworth Hospital and The Victor Phillip Dahdaleh Heart and Lung Research Clinical Research Facility. Our colleagues from RPH Pharmacy are also supporting this study.



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# Awards

## CRN EoE 10 year awards

The NIHR Clinical Research Network (CRN) East of England helps to increase the opportunities for people to take part in health and social care research. CRN East of England also ensures that studies are carried out efficiently, and supports the Government's Strategy for UK Life Sciences by improving the environment for commercial contract clinical research in the NHS and social care across East Anglia.

On Wednesday 19 June Kitty and Lauren attended the CRN research awards at The Maltings in Ely. The celebration provided a unique opportunity to commemorate and reflect on our community's exceptional efforts in delivering health and care research since the Network's launch in 2014.

Kitty and Lauren were presented with a wonderful plaque and certificate for Royal Papworth's contribution to health and care research.



# Awards

**PlaqueTec awarded Cambridge Independent 'Medtech company of the year 2024' in recognition of its unique research and recent progress made, in particular the BIOPATTERN trial sponsored by Royal Papworth and managed by the Trial Unit Collaboration.**

In May this year PlaqueTec was crowned MedTech company of the year at the annual Cambridge Independent Science and Technology Awards, held at the famous Wellcome Genome Campus. These awards are a celebration of talent and success across science and technology companies based in the Cambridge area.

Using data collected via its patented intracoronary sampling catheter, PlaqueTec is pioneering a new wave of precision medicines for coronary artery disease, a leading cause of death worldwide.

Since its inception, PlaqueTec has been working in close collaboration with Royal Papworth Hospital, with the first use of the catheter taking place at the old Papworth site.

In the last 12 months PlaqueTec has launched its pivotal multi-site clinical trial, BIOPATTERN, which is led by Dr Stephen Hoole, Consultant Interventional Cardiologist at Papworth, and managed by the Papworth Trials Unit Collaboration. The trial will create unique data to better understand coronary disease to inform future treatments, and has so far recruited 37 patients, 19 of which were at Papworth, with a target of 300 patients in total.

Simon Williams, General Manager of PlaqueTec said: "After a challenging few years, we are very excited by the progress we are now making and thrilled to be recognised by this award. It's been a huge team effort from everyone involved, but in particular we could not have done it without the continuing collaboration with Papworth Trials Unit and Dr Hoole who is chief investigator for this phase III multicentre trial.



# Patient and public involvement and engagement (PPI&E) in R&D

## What PPI&E support can we provide?

PPI&E is a necessary requirement for research funded by the NIHR and many other funding bodies. A clear description of how PPI&E partners will be meaningfully involved needs to be demonstrated in a funding application. PPI&E partners bring a unique perspective arising from their experience of living with, or caring for someone with, a healthcare condition. Learning from and incorporating these experiences promotes better quality research which prioritises the care of patients in its design, not just the 'causes' or 'cures'.

We have seven patient research ambassadors (PRAs) in R&D.

To find out more about them and what they do please [visit their section on our website.](#)

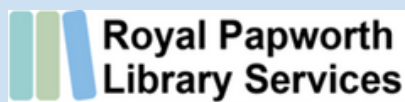
The PPIE team can help with the following:

- Document review (including lay summaries, questionnaires, project proposals)
- Focus groups
- Ongoing study involvement – steering groups etc.

It is always best to include PPI&E in the early stages of the research process and a lot of the work can be done via email. If you would like further information or to discuss a specific project please email [papworth.ppi@nhs.net](mailto:papworth.ppi@nhs.net) or contact [Katrina Hobson-Frohock](#)

<p><b>"If asked to take part in Research, try to take part if you are able. It is important to all."</b> Marijcke, PRA</p>				 <b>Royal Papworth Hospital</b> NHS Foundation Trust	
2022/23	Recruited <b>2</b> new members for wider representation	Completed <b>6</b> mandatory training courses	<b>2</b> Members part of the Mesobank Advisory group	<p>"Getting involved in research gives you a sense of purpose that you are doing something to combat these illnesses as well as a great deal of satisfaction that you are helping others in the future" Ron, PRA</p>	
Reviewed <b>12</b> documents, including lay summaries	<b>3</b> grant requests shaped	Attended <b>5</b> focus groups	<b>181</b> Hours volunteers		
<b>2</b> Paper summaries written	Member of the Royal Papworth Innovation Fund Review Group	<b>6</b> Study application development meetings	Attended <b>5</b> PRES meetings		
Attended <b>4</b> CRN meetings	Contributed to public videos	Talked at <b>2</b> lectures	Won <b>2</b> awards		
Attended <b>1</b> Tissue Bank meeting	Attended <b>6</b> Trial Steering committee meetings	Attended <b>2</b> atrium events	Attended <b>4</b> PRA meetings		

# Other news



## Help at your fingertips

Your library service can help you with:

- evidence searches
- research support
- training in study and research skills, and accessing information resources
- books, and much more

Check our [website](#) for all scheduled training sessions.

And don't forget **PapPubs!**

Papworth Publications are now shared weekly in NewsBites and listed on the [publications page](#) on the R&D website.



Keep up to date by signing up to receive [KnowledgeShare](#) alerts. They are quarterly or monthly alerts emailed to you with links to the latest publications on your topics of interest.

## Consolidation workshop for the introduction to GCP eLearning

Next face to face GCP consolidation is Wednesday 7 August 09:00 -12:30, room 097 HLRI

We are running both virtual and face to face workshops designed to consolidate the key learning from the introduction to GCP eLearning.

You must have completed the introduction to GCP eLearning within the past 18 months. The learning objectives for this interactive and engaging workshop, led by qualified GCP facilitators, are:

- Refresh core GCP learning from eLearning
- Explore the feasibility process and its importance
- Demonstrate an assessment of eligibility
- Appreciate the importance of monitoring, audit and inspection
- Explore data quality
- Define the classification of safety events appropriately
- Recognise different sources of safety information
- Give examples of study documents and how to manage these correctly
- Identify local processes which learners need to know

Book via [NIHR Learn](#). If you have any issues booking please contact [Helen Mulcahy](#).

Keep up to date with all our news.....

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<https://royalpapworth.nhs.uk/research-and-development>