



# 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



UKCRC  
Registered  
Clinical  
Trials Units



MRC | Biostatistics Unit

## BIOPATTERN

The purpose of the study is to look at a new device that can collect blood from precise points within coronary blood vessels. The device is a small tube which will be inserted into the appropriate coronary artery and that will mix and collect four small blood samples from either side of a narrowing in the blood vessel in patients who have coronary artery disease (CAD).

The collected blood will then be analysed to see what it contains and how it may be different from other samples collected. Numerous different biomolecules (components of blood that do many different things in the body) can accurately be measured in the blood that can help us better understand the disease. The hope is that by carefully studying the number and type of biomolecules present in different patients with coronary artery disease (CAD), it may lead to improved ways of treating the disease.

Once BIOPATTERN received full regulatory approvals, the Investigator Meeting was planned. This was the first time the BIOPATTERN core team (Plaque Tec representatives & PTUC Biopattern team) have met face-to-face with colleagues from the participating sites from around the UK. This provided a wonderful opportunity for networking between the sites and to share ideas with each other on how to conduct various aspects of the trial. It was also the first opportunity for Investigators and their teams to 'get hands-on' with the device, ask any queries they had and work through blood processing (which is invaluable for achieving the primary endpoint).



## UK TAVI

The UK TAVI trial explored the use of Transcatheter Aortic Valve Implantation (TAVI) in patients who are at lower risk than those in whom the procedure is currently used. Participants were required to be 70 years of age or over, with an additional risk factor (e.g. diabetes, kidney problems or previous heart surgery) and therefore considered to be at intermediate or high risk for surgical AVR. If aged 80 or over, age alone would qualify the patient for inclusion. All patients had to be suitable for both TAVI and surgical AVR with eligibility determined by a multi-disciplinary team, including surgeons, interventional cardiologists, experts in cardiac imaging and others. Once consent had been given, the patient was randomly assigned to receive either TAVI or surgical AVR. Patients were then followed up for five years, with clinical review and questionnaires to assess quality of life and functional improvement.

RPH were the highest recruiting centre and after a massive team effort, they have just completed the last five year follow ups. A special thanks goes to Rebecca Hussey who has worked on the study right from the beginning and Suzy Deeley who helped complete the follow ups and data clean up. Results to follow in the near future.

## **Clinical Research Practitioner (CRP) Forum**

**The first CRP Forum was held on Thursday 9 March**

CRPs make up nearly half of the operational delivery teams in the research and development department. Working alongside nurses and other healthcare professionals, they bring a wealth of research knowledge, expertise, and clinical skills to form a highly skilled research team that delivers safe, ethical and high-quality clinical research, across all the cardiothoracic healthcare specialties here at the hospital.

CRPs are a nationally recognised workforce and as of March 2021, eligible CRPs can apply to join the Academy for Healthcare Science (AHCS) Accredited Register. This register reflects the skills and knowledge of experienced practitioners and offers assurance and professional accountability to both employers and research participants.

The CRP forum has been set up to support staff, enable the growth and professional development of their role, as well as to showcase the expertise and wealth of research knowledge their role brings to improving the health outcomes for not only our patients at Royal Papworth Hospital, but to patients worldwide.

## **New research study opened at Royal Papworth:**

**The role of sleep in Down Syndrome Alzheimer's disease**

Some people with Down Syndrome have trouble remembering things as they get older and sometimes this is because they have Alzheimer's disease.

Scientists think that a risk for Alzheimer's disease is sleeping badly or having problems with sleep. It is thought that sleep can affect brain health.

We are interested in looking at how changes in the brain and sleep problems might cause memory problems for people with Down Syndrome.

Recruitment target is a total of 50 with 30 participants with Down Syndrome and 20 controls. Currently five of the participants with Down Syndrome will have polysomnography. The CI is currently looking for additional funding to allow the option for a further 10 participants with Down Syndrome to attend for polysomnography.

Recruitment will end in September 2025.

# Papworth Trial Unit Collaboration

## PTUC – latest news

### Effective Treatments for Thoracic Aortic Aneurysms (ETTAA): A prospective cohort study

Between 2014 and 2019, ETTAA study teams from 30 NHS hospitals recruited and followed up 886 participants with a chronic thoracic aortic aneurysm (>4cm diameter). Data was collected by local hospital research coordinators and collated by the core team at Papworth Trials Unit Collaboration. Information was collected in order to observe aneurysm growth, record clinical treatments and measure patient outcomes including survival and health related quality of life. This observational study recruited 321 women and 565 men, average age 71 years. Most were being treated for high blood pressure. Stent Grafting was conducted in 150 patients, Open Surgery in 135 whilst 489 patients underwent Watchful Waiting and 112 Conservative Management

The first ETTAA results paper has been published in the European Heart Journal. [To read this paper please click here.](#)

[A further publication can be viewed here.](#)



### R&D away day 2023

On Tuesday 17 May the R&D team had their first away day since the pandemic. The day started with ice breakers, listening to stories of how long everyone has worked in research - which for some was over 30 years! This was followed by photos around the pond, a lovely lunch before finishing the day with some team games.

It was lovely to see everyone together. The team has grown so much over the years, and it gave everyone the chance to get to know each other.

Above is a photo of the R&D away day back in 2009. Then, we had around 35 staff members and now there are over 90 members of the team!

# Studies closed to recruitment

## QUACS – Quality of Life after Cardiac Surgery

During the last 20 years, heart surgery has become much safer. As a result, greater numbers of elderly and frail patients are being offered more complex operations for various heart problems to improve their survival and improve their quality of life. However, quality of life is not always improved for all who undergo heart surgery. Although we can now measure the risk to life of having or not having the operation, we don't fully know the quality of life the patient can expect to have after their operation. As quality of life is of great importance to patients, surgeons want to be able to give patients good information as to what they can expect after they have been operated on.

This study is hoping to collect such information as that will enable patients to make as full an informed decision whether they want to go ahead with major heart surgery.

Nationally 29 NHS cardiac surgical centres took part in this study with Royal Papworth as the lead centre. 2925 patients were recruited to the study, Royal Papworth were the largest individual recruiter with 438 patients in total. Congratulations to the Papworth recruiting team on their achievement.

There is now a 12 month follow up period for the last patients recruited to the study, results will be available spring 2024.

## DAPA MI trial closed to recruitment

Recruitment to the DAPA MI trial recently closed (A Registry-based, Randomised, Double-blind, Placebo-Controlled Cardiovascular Outcomes Trial to Evaluate the Effect of Dapagliflozin on the Incidence of Heart Failure or Cardiovascular Death in Patients without Diabetes with Acute Myocardial Infarction at Increased Risk for Subsequent Development of Heart Failure).

We are doing this study to explore whether the oral medication dapagliflozin is beneficial in patients without diabetes who recently experienced a heart attack and have sustained damage to their heart muscle function. The study also aims to better understand health problems following a heart attack. At Royal Papworth we recruited 87 patients meaning our site finished in fourth place out of 64 hospitals across the UK.

Becky, Miriam Vaz, Clare East and Sarah Dennis are planning to complete all 87 of the trial closure visits within a 10-week time frame (before 8th June) which has been a challenge to coordinate. Results expected Autumn/Winter 2023.

# New studies

Well done to the teams on the following studies for recruiting their first patients, click the links for more information.

[Predict VF-11](#)

[ACE-CF](#)

[FARADAY](#)

[ANNE](#)

[Protect-V](#)

[PAPMAT](#)

[BioResource](#)

[Cohort Digital](#)

Have a new study starting or you have already recruited your first patient?  
Contact [Katrina Hobson-Frohock](#)

## Congratulations!!

### NIHR East of England Celebration Awards 2023

#### Research Volunteer Award

Congratulations to Ron Flewett and David Smith, our patient research ambassadors who both won the Research Volunteer of the Year Award last week at the NIHR East of England Celebration Awards 2023. Unfortunately, they were unable to attend the event, but Helen Bowyer, R&D Operational Manager, was kind enough to go on stage to collect their awards for them.

The Research Governance Team, which at Royal Papworth includes Chris Tippell, Emily Hodge, Lauren Patman, Kim Giraud and Marlene Taveira, was a runner up in the 'Breaking Boundaries' category for its collaboration with North West Anglia Foundation Trust. Well done to all!



# Patient and Public Involvement and Engagement (PPIE) in R&D

## What PPIE support can we provide?

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 PPIE 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](#)

## PPIE training sessions

We are starting to build a library of recorded training sessions on our website.

Visit our [latest news](#) page and look for the following:

- 'Why does research take so long'
- 'Study designs in clinical research'

## Lay summaries

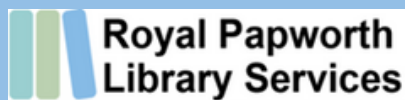
One of our PRAS, Marijcke, has kindly been working on some lay summaries of current research projects. The aim is to provide information about the study in a format that is easy to read and understand.

These are called '[Research Project Summaries](#)' on our website. Feel free to share them with patients or colleagues that you feel might find the information useful.

**Email: [papworth.ppi@nhs.net](mailto:papworth.ppi@nhs.net)**



# 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.

## Upcoming training

Site file training on Tuesday 3rd October 12:30 – 15:00. The training will be held in meeting room R102 at the HLRI.

Writing in medical notes on Wednesday 11th October 11:00 – 12:30.

It will be held in the HLRI meeting room R102. For those unable to attend in person, there will also be a MS Teams link.

If you would like to attend, you will need to log in to KnowledgeShare with your NHS OpenAthens details to book a place. If you have not got a KnowledgeShare login, please contact the library using the following [this link](#) and they can set this up for you.

## NIHR

How much do you know about the NIHR CRN East of England and how we support the delivery of research? Register for our Online Information Sessions [Here!](#)

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

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