Royal Papworth Hospital
NHS Foundation Trust

Royal Papworth Hospital
Five Year Strategy for
Research and Development
2023 - 2028

November 2022

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1. Executive Summary

Royal Papworth Hospital (RPH) moved from Papworth Everard to a purpose-built Hospital on the Cambridge Biomedical Campus in May 2019. The move followed a century of innovative healthcare and research at the Papworth Everard site and is the realisation of ambitions to make Royal Papworth Hospital part of the largest centre of medical research and health science in Europe. The co-location of RPH with multiple leading research partners on the National Institute for Health and Care Research Biomedical Research Centre Campus provides unrivalled opportunities for collaborative research excellence. These partners include Cambridge University Hospitals NHS Foundation Trust, University of Cambridge School of Medicine, Astra Zeneca Headquarters, The Wellcome Trust, Cancer Research UK and Medical Research Council amongst others.

In preparation for writing this strategy, an extensive period of consultation was undertaken. Internal consultation included leaders and member of all departments, both clinical and operational, medical and non-medical. An RPH staff poll was undertaken which overwhelmingly endorsed the importance of clinical research to RPH and its identity. We met with leadership within the University of Cambridge Medical School and leaders involved in research on the Cambridge Biomedical Campus and the Babraham Institute. We have also met with industry partners. A sense of the importance of the Heart and Lung Institute (HLRI) in the future of cardiothoracic research and a determined effort to collaborate more closely was shared by all. The strategy is also informed by a series of documents (chapter 12. Reference Documents).

This document lays out a challenge to Royal Papworth Hospital to become the best cardiothoracic research institute in the UK. This will not be an easy journey and will require investment in people, infra-structure, and significant cultural changes. The world's leading research institutes consider research in all of their clinical and operational pathways with electronic patient records built to capture data for research as part of core clinical care. There will be an expectation that all patients treated at RPH are potential research participants with sufficient research officer resource and clinician engagement to capture these opportunities. Appropriate information technology, ethical consent and information governance systems will be put in place to allow de-identified

data on all patients to be available for clinical research, subject to a patient opt-out. We will expand our research active clinicians to include all clinical departments and also include more non-medics and create space operationally for it to thrive in the pressurised workload of the Hospital. Supporting research in this way, contributes to staff professional development and can lead to an increase in staff retention. It can also be an aid to recruitment in a more competitive employment market. We will develop a research network for Allied Health and Nursing Professionals (AHNP) and Clinical Scientists and encourage, support and promote their research. Operational resources both within the Department of Research & Development and other directorates will be expanded to service the increase in research with improved approval times for studies and increased need for research delivery officers.

Key to the achievement of this strategy is building on existing collaboration within the Trust, with stakeholders on the Cambridge Biomedical Campus and with global colleagues. We will engage enthusiastically and constructively with industry partners to achieve our clearly defined research goals and innovation.

We recognise that creating a culture where research is part of the clinical care will take time. Creating the space for research and expanding involvement in research activities will be the start of this journey. Developing a critical mass of research is vital for the Trust to create a self-sustaining programme of research. It is recognised that some of these costs can be built into grant applications, but much of it cannot and needs alternative funding sources if research is to thrive. We will explore all avenues of funding to build this critical mass of research over the life of this Strategy.

Research and Innovation is a key tenet of the Trust Five Year Strategy 2022 – 2025: '**Research and innovate**' is one of six objectives in the Royal Papworth Hospital Strategy 2020-25 stating "we will continue to develop the Trust as a **centre for research and development** fully nurturing our expertise and creativity in a structured way for the benefit of patients".

This Research and Development Strategy sets out how this tenet will be achieved over the next five years and the priorities for research and innovation.
This strategy is also consistent with the Trust vision, mission and values:

Our vision is:
"To bring tomorrow's treatments to today's patients."

Our mission is:
"To provide excellent, specialist care to patients suffering from heart and lung disease."

Our values are:
- ***Compassion**. Recognises and responds to the needs of patients and colleagues.*
- ***Excellence**. Makes a difference with each small improvement and by being open to new ways of working.*
- ***Collaboration**. We achieve more together.*

Extensive evidence exists to prove that patients treated in research active hospitals have better clinical outcomes and 12 publications are listed in chapter 11 with supportive evidence. This is regardless of whether the individual patient is a participant in research. Creating a robust culture of active collaborative research where excellence in research and innovation is encouraged and rewarded is the clearest pathway to realising our Trust vision and mission and to fulfilling our Trust values. It is also a route to maintaining Royal Papworth Hospital as the best provider of clinical services for cardiothoracic medicine and surgery in the UK.

Clinical research also benefits the UK economy with support from NIHR Clinical Research Network generating £2.7 billion Gross Value Added and generating 47467 FTE jobs in 2018/19 (independent report from KPMG for NIHR *https://www.nihr.ac.uk/news/new-report-highlights-how-nihr-support-for-clinical-research-benefits-the-uk-economy-and-nhs/22489*).
For each patient recruited into a commercial clinical trial, on average the NHS in England received £9189 from life sciences companies (totally £355 million) and saved £5813 in drug costs (totally £28.6 million) where that drug became the standard of care. The Wellcome Trust Report: 'Research What's it Worth?' recognises that "Interventional research generates recurrent per year income of 25p for every £1 spent and 8p of which is health gain and 17p economic gain" (*https://acmedsci.ac.uk/file-download/54792223*).

Although the challenge is great, firm foundations have been laid. The HLRI is a

formidable resource and infrastructural investment. It represents a meeting of minds of RPH and University of Cambridge (UoC) and will be the focus of much of the collaborative research moving forward especially within the Clinical Research Facility (CRF). The relationships that will be formed in the first year of the HLRI between invested partners (RPH, UoC and industry) will have a significant influence on its long term culture and success. It is crucial these relationships develop in a positive and collaborative framework and this should be pro-actively managed by leaders within the HLRI and the invested partners from the beginning.

The RPH Charity Research and Innovation Fund is a crucial resource for RPH investigators to develop research programs on their way to applying for external grants. Recent developments within the UoC have made it easier for NHS staff to apply for and hold grants from charitable funding bodies. The Papworth Trials Unit Collaborative is now fully accredited with the UKCRC and eligible to apply for national funding. Other opportunities for institutional support are also realistic prospects as the Research and Development department has expanded and matured.

The challenges brought to the NHS by COVID-19 have been great, but they have shown us that new ways of working are possible. We have also demonstrated that with sufficient commitment and focus, extraordinary achievements in research are possible and that these achievements can have a hugely beneficial effect on the health and well-being of our patients. This is the ultimate reason we will strive to be the best cardiothoracic research institution in the UK.

This document proposes eleven targets to be achieved within the next five years to allow RPH research to grow and achieve its potential. Some are performance targets and others are enablers of research. Each target is expanded further in subsequent chapters within the Strategy. It is important to note that many of the targets, in particular those that enable research, require immediate action whilst others will be expected to be achieved within five years. These targets are set out below:

Heart Lung Research Institute (HLRI) Five Year Target – Chapter 5

1. Demonstrate proof-of-concept for at least 10 new drugs or diagnostic approaches in heart and lung diseases in the first 5 years

Investment in People and Diversity Five Year Targets – Chapter 6

1. Five 'Research Leader' (50/50) posts appointed
2. Reduction in study approval time by 25% by investment in RDD staff and cultural changes
3. Steering group established for Allied Health and Nursing Professionals and Clinical Scientists to promote research
4. A series of institutional cultural changes to promote and facilitate research

Papworth Clinical Trials Unit Five Year Target – Chapter 7

6. To expand by 25% the portfolio of trials with an emphasis on novel trial design in cardiothoracic medicine via closer collaboration with academic and industry partners

Digital Healthcare and Research Five Year Targets - Chapter 8

7. Implement research data solution for Royal Papworth Hospital by 2023 including data anonymisation, automated consent checking and natural language processing
8. Develop information technology, ethical consent and information governance systems to permit de-identified data on all patients to be available for clinical research subject to a patient opt-out

Tissue Bank Five Year Target - Chapter 9

9. Tissue Bank to be housed on a single site on Cambridge Biomedical Campus in HLRI or RPH
10. Create a Tissue and Data bank, with all RPH patients being invited to consent, creating an innovative resource for investigators

Innovation Five Year Target – Chapter 10

11. Innovation Committee to engage with innovators, funders and industry to ensure RPH attracts, develops and delivers innovation to the healthcare market

This is an ambitious strategy outlining major changes required to optimise the research potential of the Trust and in doing so transform RPH into a major cardiothoracic research institution. Delivery of these changes requires adequate investment in people, project management, administrative and operational resourcing for implementation.

2. Context

Royal Papworth Hospital (RPH) moved to its new building on the Cambridge Biomedical Campus in May 2019. The hospital encompasses 246 beds, six operating theatres, six cardiac catheterisation labs and two bronchoscopy rooms. In addition, in April 2022, the Heart & Lung Research Institute (HLRI) opened which houses University of Cambridge (UoC) research laboratories, a Clinical Research Facility consisting of a ten bed in-patient facility, four out-patient rooms and two rooms for diagnostic testing alongside dry-lab space housing UoC researchers and the RPH Research & Development Department.

The Research & Development Directorate (RDD) supports investigators from across the Trust to set-up and run research studies from early phase drug studies, surgical interventional studies through to quality of life and development of novel medical devices. RDD comprises six groups which work together to support research activity across the Trust. These areas are supported by a management and operational structure. The RDD business meetings are attended by representatives from across the Trust including each of the clinical areas, finance, pathology, nursing and RDD department representatives. The six groups are set out in more detail below:

1) **Operational Delivery**

   This group is headed up by an Operational Manager with six Research Teams covering all clinical areas within the Trust. Each team is led by a Team Leader and a balanced mix of Research Nurses and Clinical Trial Co-ordinators. The staff are employed by the R&D Directorate allowing a flexible and proactive deployment. The staff are funded through a mix of Clinical Research Network funding, commercial and non-commercial studies.

   The Research Teams work with investigators to set-up and run research studies.

2) **Research Governance**

   This team provides the support to set-up studies across the trust ensuring compliance with regulatory frameworks and contracting with sponsors.

3) **Clinical Trials Unit**

   The Clinical Trials Unit has UKCRC national accreditation and is headed up with an Operational Manager. It provides RPH investigators with support through the research lifecycle, from the development of research ideas, grant applications, study and data management through to statistical analysis and writing of research papers.

4) **Tissue Bank and Pathology Support**

   The Tissue Bank supports RPH, UoC and commercial researchers. In an average year it will provide tissue for around 40 studies. The physical location of the team and storage facilities is an ongoing challenge.

5) **HLRI Clinical Research Facility (CRF)**

   The CRF is led by Dr Mark Toshner together with an Operational Manager. It is due to open for internal studies initially, in November 2022.

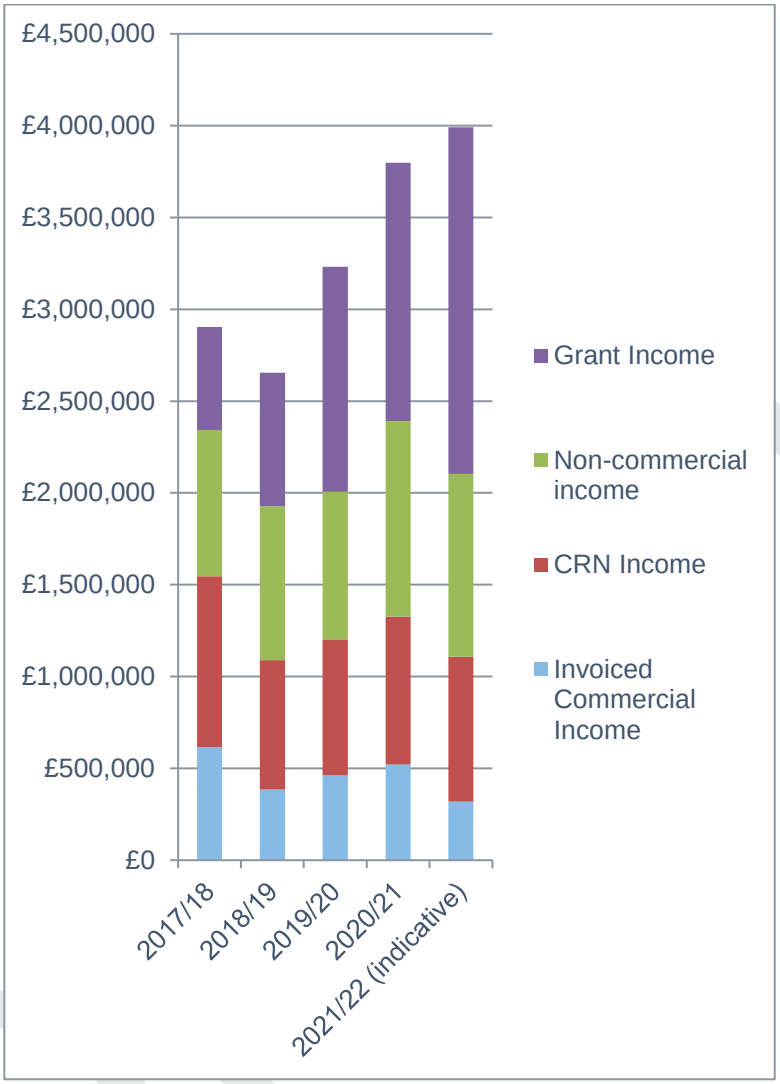
6) **Library & Knowledge Services (LKS)**

   The LKS team support investigators in the development of proposals carrying out in-depth literature reviews. In addition, they work with researchers to carry out critical appraisals and systematic reviews.

The Directorate has over 90 members of staff, a 40% increase in the last 5 years The largest increase has been in lower banded staff, providing a structure which enables progression.

Income from research activity continues to grow year on year, supporting research staff, consumables and other research related costs in the Trust.

Fig 1. Research Director Income 2017-2022



We have benchmarked research participant recruitment to similar Trusts (Royal Brompton & Harefield NHS Trust and Liverpool Heart and Chest Hospital). Recruitment across the three Trusts is broadly similar and follows a similar pattern of increases during the COVID pandemic with a subsequent decline following this period. Recruitment at RPH is consistent with the activity seen pre-pandemic. There have been 623 patients recruited this financial year with an anticipated 1200 at the end of the year consistent with pre-pandemic levels.

3. Framework and Principles

Research in the NHS is governed by the UK Policy Framework for Health and Social Care Research which was updated most recently in April 2022. This sets out 19 principles of good practice in the management and conduct of research taking into account legal requirements and other standards. We are committed to delivering our research in accordance with these principles and these are set out below (see document UK Policy Framework for Health and Social Care Research for further details).

Principle 1: Safety

The safety and well-being of the individual prevail over the interests of science and society.

Principle 2: Competence

All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.

Principle 3: Scientific and Ethical Conduct

Research projects are scientifically sound and guided by ethical principles in all their aspects.

Principle 4: Patient, Service User and Public Involvement

Patients, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.

Principle 5: Integrity, Quality and Transparency

Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.

Principle 6: Protocol

The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents.

Principle 7: Legality

The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.

Principle 8: Benefits and Risks

Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and inconveniences once they have been mitigated. (A formal, structured risk assessment is only expected where identified as essential. The risk: benefit ratio will normally be sufficiently described and considered as part of review processes such as research ethics committee review.)

Principle 9: Approval

A research project is started only if a research ethics committee and any other relevant approval body (i.e. the HRA, the Administration of Radioactive Substances Advisory Committee (ARSAC), the Human Fertilisation and Embryology Authority (HFEA) or the Medicines and Healthcare products Regulatory Agency (MHRA)) have favourably reviewed the research proposal or protocol and related information, where their review is expected or required.

Principle 10: Information about the Research

In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).

Principle 11: Accessible Findings

Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance with any applicable regulatory standards, i.e. legal requirements or expectations of regulators. In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.

Principle 12: Choice

Research participants (either directly, or indirectly through the involvement of data or tissue that could identify them) are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.

Principle 13: Insurance and Indemnity

Adequate (special provision is not expected unless existing arrangements (e.g. professional insurance, membership of NHS Litigation Authority schemes) provide inadequate cover) provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

Principle 14: Respect for Privacy

All information collected for or as part of the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.

Principle 15: Compliance

Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

Principle 16: Justified Intervention

The intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research).

Principle 17: Ongoing Provision of Treatment

The research proposal or protocol and the participant information sheet explain the special arrangements, if any, after the research intervention period has ended (e.g. continuing or changing the treatment, care or other services that were introduced for the purposes of the research).

Principle 18: Integrity of the Care Record

All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected.

Principle 19: Duty of Care

The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care professional (who may or (particularly where the research team is not local to the research site) may not be a member of the research team) retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment, care or other services. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.

It is within this framework that RPH RDD operates and delivers clinical research. RPH RDD has a robust governance and approval process with Standard Operating Procedures regularly updated which all researchers are expected to sign in an electronic log. RPH RDD also promotes the Trust vision, mission and values and works to ensure that research is undertaken consistently with these.

4. Impact of COVID-19

The impact of COVID-19 on research was two-fold. The first impact was the halting or curtailing of most ongoing clinical research, except those testing lifesaving therapies. The second impact was the rapid expansion of COVID-19 research.

At RPH research staff were split into three teams: clinically trained staff redeployed to the front-line; a team to set-up and run COVID-19 studies; and the staff who were risked as not able to be on-site who were responsible for carrying out essential telephone follow-ups. RPH was one of the first Trusts to get the Recovery Study set-up and over 40% of eligible patients were recruited to the study over the course of the pandemic.

RDD staff were heavily involved both in the vaccine research studies, collaborating with CUH and Cambridge and Peterborough Foundation Trust (CPFT) to run the Oxford vaccine study. They were also key contributors to the Trust's roll-out of the vaccine, supporting both from a clinical and administrative perspective.

The flexible model of the R&D Directorate workforce enabled a rapid transition to supporting clinical and research studies during the pandemic, and just as vitally the restart of paused studies and the set-up of new research both during and after the pandemic.

The Directorate is still catching-up with the workload created by the pandemic and study set-up is slower than pre-COVID-19. The R&D workforce, alongside the rest of the NHS staff, was impacted both physically and mentally supporting the COVID-19 pandemic which resulted in a loss of some key members of staff. This has now stabilised and has had positive effects of staff recognising and supporting each other.

One of the biggest impacts of COVID-19 on Research at RPH was the development of new research studies. There has however been a hiatus in grant applications due to researchers being busy supporting the clinical effort of treating COVID-19 patients and then restarting clinical activity. It is therefore crucial that grant application is now re-prioritised moving forward.

5. Heart and Lung Research Institute

5.1 Overview of The Heart and Lung Research Institute

The Heart and Lung Research Institute (HLRI) is a joint venture between RPH and the University of Cambridge (UoC). It draws together the NHS, academia, industry and charity to create a world-leading research environment delivering high-impact research tackling global cardiovascular and respiratory diseases.

The HLRI is adjacent to RPH on the Cambridge Biomedical Campus, the largest biotech cluster outside the United States. The building is home to state-of-the-art laboratories in genomics, population sciences, research into cellular mechanisms of disease and translational science. The HLRI also houses the Clinical Research Facility, with facilities for first-in-patient studies of new treatments, has spaces for education and training as well as dry lab spaces for UoC researchers and the RPH researchers and R&D Department.

Fig 2 Heart Lung Research Institute (HLRI)

Royal Papworth Charity contributed £5 million to support the build. Other funders include the UK research Partnership Investment Fund (£30 million); the University of Cambridge; the Wolfson Foundation; the British Heart Foundation which donated £10million; and the Cystic Fibrosis Trust which donated £5m for a Cystic Fibrosis Trust Innovation Hub.

The 380 researchers, scientists and clinicians based inside the HLRI focus on prevention, early diagnosis and treatment of cardiovascular and lung disease, by creating, testing and delivering new treatments to tackle the biggest causes of premature death in the world all on one site. It is the largest centre for cardiorespiratory research in Europe combining world-leading science, research and education.

5.2 The Heart and Lung Research Institute, Five Year Target

The HLRI has set a target of demonstrating proof-of-concept for at least ten new drugs or diagnostic approaches in heart and lung diseases in the first five years. This is an ambitious target and will required considerable collaborative work from all stakeholders to be achieved.

5.3 Clinical Research Facility

The Clinical Research Facility (CRF) inside HLRI is run by RPH staff. It has space (920m^2) for 10 inpatients at a time to take part in ground-breaking clinical studies and experimental medicine trials within a multi-bedded ward. There are also four outpatient rooms supported by two diagnostic rooms. Studies have shown that patients who take part in clinical trials fare better, regardless of whether the treatment works. People from minority communities, those who work full-time or have to make a long journey to participate are often excluded from research participation. The CRF aims to transform the way in which trials are designed, by placing patients front and centre which help to make the studies more inclusive and representative

The CRF will focus on cardiorespiratory early phase first-in-human trials and observational medicine. The plan in Figure 3 shows the design and layout of the Clinical Research Facility.

Fig 3. Plan of Clinical Research Facility in HLRI

Fig 4. Clinical Research Facility in HLRI

5.4 The Heart and Lung Research Institute, Collaboration

Collaboration between the various partner components of HLRI will be crucial to the continued success of research on the Campus. Joint interdepartmental meetings within the HLRI are key to fostering this collaboration and will have academic and social aspects to them. Team building will also be crucial and positive relationships made early will set the culture moving forward. Integration between RPH and the HLRI is also important to ensure that the best is made of the huge clinical resource for research that operates within RPH. This will also stimulate a renewed interest and enthusiasm for research amongst NHS staff at RPH. It is hoped that this will lead to further collaborations.

A freely available database of all researchers involved in cardiothoracic research (University, NHS and Industry) will be compiled with details of their areas of interest and regularly updated in order to facilitate collaboration.

5.5 Targets set for Clinical Research Facility in the first five years

The CRF has set and a number of targets for its first five years of operation, the overall target is:

HLRI Five Year Target

Demonstrate proof-of-concept for at least 10 new drugs or diagnostic approaches in heart and lung diseases in the first 5 years

This target is supported by a number of short, medium and longer term enabling targets as detailed below:

Objective	Delivery	How will we monitor and manage success
PPIE paradigm established for all new trials	short term (1-2 years)	Patient and Public Involvement and Engagement (PPIE) lead and Patient Ambassadors appointed. PPIE training and experience established for trainees
Record and share learning from PPIE, capturing impact and learning	medium term (2-3 years)	PPIE learning recorded and shared, and best practice established across all trials
Long term PPIE partnerships established	long term (4-5 years)	Evidence of increased equity of access to clinical trials. Increased proportion of patients enrolled in clinical trials with reporting from disadvantaged and minority communities
HLRI clinical research facility (CRF) established	short term (1-2 years)	Opening of new CRF, recruitment of first patients to experimental medicine trials based in the HLRI
Community-based and nurse/therapist-based rehabilitation and heart failure research programmes established	short term (1-2 years)	Recruitment at first sites for remote monitoring /intervention trials
Remote monitoring systems established for CVD and Lung infections	short term (1-2 years)	Recruitment of first patients to remote monitoring trials

New drugs taken through Phase I-II	medium term (2-3 years)	End of new Phase I-II trials of drugs developed from discovery research
Repurposed drugs ready to take into Phase III	medium term (2-3 years)	Funding, registration and start of new Phase III trials based on successful Phase II work
Phase II trials reported	long term (4-5 years)	Publications from Phase II trials
Repurposed drugs licensed and in clinical use for new indication	long term (4-5 years)	Repurposed drugs licensed based on clinical trails
New targets and diagnostic techniques identified by AI and genomics	medium term (2-3 years)	New targets and techniques validated and published
Diagnostic techniques established in clinical practice	long term (4-5 years)	New imaging and remote monitoring in use for patient management
Design, development and roll out of new decentralised trials	short term (1-2 years)	Establishment of a new decentralised trials group (2022) and reporting of clinical studies using decentralised and digital clinical trial design including engagement with regional and national investigators and underserved communities
Development of novel digital trial solutions	medium term (2-3	New trials, outreach clinics and models of care established in community-based studies

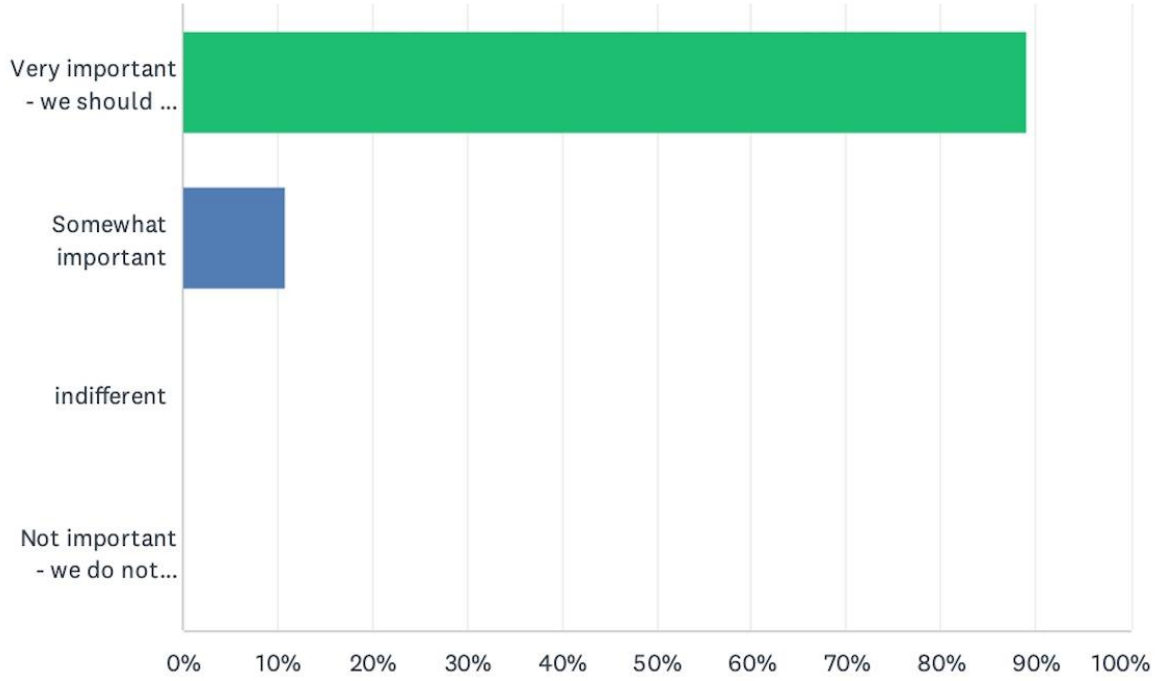
6. Investment in People and Diversity

6.1 Royal Papworth staff – the people's voice

Royal Papworth Hospital has incredible clinical and research facilities. But, in truth, Papworth really is its 'people': its dedicated staff, volunteers and patients. Our people do the work, our people create the passion and compassion, our people plan and our people deliver. It is also our people who undertake the research and innovation. The enthusiasm that staff, both medical and non-medical, have for research is clear and we will need to capture this enthusiasm to deliver the targets set out in this Strategy. In May 2022, we conducted a RPH survey of all RPH staff regarding research.

In a total of 146 respondents, 89% of staff responded to the question 'How important do you think it is that RPH participates in clinical research?' with 'Very important – we should be doing more'. This is illustrated in Figure 5.

Fig 5. Response from RPH staff poll to: 'How important do you think it is that RPH participates in clinical research?'



This is despite 45% of respondents stating that they have no involvement in research at all. 34% were Good Clinical Practice (GCP) accredited in the last 3 years (a basic requirement to undertaken clinical research). Of those who are not currently involved in research, 44% cited 'no time in job plan' as the main reason. 34% also stated that they 'did not know where to start'. When asked 'what RPH can do to improve clinical research', 37% felt staff should be 'made more aware about how to be involved in research' with 28% suggesting 'there should be more protected time for clinical research' and 20% stating that there should be 'more staff employed whose role it is to drive on high quality research'.

6.2 RPH as a Clinical Research Hospital – Cultural Changes Required

Research left to a passionate few does not constitute a Clinical Research Hospital. Research requires constant nurturing in a supportive environment where it is given sufficient resourcing and priority to reach a critical mass. Only then will research flourish and become self-sustaining.

Ahead of preparing this Strategy, we conducted interviews with Clinical and Operational Directors in each RPH Clinical Department and received unsolicited feedback from many researchers. Although some are happy with the research opportunities and the support they receive, many felt that with current operational pressures, there is little time or encouragement for clinical research. In addition, prolonged approval times for studies has led to researchers, collaborators and funders losing enthusiasm for trials with negative effects on future research. Consequently, we have set out a target to reduce these timescales within this Strategy.

In addition, there are a number of proposals that will be implemented over the next five years to support this cultural change, including:

- Research recruitment, grant success and publication output should be celebrated by all in the departments, including those involved in operational delivery of clinical services.
- All advertised job descriptions, whether medical or non-medical, will now state an expectation of involvement in research whether it is enabling, participating in or leading research.

- A session on Clinical Research will form part of all new staff induction/orientation with a view to make NIHR 'Good Clinical Practice' research training part of mandatory training for medical staff and also offered to other interested individuals.
- Contribution to research will be discussed in all annual appraisals and in all Business Unit and Directorate Meetings as a standard agenda item.
- All patient admission documentation will highlight that RPH is a Clinical Research Hospital and that patients should expect to be approached about involvement in Clinical Trials highlighting the benefits to the individual and healthcare in general in participation.
- Dedicated Research and University representation will be mandatory on all consultant appointment panels.

Staff retention remains a major issue within the NHS and RPH, despite its highly specialised environment, is no exception. This affects certain staff groups more than others. The ability to be involved in clinical research has been identified as a positive contributor to professional satisfaction and creating opportunities, for example for cardiac physiologists, may improve staff retention.

6.2 Investment in Medical Researchers

Investment in medical researchers will be a key priority at RPH. Those who lead medical research, also create opportunities for others to be involved in research, thereby enabling colleagues to participate and learn the 'trade' of research to become the future research leaders. RPH must aim to have a 'Research Leader' in each department. These leaders will have a significant amount of their time dedicated to research, on average around 50%. They will be expected therefore to do correspondingly less clinical work. They will be given a period of three to five years in which they will be expected to gain competitive grant funding especially from National Institute of Healthcare Research (NIHR). They will also be expected to be a catalytic facilitator of research for others within their Directorate. Their progress with be monitored by an annual report from the appointee and an annual appraisal by the Director of R&D. It is proposed that if after the probationary period the researcher does not meet the pre-specified target, the research money will be removed and made available to another person. An alternative approach would be for the entire post to be

non-tenured subject to review and this may be appropriate for certain candidates who are new to RPH.

Attracting the best candidates can be challenging and it is of fundamental importance that RDD and the University of Cambridge representative are involved in these appointments and indeed all new consultant appointments to ensure appropriate calibre of candidates from a research perspective.

It should be noted that these posts should not be confined to medical staff and opportunities for able non-medical research should be supported. Funding for these posts should not be at the expense of pre-existing research SPA allocation which has already seen a downward trend over the past few years, so additional funding will need to be identified.

Other RPH staff are involved in research in different capacities including conducting collaborative national database work without the requirement of funding but resulting in high impact and practice changing publications. Some colleagues conduct clinical research as a smaller part of their job plan and others conduct commercial clinical trials. All are of value to RPH and its patients and should be encouraged and appropriate mechanisms for reward should reflect this.

6.3 Investment in non-medical researchers

There is a need to develop non-medical research at RPH to ensure a balanced portfolio of research across the whole Trust.

A Steering Group will be created to include research leads of nursing, the allied health professionals, clinical scientists and other non-clinical areas. This group will work to develop models of integrating research into role profiles of staff across the Trust, in line with the Trusts Strategy. The aim is to have the group active by Q2 of 2023.

The Trust has recently employed a Head of Nursing with responsibility for research in their job plan. This post acts as a link between the R&D Directorate and the Nursing Directorate.

The recently launched Research and Innovation Fund has an aim to fund research from non-medics, and one of the 5 successful applications in the first round was given to a Clinical Scientist.

Other Trusts across the UK are setting up an Embedded Researcher programme for Nurses, Allied Health Professionals (AHPs) and Clinical Scientists giving them protected time in their job plan. The James Paget University Hospitals NHS Foundation Trust in Great Yarmouth is an exemplar, with a nurse and a physiotherapist already in post, each with two days protected time to carry out and enable research within their areas. This is a model which would work well at RPH and will be explored further as part of the implementation of this Strategy.

CUH has a Professor of Nursing and a more advanced non-medic research programme. Links have been established with their research group to learn from their experience and further foster links between the two Trusts. We also plan to establish links with other University Partners including University of Cambridge, Anglia Ruskin University and University of East Anglia with the same objective.

6.4 Investment in R&D core infrastructure

The R&D Core infrastructure is funded through a variety of mechanisms. There is an annual Trust budget of around £70K, CRN funding of c.£700K, infrastructure costed into grant applications, research capacity funding (from NIHR held grants) and funding from the per patient recruitment to commercial and non-commercial studies. Together these cover the £2.5m pay budget for the R&D Directorate staff.

In 2022/23 the department has reached an impasse where all the staff are fully utilised and having to turn studies away due to lack of capacity. 11 studies have had to be declined due to lack of staffing compared with six in 2020-21 and two in 2019-20. Studies are taking longer to set-up, and we are currently limited in the support we are able to offer new investigators in writing grant applications due to lack of capacity.

With the opening of the HLRI in April 2022 and the additional facilities within the Clinical Research Facility that will be available for carrying out more complex studies or high throughput studies (due to open in November 2022), it is envisaged that there is a

significant potential for growth in the volume of research that is carried out within the Trust.

A deep dive has been undertaken into the areas of the department where we feel resources are stretched and not enabling us to reach ours or the Trusts potential. There are two main areas that require investment and to progress research at the Trust: becoming an exemplar in the development of medical devices; and more practically getting studies set-up quicker. We know from previous experience that once we have employed staff, that within 12 months they are generating enough income to cover their salaries. These are explored in more detail below:

1) **Expanding expertise in non-medical devices**
   In order to do this, we would employ a Clinical Project Manager with expertise in novel devices and the regulatory framework that surrounds these. Integral to the success of this post is investment in a quality management system (QMS) which Papworth Charity have agreed to fund.

   There is an opportunity for RPH to be a lead nationally in this area as there is a gap in expertise generally due to the changing regulatory framework. This would generate additional income as the Clinical Trials Unit would be able to support investigators nationally to set-up and run studies with the associated income.

2) **Facilitating faster set-up of research studies**
   The complexity of studies carried out in the Trust has changed, with far more studies requiring complex visits or longer-term follow-up. These studies require a more in-depth review prior to study set-up to ensure the Trust has the capability and capacity to run the studies. This alongside the back-log of review from the pandemic has meant that approval times are significantly longer than pre-pandemic and additional resource is required to support the governance activity. From the studies that we have turned away this year a modest estimate of lost income to the Trust would be £50000. This revenue would pay the salary of the new staff member.

6.5 Diversity in Research

We are committed to equality, diversity and inclusion in everything we do, from ensuring equity of access to research studies to ensuring a diverse research workforce.

It is vital that the research carried out at RPH is as inclusive as possible. In particular, research sponsored by RPH will be designed to ensure that it is accessible to under-served communities to ensure the results are generalisable to a broad population. This is challenging for a national tertiary referral centre and innovative approaches will need to be considered and developed. Examples of how this has been addressed in recent studies include:

1) development of an easy read guide to be read as well as or instead of the patient information sheet to support people with a lower reading age / learning disability
2) Electronic or telephone follow-ups rather than in-hospital visits

Developing appropriate information technology, information governance and ethical pathways to allow de-identified data from all patients treated at RPH (subject to patient opt-out) will also help to ensure that research derived from that data is more representative of all patients treated at RPH.

The Cambridge Biomedical Campus has an active research PPIE Group of which we are a member, and one of the current focuses is how to increase research participation from under-served communities. The population in the East of England is spread over a large area. Accessing areas of social deprivation and poor cardiothoracic health is vital to ensure that the whole population of the East of England can benefit from inclusion in clinical research and indeed that the clinic research that we conduct is representative of the population that we serve. This is a focus for the NIHR Clinical Research Network (CRN) to overcome and remains a significant challenge. The use of the NIHR CRN and indeed collaboration with the newly formed Cambridge and Peterborough Integrated Care System provide potential opportunities to address this. Partnership with other healthcare providers and digital solutions to research may also be useful.

Investment in People and Diversity Five Year Targets

1. Five 'Research Leader' (50/50) posts appointed
2. Reduction in study approval time by 25% by investment in RDD staff and cultural changes
3. Steering group established for Allied Health and Nursing Professionals and Clinical Scientists to promote research
4. A series of institutional cultural changes to promote and facilitate research

7. Papworth Clinical Trials Unit

7.1 Overview of Papworth Trials Unit Collaboration

Papworth Trials Unit Collaboration (PTUC), led by Professor Robert Rintoul, sits within RDD as a fully accredited UK Clinical Research Collaborative Clinical Trials Unit. Initially awarded provisional registration in 2015, PTUC achieved full accreditation in 2018 and we have recently submitted our quinquennial renewal application, the outcome of which is expected in early 2023.

Clinical Trials Units (CTUs) are specialist units which have been set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies with the capability to provide specialist expert statistical, epidemiological and other methodological advice and coordination to successfully execute clinical trials. Specifically, PTUC has expertise in the coordination of trials involving investigational medicinal products which must be conducted in compliance with the UK Regulations governing the conduct of clinical trials.

Accreditation, as has been achieved by PTUC, is awarded on the provision of evidence to an international panel of experts of their capability to centrally coordinate multi-centre clinical trials (i.e., having overall responsibility for the design, development, recruitment, data management, publicity and analysis of a portfolio of trials), and that they have established robust systems to ensure conduct and delivery of clinical trials to the highest quality standards. The table below sets out an overview of the PTUC activity over the last five years.

Fig 6. Overview of PTUC activity

Number of studies in set up (as of July 2022)	7
Number of studies in recruitment (as of July 2022)	8
Number of studies in follow-up (as of July 2022)	1
Number of studies in analysis (as of July 2022)	4
Number of peer reviewed publications published in the last 5 years (2017 – 2022)	53
In relation to the number of peer reviewed publications published in the last 5 years, please indicate how many individual studies this represents.	39

As such, the PTUC, has the remit of acting as a Clinical Research Organisation for externally sponsored trials, or working with our own trust staff from initial concept of a research trial to be sponsored by the trust through all stages of financing; set up; running; close out and publication.

PTUC holds collaborative partnerships with both the Medical Research Council (MRC) Biomedical Statistics Unit in Cambridge and Kings College London, for the provision of services detailed below:

- ***Statistics***

  The MRC Biostatistics Unit (Cambridge), provides on-going support and expertise from a team of five statisticians led by Dr Sophia Villar, an MRC Investigator in the clinical trials methodology group, part of the Design and Analysis of Randomised Trials theme. Statistical support is provided across the whole trial's pathway. The 5-year aims are a) to further develop innovative methodology that optimise trial design; b) continue to offer clinical trial training opportunities for postgraduate students to undertake statistical research projects, at MSc level and to increase engagement for PhDs.

- ***Health Economics***

  The collaboration is led by Professor Julia Fox-Rushby, who draws on support from her team of six health economists and the wider group of 12 health economists at the Department of Population Sciences at King's College London. They provide a) support within research proposals and fellowships; b) training through short courses; c) design of resource use and cost data collection and d) modelling cost-effectiveness of interventions beyond trials to support decision-making. In the next 5 years, the aim is to supervise more post-graduate degrees with a methodological focus on increasing the efficiency of resource use and cost data collection in clinical trials, using case studies in cardiothoracic medicine.

7.2 Papworth Clinical Trials Unit Successes

Over the last five years, since full UKCRC registration, annual grant income has three-fold risen from £0.4M to £1.2M. Recently PTUC has been awarded contracts to deliver the NOMAB (£520,944) and BIOPATTERN (£1,347,241) studies.

The number of individual studies that have been published on has risen from 27 to 39. In recent years the unit has expanded its statistics, health economics, information systems and quality assurance teams to provide increased depth and resilience.

During COVID first wave, PTUC co-ordinated the RECOVERY trial at RPH, recruiting 38% of eligible patients, the highest of any NHS Trust.

7.3 Papworth Clinical Trials Unit Strategy for the next Five Years

The PTUC research strategy over the next five years is:

a) To identify, implement and support novel trial designs.

Over the last four years the Unit has designed and run five studies with an adaptive design and two more are in an advanced stage of development. PTUC, through collaboration with the Cambridge MRC Biostatistics unit has a particular strength in this area and will continue to promote updates of novel (adaptive) designs among the clinical and research membership of the collaborative partners to facilitate development of further innovative design studies.

b) Continue to expand our methodological research portfolio

CTU is committed to further developing and expanding our methodological research portfolio. Using existing trial data our collaboration partners at Kings College London; Health Economics for Life Sciences and Medicine unit are particularly interested in testing methods to improve the efficiency of resource use and routine health service data in clinical trials as well as developing and testing mapping algorithms from disease-specific measures to health state utilities. It is believed that there are new opportunities to work with trials assessing screening and forms of personalising therapies in cardio-thoracic medicine.

Over the last four years the Unit has developed monthly ‘open surgeries’ where researchers can present and discuss trials ideas with a panel of research methodologists (biostatisticians, health economists, R&D managers, clinical project managers). This approach has worked very well and several innovative adaptive

design studies have evolved from this. The Unit plans to expand this and use this model in annual research skills/design courses.

c) Develop new collaborations with Cambridge Research Institutes and SMEs. Since full registration Royal Papworth Hospital has relocated from Papworth Everard to the Cambridge Biomedical Campus and is now co-located with multiple large biomedical research institutes (Cancer Research UK, MRC Laboratory Molecular Biology, Welcome Trust/MRC Cambridge Stem Cell Institute), pharma (AstraZeneca), Cambridge-based biotech companies and NHS Trusts (Addenbrooke's, future cancer hospital). This brings many opportunities for PTUC to work with principal investigators and research groups in these organisations and beyond to develop well designed studies along the lines outlined in a) and b) above.

7.3 Strategy Target

The NIHR have recently announced a new funding call that replaces the current NIHR Research Design Service (RDS) and Clinical Trials Unit (CTU) support. Those contracts currently in place come to an end in September 2023. The new funding call is a one-stage, open competition to designate and fund NIHR Research Support Service (RSS) in England. The aim of the NIHR RSS scheme is to provide an integrated research design, development, collaboration and implementation system with centres that can provide seamless support from pre-application through to post-application phases for all researchers (NIHR- and non-NIHR funded) working across the remit of the NIHR. The funded centres will operate to ensure a *collaborative community* is established to deliver the best advice and support to each researcher, regardless of their location; to coordinate the identification of research methodology needs; and to share best practice.

PTUC does not currently receive funding through the current, soon to be replaced, NIHR CTU support mechanism. However, in a collaborative application with the NIHR East of England Research Design Service and regional CTUs (Cambridge and Norwich), our aim is to firmly place the Papworth Trials Unit Collaboration as an established and effective partner in this current funding application with the dual purpose of:

1. identifying ourselves as a CTU specialising in the delivery of cardiothoracic surgical trials with a specialist expertise in development of medical devices and support of medical device SMEs.
2. realising a successful funding application that benefits PTUC in terms of tangible resource allocation

Papworth Clinical Trials Unit Five Year Target

To expand by 25% the portfolio of trials with an emphasis on novel trial design in cardiothoracic medicine via closer collaboration with academic and industry partners

8. Digital Healthcare and Research

8.1 Central role of Digital in research – leveraging technology to work for research

Digital healthcare holds considerable promise to enable research at RPH and on the Cambridge Biomedical Campus but progress has been slower than anticipated. The concept of a comprehensive database of clinical information that is easily accessible to researchers is a powerful one and would enable a number of key R&D developments set out in this Strategy. These include improvements in recruitment to clinical trials, cohort observational and epidemiological studies and the use of artificial intelligence and machine learning to gain insights that can be translated back to the bedside in the form of clinical decision support. Furthermore, our Research aspirations extend across the Cambridge Biomedical Campus and beyond to other NHS organisations, Universities, Industry and International Collaborators.

Central to the provision of data for research is the use of different electronic patient record systems (EPR) at Royal Papworth and Cambridge University Hospitals. The decision regarding the potential for and timing of convergence onto a single system are beyond the scope of this Strategy. Nonetheless it is important to note that a single EPR across the Cambridge Biomedical Campus would simplify research workflows at the patient level and would offer some advantages for the development of a research database. It would also remove the significant obstacle to collaboration with CUH researchers that different EPRs currently presents. Equally, not all of the challenges would be addressed by this move, in particular for those providers who would remain on separate systems. It is also important to acknowledge the ongoing implementation of the Cambridgeshire and Peterborough Shared Care Record which will provide a unified view of the patient record across all providers and later provide research and Population Health Management tools. Fundamentally, it is critical that we do not delay the development of data solutions for research while the decision on EPR convergence are made. Of equal importance is a focus on the quality of data and entry of data in a manner that allows future research.

We are therefore working closely with CUH, CUHP and the Eastern Academic Health Science Network (EAHSN) to meet our Vision for Digital Healthcare in Research and address the following key challenges:

Fig 7 Key challenges to Digital Healthcare in Research

These are outlined in more detail below:

Cybersecurity – the database must be secured from Cyberattack

Multiple sources – it will be necessary to include information from multiple sources from across the NHS and other external collaborators. Information standards are therefore critical to the assimilation of these data

Unstructured data – there are large amounts of unstructured data in electronic patient records which need manipulation to form part of a machine readable dataset

Changing nomenclature – both medicine and the nomenclatures used are subject to continuous change which must be addressed to keep historical records in line with those from the present

Consent – information governance is central to a research database and consent must be easily addressed on a large scale

External collaboration – it must be possible to collaborate externally with identifiable, pseudo-anonymised and fully anonymised data otherwise the use of the data will be constrained

Our strategy and approach to each of these is detailed in the sections below.

RPH has a huge and almost unique access to clinical information. Accessing this data for clinical research represents a significant opportunity. We will seek to ensure that information technology, consent and information governance systems are established to ensure that de-identified data on all patients treated at RPH can be made available to clinical research subject to patient opt-out. Recent studies have examined the performance and feasibility of opt-out based research versus the more conventional 'opt-in' (Henshall et al ANZ J Psych 2021). Opt-out models were feasible and favoured by 80.2% of participant. Opt-out models have the advantage of vastly increasing access to research opportunities and enables greater equality of access to minority and marginalised groups who are often denied the opportunities afforded to them by research. This thereby addresses inequality of access and ensures that clinical trials are more representation of the population.

Clinical imaging plays a large part in cardiothoracic research. Imaging taken for clinical purposes are often required for research with uploading of de-identified data to corelabs. However, de-identification is often labour intensive and time consuming, most especially for echocardiograms. In order to optimise clinical research, we plan to work with the Digital team to develop a mechanism embedded within the PACS that allows easy de-identification of data so that it can be used within clinical trials if the patients are trial participants.

8.2 Current position

There has been significant progress in recent months in addressing some of these challenges at Royal Papworth. Data captured in our Electronic Patient Record is now available in a near real-time research database that is cloud hosted and cybersecure. Furthermore, a tool has been made available that allows relatively easy interrogation of what are complex data sets with a focus on improving recruitment to clinical trials. The data are available from our EPR go live in June 2017, as of September 2022 the research system held the following information:

Fig 8 Data held on research system of Electronic Patients Record, June 2017 - Sept 2022

Patients	**304.8K**
Encounters	1.8M
Appointments	2.6M
Results eg Pathology, Radiology	23.4M
Clinical Observations including CDC Form data	41.6M
Diagnostic Reports	3.2M
Medication Statements	3.2M
Medication Administration	6.5M
Requests	3.5M
Referrals	336.7K

8.3 Information Governance and Consent

It is essential that Information Governance is involved in the development of digital healthcare for research to ensure full compliance of any solution with data processing regulations.

Consent is a key mechanism to allow data processing and has been simplified by the implementation of the National Data Opt-out mechanism. This provides a central means of recording an individual's dissent to share their healthcare data for research and planning purposes. At RPH our checks are currently manual. However, our solutions will be developed to automatically access this information prior to any further processing.

Any research solution must be able to provide identifiable, pseudo-anonymised and fully anonymised data. At present our research database contains patient identifiable data only but full anonymisation to facilitate external collaboration is in development. This will enable our engagement across the Campus and with Industry.

8.4 Data and collaboration

A fully comprehensive database suitable for use at RPH and across the Cambridge Biomedical Campus is challenged by the complexity of connecting different sources most notably the different EPR systems used by CUH and RPH. Different RPR systems between hospitals on the Cambridge Biomedical Campus represents a potential obstacle to clinical research collaboration which is of particular importance for the Clinical Research Facility in the HLRI whose aim is to focus on collaborative research.

A move to a single EPR across the Campus would undoubtedly simplify this however it would not provide a solution for legacy data or for other collaborators outside Cambridge. Other approaches are possible including the use of standards based information exchange (HL7 – FHIR) which has been built into our current solution and future planning. This international language for healthcare information exchange is used by many system providers and its uptake continues to increase. HL7-FHIR permits the near real-time exchange of healthcare data and is used by the systems at CUH and Royal Papworth.

Unstructured data within EPRs remains a challenge. Many users of systems prefer to enter data as free text due to the complexities of clinical nomenclature and the workflows needed within systems to record it. It is estimated that only 15% of clinically important information is recorded in a structured manner in any EPR. Natural language processing has been developed to address this important need and involves the processing of free text into structured data. This will be implemented as part of our future solution.

Clinical terminologies are complex and evolving. As a consequence, relationships between data can change and sometimes be lost over time. A diagnosis recorded in 2017 may have no relevant match in 2027. To address this, NHS-England have

developed a National Terminology Server which uses HL7-FHIR to match and maintain consistency across healthcare data sources. Our system is being designed to connect to it to ensure that our data remains usable in the future.

8.5 Machine Learning and Artificial Intelligence

Both Machine Learning and Artificial Intelligence are key enablers to the future delivery of better health outcomes and are a focus for international investment in research. Any solution must enable the use of this technology but just as importantly allow the translation of such research back into clinical practice. Machine learning and artificial intelligence remain priorities for investment for Industry. It is important that RPH engages with Industry to collaborate on these research opportunities.

Our planned data architecture provides the means to use Machine Learning techniques on patient data to train algorithms that can then be proven in collaborating institutions. These algorithms could then be configured into clinical decision support software to improve clinical pathways and patient outcomes.

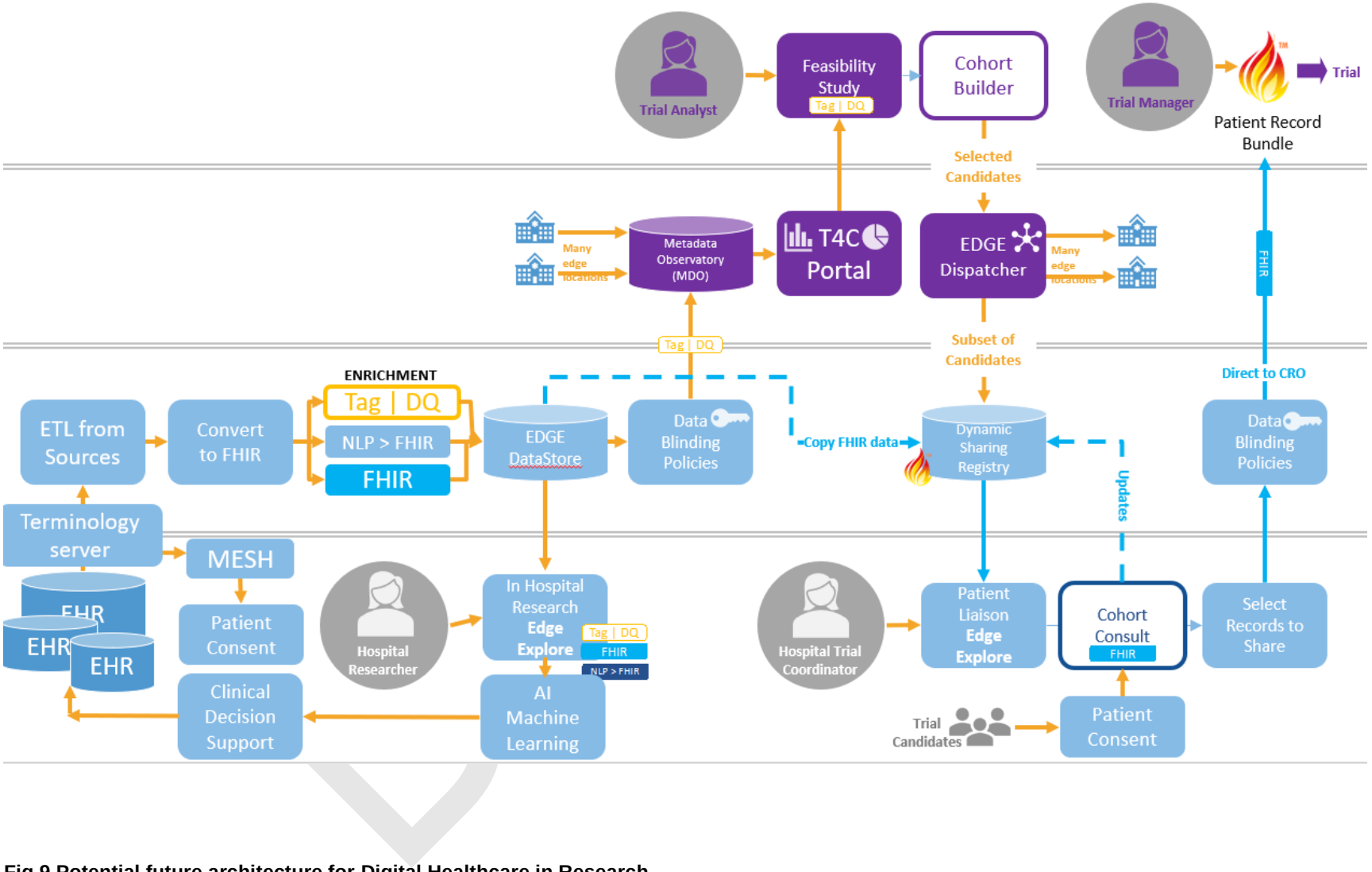


Fig 9 Potential future architecture for Digital Healthcare in Research

8.6 Collaboration

Collaboration across the Cambridge Biomedical Campus including NHS partners, Industry, the University and the wider Integrated Care System is essential to the development of research tools that are fit for purpose and useful to the Research community. The approach must also involve collaboration across clinical, research, information governance and legal disciplines as well as patient interest groups and other professional organisations. This must be done at the level of funding application and system design in order to deliver in a meaningful and timely fashion.

8.7 Conclusion

In conclusion we are now in the position to develop digital tools to leverage healthcare data for research. Some progress is already being made and it is important that this is consolidated and built upon to contribute to solutions for the whole Campus and beyond and to meet our Vision for Digital Healthcare and Research.

Digital Healthcare and Research Five Year Targets

1. Implement research data solutions for Royal Papworth by 2023 including data anonymisation, automated consent checking and natural language processing
2. Develop information technology, ethical consent and information governance systems to permit de-identified data on all patient to be available for clinical research subject to a patient opt-out

9. Tissue Bank

9.1 An Overview of RPH Tissue Bank

The RPH Tissue Bank is an exemplar of the innovative work carried out at RPH supporting not only research within the Trust but also with our Cambridge Biomedical Campus colleagues and national and international researchers. Groups which utilise the Tissue bank to provide samples include the University of Cambridge (including a number of investigators who will be relocating to the HLRI), Astra Zeneca, Sanger and BRC researchers.

The Papworth Tissue Bank has derogation under the Human Tissue Act to approve projects under a generic ethics arrangement which allows researchers to be able to access tissue without the requirement for them to gain Research Ethics Approval through the IRAS/ HRA system. This allows the Tissue Bank to be able to prospectively collect human tissue samples in accordance with researcher's requirements allowing bespoke and targeted collection. This accounts for over 75% of the tissue banking carried out and is tremendously useful resource allowing research to be more nimble and agile and progress more quickly. Note that this system is not available to many tissue banks and is much admired by other academic institutions. Currently, only a relatively small proportion of the tissue banking is collection of samples on a 'just in case' basis and tends to be reserved for a selective group of samples for rare disease and sample types.

9.2 Tissue Bank and Potential

The RPH tissue bank is an almost unique source of biological material to the cardiothoracic research community. The Tissue Bank set up leverages the huge clinical activity at RPH and makes it available to cardiothoracic researchers to improve healthcare by translational research. Tissue Bank represents a major resource for both RPH, Cambridge Biomedical Campus researchers and industry collaborators. There are currently 108 studies within RPH Tissue Bank that are active or in set-up. Over 50% of the studies we supply to are investigators who are / will be working in the HLRI or other campus partners including AZ, CR-UK and the UoC. The table below sets out the origin of the trial for samples collected in the Tissue Bank:

Fig 10 Original of trial the RPH Tissue Bank is current involved in

HLRI Investigator	25
CBC Campus partner	31
Other commercial / non Campus s	35
RPH project	17

9.3 Major Challenge to Tissue Bank

Whereas the move from Papworth Everard has been positive for most other parts of RPH clinical research, the same is not true for RPH Tissue Bank. At the Papworth Everard site, the Tissue Bank was nested within the RPH Department of Pathology, with dedicated staff, freezer space and specimen preparation area. The move to the Biomedical Campus has left RPH with no dedicated department of Pathology, no dedicated freezer space or preparation area. What has followed has been a series of temporary sub-optimal solutions involving leasing space at significant cost and inconvenience. Negotiating these solutions has taken considerable time that RDD staff have therefore not dedicated to supporting other research. The temporary solutions have resulted in RPH Tissue Bank staff working across multiple sites, sometimes with access problems.

In April 2022, Tissue Bank was required to move out of the space it leased on the Cambridge Biomedical Campus within the Clifford Allbutt Building. Every effort was made to find a solution on Campus in which all Tissue Bank activities could be carried out together, but no space was available. The current arrangement is for blood processing to take place in RPH, cutting of sections in a lab in the Jeffrey Cheah Building and fresh tissue processing in the Laboratory of Molecular Biology. The freezers have been moved off-site to a commercial facility in Sawston. This split site arrangement is clearly sub-optimal and not conducive to maximising its potential as well as increasing costs for researchers due to the additional costs of sample storage and the additional staff time required to undertake activities.

There is no prospect of RPH Tissue Bank fulfilling its potential until it has a long-term home with dedicated facilities. The most obvious site would be within the HLRI and bespoke space is available although it lies in the University of Cambridge allocated floor space which poses new challenges. But by working together it is very much hoped that the RPH Tissue Bank can be located at the HLRI. Failing this, then a longer-term solution is a priority for the next five years and onsite at RPH remains a strong second option.

Tissue Bank Five Year Target

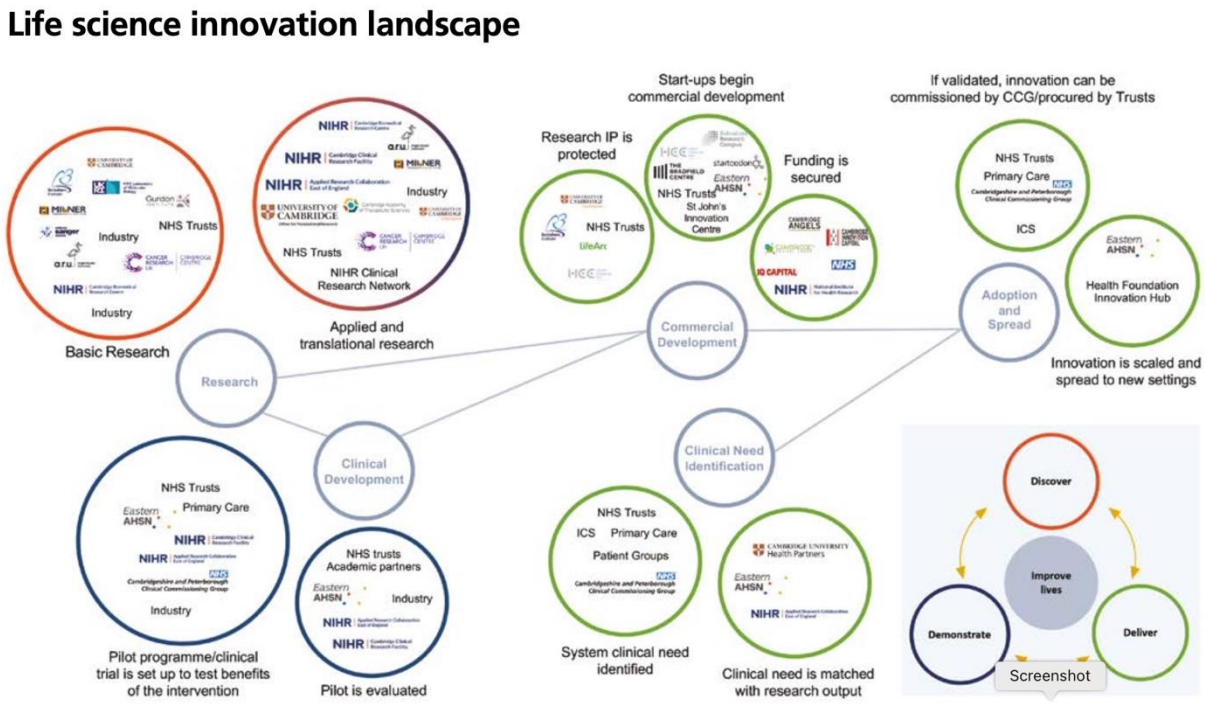
1. Tissue Bank to be housed on a single site on Cambridge Biomedical Campus in HLRI or RPH
2. Create a Tissue and Data bank, with all RPH patients being invited to consent, creating an innovative resource for investigators

10. Innovation

Innovation goes hand in hand with research. But success in one, does not guarantee success in the other. Both require nurturing and investment and require a significant critical mass to bring longer term rewards to the Trust.

Innovation in healthcare can be challenging and expensive (see life science innovation landscape below):

Fig 11 Life science innovation landscape



https://www.enterprise.cam.ac.uk/about/our-performance/

The Trust should learn from the approach that industry takes. An Innovation Committee will be convened to ensure we have an oversight of all potential innovations being developed. An assessment of each proposal's novelty, deliverability, financial viability and marketability can be made in a structured manner according to pre-specified metrics. The Innovation Committee should have links with commercial partners and where appropriate funding bodies, both charitable and commercial. The committee should contain the relevant expertise in business, commercialisation and MedTech development. Developing commercial successful technology can be difficult and very

expensive and pro-active links with industry and funding bodies will be required. The Innovations fund is a vitally important link in the chain for RPH research and innovation. However, it is not a substitute for an 'industry-like' approach as described above. Innovation in other areas can be more nimble, with innovations in healthcare management, patient flow and indeed software all areas where innovations can bring benefits to patient care and potential revenue.

RPH intellectual property (IP) policy will reward researchers for innovation and encourages collaboration rather than secrecy. The biggest gain to RPH will be reputational and setting the example of a collaborative approach that will attract researchers to RPH for innovation rather that driving people away.

RPH should consider bidding to become an NIHR HealthTech research centre. This allows closer relationships with innovators and help us to develop a more structured approach to innovation.

Digital innovation will play a large part in this strategy and central to this will be getting the right electronic patient record (EPR) software and PACS system linkage. The EPR must be configured to facilitate research. This will require flexible patient pathways for delivery of clinical research which is compatible with and familiar to other researchers on the Cambridge Biomedical Campus. The ability of the EPR to extract de-identified data (with appropriate information governance) is a powerful tool for clinical research. In addition, collaboration with industry on the use of these data for researcher databases and machine-learning is a major area of current and future innovation. In collaboration with colleagues on the Biomedical Campus, we will explore further how to optimise the relationships with industry to get the best for our patients and RPH.

Innovation Five Year Target

Innovation Committee to engage with innovators, funders and industry to ensure RPH attracts, develops and delivers innovation to the healthcare market

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