

## Board of Directors (in Public)

### Item 3.3

**Subject:** Research & Innovation Strategy Mid-Year Report, 2017/18  
**Date of meeting:** 28<sup>th</sup> November 2017  
**Prepared by:** Dr Mark Jackson, Director of Research & Innovation  
**Presented by:** Dr Mark Jackson, Director of Research & Innovation

| BAF Ref | Impact on BAF |
|---------|---------------|
| 2.1     | None          |

### 1. Executive Summary

This report provides a high level summary against the principal objectives set in the 2015 – 2018 Research & Innovation Strategy.

Our research portfolio continues to successfully diversify in two of the three areas identified for development in the strategy.

Our research partnerships are flourishing and we are on the cusp of a major initiative with Liverpool University which would be transformational for research in the City.

Our innovation activity is developing; we continue to adopt new technology in a managed way and we are partners in a product we have co-developed which is about to go to market.

Our recruitment into trials is good, and previous concerns around finance have been somewhat mitigated, but a few issues remain to be resolved.

Overall, the Research & Innovation strategy is delivering.

### 2. Introduction

This report provides a high level summary against the principal objectives set in the 2015 – 2018 Research & Innovation Strategy.

### 3. Progress against Strategic Objectives

#### New Areas of Research

In addition to growing our existing portfolio of research (see below), the strategy committed to the development of three emerging priorities likely to represent the next generation of clinical care:

## Personalised Medicine, including Genomics

The Trust is recruiting to the prestigious 100,000 genome project, and is currently a nationally recognised high recruiter of lung cancer patients.

It is also recruiting to three Vertex studies and three other personalised medicine related studies, all of which are Cystic Fibrosis trials testing new medications that have been produced to target different genetic mutations of the condition.

The Trust has developed a comprehensive genomics strategy (the first in the country) which is now being implemented. In addition to educating the workforce on the uses and benefits of genomics, the Trust has developed its Inherited Cardiac Conditions offer into a defined service. This has seen improved relationships with our strategic partner, the Royal Brompton & Harefield (RBH) Hospital who will provide the genetic testing for our patients together with the appointment of the first dedicated Consultant to the service.

The Trust has also secured a £68,000 grant from the Innovation Agency to develop a programme of “structural personalised medicine” in patients with Adult Congenital Heart Disease, led by Dr Rob Cooper, the new Consultant appointment to the Inherited Cardiac Conditions service. In collaboration with 3DLifePrints, Dr Cooper is generating a series of three dimensional physical models of ACHD condition exemplars from CT imaging. The models are used for patient & professional education, matching prostheses to anatomy, and ultimately guiding selection of the best treatment for each individual patient.

## Regenerative Medicine

Sadly, our early success in this theme has been compromised by resignation of our principal collaborator from his academic position at the University of Liverpool. However, he continues to supervise one higher degree student in surgery from his new post in Nottingham. We are hopeful this relationship will develop over time.

## Digital Healthcare

We are one half of an exciting partnership with McMasters University, Canada to trial the utility of patient monitoring equipment that can be initiated in Hospital but follows the patient home. This will allow us to extend our ability to monitor the recovery of our patients remotely. SMARTVIEW has been user acceptance tested on our Ward in August 2017 and will commence recruitment in 2018. This collaboration is set to be long term, and will provide access to a number of digitally focused projects over the coming years.

The Trust has also completed feasibility work with Custodix, who will provide data extraction capability to allow us to offer pseudonymised data to industry as an engagement tool for the commissioning of future research. This work has the added benefit of providing, in the medium term, secure server space to house a joint data warehouse that we will establish with RBH as part of our ICMS collaboration. This will come for free.

Additionally, the Trust has contributed to the Health Research Informatics Strategy for the City, led by Liverpool Health Partners.

## Existing Strengths

Our strategy also required the development of research in areas of existing strength. Below is a high level summary of our most impactful (i.e. not all) projects, either underway or scheduled to commence very soon:

### Cardiology

**RIPCORDER2:** A randomised controlled trial to compare routine pressure wire assessment with conventional angiography in the management of patients with coronary artery disease. This the first ever multicentre study managed on a Trust designed innovative digital platform.

**PRAISE:** Is assessing the suitability of monitoring the delivery of heat to remove sections of heart tissue responsible for the occurrence of atrial fibrillation (AF). The process is guided by an Ablation Index which may be useful in predicting which lesions are less likely to recover. Creating durable ablation lesions during pulmonary vein isolation (PVI) is of critical importance to prevent late PV reconnection, which is responsible for the great majority of arrhythmia recurrence in patients with paroxysmal AF.

**COMET:** Aims to assess if there is a significant difference in the clinical performance of two approved pressure wires (a thin wire which measures blood pressure in the artery). The results will guide future selection of wires.

**CRAFT:** Aims to establish the efficacy of pulmonary vein isolation using a new type of cryoballoon ablation compared with radiofrequency ablation in patients with atrial flutter and no prior documented atrial fibrillation.

**SOUNDSCAR:** A prospective non-randomized trial to assess accuracy of intracardiac echocardiography (ICE) for characterization of arrhythmogenic substrate in patients with ischaemic cardiomyopathy undergoing ventricular tachycardia ablation. If successful, ICE may replace intracardiac electrical mapping leading to shortened procedures.

**GO-DCM:** Aims to identify clinical biomarkers that could be used to predict outcomes in patients with dilated cardiomyopathy and determine the applicability of these to other heritable cardiovascular diseases.

### Surgery

**VIOLET** - Is a NIHR funded randomised trial comparing the effectiveness, cost-effectiveness and acceptability of VATS lobectomy versus open surgery for treatment of lung cancer.

**VISION CARDIAC SURGERY** - Is a large, multicentre, international observational cohort study evaluating the frequency and early identification of subtle and major vascular events at 30-days after surgery in patients undergoing cardiac surgery. This is a collaborative study between LHCH and the Population Health Research Institute, Ontario, Canada aiming to recruit about 1000 patients.

**SMArTVIEW** – Is a randomised trial that will explore the benefits of technology enabled remote automated monitoring and self-management as a vision for patient empowerment following cardiac and vascular surgery. This new study is anticipated to start in January 2018. This is also a collaborative study between

LHCH and the Population Health Research Institute, Ontario, Canada aiming to recruit about 100 patients.

UK TAVI - A multicentre randomised controlled trial to assess the clinical effectiveness and cost-utility of Transcatheter Aortic Valve Implantation (TAVI), compared with conventional surgical aortic valve replacement (AVR) in patients with severe symptomatic aortic stenosis at intermediate or high operative risk.

### Surgery & Cardiology

CASA AF: This trial is funded by the National Institute for Health Research as a joint project with our ICMS partner, the Royal Brompton & Harefield Hospital). It aims to compare the effectiveness of catheter ablation with thoracoscopic surgical ablation (keyhole surgery ablation) for patients with long standing persistent atrial fibrillation.

### Respiratory

AZTEC AZLI – An open-label, randomised, cross-over pilot study of Aztreonam for inhalation (AZLI) plus IV Colistin® versus standard dual intravenous therapy comparing for the treatment of exacerbations of Cystic Fibrosis (CF). This study aims to investigate whether it is safe and effective to use one inhaled antibiotic and one via a drip, instead of the current standard of practice of two antibiotics via a drip.

THORACIC - A two centre study involving the Liverpool Heart and Chest Hospital and Alder Hey Children's Hospital recruiting Cystic Fibrosis (CF) patients with and without *Pseudomonas aeruginosa* bacteria infection attending the CF clinics at Alder Hey Children's hospital and the Liverpool Heart and Chest Hospital. The study aims to assess through the use of diagnostic metagenomics approaches of sequencing technologies to rapidly identify pathogens from patient samples including nasal swabs and sputum samples, particularly for the identification of common pathogens such as *P. aeruginosa* and *S. aureus*.

### Anaesthesia / Critical Care

TEG6 – Aims to establish whether a new device for monitoring blood coagulation in theatres can be applied successfully in the ITU and also bring benefit to patient management in terms of time to actionable results, use of blood products and cost.

### Partnerships

Across the last six months, the Trust has also engaged fully with the University of Liverpool Clinical Research Review. The recommendations of this review were quite critical of the University's strategy, drawing on failure to secure Biomedical Research Centre status as evidence. It exposed the disconnect between the University strategy and the health needs of the City, suggesting that cardiovascular disease should be seen as an emerging research priority. Seizing upon this opportunity, the Trust has:

- Explored with vascular colleagues at RLBUHT the potential for future collaboration.
- Lobbied at University Assurance Committee and Task & Finish Group level for this recommendation to be taken seriously.

- Received an approach by a clinical academic of international standing that would be interested in heading up a new University Department of Cardiovascular Research if the opportunity could be created.

The above academic visited Liverpool on 20<sup>th</sup> September to progress discussions; this meeting went exceptionally well. Since then, the University Vice Chancellor has agreed to allow us to put together a “package” that might be attractive enough to secure the services of the academic (and team) for the City. Whilst there is still a long way to go, this is the most positive sign ever that the University will take cardiovascular research seriously.

Linked to the above objective is the desire to see more Professorial positions amongst our staff. Naturally, securing a Department of Cardiovascular Research at the University would result in a number of our staff receiving such positions, but the Executive are keen to establish leadership in education as well, targeting nursing and other staff groups. To progress this, meetings were held with John Moores and Edge Hill Universities in September and October. As a result, John Moores may well contribute to the package above and Edge Hill have sought our support in their application to establish a new medical school which will bring clear routes to senior joint positions in both research and education.

Liverpool Health Partners (LHP) have recently commissioned a review of themselves with an objective to develop a shared vision for research across Liverpool. This review has recently concluded, and the recommendations are being worked upon. The Trust is a founding partner of LHP and a key stakeholder.

### Capacity & Capability

The Trust is presently running a major fundraising campaign to purchase a Da Vinci robot for use in cardiac and thoracic surgery. A key component of the business case supporting this development is the engagement in research into the benefits of robotically assisted surgery. Plans to make this aspiration a reality are currently underway.

The Trust remains committed to its research partnership with RBH known as the Institute for Cardiovascular Medicine & Science (ICMS). A key development this year has been the attraction of technology (Medtronic) and pharmaceutical (Astra Zeneca) partners to join the collaboration. Their subscription fees are being used in part to develop a postdoctoral research position to support the clinical teams. This post will be filled by December 2017. New collaborations are emerging in adult congenital heart disease, cardio-oncology and inherited cardiac conditions.

### Innovation

The Trust continues its strong interest in innovation. We have secured an honorary position in the newly opened joint enterprise owned by the University of Liverpool and John Moores University called Sensor City. Through this position Dr Matata will have opportunities to bring industrial partners together with clinicians who wish to implement innovations to advance patient care.

The Trust is a principal collaborator on a major EU funded innovation in procurement grant which, in addition to developing a new model for the purchasing of implanted device services will develop and deploy remote follow up in patients with these devices. This work is worth approximately £1m in grant funding to the Trust over the next four years.

The Trust has been working for over a year with its Industrial partner CareCube in the development of a new catheter laboratory management system. CareCube is a laboratory scheduling, status at a glance, and WHO checklist solution all in one. The Trust has shared intellectual property in this product which is just about to go to market. LHCH will act as a reference site.

The Trust has secured a national innovation UK award in collaboration with an industrial partner and Liverpool University to develop a new diagnostic tool based upon biomarker assay. The vision is this will be used in the emergency departments to identify possible early onset aortic aneurysm. The solution will be trialled at LHCH and the Brompton under ICMS.

The Trust has continued to support the introduction of new technology governed by the Clinical Audit & Effectiveness Group. Over the last six months, three new technologies (new thoracic stent grafts, cryoballoon ablation for atrial flutter and a new 3D mapping system for complex ablations) have been introduced which are now all in use.

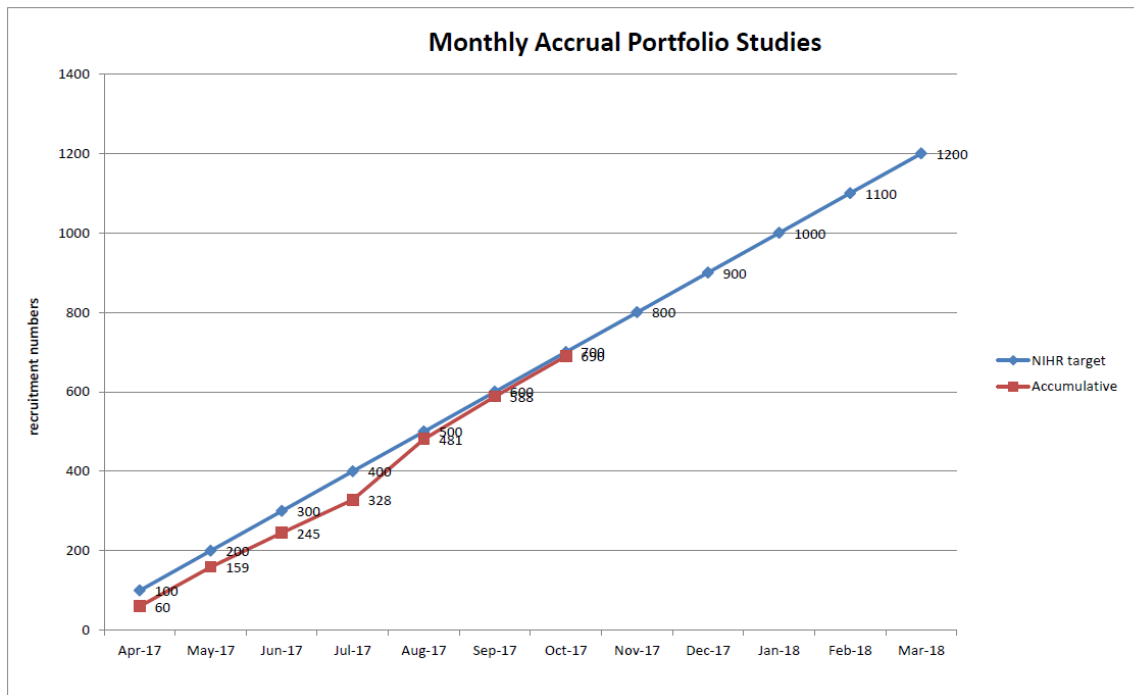
The Trust has recently been approached by IBM Watson to engage in Artificial Intelligence and Machine Learning research. IBM Watson is a question answering computer system capable of answering questions posed in natural language. New chest pain guidelines which recommend CT scanning as the first line investigation will for suspected coronary disease will place demand on radiologist reporting that cannot be met. The objective is to train IBM Watson to recognise normal from abnormal scans leaving radiologists to focus their skills on those scans needing their attention.

October 2017 saw the launch of the Innovation Factor, an online tool provided as part of our contract with TrusTECH, our intellectual property management partner. This simple tool provides readily accessible help and advice for staff to contribute ideas for innovation and improvement. These are reviewed both internally by ourselves and TrusTECH to ensure the correct support can be provided.

## **Progress against Operational Objectives**

### **Recruitment**

The Trust got off to a slow start to the year with recruitment underperforming against plan (figure 1).



However, recruitment has picked up over the past few months principally driven by good performance in RIPCORDER2 and FUTURE. RIPCORDER2 is the Trusts first multisite randomised clinical trial where we are providing all trial management services. FUTURE is the first observational cardiovascular study to have appeared on the national research portfolio in recent memory. Observational studies are much easier to recruit to than intervention based trials, yet carry the same “weight” in performance terms.

The Trust remains as the top recruiter nationally for the TAVI trial. The outcomes of TAVI will determine the future of TAVI as a nationally commissioned service, or not.

## Grants

Recent grant funding successes that are either underway now or about to start in the next 12 months include:

- RIPCORDER2 - £1.9m to evaluate the role of pressure wire at diagnostic angiography: Does routine pressure wire assessment influence management strategy at coronary angiography for the diagnosis of chest pain?
- CRAFT - £850K to evaluate Cryoballoon PV Isolation as First Line treatment for Typical Atrial Flutter.
- Medtronic - £150K funding as subscription to ICMS as the technology partner
- GO DCM - £140K to define the genetics, biomarkers and outcomes for dilated cardiomyopathy
- Biomarkers of Acute Dissection - £133K to develop a new diagnostic tool that can be used in the emergency situation; in conjunction with Liverpool University and Industry
- SOUNDSCAR (CARTOSOUND-BASED SCAR CHARACTERIZATION) - £89K to evaluate the potential of intracardiac echocardiography to determine arrhythmogenic substrate.
- Astra Zeneca - £80K funding as subscription to ICMS as the pharmaceutical partner
- 3DLifeprints ACHD Project - £68K Funding between St. Jude Medical & North West Coast Academic Health Science Network
- Cardio-oncology common dataset - £55K Funding from Boston Scientific. ICMS project.

- Sensor City Surgical Site Infection - £47K – feasibility assessment of efficacy of using sensor technology for postoperative surveillance of surgical site infections
- RITMOCORE - £46K Funding for the grant so far with a further £670K to arrive in November 2017
- CLAHRC - £6K Funding for two internships posts

*Note: Grants include value contributions from equipment and other assets; Expenditure is usually very closely matched to income and also includes income that will be paid to other partners for the contribution they make.*

## Finance

Research & Innovation is a self-funding service line. The risk that research may well run out of money was raised at the Board a year ago. Since then, we have been working hard to mitigate this risk through internal cost improvement and complete revision of our fees and income recovery processes. This has reduced the overspend from £120K pa to £52K pa on a like for like basis. There remain a number of outstanding issues to resolve which includes Liverpool Health Partners subscription fees and a number of payments from the Charity which if resolved would put research back into surplus, despite annual cuts to our core funding from the Clinical Research Network (6.7% in 17/18).

In addition to the reputational, quality and workforce benefits of research, it also attracts added financial savings from (for example) driving the switch to more efficient or cheaper care, supporting the junior doctor rota from fellows employed on research contracts or the provision of equipment supporting research for free. Taken together, our latest audit suggests over £77K pa of added value from research.

## **4. Conclusions**

The research strategy is being delivered as planned.

## **5. Recommendations**

The Board of Directors should use this report as assurance of the delivery of research & innovation activity in accord with the strategic plan.

The Board should receive more detailed explanations of some of this work at the Research & Innovation showcase scheduled for December 12<sup>th</sup> 2017.