

Board of Directors (in Public)

Item 4.2

Subject: Research & Innovation Report
Date: 30th May 2017
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BAF Ref	Impact on BAF
2.1	None

1. Executive Summary

The purpose of this paper is to provide an annual update report on activities within Research & Innovation in the period April 2016 – March 2017. The main report presents a high level overview. A forward plan provided in appendix 1.

The Trust has delivered on most ambitions detailed in the strategy for the current year. In addition, new initiatives have been implemented. Achieving financial balance remains a significant challenge in the face of significantly reduced Network funding and increasingly complex trials that Industry do not want to fund fully. There is a significant opportunity on the horizon following the recently concluded University of Liverpool Clinical Research Review that has identified cardiovascular disease as a potential growth area. Its success will be determined by the attitude of the University to embrace real change.

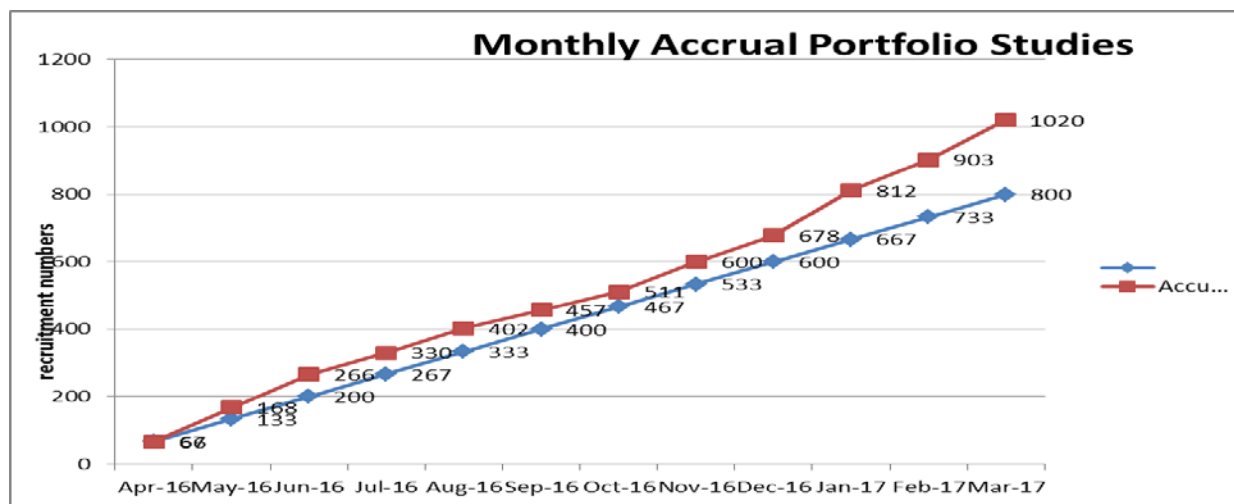
2. Background

The Board approved the current strategy for Research & Innovation (2015-2018) in April 2015.

3. Issues

Overall Recruitment

The reporting period April 2016 – March 2017 has seen the team surpass the annual patient recruitment numbers set by NIHR by 20% on the previous year. A total of 1020 participants were recruited into a clinical trial in the reporting period vs. a target of 800.



The whole team work in collaboration with the North West Coast Clinical Research Network. We have been able to access CRN Taskforce Research Nurse and Data Facilitator support for several key studies this year, which has contributed to increased recruitment and improved data completeness.

Financial Pressures

The department has been subject to a number of additional financial pressures since the beginning of 2015/16 and throughout 2016/17 which has resulted in an increase in overall expenditure above income received. Examples of some financial pressures are listed below:

- Liverpool Health Partners contribution each financial year
- Additional salary costs for new members of staff
- As clinical trials progress and participants move into the follow-up phase, the amount of payment per participant decreases, resulting in lower income received as the trial progresses. 2016/7 has seen more trials in the follow-up phase than in 2015/16.
- 19.4% reduced income from CRN due to CIP impact on their nursing budget

We have prepared a financial plan which will address some of these challenges with the aim of restoring financial balance. A Finance Position Paper was circulated to the May 2017 Research & Innovation Committee but is still to be approved. This paper will be discussed further at the June meeting before going to the Executive committee.

Cancer

Patient recruitment into lung cancer surgical trials continues to enhance our portfolio, and this is an area of growth for the department. We continue to support recruitment to the Liverpool Lung Project and have agreed to take on an additional study – LUCID – for this patient cohort. The planned start date of January 2017 has been delayed to June 2017 and was outside of our control. We continue to receive some additional short term research nurse support from the NWC CRN to aid recruitment to the Liverpool Lung Project. The addition of Professor Pieter Postmus to our team in collaboration with the Clatterbridge Cancer Centre has not realised the many anticipated benefits. It is highly likely that this post will not continue beyond the current contract to 2018.

Personalised Medicine

Recruitment into the rare hereditary cardiac diseases arm of the national 100,000 genome project has been sporadic. It continues to be a challenge to meet our trajectory for this arm of the 100,000 Genomes project. We have been successful in implementing an improved model of screening for this group of patients on EPR with the help of the Informatics team. We have support of a genetics consultant for 1 day per week and this is providing much needed resource and focus for recruitment into the 100,000 genomes project. The imminent addition of a dedicated ICC Consultant post will also have a positive impact later in the summer 2017. We have established a Genomics Strategy Committee which meets bi-monthly.

The lung cancer arm of the 100,000 genomes project began recruiting patients from the trust in May 2016. Recruitment has gone from strength to strength with the team achieving contractual trajectories each month. We are working collaboratively with the North West Coast Genomics Medicine Centre to ensure we are maximising recruitment where possible and have been recognised at a national level for our commitment to and progress in this project.

The 100k genomes project is to be extended until March 2018.

The multi-million pound, UK-wide TRACER X project continues to actively recruit patients – this study exploits the map of the human genome. Locally, LHCH, the Royal Liverpool and Broadgreen University Hospital and Liverpool Biobank at the University of Liverpool are working together to explore and reconstruct the genetic architecture of each patient's disease.

We are collaborating with the Wolfson School of Personalised Medicine, part of the University of Liverpool, on a study which is using Big Data to identify patients with heart failure who are also at risk of renal failure as a result of polypharmacy. The project is a result of a collaboration between Dr Wright and Professor Sir Munir Pirmohamed. Patient and public involvement is built into this project as well as involvement from the Trust's SURE patient group and a number of LHCH patients.

A further collaboration with the University of Liverpool and the Royal Brompton and Harefield Hospitals NHS trust is in the pipeline for 2017/18 and will look at patients with breast cancer who also develop heart failure.

Regenerative Medicine

Although we have not yet embarked on any regenerative medicine projects, we have made significant progress in this area.

We continue to develop our collaboration with PeptigelDesign. They are a local SME who have developed injectable peptide based hydrogels for cardiac regeneration applications, around trial of its biodegradable biocompatible cardiac prosthesis which acts as a new structural type of aortic stent.

We have also identified an academic partner for regenerative medicine, John Hunt, Professor of Musculoskeletal Biology at the Institute of Aging & Chronic Disease, University of Liverpool, and have opened up our lab to collaborative work with his team. There are currently 2 projects being conducted in collaboration with Mark Field and Professor Hunt.

Digital Healthcare

The SENSOR project aims to reduce hospital readmissions for COPD exacerbations by using self-monitoring to educate, empower and engage patients to better self-manage. The project includes 16 patients and improvements have been introduced based on patient feedback. A total of 62% of patients are still engaged with this model of care. The project ended March 2017.

The SMArTVIEW project is being piloted on Elm Ward. This is collaboration with the Population Health Research Institute (PHRI) in Ontario, Canada, which will use the SMArTVIEW e-Health-enabled service delivery program.

We have made some progress in advancing our work with Farsite, a software query tool that allows information to be searched from general practice. A total of 2 GP practices in Knowsley have implemented this software, resulting in the introduction of Shared Medical Appointments led by Dr Wright. A total of 9 patients have experienced this new model of care. It has been very well received by patients and staff. Patients receive a joint consultation together with other patients with the same medical problem providing the opportunity to hear and learn from each other. This is a highly efficient use of time and promotes self-care and autonomy amongst patients. There are ongoing discussions city-wide to encourage GP's to be part of this initiative. The Trust is collaborating with the University in developing a Health Informatics Strategy for the City, and LHCH are leading the Farsite component of the strategy.

We are now working with InSite a commercial company who matches up patient populations identified from EPR's with interested industrial partners. The software the system is built upon allows the type of collaborative working with which we piloted in a previous aortic project. This particular software is free of charge.

We have succeeded in further increasing our capability for research and innovation within the Trust. An innovation module was introduced into the BSc in cardiothoracic care. Three Trust members of staff have so far completed this module. The research team has developed an induction course for new staff and this was used for the first time in April 2016 with positive feedback. Research and Innovation are now incorporated into the corporate induction programme.

Cystic Fibrosis

The cystic fibrosis trials at LHCH significantly contribute to the body of knowledge relating to this condition, but they offer some hope of treatment to patients where no treatments currently exist.

The Vertex suite of trials evaluates the efficacy of VX661 in combination with ivacaftor in patients with a particular gene mutation (heterozygous for the F508delCFTR mutation on the cystic fibrosis transmembrane conductance regulator (CFTR) gene and a second allele with a CFTR mutation predicted to have residual function). If successful, this product could enable people with this mutation to live free of the effects of their condition.

The CF team have also recruited a patient into a study who was the first recruited patient within Europe in July 2016.

Innovation

We have 2 innovation champions who are committed to promoting and taking forward innovation across the Trust. The Head of Research & Innovation is part of the Innovation Scout Programme delivered by the North West Coast innovation Agency, providing access to knowledge, skills and collaboration events.

ICECAP – The electronic trial management system software is fully utilised and has been successfully implemented for the RIPCORDER 2 study.

The SACRED study which evaluated the introduction of a new approach to the management of radial artery puncture sites using 'patent haemostasis' has emerged as the evidence-based, best approach. This is a very exciting piece of nurse-led research. Mobilising sustainable leadership for the study is a challenge given current work pressures.

ICMS - Institute of Cardiovascular Medicine and Science – collaboration between Liverpool Heart & Chest Hospital, University of Liverpool, Royal Brompton and Harefield Hospitals and Imperial College, London. September 2016 saw the 5th Annual Symposium take place at the National Heart and Lung Institute, London, with over 100 delegates in attendance. The keynote speech on personalised medicine was delivered by Professor Sir Munir Pirmohamed, with Professor Kim Fox also contributing to the program. Sessions included sharing progress and initiatives on all aspects of the 4 work streams. We have created a formal partnership with Medtronic, a medical device company and are about to formalise a partnership with a big pharma company. Next steps need to focus on further enhancing our relationship with all partners. The ICMS annual report forms part of this month's agenda for the Board of Directors, and additional detail may be found [here](#).

RITMOCORE - We are a key consortium partner and the only NHS Trust in a European Consortium which is developing an innovative approach to public procurement in the arrhythmia patient population. The launch meeting took place November 2016 and the project will last 4 years. Funding for this project has been allocated from the Horizon 2020 fund. The aim is to develop an exciting new approach to procurement of ICDs, including the development and implementation of remote monitoring of pacemakers, integrated care including the development and testing of digital apps, development and testing of a risk sharing model and use of patient related outcome measures (PROMS). There will be many opportunities to apply the innovative risk sharing model within other specialities across the Trust after the evaluation process has been completed. In addition the lessons learned being part of transforming care in terms of patient self-management will be transferable to all patient groups.

Collaboration

We have been very successful in collaborating with external partners. We have longstanding positive relationships with companies such as Medtronic, Boston Scientific, and Quintiles, and, in are building new relationships in the areas of regenerative medicine (PeptigelDesign) and digital healthcare (Aseptika).

We have a potential opportunity to further develop our services into stroke management and are in early discussions with Medtronic about taking this forward. We have also extended our academic links, strengthening our links with Liverpool University and forging a connection with the Population Health Research Institute (PHRI) in Ontario, Canada (SMARVIEW).

Public and Patient Involvement

The Lord Leverhulme Trust continues to support the role of Research Patient Ambassador, and are very pleased with the progress made throughout 2016/17.

The Research and Innovation Department at LHCH continues to receive overwhelmingly positive feedback from patients who have taken part in research and their families. Patients report that they feel they have a more personalised service, and research nurses will always go above and beyond the role for the benefit of patients.

The Service User Research Endeavour (SURE) Group continues to champion the patient perspective within every research project and plays an invaluable part in research and innovation within the Trust. It is now trust policy to provide a Local Briefing Paper to all patients recruited into a trial. This is given to the patient alongside the mandated Patient Information Sheets and Consent Information and enhances patient understanding and communication.

The Patient Ambassador continues to exceed all expectations of this role through his work across the North West Coast region and beyond, raising considerably the profile of LHCH as a centre of excellence for public involvement in research and innovation.

Keith accepted a position on the NWC LCRN Partnership Group. This is an Executive Board Level Group which represents the wider interests of the CRN NWC region. He is Public and Patient Involvement (PPI) Lead for the NorthWest Coast Public and Patient Involvement (PPI) Lead for the NorthWest Coast Genomic Medicine Centre delivering the 100,000 Genome Project.

Keith has joined a Steering Group of National cardiovascular outcomes research (NICOR). The steering group supports one of the six cardiovascular national clinical audits that NICOR manages, a National Audit of Percutaneous Coronary Interventions (NAPCI) which audits PCI procedures in the whole of UK in NHS and most of the private providers.

Keith also took part in the 'NIHR at 10' conference in London in May which celebrated NIHR's tenth birthday. Keith was a member of the panel in a plenary session on the importance of public involvement in research, the difference it has made to NIHR's work over the last ten years, and what it will help us do in the future. The session is also now also available on YouTube.

4. Conclusion

Activity in the first half of 2016/17 has progressed implementation of the Research & Innovation Strategy in many areas. The strategy is mainly on track to deliver as planned at the end of 2017/18.

5. Recommendations

The Board is asked to review this report and be assured that good progress is being made against the Research & Innovation Strategy.

A forward plan is set out in appendix 1.

Appendix 1: Forward Plan for Research & Innovation 2017/2018

The Challenges

LHCH Research and Innovation is facing a number of tough financial challenges:

- Reduction in Funding from the Clinical Research Network.
- Financial pressures on our industrial partners potentially reducing available commercial income.
- Increasingly specialist and complex studies requiring intensity of workforce resource input.
- Workforce Pressures.
- Sourcing Trials.

The department has been subject to a number of additional financial pressures since the beginning of 2015/16, continuing into 2016/17. As a consequence of this, there is an increase in overall expenditure above income received.

A Financial Position Paper outlines all challenges and will be discussed at the Research & Innovation Committee June 2017 prior to discussion at the Executive Committee.

Reduction in Funding from the Clinical Research Network

This has been highlighted earlier in the report. The CRN have applied CIP's resulting in the reduction in funding to the Trust.

The Financial Position Paper highlights the improvements we are making to achieve financial balance.

Financial pressures on our industrial partners potentially reducing available commercial income

Anecdotally, our experience in 2016/2017 has been that our industrial partners are reporting greater financial restrictions compared with previous years and we notice a corresponding increase in the scrutiny to which trial finance is subjected. We will however only take on trials which contribute academically to the Trusts objectives and / or make a small surplus.

Increasingly specialist and complex studies requiring intensity of workforce resource input

Alongside financial reimbursement, recruitment of high numbers of patients must be a strategic goal for LHCH, given the importance attached to this by NIHR, through the Local CRN. However, this aspiration is not necessarily consistent with high quality research or improved patient care.

Given the competing priorities for research, the Research and Innovation Committee needs to be equipped with robust, relevant information when deciding whether or not to approve a trial for LHCH participation. Accurate assessment of financial costs for each proposed trial will be included with the trial protocol documents when presented by the Principal Investigator.

Workforce Pressures

The LHCH research portfolio is rapidly expanding into new areas whilst we continue to support the existing trials. In particular, we are aware of the potential to recruit more participants to research trials which is limited by the number of research nurse hours available.

Financial and participant recruitment challenges add pressures to the workforce with the consequent challenges associated with managing competing priorities. Going forward, we will only take on trials which are remunerated in accord with effort expended, and we will establish a much more holistic approach to matching workload with current activity.

A Band 7 Senior Research nurse post is required to provide career structure and support to delivery of the trust strategy. The lack of this post has been identified in the recent span of control exercise across the Trust.

Sourcing Trials

It is believed by the team of the R&I Department that on a proportion of trials that could be conducted at LHCH ever reach the R&I Committee. Decisions to refuse trials may be made by well-meaning clinical staff aware of capacity issues and not wishing to exacerbate them. However, decisions about which trials to accept need to be made using robust information.

Additional challenges:

- Impact of unsuccessful BRC application for the city of Liverpool due to weak collaborations and partnerships.
- It is not yet known of the potential impact on research of delivering the Sustainability and Transformation Plan across Merseyside and Cheshire.
- The recent University of Liverpool Research review has identified cardiovascular research as a gap. It is not known at present how this will be successfully addressed.

The Plan

Bringing Large Projects to LHCH

- Priorities for the coming year have been agreed with the aim of maximising recruitment, whilst ensuring quality of research which will contribute to the body of medical knowledge and, thus, produce changes in practice. Some of our large projects which will be active in 2016/17 are described below.
- RIPCORDER 2 is now open and recruiting. We have recruited lower numbers of patients than expected predominantly due to patient unsuitability and patient choice.
- CASA AF is collaboration with Royal Brompton and Harefield NHS Trust aimed to recruit 40 people at LHCH in the period from April 2016 to July 2017. Recruitment into this study has been disappointingly low. Reasons for this include patient choice and the Trust not

being referred patients at the optimal point for inclusion into this study. The Consultant body are reviewing strategies to improve.

- We are opening two new studies in partnership with Boston Scientific which are planned for summer 2017 and we expect recruitment to be substantial for each of these studies.
- The FUTURE study opens mid June 2017 recruiting healthy volunteers. As well as contributing to our overall recruitment target, this study is looking to recruit suitable staff members and will heighten awareness and engagement with research in the Trust.
- Cardiac Vision is a large study looking at post-operative cardiac pain in collaboration with the Public Health Research Institute, Ontario, Canada.
- Collaboration with Liverpool John Moores University has facilitated additional research activity in exercise training and imaging of patients with ICC. We continue to develop this exciting collaboration into 2017/18. The collaboration is already established with LJMU for patients with Cystic Fibrosis.

Addressing the Issue of Reduced CRN Funding

Partnership working with CRN is vital to the LHCH research profile as well as through its financial support. It is important, however, to understand fully the importance of the latter in going forward.

CRN funding pays for staffing only, with no provision for overheads and other indirect costs, such as management costs. In 2015/2016, 58% of our staffing costs were met by CRN funding, which means that only 42% of the workforce was, in theory, available to conduct commercial trials, which provide resources to pay for indirect costs.

The key message is that the reduction in funding from the CRN will be addressed through effective business planning in the sourcing, costing and approval of trials. As such, the removal of funding could be seen as making staff time available to commercial trials which will bring income to cover indirect costs.

It is important to note that we receive minimal funding for the 100,000 genomes project from the North West Coast GMC. We do not receive any income for this project from the CRN.

Future Collaborations

The landscape of the future is one of collaboration, and research is not immune from this influence. We will build our relationships with Liverpool University further, exploiting the opportunity raised by the recent clinical research review. However, we see much more benefit in playing to the strengths of all actors in our health economy who are active in cardiovascular research and care. This may mean developing a network populated by a number of Universities, working with a number of health care providers (specialist, acute, primary care), commissioners and Industry to deliver research that can significantly improve the cardiac (and respiratory) health of our local population.

Summary

Going forward into 2017/18 to address the challenges that face LHCH Research and Innovation will involve a strategic approach to sourcing and approving trials. This will determine success in both financial management and recruitment. This will involve a system for simply planning and monitoring of trials and this depends on robust and timely data availability. CRN funding reduction appears significant, but the impact of this will depend on the resources made available by the commercial trials conducted throughout the year. There needs to be a change in mind-set regarding future research collaborations in our health economy if local research is to impact significantly upon patient health and wellbeing.