

Research & Innovation Strategy 2018/19 to 2020/21

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July 2018

1. Introduction

Liverpool Heart & Chest Hospital NHS Foundation Trust (LHCH) Research & Innovation Strategy is a three-year plan that outlines the key priorities for research and innovation within the Trust until 2020/21.

2. Background

Research aims to generate new knowledge using systematic and rigorous methods whilst innovation involves the local implementation (through adoption and spread) of research findings in order to establish their effectiveness.

Participation in research and innovation brings many benefits for the NHS. Through advances made, quality of care and health outcomes are improved for our patients whilst the United Kingdom's position in the international science industry is strengthened and economic growth and investment promoted¹. Furthermore, research active NHS Trusts tend to have better patient outcomes and benefit from the competitive advantage gained through improved knowledge management and in particular, the ability to use and generate research knowledge². Research & innovation also builds a reputation of excellence with the public, commissioners, primary, secondary and community care, and places us in the driving seat to become thought leaders in the development of our services.

3. The Research & Innovation Landscape

3.1 NHS England Research Plan

The NHS England Research Plan³ identifies priorities for the promotion of research and innovation through:

- Driving the direction of research - Supporting NHS transformation, and operational performance, by ensuring that research commissioned addresses the future needs of patients and local NHS systems.
- Contributing to creating an NHS environment that fosters research and innovation - Supporting commissioners, Commissioning Support Units, Academic Health Science Networks, and national programmes to facilitate research in the NHS.
- Supporting use of evidence in decision making & translating research into practice - Using a range of mechanisms to share good practice, including networks and guidance.

3.2 The National Institute for Health Research and Clinical Research Networks (CRN)

The National Institute for Health Research (NIHR) is a nationally distributed organisation, funded through the Department of Health, concerned with maintaining a system in which the NHS supports those conducting research to meet the needs of patients and the public⁴.

The NIHR Clinical Research Network (CRN) consists of 15 local Clinical Research Networks across England⁵, delivering research across 30 clinical specialties. These are managed within 6 divisions:

Division 1: Cancer

Division 2: Diabetes, stroke, cardiovascular disease, metabolic and endocrine disorders, renal disorders

Division 3: Children, genetics, haematology, reproductive health and childbirth
Division 4: Dementias and neurodegeneration, mental health, neurological disorders
Division 5: Primary care, ageing, health services and delivery research, oral health and dentistry, public health, musculoskeletal disorders, dermatology
Division 6: Anaesthesia/peri-operative management, critical care, injuries/emergencies, surgery, ENT, infectious diseases/microbiology, ophthalmology, respiratory disorders, gastroenterology, hepatology.

Each Division has a local specialty group lead; LHCH has two specialty research group leads on its staff: Dr Jay Wright (Cardiology) and Dr Nigel Scawn (Anaesthesia). This role involves the promotion of research across the North West Coast footprint.

3.3 Academic Health Science Networks

The UK Government has identified Life Sciences and Healthcare as important sectors to generate new economic growth as well as increasing the quality of care for patients within the NHS.

Academic Health Science Networks (AHSNs) present a unique opportunity to align education, clinical research, informatics, innovation, training & education and healthcare delivery. Their goal is to improve patient and population health outcomes by translating research into practice, and developing and implementing integrated health care services. They support knowledge exchange networks to build alliances across internal and external networks and actively share best practice, and provide for rapid evaluation and early adoption of new innovations.

From 2018, AHSN's will have a new responsibility to promote the faster adoption and spread (diffusion) of proven innovations.

4. **Key Partnerships**

4.1 North West Coast Clinical Research Network (NWCCRN)

LHCH's local network (North West Coast) is hosted by The Royal Liverpool and Broadgreen University Hospitals NHS Trust. It is responsible for ensuring the effective delivery of research in the Trusts, primary care organisations and other qualified NHS providers throughout the North West Coast area.

This organisation provides our core NIHR funding which is used to support our research nurses and administration staff.

4.2 The Brompton & Harefield Hospitals NHS Foundation Trust (RBH)

As co-founders of the Institute of Cardiovascular Medicine (ICMS), RBH are our natural research allies. With them comes access to their expertise and facilities (e.g. the biomedical research unit) together with the research staff and facilities of Imperial College London as their principal academic partner.

4.3 University of Liverpool

Following their agreement to join the ICMS Board in 2014, the University of Liverpool are now emerging as strong research partners and are to be the primary vehicle for the creation of an academic staff base at LHCH. They are now our principal academic partner in ICMS.

This relationship has gathered significance and momentum following the Clinical Research Review, which made two impactful observations relevant to Liverpool Heart & Chest Hospital (LHCH):

1. The research strategy of the University is disconnected from the health needs of the City
2. Cardiovascular disease research is an area of emerging strength, and should be considered for future prioritisation by the University

This has led to a “sea change” in the attitude of the University culminating in cardiovascular disease becoming a new strategic research priority for the future. As such, Liverpool University feature strongly in our plans for the lifetime of this strategy.

4.4 Liverpool John Moores University (LJMU)

A strategic partnership currently exists between the Trust and LJMU principally in the area of Sports and Exercise Medicine. We plan to build upon this relationship in taking forward our strategic plans for the development of cardiovascular research in the City.

4.5 Edge Hill University

There are strong existing relationships with Edge Hill in teaching and education, but not research or innovation. Their future plans to establish a medical school together with strength in research led by Nursing and Professionals Allied to Medicine make them a candidate for development across the lifetime of this strategy.

4.5 Liverpool Health Partners (LHP)

LHP is Liverpool’s Academic Health Science System, and is a collaboration between local Universities and Trusts charged with facilitating the generation of new knowledge.

LHP has undergone a major review in 2017, and new priorities are emerging. Cardiovascular disease and respiratory disease (including cancer) are likely to feature strongly within their chronic diseases priority area.

LHP are also set to be a strong voice in major service configuration in the City, strengthening the importance of LHCH being at this table.

4.6 The Innovation Agency: North West Coast Academic Health Science Network (NWCASHN)

The Innovation Agency are our primary partner for implementing innovations in practice. During the lifetime of this strategy, they will work to understand our business more fully, achieving faster diffusion of proven innovations by better matching existing innovations to clinical need.

4.7 Collaboration for Leadership in Applied Health Research and Care

Collaborations for Leadership in Applied Health Research and Care (CLAHRC) are partnerships between a University and surrounding NHS organisations in undertaking high quality applied health research focused on improving patient outcomes. The North West collaboration’s primary theme is health inequalities, supported by evidence synthesis, knowledge exchange, engagement and effective implementation, public health, mental health, managing complex needs and delivering personalised health and care.

4.8 TrusTECH

The Trust has a contract with TrusTECH, the North West NHS innovation service that supports the exploitation of intellectual property and assists with raising the cultural awareness of innovation and the identification of small & medium sized enterprises wanting to test innovative products in the NHS.

5. **Research & Innovation Activity at LHCH**

5.1 Previous Performance

Our previous research strategy has delivered much, including:

Top Five Achievements

1. Delivery of HEAT-PPCI, the largest single centre trial in Cardiology which demonstrated a reduced incidence of major adverse ischaemic events in the setting of PPCI with heparin compared to bivalirudin, with no increase in bleeding complications. This work led to changes in international guidelines and substantial cost reductions globally.
2. Significant involvement in the testing of a personalised medicine (Ivacaftor) that has led to the development of a highly effective drug for the condition in patients with particular mutations in the cystic fibrosis transmembrane conductance regulator gene. Ivacaftor was the first drug that treats the underlying cause rather than the symptoms of the disease, essentially offering a cure to Cystic Fibrosis patients with the appropriate genotype.
3. Development of the country's first Research Patient Ambassador. Funded from a donation by the Leverhulme Trust, this pioneering role has had significant impact not only on patient and public involvement at this Trust but throughout the country also. Keith Wilson was recognised for his contribution in the 2018 North West Coast Clinical Research Network awards.
4. A research based recommendation to modify the European Heart Rhythm Association (EHRA) symptom classification in atrial fibrillation (AF) which was subsequently adopted in the 2016 European Society of Cardiology guidelines.
5. Co-partner in the UK Lung Cancer Screening Trial - a pilot randomised controlled trial of low-dose computed tomography screening for the early detection of lung cancer. This work demonstrated that lung cancer screening in the UK could potentially be implemented in the 60-75 years age group and lead to much early surgical resection and potential cure of the disease.

Further development of the Institute of Cardiovascular Medicine & Science - We have:

- Added the University of Liverpool as the Academic Partner to LHCH
- In partnership with Finance colleagues, successfully renegotiated the aortic tariff with NHS England leading to reimbursement much more reflective of the true costs incurred

Development of Patient Reported Outcome Measures – we have a national profile with this work and are soon to report to NHS England on the utility of PROMS in elective revascularisation.

Strengthening our links with Academia – In addition to the improved relationships with local Universities (Liverpool, Liverpool John Moores and Edge Hill), we have an excellent working relationship with Coventry University and McMasters University, Canada, both as a result of the SMARTVIEW trial, due to commence in 2018. We have legacy higher education relationships

with Imperial College that predate the University of Liverpool joining ICMS as our Academic Partner.

Increasing Recruitment to Clinical Trials – Our performance to the NWCCRN recruitment targets has been met.

Disseminating Research Activity Internally and Externally – We have delivered:

- ‘talking heads’ short films focusing on the importance of taking part in research by some of the Trust’s consultants who are proactive in delivering research
- Placing of framed posters throughout the Trust showcasing the research team
- Involvement of patients with Cystic Fibrosis in the research governance process by becoming members of our Patient & Public Involvement (SURE) Group

Research Training & Development– Staff have been proactive in accessing training throughout the life of the previous strategy. Staff have been committed to attendance at trial specific training days, enabling them to share best practice and benefit from a shared approach to successful recruitment of participants, maximising available resources. Staff have also accessed and completed the cardiothoracic degree modules available in the Trust. Attendance at the ICMS symposia has also provided additional knowledge and bettered collaborative working.

Improving the Quality of Our Clinical Trials Unit – To date we have successfully delivered four in house trials; an additional two are currently in the active recruitment phase.

Improving the Outcomes of Our Research Laboratory – the laboratory are now leading some own account research whilst supporting our clinical trials activity.

Improving Research Income – a new research financial framework has been implemented which apportions payment using a more robust, transparent and fair model. This work has supported financial recovery in 2017/18 and helped deliver a break even position.

5.2 Research Activity at LHCH

LHCH is a research active organisation. The majority of research conducted at the Trust is commercially funded although there is a growing number of studies being NIHR (e.g. CASA-AF, UKTAVI trial,) funded.

Recruitment to trials throughout the lifetime of the previous strategy is shown below:

Year	Patients Recruited
2015/16	655
2016/17	919
2017/18	1020

The type of research that we are conducting is becoming more complex. As a consequence of the specialist nature of the patients we treat, there is little opportunity to participate in large cohort or observational studies. This is important when comparing performance data with other Trusts in our region.

Our research portfolio continues to be spread across all specialties in the Trust including cancer, cardiovascular disease, critical care, respiratory disease, radiology and surgery. Whilst our research portfolio is dominated by research led by medics, there is a small but significantly growing core of non-medical research led by nurses, physiologists and physiotherapists.

5.3 Innovation Activity

Previous successes in innovation include:

- The development of CareCube – an integrated catheter laboratory scheduling, status at a glance and safety checklist software suite has been implemented locally and is poised for commercialization.
- The use of Augmented Reality – interactive video clips linked to static images activated from image capture on mobile phones was used as part of the patient education in our Community based BREATHE campaign.
- An honorary position in the newly opened joint enterprise owned by the University of Liverpool and John Moores University called Sensor City. This position will bring industrial partners together with clinicians who wish to implement innovations to advance patient care.
- A collaboration on a major EU funded innovation in procurement grant which, in addition to developing a new model for the purchasing of implanted (simple) device services will develop and deploy remote follow up in patients with these devices. This work is worth approximately £800,000 in grant funding to the Trust over the next four years.
- 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 the umbrella of ICMS.
- Support for the introduction of new technology governed by the Clinical Audit & Effectiveness Group. Over the three years, many new technologies have been introduced the Trust: (Micra Transcatheter Pacing System (TPS), Extra-Corporeal Membrane Oxygenation (ECMO), Glysure Continuous Glucose Monitor, LiquoGuard 7 (Automated CSF drainage and pressure control device), Coronary Sinus reducer, Nutriseal Nasogastric tube (v2), AcQMap electro-functional EP mapping system, Right anterior thoracotomy approach for AVR, Percutaneous mitral valve-in-valve implantation using Edwards balloon-expandable TAVI device, Bolton Relay Thoracic Stent graft, Bolton Relay NBS Plus Thoracic Stent graft, custom Made Bolton Relay Thoracic Stent graft, Pulmonary Vein Isolation using Cryoballoon as first line treatment for patients presenting with Atrial Flutter, Rhythmia: High definition 3D mapping system for complex ablations, Robotic Cardiac Surgery, Robotic Thoracic Surgery, Cook's Arch Brand Stent Device, use of routine TEVAR techniques in a novel anatomical position (ascending aorta) delivered through a novel route (transapical) in selected patients with acute Type A aortic dissection turned down for conventional emergency surgery)
- 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.

5.4 Research & Innovation Resources

Resource	Amount
Head of Research & Innovation	1.0 wte
Head of Clinical Trials	1.0 wte
Research & Innovation Manager	1.0 wte
Research Patient Ambassador	1.0 wte
Research Audit Officer	1.0 wte
Research Nurses	13.2 wte
Research & IT Systems Lead	1.0 wte
Ripcord IT Systems Developer	1.0 wte
Research Admin/PA	1.0 wte

Much of our research relies on collaboration with key support services and the Research Department works closely with cardiac diagnostics, informatics, pharmacy, pathology and radiology to ensure that the Trust has the capacity and capability to set up and effectively run our studies.

5.5 Research Funding

Funding is received from the CRN to cover the costs of working on National Institute for Health Research (NIHR) adopted studies e.g. research nurses, research administrative staff and key-service support departments' research-related activities. The Trust also receives income from industry-sponsored research; the majority of which goes directly to the specialty undertaking the research, though the Research Department does retain a proportion to cover costs and for capacity building.

Our track record in winning grants has also improved over the lifetime of the previous strategy.

5.6 Research and Innovation as Priorities

As a tertiary Centre reliant upon being at the cutting edge of its services to preserve market advantage, the senior leadership team of LHCH recognise the crucial contribution research and innovation can make to the future success of the Trust. As such, in 2017, the Trust updated its vision statement to include direct reference to research:

'to be the best - leading and delivering outstanding heart and chest care and research'

As such, research & innovation has now been accepted as a strategic objective for the Trust in its own right, providing a clear mandate to ensure our services are underpinned by evaluation, learning from others, and thinking creatively to achieve advantage.

Research and innovation will however also influence the remaining four strategic objectives thus:

1. Quality & Patient Experience – better models of care or new treatments will lead to better outcomes for patients and improvements in experience
2. Finance and Best Value – better quality care is usually cheaper; achieving standardisation from following evidence leads to reduced costs
3. Best NHS Employer – staff are attracted to working in organisations that are seen as leaders in their fields of specialism
4. Partnerships – research and innovation draws upon the skills and resources of other organisations that can complement our own when delivering programs of work

6. Our Vision for Research & Innovation

By 2020/21, our ambition is that research and innovation will have directly contributed to the Trusts overall vision by the establishment of a national profile for the quality of research and innovation led from our Trust.

7. Strategic Objectives

Realisation of this vision will be evidenced from the achievement of the following strategic objectives specific to research & innovation:

7.1 Develop and Enhance New Strategic Initiatives and Relationships

The Liverpool Centre of Cardiovascular Sciences

Liverpool University will prioritise cardiovascular disease as a new strategic objective from 2018. Together with the Trust, we will appoint the first Professor of Cardiovascular Medicine ever in the history of the University of Liverpool. This development will be backed with sufficient investment to establish a small team of researchers whose physical base will be LHCH.

Liverpool John Moores University have also indicated their intent to become a strategic partner in this initiative. During 2018, they will identify funding to contribute to this partnership to establish senior appointments that can complement the strengths brought by the successful professorial candidate together with strengthening their own research plans.

Collectively, this three-way partnership will establish, by 2019 a new Liverpool Centre of Cardiovascular Sciences. The Centre will have the following three objectives:

1. Build a unifying cardiovascular research strategy for the City
2. Coordinate all cardiovascular (related) research in our health economy
3. Make a meaningful contribution to the CVD cross cutting theme of the Cheshire & Merseyside Health & Care Partnership from the implementation of the findings of cardiovascular research and innovation

Establishment of the Centre will be the cornerstone of this strategy through which all its future cardiovascular research will be implemented.

Being a leader in developing the Centre will realise the following benefits:

- Improved reputation, both home and abroad
- A route to the development of senior academic appointments not only in research and innovation, but education also.
- Mentoring and coaching for our developing researchers, both medical and non-medical
- The development of long lasting collaborations with partners within our health economy, and ultimately beyond
- Improved grant funding and publications
- Most importantly, direct improvements to clinical care for the benefit of our patients and their families

British Heart Foundation (BHF)

Together with the University of Liverpool, we have held preliminary discussions with the British Heart Foundation about sponsoring elements of the new Centre for Cardiovascular Research.

The BHF currently place most of their research funding into the six national Centres of research excellence. This is not likely to change. However, they are considering how best to leverage their care and prevention budget, and discussions held led to a suggestion that the BHF may create "Centres of Clinical Excellence" in the future. Such Centres would benefit from relatively unrestricted grant funding to advance translational research and innovation in ways that lead to direct and tangible benefits to patients. Whilst there were no promises given, it was recognised that the plans for the new Centre, together with the recognition of the investments already promised and committed, place Liverpool as an ideal place to establish such a new venture.

Comparative Effectiveness Trials

Recent changes in research legislation at the Health Research Authority⁶ now permit the comparison of established treatments with proportionate patient consent requirements and allows engagement in trials by staff without the need for GCP registration. This has significantly lowered the barriers to entry for the conduct of pragmatic trials with minimal inclusion and exclusion criteria, allowing the recruitment of high volumes of patients over relatively short periods of time and the generation of knowledge directly relevant to routine clinical practice. We pioneered this methodology with our own HEAT PPCI trial⁷.

The Trust has invested a sub-unit of the Research & Innovation function to take forward such trials (Improving Clinical Effectiveness through the Continuous Assessment of Practice: ICE CAP). ICE CAP now has a developing track record of promoting high quality research in both medical and non-medical specialties, and is committed to the initiation of three comparative effectiveness evaluations over the next three years. Principally through the identification of opportunities to standardise clinical practice, these evaluations will yield benefits to quality and finance as well as generating new knowledge.

The University of Liverpool are currently undertaking a review of the two accredited clinical trials units in the City. It is likely that the two will be consolidated into one. We will lobby strongly to establish ourselves as the foci to the advancement of cardiovascular related trials and evaluations within this consolidation, thereby complimenting the ICE CAP offer and the Centre for Cardiovascular Research initiative.

The Aortovascular Partnership

Aortic and vascular surgery share many similarities. For a number of years, our aortic surgeons have been developing relationships with their counterparts in vascular surgery at the Royal Liverpool & Broadgreen University Hospitals. Using the Centre for Cardiovascular Research as a focal point, the plan is to formally create a sub-division of the Centre for cardiovascular surgery where joint studies between aortic and vascular surgery can flourish. Colleagues will benefit from the critical mass and support brought by this major new venture from the two sponsoring Universities.

Robotics Research in Surgery

In 2017, the Trust invested in a Da Vinci robot to complement its ambition to strategically develop surgical services. One of the conditions of purchase was the development of high quality trials in robotically assisted surgery.

2018 will see the development of skill and expertise in using the robot, perfecting new models of care and the delivery of high quality outcomes. 2018 will also see the development of appropriate research protocols in both cardiac and thoracic surgery such that applications for external funding can be pursued with confidence during 2019.

Cardiomyopathies and Cardio-Oncology

Although different cardiology disciplines, these two sub-specialties share a common developmental need – big data. Both have been developed in association with our strategic partnership with the Royal Brompton & Harefield Hospital as the Institute of Cardiovascular Medicine and Science.

In 2018/19, we will develop new structures within both specialties for data collection between the LHCH, Brompton and Harefield sites. These data will be used to establish new prospective registries and / or projects which can address real world questions in these two newly emerging cardiology disciplines.

Interventional Endoscopy

The Trust hosts a regional service for interventional endoscopy. The specialty is technology led, and the evidence base is fast moving. We have a great opportunity to develop interventional endoscopy as a new priority provided the Trust can create capacity in its consultant workforce. A business case is being developed to add another Consultant Respiratory Physician to this service which would unlock the untapped potential in this area of care.

Artificial Intelligence in Radiology

Digital Healthcare is set to revolutionise the way medicine is practiced in the future. One such area of intense development is artificial intelligence (AI).

The Trust will prioritise activity in this area within Radiology. There are already emerging collaborations with IBM Watson in the identification of nodules from abnormal CT angiograms and Aidence in the identification of very early stage lung cancer. These collaborations will be built upon across the lifetime of this strategy but will not be exclusive.

Cardiovascular Imaging

The Trust is presently building a business case for purchasing a new computerised tomography scanner and a new magnetic resonance scanner. Both scanners are crucial to improving our capacity to undertake scanning as a key diagnostic tool in our research.

We have a growing reputation for participation in trials that require cardiac imaging, and with this is coming a developing pipeline of high quality trials for the future. The ambition, by the end of this strategy is to have created a small number of dedicated research sessions that can service the needs of ongoing research that utilises cardiovascular scanning.

Adult Congenital Heart Disease

The Trust will formally take on the Adult Congenital Heart Disease Service in partnership with Alder Hey, the Women's Hospital and the Royal Liverpool & Broadgreen Hospitals during 2018.

It is well established that there is a dearth of evidence about models of care in congenital heart disease⁸. We will seek to fill this gap through the conduct of high quality research, utilising the existing experience of our ICMS partners at the Brompton and Harefield who have a well-established track record in this specialty. Joint appointments are also a possibility.

Given the size of the task in taking on this service (recruitment, protocolisation, data collection and associated service developments), it is unlikely that research in adult congenital heart disease will develop until the latter part of 2019.

Community Cardiovascular and Respiratory Services

Following establishment of these services as innovative models of care, we will seek out opportunities to be involved in trials and innovations that can directly enhance the quality of care delivered.

Liverpool Health Partners

The Trust is a founding member of Liverpool Health Partners, and has committed to continuing to support the partnership for the next three years, and plan for the next five to ten years beyond. There are a small number of emerging priorities that the Trust will be supporting through this strategy:

1. The establishment of an Industrial Gateway Office – this venture will bring new commercial business to the City, enhancing our portfolio of commercial research.
2. The establishment of a Joint Research Office – this venture will standardise research management across the City freeing up valuable time to focus on the development and implementation of our local strategy.
3. The conduct of research in areas of priority – whilst these are still being finalised, we anticipate synergy between these and outputs of the clinical research review, crystallised as cardiovascular and respiratory disease.
4. The pursuit of Biomedical Research Centre (BRC) for the City – LHP has led previously unsuccessful bids. The strategic reformation of LHP has the attraction of a BRC as the ultimate prize.

Institute of Cardiovascular Medicine & Science (ICMS)

Our commitment to our strategic partnership with the Royal Brompton & Harefield Hospitals and Imperial College remains strong. Our improved relationships with the University of Liverpool and Liverpool John Moores will bring added strength.

During 2017, we have secured a much stronger financial footing for ICMS, and in January 2018, were able to appoint our first dedicated research associate, who will take up their post in April 2018. This person will have responsibility for converting the ideas generated in the ICMS subgroups who met during the 2017 annual symposium into reality.

We will further develop ICMS through seeking out and adding industrial, pharmaceutical and technology partners to the collaboration as associates, further extending the depth and range of ICMS activity.

7.2 Continued Promotion of Research & Innovation in our Existing Priority Areas

Our existing priority areas are:

- The themes adopted by the Institute of Cardiovascular Medicine & Science, currently:
 - Interventional Cardiology
 - Heart Failure (Devices)
 - Arrhythmia (Electrophysiology)
 - Aorta & Valve Surgery

although there is a recognition ICMS needs to be more flexible for the future, developing strength where it has the capability

- Respiratory Medicine
- Lung Cancer
- Cardiac Surgery
- Personalised Medicine (including genomics and the 100,000 genome project)
- Cystic Fibrosis
- Critical Cardiothoracic Care
- Cardiothoracic Anaesthesia

We will continue to build upon strength amongst medics, nurses, professionals allied to medicine, healthcare scientists and management gained from past activity in these areas by:

- Seeking out and reviewing all opportunities for participation in the non-commercial and commercially sponsored research of others relevant to our services
- Actively promoting research designed, developed and implemented by our own researchers
- Ensuring the conduct of rigorous feasibility assessment and capacity planning in conjunction with Trust clinical services prior to taking on new studies, both as part of the annual planning cycle and as our pipeline of activity develops across the year

7.3 Build a culture that promotes supports and values research and innovation activity within the Trust

Research and innovation activity will be considered as core business within the Trust and will be seen as part of everybody's job whether clinical or non-clinical.

We will pursue an increased awareness of the value of research and innovation in the Trust via:

- An annual multidisciplinary Research and Innovation Showcase presented each year to the Board of Directors. The showcase will provide a vehicle for our flagship research and innovations to demonstrate the value added to care, thereby directly complimenting the Trusts newly recast vision statement.
- Seeking out and developing a small number of Research & Innovation rising stars. The role of these staff will be to promote research & innovation across their workforce.
- Use of internal communications (e.g. Weekly eBulletin and quarterly "Pulse" magazine), team brief and our Twitter account to raise the profile of local research and innovation opportunities and recent successes, including the demonstration and celebration of the implementation of our own research into clinical practice.
- Holding an innovation workshop for clinical leads, supported by our innovation partners. The current local and national innovation landscape will be described and the Trusts priorities for innovation identified in order to better support the identification solutions for the future.
- Ensure research and innovation is included in the Trust Business Planning cycle. This will involve the Divisions in the research feasibility process to ensure good planning and communication. This will promote the benefits of research within the Divisions, breaking down barriers and ultimately positively influencing the patient's experience of research and innovation at LHCH.

7.4 Develop capacity and capability for research and innovation within the Trust

There is a need for more staff to be engaged in research & innovation and to ensure that relevant staff have the necessary knowledge, skills and confidence to carry out high-quality work in these areas. Such staff will become the research leaders of the future. This objective will be promoted by:

- Non-Medical Consultant positions – We will work with service leaders to develop new positions with formal allocated time in their working week to undertake research and innovation. We will prioritise the development and ongoing needs of these individuals to ensure their time spent on research and innovation maximises value for them and the Trust.
- Personal Development – We will seek out and promote other development opportunities linked to the strategic goal of the NWCCRN to improve research capability and capacity through the development of new Chief Investigators. These individuals will become our research leaders of the future ensuring the continuation of LHCH as a driver of research & innovation. We will also embed an enhanced career structure for research nurses, ensuring the successful candidate is supported in the development of a programme of research led by nurses or professionals allied to health. Collectively, we will move towards the protection of time for all staff groups to dedicate to the conduct of research & innovation where this can be achieved without impact to the clinical service.
- Matching well supervised higher degree opportunities to individuals. Some of our “rising stars” may wish to pursue a career in research and innovation. Through our partnerships with Liverpool University, John Moores and Edge Hill, we will seek out initiatives that provide excellence in research and innovation training for all staff together with complimenting the future needs of the Trust.
- Education and Training – we will develop (or signpost to) on-line research and innovation training, facilitating easy access and "bite sized" learning. This will provide a taster to staff who are thinking of becoming more active in research and innovation, perhaps as a prequel to starting their first position.
- We will ensure the clinical skills of research nurses are kept as up to date as their research skills. This is necessary to ensure research nurses can work autonomously alongside their clinical counterparts.
- Notwithstanding the ICE CAP initiative that removes the need for universal GCP registration prior to undertaking research, we will continue to support and ensure the completion of Good Clinical Practice training by staff members involved in, or wanting to become involved in, leading research.
- Academic Staffing – We will continue the growth of our academic staff base and ensure they receive appropriate administration support freeing them to do what they do best. This objective will be greatly enhanced by the new Centre for Cardiovascular Disease Research. This will also afford the possibility of appointing further Research Fellows to the Trust in line with the attraction of external funding.
- We will continue the support of a senior member of staff to act as the Trust “Innovation Scout”. This role has proved valuable over the past three years in developing new innovation relationships and associated opportunities.
- Including research roles and responsibilities into job descriptions of newly appointed clinical staff where appropriate.
- Devising a new rewards system for leading research linked to recruitment and income (grants or commercial).
- We will introduce a monthly Departmental led seminar programme for the Trust. This will ensure good communication within the Department about activity and opportunities but also serve as a promotional tool to all staff.

7.5 Maximise opportunities for our patients to take part in research

The Trust will offer more opportunities for patients, and where appropriate their relatives, to become involved in research to ensure that more patients are engaged in research and that there is equity of access to opportunities.

Opportunities for participation in relation to NIHR funded and commercial studies will be maximised by:

- Improving overall performance with respect to NIHR recruitment and time to target.
- Increasing awareness and capability of principal investigators to meet expectations with respect to recruitment and time to target.
- Exploring research opportunities from non-NIHR sources.
- Maintain our current high levels of NIHR adopted & commercial studies, growing where additional resources can be provided.

There is also a need to ensure that the population served by LHCH is aware that it is a research active organisation. This will be achieved by:

- Ensuring the Trust research internet pages are accurate and up-to-date.
- Supporting and participating in NIHR campaigns and initiatives which aim to encourage patient awareness and participation in research (e.g. the 'Ok to Ask' campaign').

7.6 Maximise opportunities for research and innovation collaborations with external partners

Collaboration with industry and academic partners can bring significant benefits for the Trust and its patients. These include sharing of resources, both financial and non-financial (e.g. skills, technologies), that ultimately enable more rapid translation of research ideas into innovative solutions in patient care. Consequently, in addition to and building upon our current strategic partnerships described earlier, the following will be explored:

- Potential new research partnerships within our community (such as with primary care, community care providers and local commissioners and other academic units) with a long-term aim to promote the LHCH economy for research and innovation.
- Collaboration with the CLAHRC particularly where opportunities exist to address the North West Coast's CLAHRC themes.
- In collaboration with the Innovation Agency and TrusTECH, facilitate the engagement with industry, particularly Small & Medium Enterprises who are usually willing and eager to test their new technology in real world settings.
- Over and above the significant partnership development with academia that will emerge from the development of the Centre for Cardiovascular Disease Research, we will establish honorary academic positions at all levels within the structure of the Universities that cement our contribution to education as well as research.

7.7 Identify and Implement New Innovations Likely to Benefit the Trust

The Trust will develop a strategic relationship with Red Ninja, a Liverpool based design-led technology company. The Chief Executive Officer of Red Ninja undertook a period of training in the Trust as an aspiring Non-Executive Director during 2017/18, and wishes to continue an association which is beneficial to the Trust, Red Ninja and our patients & families.

The Trust will ensure it reviews those products prioritised as part of the Innovation tariff, those that emerge from the national prioritisation exercise being developed as part of the accelerated access review and others that come to its attention as part of routine horizon scanning and network development.

In preparation for this strategy, the Trust held an innovation prioritisation exercise with the Operational Board. Thirteen innovations were identified, which fell into three broad categories:

1. New means of detecting indicators of disease captured through internet-enabled devices. Patient-generated data captured through internet-connected devices enables providers to prevent escalations of known health issues on an ongoing basis, and ideally, in real-time.

The challenge with these technologies is leveraging them in ways that are not merely window dressing, and using only the information that could change the course of clinical care and improve outcomes.

2. Developments in artificial intelligence (AI) technologies can support clinicians in making efficient, evidence-based treatment decisions. AI-based computing systems will be crucial aids in processing the ever-expanding volume of diagnostic results, patient generated data, and academic literature that will otherwise overload clinical teams, or simply go unused. AI offers a world of possibility around raising quality—using AI to better predict risk and tailor care plans to specific patients for better outcomes. The possibility of substantial gains in productivity, efficiency, and cost avoidance are also possible.
3. In order to keep pace with the evolving standard of care, providers must explore—and in select cases adopt—new clinical interventions that allow treatments to be more targeted and customised to individual patients. While many of these technologies are still far from widespread adoption, the Trust should have a general sense of where the major disruptions may come from, and how they could transform diverse parts of the delivery system—from acute interventions to ongoing care management—in the long term.

Each identified potential candidate for development, adoption and adaption will be reviewed in association with the relevant clinical and managerial team to ensure perceived benefits are likely to be realised, and any risks mitigated. Outputs from this innovation prioritisation exercise will provide an initial focus.

We will continue to support the development, implementation and commercialisation of new innovations. Future systems likely to proceed to commercialisation include CareCube, PANDA and the Trusts Clinical Trial Management System.

7.8 Performance and Governance

Managing research and innovation is the responsibility of the Research and Innovation Committee. Assurances and risks are escalated to the Trusts Quality, Patient & Family Committee via the Trusts standard exceptions report, which in turn are reported to the Board of Directors.

There is a need to ensure that high standards of performance and governance are maintained. In order to achieve this, the Trust will:

- Rebuild the annual work plan of the Research and Innovation Committee, principally to take account of this new strategy and the significant recent improvements in strategic relationships.
- Develop an integrated performance dashboard that unifies all research and innovation performance statistics, including recruitment (including the 100,000 genomes project), performance in initiating and delivering NIHR research (the PID) and Chief Executive Scorecards (issued by the local clinical research network).
- Maintain an ongoing audit of all Trust research at project level, reviewing governance arrangements and rectifying any gaps and risks identified.
- Ensure all research is conducted in accordance with the Standards of Good Clinical Practice (GCP), where necessary.
- Be subject to a MHRA inspection once every three to five years' dependent upon risks raised from previous reviews (last MHRA review resulted in relatively minor recommendations).
- Ensure growing success in the attraction of research & innovation grants, award of higher degrees and the publication of research findings in peer reviewed journals.

8. Finance

8.1 Income

Liverpool Heart and Chest Hospital receives research income from the Local Clinical Research Network (LCRN), Commercial Trials (incl. NHS funded research via the University) and from the LHCH charity.

- a. LCRN - This income stream has been steadily reducing over the last few years. In 2017/18, £435k was received to support specific posts and is matched to costs accordingly (£463k in 2016/17 and £514k in 2015/16).
- b. Charity – The LHCH Charity has supported research activities for a number of years through an annual funding allocation. In 2017/18, this was £50k (£50k in 2016/17 and £50k in 2015/16) and included £20k specifically donated for research from the Leverhulme Trust to support a “patient ambassador”. The Trustees will consider any contribution for 2018/19 in July but have previously given an expectation that the research unit should be self-financing.
- c. Commercial Income – This income comes from a variety of sources, mainly Universities and commercial companies to deliver research, undertake clinical trials or to fund specific events.

This income is recognised by the Trust as costs are incurred, rather than when it is received, and is held on the balance sheet as deferred income until required. In addition, a proportion commercial income for each trial is allocated to the Principal Investigator's (PI) fund held on the balance sheet. These monies reflect the additional time the PI undertakes outside of their clinical role, to lead research and clinical trials. These monies are used to fund conference, training, travel, visiting lecturers and other costs, essential to developing the Trust's research capability and capacity.

8.2 Expenditure

Expenditure covers all direct pay and non-pay incurred by the research unit, as well as recharges from pharmacy and radiology to cover LCRN requirements. A charge is also made to cover the capital charges and domestic costs for the buildings occupied. (In 2017/18 these charges are £29,389). No other overheads are charged to the unit.

In 2017/18, to improve the financial sustainability of the trusts research activities, the LHCH financial framework for commercial trials was reviewed; this resulted in the proportion of commercial income transferred to Principal Investigator (PI) funds reducing from an average of approximately 60% across all trials, to an average of 20%.

8.3 2017/18 Financial Performance

The financial strategy for research activities was strengthened for 2017/18 with dedicated finance support and revised framework for commercial activities. The table below shows the income and expenditure position for research in 2017/18. The positive in-year movement of £141k reflects a surplus generated on activities during the year. This is an improvement on 2016/17 when £90k was required from the research funds held on the balance sheet in order to support the unit's expenditure.

8.4 Income & Expenditure Position

	LCRN £	Charity £	Commercial £	Total Income £
Income	435,170	50,000	1,134,513	1,619,683

Expenditure	Pay £	Non-Pay £	Total Expenditure £
Cardiac Lab	61,831	17,939	79,770
R&D	562,277	31,299	593,576
Clinical Trials	398,303	445,060	843,363
Pharmacy	26,792	0	26,792
Radiology	46,793	0	46,793
Premises Costs*	0	29,389	29,389
Expenditure Total	1,095,996	523,687	1,619,683

* Capital charges and domestic costs

Note that income is matched to expenditure each year through management of deferred income on the balance sheet.

8.5 Balance Sheet Position

	Opening Balance 2017/18 £	In year movement £	Closing Balance 2017/18 £
R&D Deferred Income	436,375	69,208	505,583
Principal Investigator Funds	728,847	71,956	800,803
TOTAL	1,165,222	141,164	1,306,386

8.6 2018/19 Budget

For 2018/19 it has been assumed that commercial income will be similar to that received in 2017/18. A contribution of £20k has been assumed from Charitable Funds, which equates to the value of the Leverhulme donation. If delivered, these income levels would cover the budgeted in-year costs and the balance sheet would remain intact.

	LCRN	Charity	Commercial	Total Income
Income	402,467	20,000	1,275,777	1,698,244

Expenditure	Pay	Non-Pay	Total Expenditure
Cardiac Lab	64,494	21,571	86,065
R&D	617,575	37,916	655,491
Clinical Trials	529,295	337,660	866,955
Pharmacy	25,344	0	25,344
Radiology	64,389	0	64,389
	1,301,097	397,147	1,698,244

Points to note:

- The pipeline of research projects is approximately 6 months and so predicting commercial income levels with certainty is difficult.
- One year on, recent changes made to the financial framework for commercial activities and tight cost control has so far succeeded in improving the financial sustainability of the unit with income now covering identified costs.
- Deferred income on the balance is available to support future investment requirements and stands at £1.3m; however, £800k of this is identified against individual PI funds.
- The unit is contributing to capital charges and domestic costs but not to any other general Trust overhead. Further work is needed in order to ensure that the full costs of delivering any research activity is appropriately charged to the project and that the Trust being adequately compensated for diagnostic and non-clinical support.
- Following an internal review in 2017, it was identified that VAT on commercial income has not always been accounted for correctly. Processes have been corrected but the Trust has been required to retrospectively raise VAT invoices (going back 6 years). There is a risk that given the age of the invoices, not all will be paid, but the money will be claimed back from HMRC from the Trust. This risk is estimated at a maximum of £250k.

The Trusts current policy of accounting for research income is not compatible with IFRS 16 Revenue Recognition, which is compulsory from 1st April 2019 onwards. This accounting standard requires that income is recognised when the conditions for payment are met and not simply to match costs. We are still awaiting Treasury guidance on how this standard is to be interpreted in the public sector, but it is likely that the Trust will need consider how to manage the peaks and troughs associated with profits and losses.

9. Conclusions

The previous research & innovation strategy established Liverpool Heart & Chest Hospital as a credible research organisation.

This strategy:

1. Develops LHCH as a major player is contributing to the health needs of the City through research and innovation.
2. Recognises the importance of research and innovation for the Trusts future success, and ensures it receives appropriate management time accordingly.

3. Develops our established research strengths, and seeks new ones in accord with the Trusts clinical developments.
4. Invests appropriately in staff capability and knowledge to help keep our Trust at the cutting edge of service delivery.
5. Ensures communications are robust, allowing all who wish to take part to become involved.

10. References

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⁶ Health Research Authority, Medicines and Healthcare products Regulation Agency and the Devolved Administrations for Northern Ireland, Scotland and Wales. Joint Statement on the Application of Good Clinical Practice to Training for Researchers. Version 1.1, October 2017

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⁸ Drury NE, et al. *Eur J Cardiothorac Surg*. 2017;doi:10.1093/ejcts/ezx388