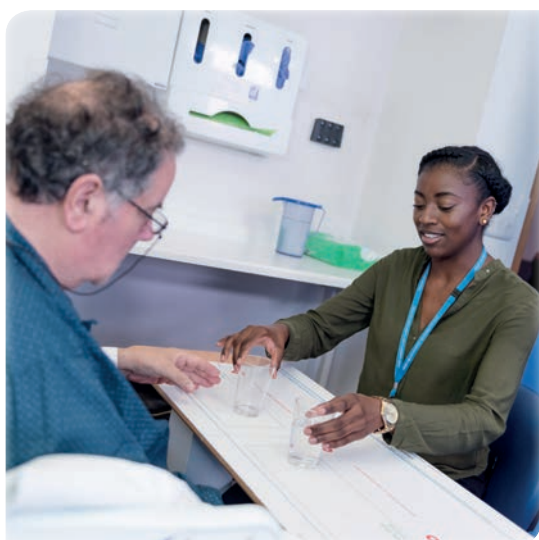
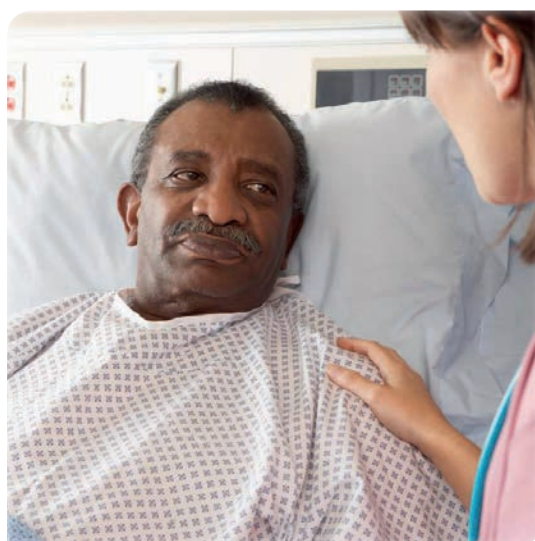


Research and Innovation Strategy 2019-2024



Excellence in patient care underpinned by research and innovation



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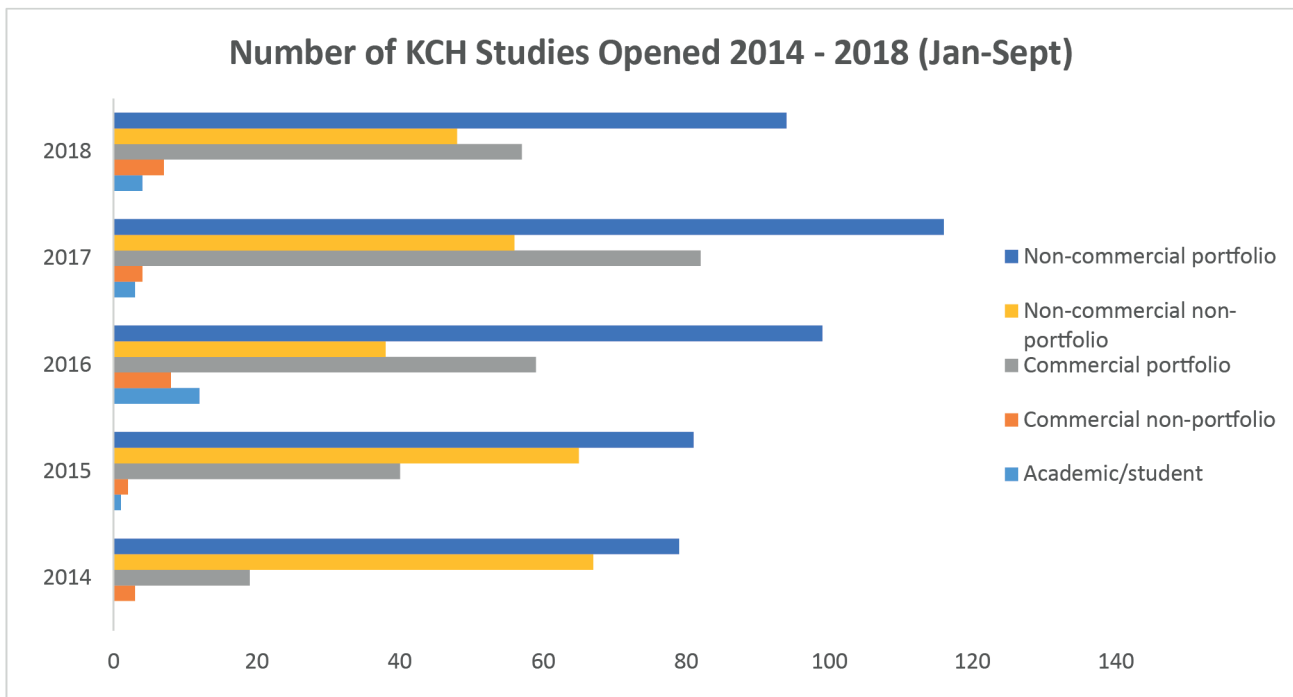
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Scope of strategy

This is the King's College Hospital (KCH) NHS Foundation Trust Research and Innovation (R&I) strategy. It links in with the Trust strategy and the highlighted clinical peaks as well as demonstrating the linkages with King's College London (KCL) and the King's Health Partners Institutes.

Research and Innovation at King's College Hospital (KCH) is ideally placed to support the Government's vision for improving the health and wealth of the nation through research and innovation. The UK Government's January 2017 green paper on a modern industrial strategy for better living standards and productivity identifies ten pillars of growth. The first of these is science, research and innovation.

With around 620 research studies being conducted across the Trust at any given time, King's College Hospital is in a position to considerably contribute to strengthening the science, research and innovation pillar of growth.



The baseline basic science profile and interests at KCH position the Trust to be a player in the “medicine of tomorrow”.

In addition, the multi-ethnic local populations in SE London and Bromley, boasting some of the world’s largest cohort databases in chronic conditions makes KCH distinctive and attractive.

Access to “the world on our doorstep” means that the Trust has the potential to research health topics of global concern.

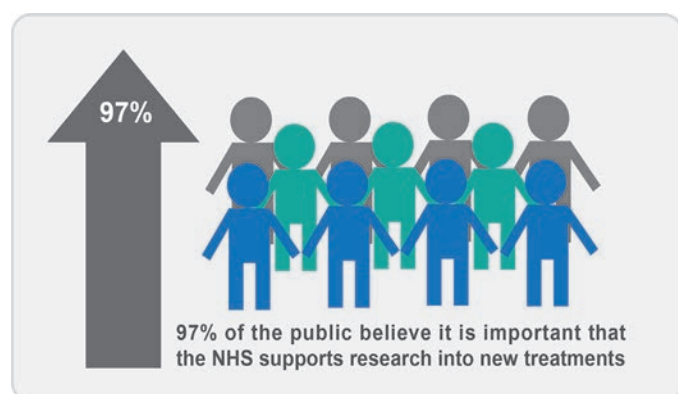
The R&D environment nationally is complex (appendix1) in terms of funding, regulators, national initiatives and issues, with a landscape that is continually changing. These areas are all taken into consideration within this strategy document.

Research relies on the close relationships and collaborations between King’s College London and King’s College Hospital, as well as other partners, and these are tightly interwoven. The aims, enablers and actions that are set out in this strategy, are nonetheless for the Trust to implement.

“The UK Government’s January 2017 green paper on a modern industrial strategy for better living standards and productivity identifies ten pillars of growth. The first of these is science, research and innovation.”

Patients at the heart of everything we do

We aim to routinely offer patients across all our clinical specialities and sites the opportunity to participate in high quality clinical research studies. 97% of the public believe it's important the NHS supports research into new treatments. ¹



There are approximately 620 research studies conducted across the Trust at any given time. Each research study is an opportunity for patients and staff to access information, advice and care, sometimes symptom relieving or lifesaving, which would not otherwise be available.

KCH make information relating to research studies readily and routinely available to all patients using the appointment and consultation processes, social media, national campaigns, literature, displays, open days and other outlets, in a regular and sustained manner.

KCH have an active and extensive community of patients and public, across all our sites, who are involved in research development, design, conduct and strategy.

Examples of patient and public involvement in research

Community for Research Involvement and Support by People with Parkinson's (CRISP)

An expert patient group formed to promote patient and public involvement (PPI). Its purpose is to raise awareness of research, highlight the importance of participation of people in clinical research, and encourage patients and their carers to ask about clinical research when with their consultant. Find out more about the work of CRISP at <https://www.youtube.com/watch?v=jERbtXASRAI>

King's Motor Neuron Disease Care and Research Centre

Advisory Group which meets quarterly via video conferencing. The group seeks patients' views on improvements to the clinical service, patient information and prospective research projects.

CASTLE Study (Changing agendas on Sleep, Treatment and Learning in Children with Epilepsy)

The research team are really committed to making sure that their research is relevant for children and young people with rolandic epilepsy, and their parents / carers. Their family consultation work aims to make sure children and their parents / carers guide the way the research is designed, carried out and shared with others.

Research at KCH could not happen without all the people who offer their time and commitment to shape and take part in our research studies and clinical trials. Being involved in research can lead to individuals who use KCH clinical services feeling more empowered, and provides a route to influence change and improve issues, which concern those most.

SWOT analysis of current R&I position

Strengths

- Diverse portfolio
- Full range; basic science, drug/device trials, translational and HSR
- Balance of commercial and non-commercial work – nationally significant activity in both
- Numerous and diverse local populations representative of NHS
- Partnerships established to develop Institutes: Neuro, Haem, Cardio, Liver, CSI, Diabetes
- Several research-focused laboratories
- Financial record
- 3yr growing recruitment and income
- Surplus for Trust from commercial work
- Performance
- Many publications – inc. high impact journals
- NIHR target performance good
- Excellent PPI record in R&I

Weaknesses

- Research-associated income lower than peers as no NIHR infrastructure – e.g. BRCs
- Sub-optimal transparency of income flows and cost coverage
- Unclear KCL Income (overheads) recovery
- Underdeveloped IP support, plan, growth
- Infrastructure in KHP / KCL
- Unclear joint strategy with KCL re academic development / appointments
- Sub-scale basic science infrastructure
- Underdevelopment
- No central on-site R&I support facility
- PRUH is underdeveloped
- Unclear prioritisation of development areas
- Links / engagement of R&I with Divisional Management sub-optimal
- Patchy R&I awareness and activity x-site/s

Opportunities


- Development Cogstack clinical analytics platform
- Genomics, cell therapy & precision medicine development in a networked approach (GST)
- Collaborations with IoPPN and SLaM on delirium and dementia
- Critical care facility for leading Euro R&I
- Build nursing and AHP research base Bromley population for translational research (OHSEL)
- Business model to increase income (esp. commercial), and margins
- Better commercial relationships and contacts
- Co-working with KCH Charity to increase funds for R&I and use them strategically
- Gain share for clinical trials with funded drugs / devices making savings for NHS (NHSE)
- More use of Wellcome CRF for commercial work
- strategic alignment with KCL school of medicine and IoPPN on KCH campus

Threats

- Static funding to NIHR by Govt. for 5 years
- Excess treatment costs coverage
- Potential removal of RCF
- NIHR strategy for Networked research
- Potential loss of CLAHRC
- Commercial competition and funding squeeze
- Research profit taken for CIP v investing in researchers
- Infrastructure and investment
- Undefined clinically appropriate R&I space
- Viapath v. KCH laboratory support for Genomics / Precision Medicine
- lack of clearly designated research labs within KCH means need for strategic direction to, and management of specialist labs to facilitate research space, clinical / academic interlinking, mentorship and development

A row of laboratory test tubes in a rack, with a blue horizontal bar below the text.

Our vision



As a world class innovator in research we will drive the development of treatments for tomorrow; cell based, clinical and surgical.

Building on our international reputation for research, through our centres of excellence, industry partnerships and academic networks we will deliver world class research across our key areas of excellence: critical care & trauma medicine, haematology, neurosciences, liver disease, transplantation, fetal medicine, metabolic paediatrics and end of life services.

We will do this to drive new and improved specialist treatments and innovations for the benefit of patients locally, nationally and globally.

Our strategic aims, enablers and objectives

Aim 1

Increase commercial and academic research activity ensuring equity of access for all patients and staff across all sites and clinical specialities.

Aim 2

Develop an Advanced Therapies and Biomedical Sciences Hub to develop / deliver therapies that are based on cells, genes and small molecules.

Aim 3

Develop a supportive Trust wide research culture including a workforce who appreciate and are skilled in the conduct and use of research and innovation outputs.

Enabler 1

Finance and financial models

Establish a financial model that is transparent and fair ensuring that capacity building elements from commercial research are reinvested in research.

Enabler 2

Partnerships

Contribute, collaborate and nurture relationships with key partners, with particular focus on the King's Health Partners Institutes programmes.

Enabler 3

Clinical R&I infrastructure

Investment in leadership, Quality Assurance, Research Governance and Contracting.

Cross cutting Enabler 4

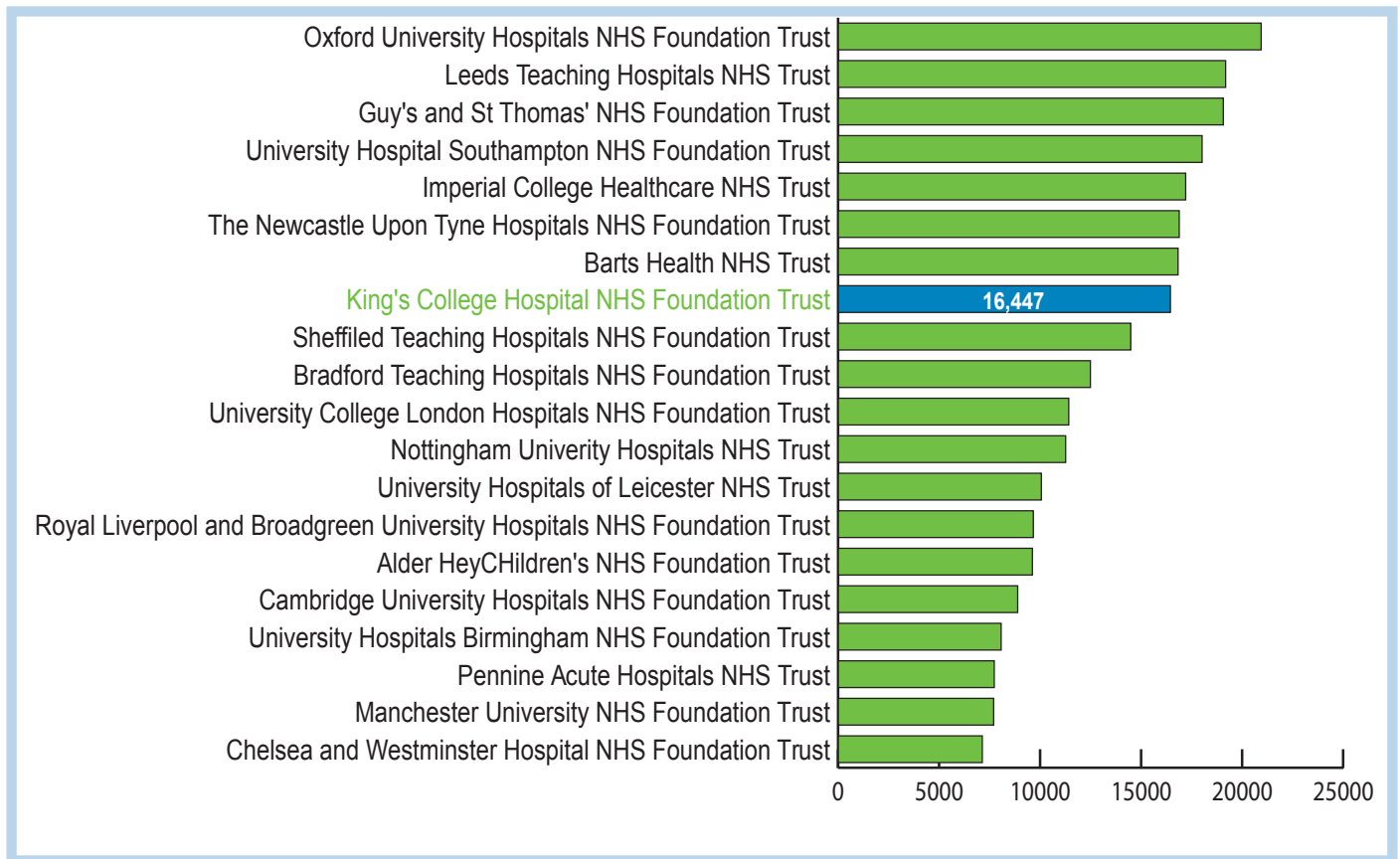
Data and Digital Innovation
Harnessing new technologies and ways of working



Aim 1

Increase commercial and academic research activity ensuring equity of access for all patients and staff across all sites and clinical specialities

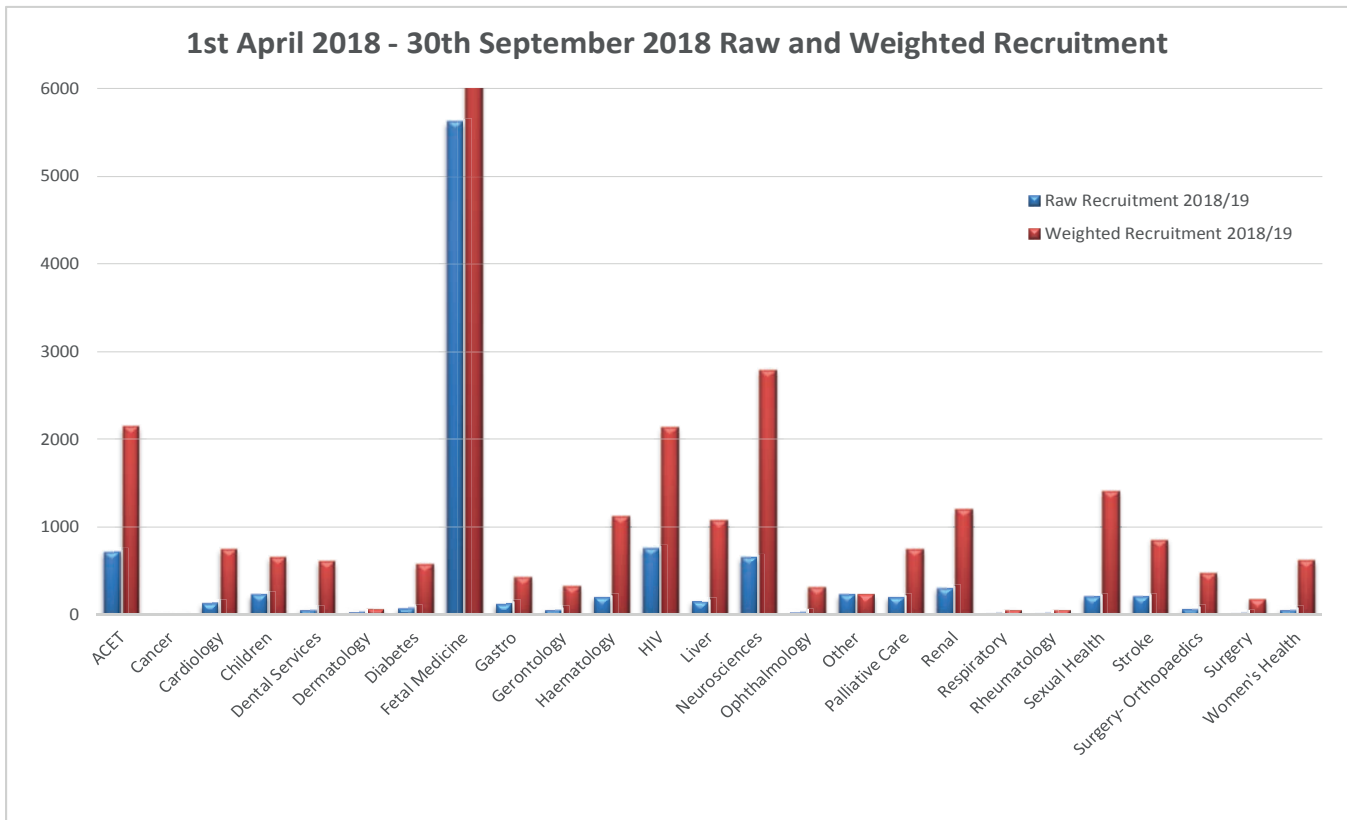
KCH are already one of the top research active trusts in the country. In 2017/18 KCH was the eighth highest recruiting trust in the UK for non-commercial portfolio studies.(NIHR league table)



All patients, regardless of their disease area or hospital, should have the right to participate in clinical research should they chose to do so. Currently, we are failing to deliver equitable access to clinical research to patients at PRUH and South Sites, with the majority of clinical research activity taking place at the Denmark Hill site. By providing infrastructure and support to PRUH and South Sites, the aim is to increase recruitment opportunities in a number of research areas.

There is considerable variation across the Research Delivery Units in terms of patients enrolled into academic research studies (further performance information in appendix 2), with opportunities to grow research across the Board. The implementation plan details how this will be achieved over the five-year period.

Funding is a major enabler to achieve this strategy and is discussed in the Enabler 1 section. The main source of non-commercial funding is from the NIHR Research Network. This is predominantly funded on an activity-based model, with funding following the number of patients recruited.

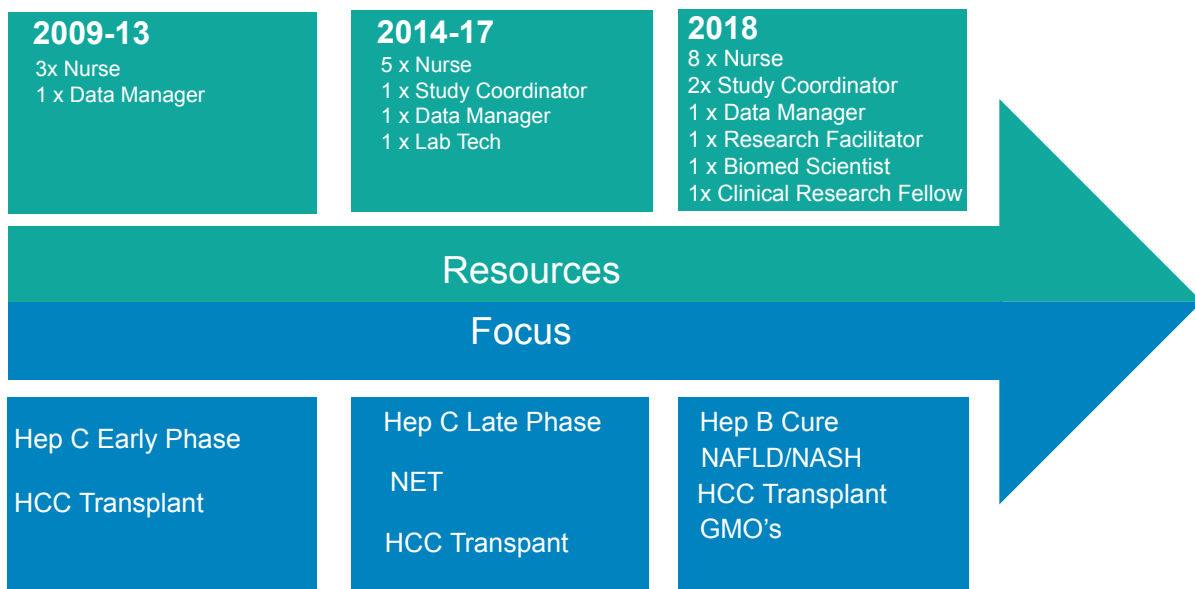


Fetal Medicine's Weighted Recruitment totals 9,675

Attracting commercial contract funding is vital to the delivery of the research strategy, having a record of accomplishment in recruiting to time and to target (see appendix 1), robust governance structures and a facilitative environment will enable KCH to maintain and grow its position as one of the major Trusts where commercial companies place their research studies.

KCH has a number of clinical peak areas, which match well to the current areas of research excellence. These areas have a mixed portfolio of commercial and academic studies and have matured into efficient and effective research groups - An example is the KCH Liver Research Delivery Unit, which has grown exponentially over the last four years and now has 12 distinct areas of interest. One aim of this strategy is to use the enablers noted on pg 18-25 to grow commercial and academic research in other key areas.

Liver research through the years

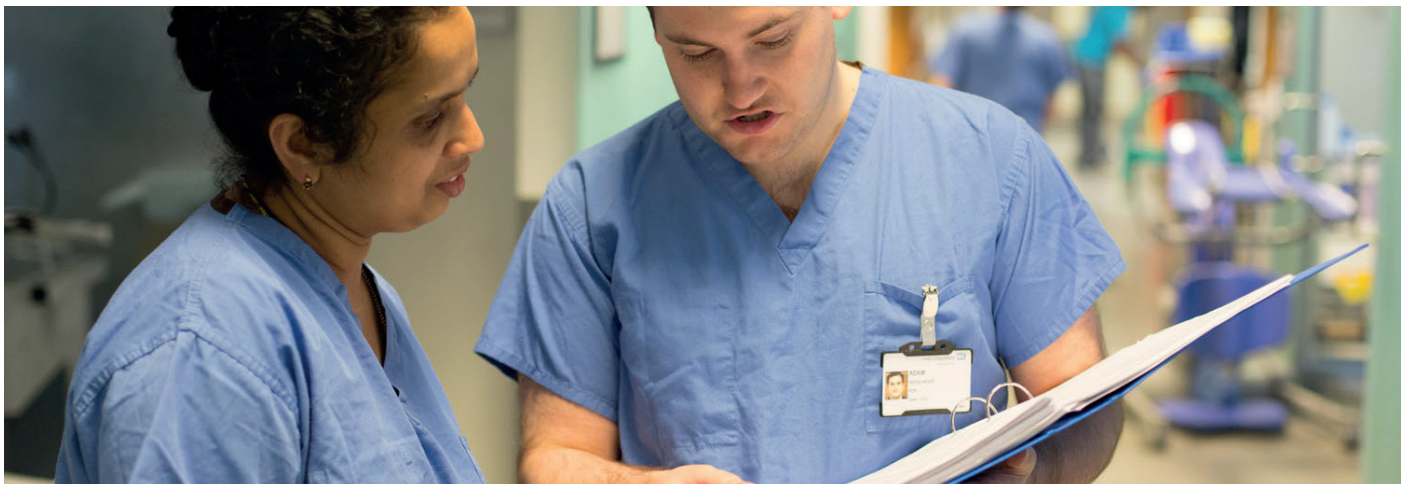


Aim 2

Develop an Advanced Therapies and Biomedical Sciences Hub to develop / deliver therapies that are based on cells, genes and small molecules

The Industrial Strategy for Life Sciences highlights the lack of current capacity for advanced therapies, and the potential for a scaling up of capabilities to deliver these to large regional populations. KCH is well placed to support the Government in overcoming these challenges.

ATMPs include allogenic or engineered autologous cells, gene therapies and small molecules. KCH has been ahead of the curve being the producer of several of these products in house (Kings Cell Therapy Unit) and in collaboration with KCL labs at the Rayne Institute. The cell therapy unit delivers both NHS funded therapies like haematopoietic stem cell transplantation for haematological malignancies, islet cell transplantation for diabetes and hepatocyte transplantation for liver based metabolic disorders and acute liver failure. This unit also encompasses viral vector production and mesenchymal stromal cell facility manufacturing products for research trials under GMP conditions. This viral vector work and the clinical grade MSC cell therapy provide opportunities to lead in Europe and beyond in the clinical and first in human studies over the next years.



Great strides have already been made on our journey scaling up capacity and capabilities to deliver advanced therapies to patients. KCH are the national leaders in delivering immune modifying therapy to patients with multiple sclerosis, and have a CAR-T cell program in haematology, dendritic cell therapy in neuro-oncology, hepatocytes and pancreatic cell implantation as examples.

The NIHR-Wellcome King's Clinical Research Facility (CRF) is a purpose-built facility to support clinical trials in mental health, neurology, general and acute medicine. The site houses high-quality experimental medicine facilities, where specialist clinical research and support staff work together on patient-orientated commercial and non-commercial studies. A key element of the KCH R&I strategy is to work closely with the CRF senior team to ensure the strategies of the CRF and KCH align (NIHR award for the CRF is to SLaM) and that this dedicated research space is optimised for KCH patient recruitment, especially in the complex experimental medicine arena.

The Cell Therapy Unit nested in the CRF positions KCH to grow genomic, cell and biologic therapies through research. The Trust is positioned to lead in CAR-T not only in cancer modifying treatments but also in conjunction with our partners, to develop and deliver innovative immune modulatory therapies in critically ill patients.

KCH capacity and capabilities to deliver across advanced therapies are further strengthened by several specialist laboratories; including unique Liver Genetics lab, haemato-oncology and neurosciences provide innovative genomic and precision medicine integrating clinical service function with research capacity and skills.

The advanced therapies programmes, which underpin the core concept of research underlying service delivery ranks among the best in the world. KCH plans to co-locate these services, as a precision and personalised medicine hub, which will allow growth and innovation in this developing field, focusing on our clinical peaks and across the life course.

Development of the hub and continued growth in this research space is reliant on the four enablers within this strategy – finance, partnerships, particularly with the relevant KHP Institutes, robust research governance and digital. The implementation plan on pg 28 details how this will be achieved over this five-year period.

Appendix 4 - Provides further information on the active ATMP areas within KCH.



Aim 3

Develop a supportive Trust wide research culture including a workforce who appreciate and are skilled in the conduct and use of research and innovation outputs

Improvements in patient outcome, experience and quality of care are all benefits derived by a Trust participating in clinical research. In addition, there are opportunities for financial gain and improved staff satisfaction within a research active organisation. A culture where clinical research is encouraged and valued provides a supportive environment for skilled researchers to conduct high quality clinical research and realise the stated benefits at pace. It will also help attract and retain the best clinical research talent – medical, nursing and Allied Health Professionals - whilst nurturing a new generation of clinical researchers.

To establish such a culture, all of our staff should understand and appreciate the value of participating in clinical research. *“Organisations in which the research function is fully integrated into the organisational structure can out-perform other organisations that pay less heed to research and its outputs.”*²

A change in the culture of any organisation must begin at the top. There is R&I representation at Board level via the Trust medical Director; a proposal for full representation for clinical research and development at trust board and trust executive committee will be made in year 1 of the strategy.

At the next level, R&I leads should provide leadership and representation within groups (usually in the context of research advisory group / governance or multidisciplinary meetings (MDM) and management meetings ensuring research is an integral part of the Trust operational management system. Currently R&I representation at these meetings is variable across individual care groups. At this operational level, the newly formed R&I Risk and Governance meetings will feed into the Trust Patient Safety Board, and a quarterly R&I report to the Trust Quality and Research Committee (QARC) will be a standing item on the agenda.

At a clinical level, R&I staff will participate in multi-disciplinary team meetings to raise the profile of research and to highlight active research studies. R&I Directors will be central players at the Trust Clinical Director’s Executive.

There will be a focus on the academic development and opportunities for nurses, midwives and Allied Health Professionals to undertake their own research with strong links made with KCL Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care. Research nurse representation will also be included within the Trust Nursing Executive Structure.

More will be done to promote the significant clinical research successes and achievements, a dedicated research communications strategy will be formulated and operationalised in collaboration with colleagues from trust communications.

Regular research metrics will be included as part of the Trust published performance reports. Clinical and non-clinical staff need to be equipped with research knowledge and skills relevant to their roles, and be empowered to use that knowledge to ensure every patient is offered the

opportunity to participate in research. This will be addressed within the new R&I communications strategy which includes a website with dedicate resource and training area, and a suite of research awareness tools.

Discussions with relevant teams regarding promoting research within the Trust induction programmes and clinical skills team, as well as face-to-face training from the R&I Leadership team and individual research teams will significantly raise the profile of research across the trust and equip staff with the relevant skills and knowledge to promote research in all areas.

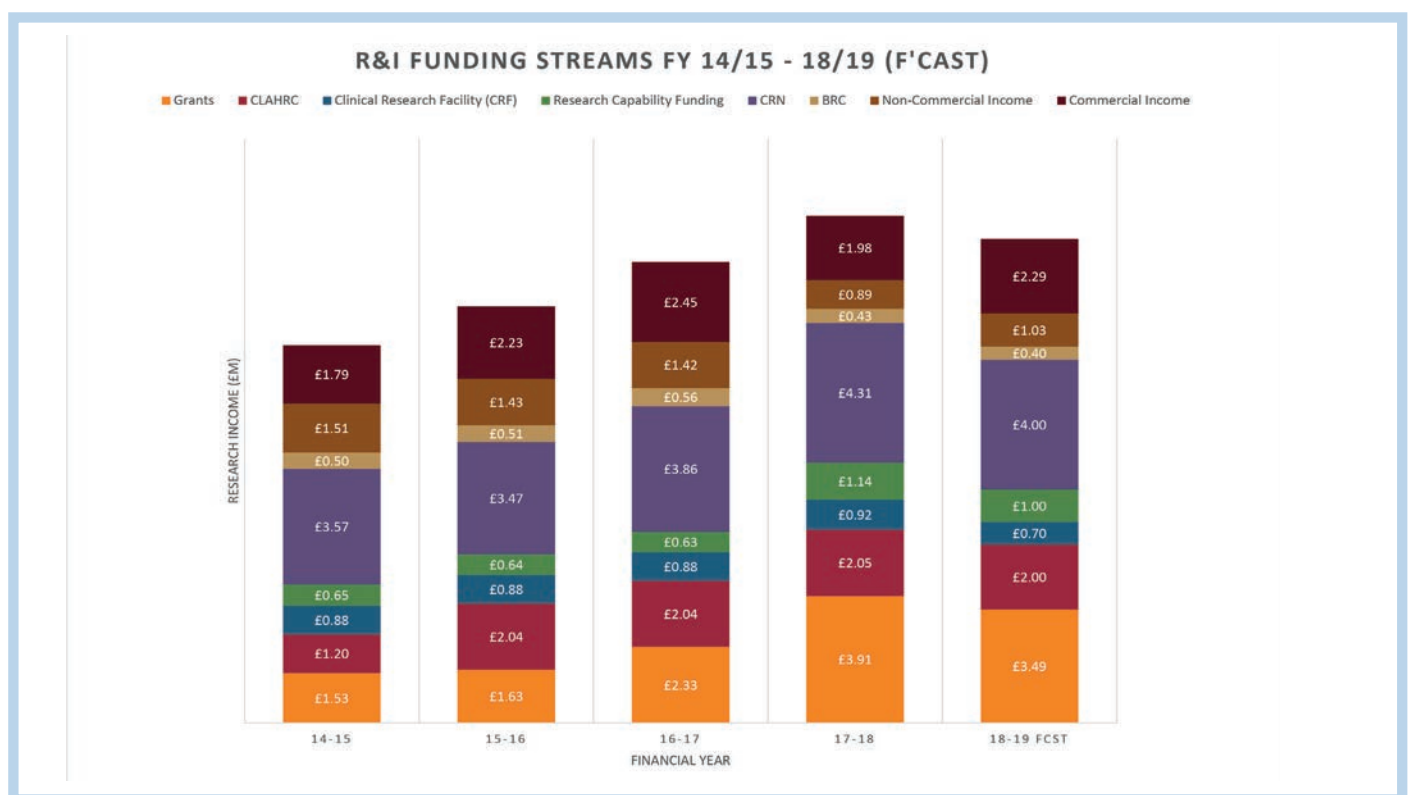


Enabler 1

Finance and financial models

Establish a financial model that is transparent and fair ensuring that capacity building elements from commercial research are reinvested in research

The significant majority of KCH income for R&I is externally generated through a variety of sources (see appendix 3 for details of the individual funding streams). Graph below demonstrates the financial income over the last five years.



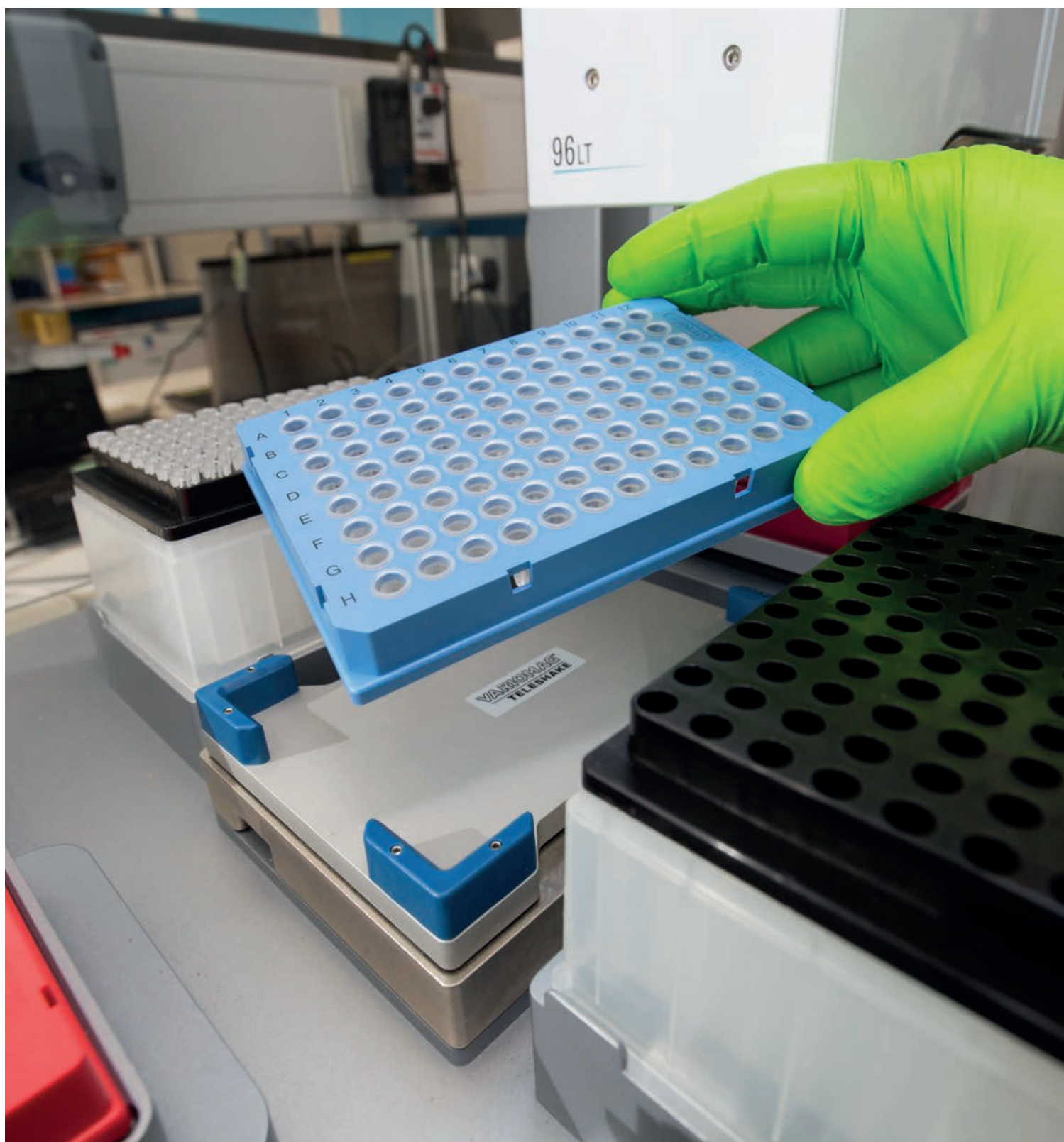
A key aim of this R&I strategy is to establish a financial model that is transparent and fair, ensuring that capacity building elements from commercial research are reinvested in the service.

Lack of transparency and control over research income has been identified by doctors nationally as one of the leading barriers to conducting clinical research³. With NHS budgets under ever-increasing pressure, there is little or no scope for large-scale investment into clinical research infrastructure from KCH. It is critical, therefore, for R&I to be empowered to become a near self-sufficient service independent of NHS budgeting restrictions and for revenues generated by commercial clinical research work to be re-invested back into the service.

It is essential for the long-term growth and sustainability of the clinical research infrastructure that a workable financial model for managing R&I non-commercial income is established and respects the eligible activities that can be funded from these income streams. KCH R&I will support the Trust commercial team in the development of IP, commercial and spin off companies, together with our KCL Partner.

A piece of work will be undertaken by the R&I Directors and R&I Finance team to review the financial arrangements related to grants where KCH patients and data are utilised, but grants are held in KCL. A system will be established with KCL for reciprocal sharing of information re all grants held that involve both organisations. This will ensure that where activity is taking place at KCH sites legitimate costs incurred will flow back to KCH.

A robust KCH R&I finance system needs to be put in place to manage the vast number of Purchase Orders and invoices now required for all research that occurs within the Trust. Currently all R&I finance staff are funded from external research sources, which limits the capacity to effectively manage this complex area. Negotiations with procurement and Human Resources around the unique way the external research funding has to be managed will be undertaken by the R&I Directors team with the aim of ensuring that funding can be spent efficiently within the financial year.



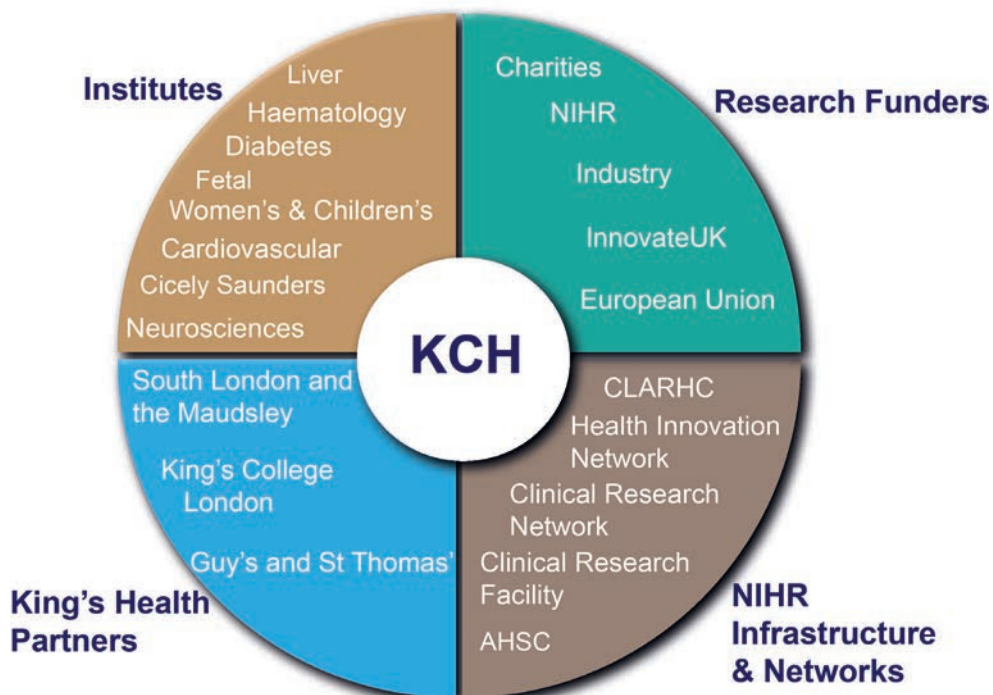
Enabler 2

Partnerships

Contribute, collaborate and nurture relationships with key partners, with particular focus on the King's Health Partners Institutes programmes

In order to realise the R&I vision, KCH needs to be part of strong and effective partnerships. These partnerships will enable us to enhance the research portfolio for patient benefit through working across organisational boundaries, realising opportunities to access a broader range of resources and expertise and providing us with a competitive advantage.

KCH Partnerships



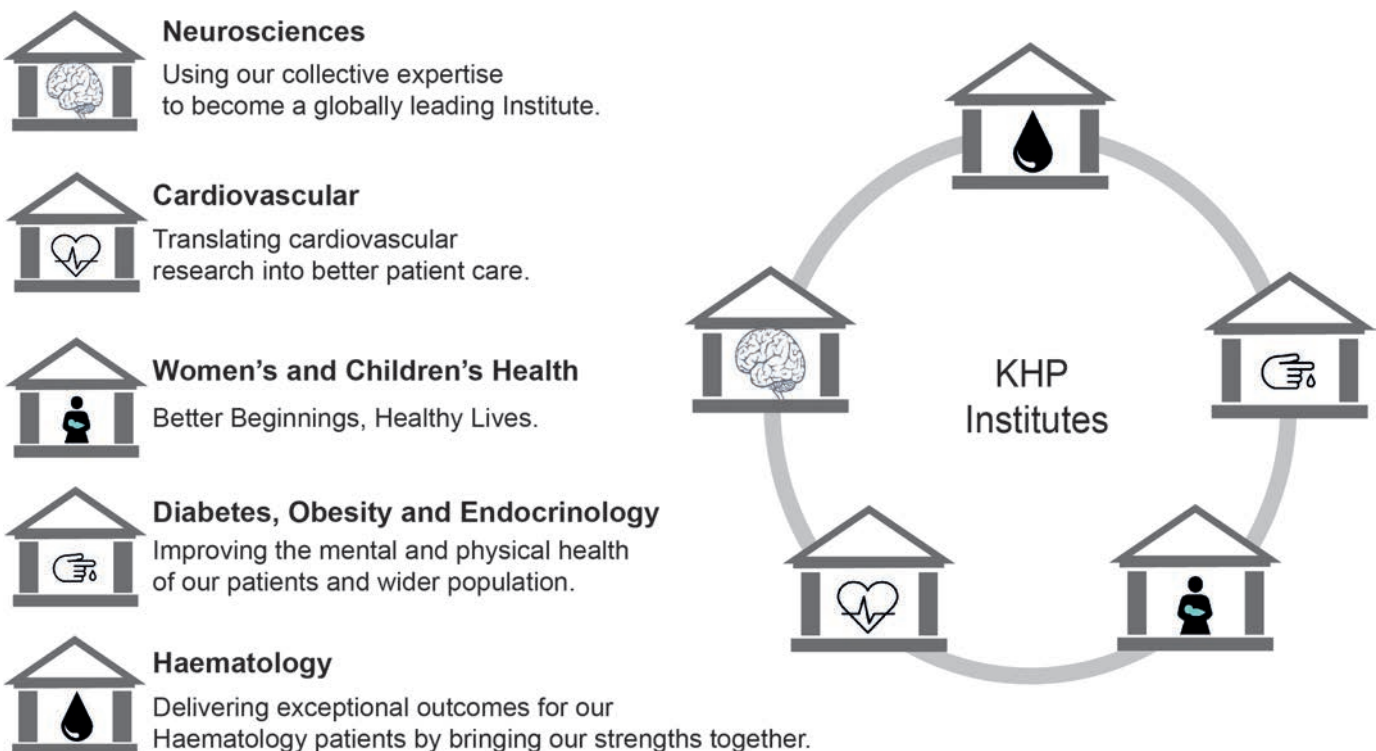
King's Health Partners Institutes Programme

King's College London, is the Trust's major research partner, and is one of the UK's leading teaching and research universities, ranked in the top 6 in the UK.

KCH is one of the four organisations within King's Health Partners, the others are King's College London, Guy's and St Thomas' and the South London and the Maudsley NHS Foundation Trust.

This partnership gives the Trust access to broad, cross-cutting networks of clinical and academic expertise. These collaborations further enable KCH to access an expanded network of cutting edge infrastructure thus enabling the acceleration of the translational research programmes from bench to bedside.

KCH has distinctive specialist areas of international calibre, reflected in the KHP Institutes programme. The Trust is fully engaged in the Institutes programmes, hosting the Haematology and Neurosciences programmes at Denmark Hill; KCH research strengths and clinical peaks align well with these programmes. There are also valuable ongoing collaborations with the Liver, Fetal Medicine and the Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation Institutes. Detailed information regarding the Institutes (Appendix 5).



Partnerships with Networks, NIHR Funded Infrastructure, commercial companies and research charities are vital. Significant research income derives from these sources, as well as a high volume of collaborative research that ultimately gives patients quicker access to new drugs and treatments.

Enabler 3

Clinical R&I Infrastructure

Investment in leadership, quality assurance, research governance and contracting

Efficient delivery and management of clinical research is a prerequisite to ensuring it is conducted safely and in compliance with regulatory requirements. Any clinical research conducted at the trust must be feasible and able to be delivered safely. To achieve this consistently, a resourced and flexible R&I central team, including robust governance, data, finance, contract, leadership and quality assurance support is essential.

A range of national legislation and policies, professional codes and statements of practice defines research governance requirements. The Department of Health's (DH) Research Governance Framework for Health and Social Care (2005) defines the governance arrangements for all research within the remit of the Secretary of State for Health. This includes those activities undertaken in or by DH's non-departmental public bodies and the NHS*. The framework describes legislation on clinical trials involving medicine and general principles of good practice for all types of research. The framework encompasses five domains: ethics; science; information; health, safety and employment; and finance.

The R&I Directors, along with the R&I governance and contracts team, are responsible for ensuring that processes are in place to ensure research undertaken complies with all regulations and is carried out safely and ethically. The R&I governance office also undertake all the checks required for KCH to sponsor a research study. The designated sponsor takes legal responsibility for ensuring that any research complies with the appropriate legislation and policy and that the necessary insurance is in place.

R&I governance facilitators work collaboratively with individual researchers and teams to ensure robust feasibility is undertaken for studies that are being proposed, and provide support and guidance to aid submission to the Health Research Authority (HRA) for ethics and study approval.

An initial restructure of the R&I governance and contracts team has taken place and increased support made available for PI's within KCH. A number of gaps have been identified, particularly in relation to Quality Assurance and audit functions. Going forward, a new full time QA Manager post will be established, with a key aim of setting up and implementing a robust risk based QA and audit programme for research.

A number of committees will be started, or further developed, and actively managed to ensure that the Trust has oversight of the research governance process and risks. These committees include:

- Research Governance and Risk Committee
- Advanced Therapies Oversight Committee
- Biological Safety Committee
- Biobank and HTA Committee

Ring fenced time for R&I Leads to undertake a leadership and governance role within their research delivery unit is vital; with each Research Delivery Unit having a robust research governance and feasibility process in place.

A comprehensive communications strategy, for both internal and external audiences, for R&I will be developed in conjunction with the Trust communications team.



Enabler 4

Data and Digital Innovation

Harnessing new technologies and ways of working

The digital revolution provides an opportunity to improve and facilitate research at all levels – national, regional and local. The new approaches to analysing data, cloud computing, machine learning and artificial intelligence are already influencing health research.

At a national level Artificial Intelligence and ‘big data’ analytics of healthcare data has been placed at the centre of the life sciences industrial strategy. The NIHR are in the process of developing an England wide digital strategy for research <https://sites.google.com/nihr.ac.uk/nihr-digital-strategy/home> which focuses on spreading the use of digital, finding the right balance of innovative use of data whilst gaining the trust of patients and the public, and increasing the transparency of organisations with initiatives. An example of increased transparency is the NIHR Open Data Platform <https://odp.nihr.ac.uk/qlikview/> provides information across all organisations at an individual study level allowing benchmarking and review of the whole portfolio to be undertaken.

At a regional level, KCH will collaborate with the London Health Data Research hub, led from KCL. The aim of the London hub is to connect healthcare and biomedical data to enable NHS, academic researchers and industry to utilise scientific information and emerging technologies.

Locally KCH have a number of key initiatives regarding data and digital innovation that will facilitate delivering this strategy.

EDGE System-This is the local portfolio management system used across London (data from this source feeds into the NIHR open data platform and is the data source for NIHR activity based funding). In addition, it supports a wide range of research management functions, which empower research managers, data analysts, research nurses, clinicians and support services to make the most of their information. Multiple institutions can collaborate on a range of projects and reporting tools can help streamline the research governance and approval process. EDGE is used at KCH by the R&I team to record the governance while setting up a study, to pull reports for performance and data analysis and by the research teams to record participant activity and to generate bespoke reports.

COGSTACK - This an information retrieval and extraction platform developed by Maudsley BRC. It implements new data mining techniques within NHS Trusts – specifically, the ability to search any clinical data source (unstructured and structured), and natural language processing (NLP) applications developed to automate information extraction of medical concepts. There is already an established COGSTACK programme within KCH that R&I will closely collaborate with. There are plans to incorporate King’s Electronic Record Research Interface (KERRI) with COGSTACK, which will allow for extraordinary interrogation of KCH electronic data sets and alignment with clinicopathological and trial ready profiles and/or response to interventions. Patients have been involved in the development of this project particularly in relation to data usage and the possibility of consent to approach for research projects. Linked to the implementation of COGSTACK is the vision for a Bioresource and bio banking facility that would be attractive to commercial partners

and academic researchers, however this is reliant on a funding source being identified to take this project forward.

In addition to COGSTACK, KCH will utilise, along with our partners, the big data constructs available through EPR and specialist databases, recognising that this will be a growth area in the future. Patient data is an increasingly valuable resource to NHS Trusts. A key piece of work to be undertaken jointly by the KCH commercial directorate and R&I is to put in place a costing structure for licences to use patient data (ensuring compliance with data protection and other regulations). This will ensure that commercial companies recognise the value of this data, whether this is for undertaking research, service evaluations, technical software development or other uses.

“At a national level Artificial Intelligence and ‘big data’ analytics of healthcare data has been placed at the centre of the life sciences industrial strategy.”



Strategic Objective 1

Increase commercial and academic research activity ensuring equity of access for all patients and staff across all sites and clinical specialties

Key Outcomes

- Consistently in the top ten recruiting Trusts in the UK for CRN portfolio studies
- Increase number of patients participating in clinical research at the PRUH and South Sites
- Increase number of staff participating in clinical research across all Trust sites
- Growth in commercial contract and academic grant income

Prioritised Initiatives

- Fair and transparent funding model in place to support delivery of portfolio and commercial research capacity building elements from commercial research to be reinvested in R&I allowing appointments in key posts to grow research delivery
- Maintain and expand key areas of clinical research excellence such as liver, neurosciences, critical care, haematology and fetal medicine.
- Identify, develop and support new principal investigators at all sites
- Funding for R&I Lead roles secured, including new lead role for PRUH
- PRUH laboratories accredited for research
- Research workforce strategy to develop AHP and nurse-led research as well as research staff trained and expert in delivering commercial and portfolio research
- Training programme and research competency framework introduced, leading to a skilled workforce fit for future delivery (clinical service and research)
- Becoming an international centre for digital endpoints in clinical trials: In line with regional (HIN), national and EU calls relating to digital delivery of clinical outcomes
- Develop and implement consent to contact policy for all research at the trust – as part of COGSTACK programme - To include automatic consent for research on stored pathological samples
- Build on pilot work identifying high active RDU's with low or poor record of running portfolio adopted studies and encourage reversal of trend.
- Seek patient input into setting of research priorities via a network of nationally accredited expert patient group in each major RDU following the example of CRISP in Neuroscience
- Development of a robust communications strategy to enable sharing of best practice and to attract industry funders
- Build on the research strengths and support development of weaknesses identified in SWOT

Key Metrics

Short term (Yr 1-2):

- > Baseline metrics for recruitment at site level implemented.
- > Increase proportion of Trust research 'in-house' studies gaining NIHR adoption
- > Transparent funding model introduced
- > R&I and PRUH clinical leadership funding secured

Medium term (Yr 3-4):

- > Recruit 18,000 plus patients into NIHR portfolio research across all sites annually
- > Top 10 position in national NIHR recruitment rankings secured
- > Increase clinical research recruitment at PRUH and South Sites by 25%
- > Increase number of grants awarded by 10%
- > Competency framework introduced for all staff delivering research – nurses, AHPs and Practitioners

Long Term (Yr 5):

- > Patient and staff surveys demonstrate equity of access to clinical research at all trust sites
- > 5% increase in income from commercial research studies
- > COGSTACK programme includes consent to approach fields for all KCH patients



Strategic Objective 2

Development of the Advanced Therapies Medicinal Products (ATMPs) and Biomedical Sciences Hub to develop / deliver therapies that are based on cells, genes and small molecules

Key Outcomes

- Establishment of clinical facilities and robust governance infrastructure to deliver ATMPs safely and effectively

Prioritised Initiatives

- Establish trust level ATMP oversight group to provide information on ATMP research and to provide expert advice to potential new investigators and collaborators
- Robust governance structure and processes in place to deliver first in human studies in full compliance with all regulations
- Establishment of robust biological safety committee (across research and clinical areas)
- Development of the ATMP Academy - to train future workforce for the development and delivery of ATMPs
- Further develop relationship with biotech/pharma to co-develop new therapies.
- Alignment of KHP Institutes and KCH R&I strategies to co-deliver shared vision
- Further develop CRF into experimental hub - with an oversight Board to agree access for priority studies
- Renegotiate role and access to CRF with respect to ATIMPs, ensuring that the facility has the right space and trained staff to undertake these activities in conjunction with KCH research teams



Key Metrics

Short term (Yr1-2):

- > Appointment of operational staff to include part time Biosafety officer, quality manager and clinical lead
Biological safety committee established and meeting quarterly.
- > Advanced therapies oversight board established

Medium term (Yrs 3-4):

- > Participate in pharma funded Clinical trials of ATMPs with the Income invested to further strengthen the advanced therapies delivery Infrastructure.
- > Agree ATMP Academy structure and deliver first ATMP annual training course by 2020.
- > 40% of CRF capacity dedicated to KCH experimental medicine studies

Long Term (Yr5):

- > Purpose built infrastructure for development and delivery of the ATMPs in partnership with pharma / biotech companies to ensure its financial sustainability
- Align IT systems to allow obtain research consent from patients/carers.
- Utilise COGSTACK for Bioresource and bio banking Initiatives
- Co location of services and labs into a central location to become the advanced therapies hub.



Strategic Objective 3

Develop a supportive Trust wide research culture including a workforce who appreciate and are skilled in the conduct and use of research and innovation outputs

Key Outcomes

- Quality Management System in place
- Research is part of Trust “business as usual”
- Research represented at all levels within KCH, from care groups to Trust Board
- Consistently meet national targets for initiation and delivery of research

Prioritised Initiatives

- Strengthen the R&I structure to optimise and sustain high quality research delivery across all trust sites - key appointment will be Quality Assurance Manager
- Identify, secure and allocate adequate office, clinical and laboratory space for both R&I governance and contracts team and delivery teams across all sites
- Establish robust systems within the research management office to ensure rapid identification and dissemination of research opportunities to research community
- Ensure national targets for initiating and delivering research are consistently met [see appendix 1 for current performance]
- Ensure robust systems for accurate central data collection (EDGE) on research performance are in place to allow production and dissemination of appropriate reports to relevant personnel
- Robust and adequately resourced contracting process in place
- Raise the profile of R&I internally and externally with a strong communications strategy, branding and marketing.
- Research is a distinct sub group (not sitting under strategy) within the Trust corporate Directorate, with senior R&I representation on all decision making committees within Trust
- Research metrics are reviewed by the Board and are part of the Trust monthly performance management reporting
- Promote and increase the understanding of all trust staff of the benefits clinical research delivers in terms of patient outcomes, quality and fiscal savings
- Work with clinical divisions and directorates to ensure clinical research is embedded into planning and delivery of routine clinical care, and is part of the Trust business planning process
- Information regarding research is part of Trust induction
- Strategy for the research workforce to be developed in conjunction with KCL Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care to ensure staff are supported regarding academic career pathways

Key Metrics

Short term (Yr 1-2):

- > QA Manager appointed
- > Quality Assurance system in place backed by appropriate suite of research Standard Operating Procedures (SOPs)
- > Consistently meet national research targets for study initiation and recruitment
- > 80% of contracts fully executed within 8 weeks
- > Tailored reports to each RDU on monthly basis to aid performance
- > R&I training programme implemented – to include competency framework for all Research delivery staff.

Medium term (Yr3-4):

- > R&I communication strategy implemented
- > R&I team housed on main Trust site

Long Term (Yr 5):

- > Research is part of Trust Business Planning process
- > Research conversation part of all senior staff appraisals
- > Research workforce strategy in place
- > Regular articles in regional and national press highlighting research successes at KCH



Abbreviations, acronyms and appendices

Nurses
Station

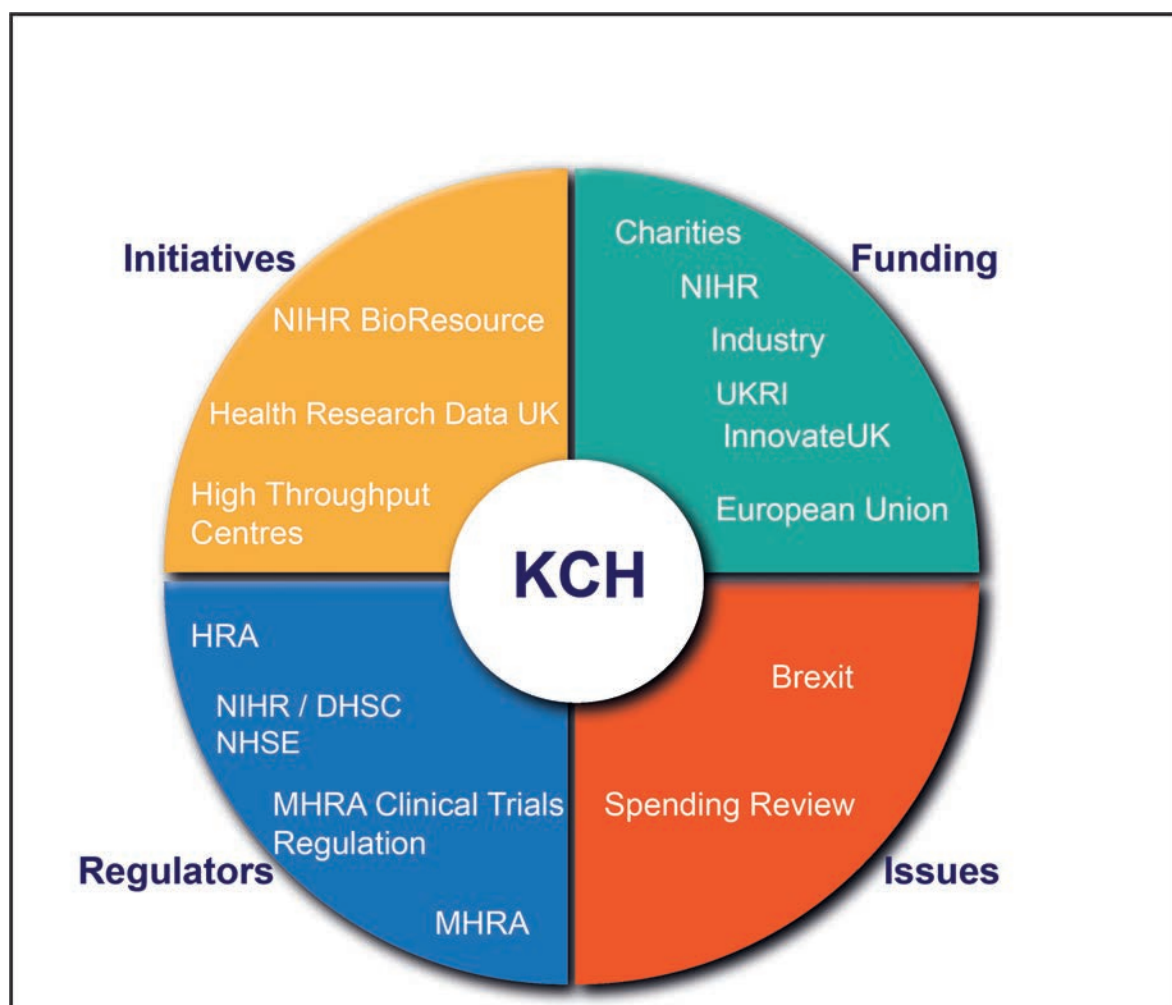


Abbreviations and Acronyms

AHSN	Academic Health Science Network
ALBs	Arm's Length Bodies
AMRC	Association of Medical Research Charities
BMJ	British Medical Journal
BRC	Biomedical Research Centre
CLAHRC	Collaborations for Leadership in Applied Health Research and Care
CRF	Clinical Research Facility
CRN	Clinical Research Network
CRUK	Cancer Research United Kingdom
CTA	Clinical Trials Assistant
HSMR	Hospital Standardised Mortality Ratio
IfLS	Institute of Life Sciences
IoPPN	Institute of Psychiatry, Psychology & Neuroscience
KCH	King's College Hospital
KCL	King's College London
KHP	King's Health Partners
KHP CTO	King's Health Partners Clinical Trials Office
KPI	Key Performance Indicator
LHS	Learning Health System
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health Research
PIN	Patient Involvement Network
PPE	Patient and Public Engagement
PPI	Patient and Public Involvement
PRUH	Princes Royal University Hospital
R&I	Research and Innovation
RCF	Research Capability Funding
SME	Small and Medium-sized Enterprises
SLaM	South London and Maudsley Hospital
SOP	Standard Operating Procedure

Appendices

Appendix 1 - Complex national R&I environment

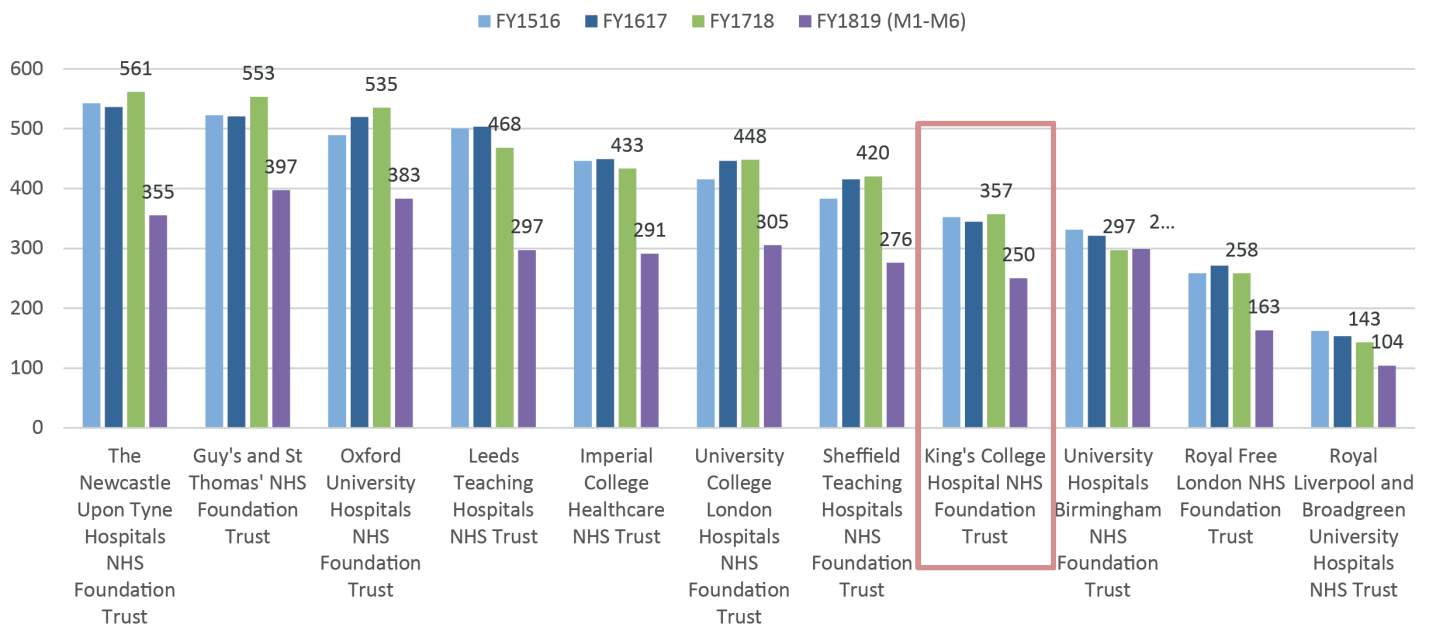


Appendix 2 - Data

National Data

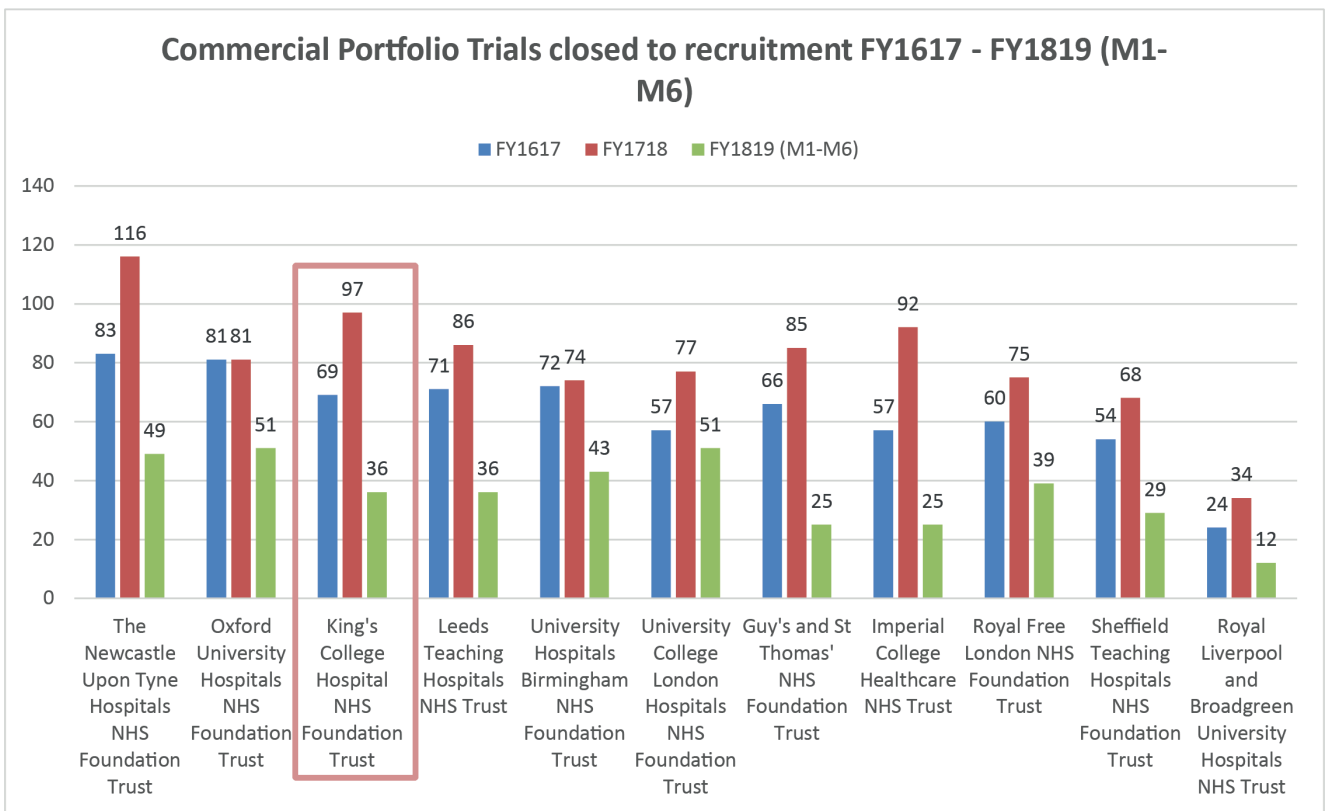
Graph 1:
National benchmarking data showing KCH 8th highest recruiting Trust in England 2017 / 18

CRN Portfolio Studies (non-commercial & commercial) - Number of studies recruiting FY1516 - 18/19 (M1-M6)



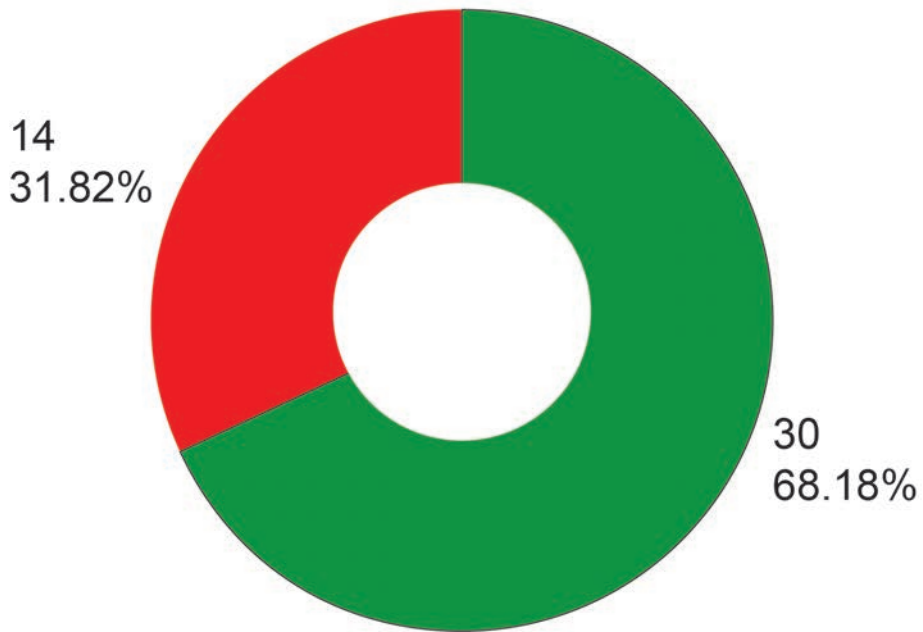
Graph 2:

National benchmarking data showing KCH closed the third highest number of commercial studies during 2017 / 18. A key metric for NIHR and Industry partners.



Graph 3:
Time and Target performance for commercial studies

Recruitment to Time and Target (RTT) Closed (in FY1819),
Non - Commercial Studies



Regional Data

Graph 4:
Portfolio recruitment in South London



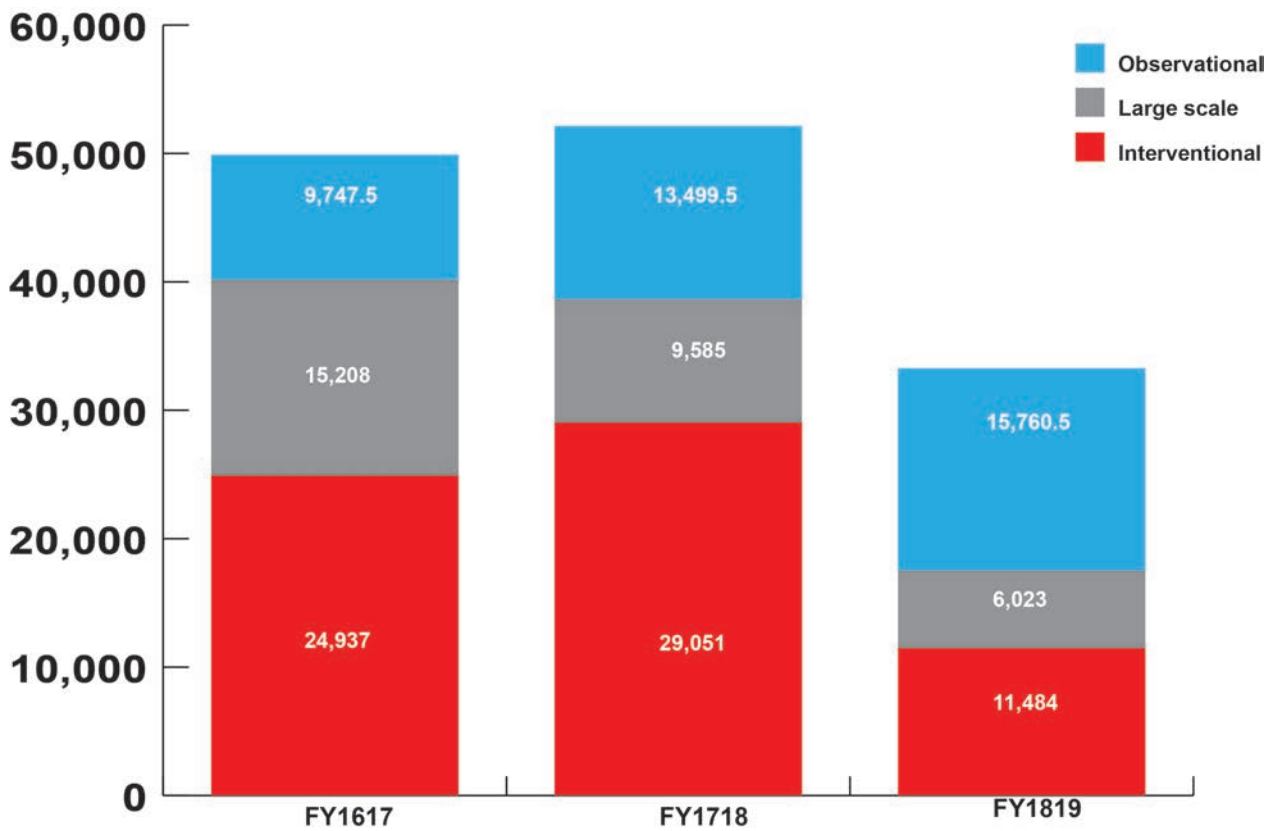
Graph 5:
Weighted recruitment in South London



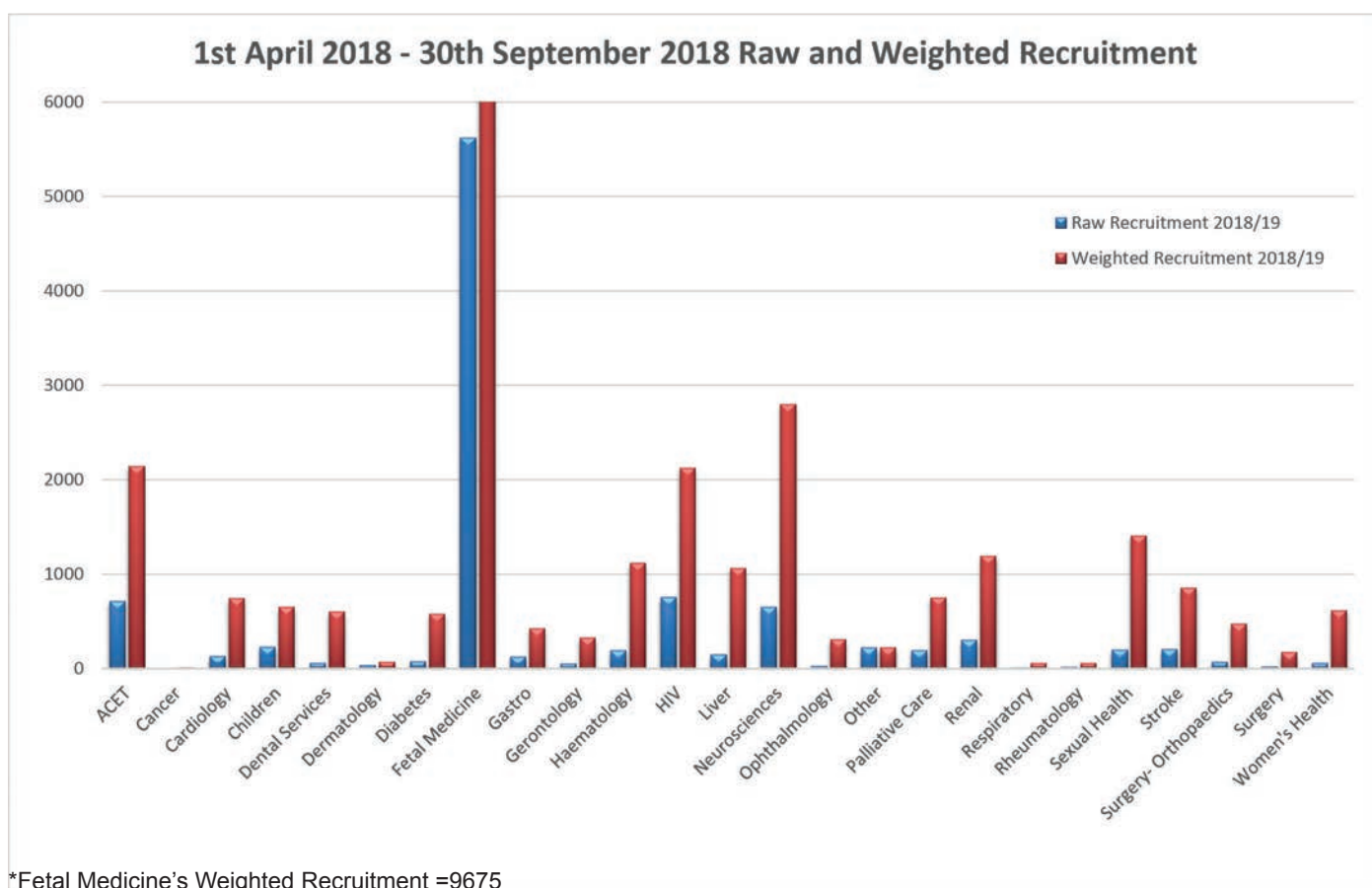
Local Data

Graph 6:

A steady increase in the weighted recruitment within KCH will ensure that the research network funding to support key research staff. Funding follows recruitment at a national and regional level.



Graph 7:
Weighted recruitment across KCH Research Delivery Units



There is significant variation in weighted recruitment across the research delivery units (RDUs). This is currently not reflected in the network funding allocations, with some areas subsidising others considerably. The introduction of a transparent funding model, which incentivises activity and ensures network funding is used only on eligible activities, should ensure a level playing field for all RDUs. The model will also provide a tool to business plan as weighted activity data is provided monthly to all RDUs.

Appendix 3 - Funding

R&I at KCH is predominantly funded from six main external sources.

Figure 1: Funding streams and totals for 17/18 and 18/19

Funding Stream	17/18 Actual	18/19 Budget	Movement Decrease (+) Increase (-)	Movement %
	£'000	£'000	£'000	
CRN	£3,907.3	£3,898.6	£8.7	0.2
RCF	£1,071.2	£1,026.1	£45.1	4.2
BRC	£348.6	£400.2	£51.6	-14.8
Grants	£6,610.3	£5,894.7	£715.6	10.8
Super Surplus	£594.2	£600.0	£5.8	-1.0
PI Accounts	£2,873.6	£3,379.5	£506.0	-17.6
Sub total - External	£15,405.0	£15,199.1	£205.9	1.3%

Grants – Grants are awarded competitively and are held by the Chief Investigator. Funding is agreed over a set number of years for staff and non-staff costs. The vast majority of grants are held in KCL, however NIHR insist that certain grants such as Research for Patient Benefit are held within the NHS. Any underspends are required to be returned to the funder once grant completed.

RCF (Research Capability Funding) - Annual award to research active Trusts in proportion to the total amount of other NIHR income received by that organisation, and the number of NIHR Senior Investigators associated with the organisation. Funding pot nationally has reduced over last three years and expectation is that funding will continue to decrease. Third of KCH RCF is related to CLARHC and is passed directly to the CLARHC Director for distribution. Underspends are required to be returned annually to NIHR

BRC (Biomedical Research Centres) – KCH participates in a number of themes within the GSTFT and SLAM BRCs. Funding is provided predominantly for staff costs for these themes - funding on actual costs incurred, so breakeven position at year-end.

PI accounts – Individual accounts mainly containing commercial contract income with a small number of non NIHR grants also included. Research staff are often employed through these accounts to work on contract commercial studies. A piece of work to review these accounts and ensure they are fit for purpose will begin during 2018/19.

Super Surplus – R&I overhead from commercial contract studies carries out on KCH premises and utilising KCH patients and data. For the first time in 2018/19, this has been reinvested in R&I to support PA time for R&I leads and fund some key posts in Quality Assurance and Audit and research management. Funding is dependent on the profit generated from commercial studies and flows back to the KHP partners dependent on activity.

CRN (Clinical research Network) – This NIHR funding source is currently based on recruitment activity to non-commercial NIHR portfolio studies. There is a national model where recruitment numbers are “weighted” as a proxy for complexity.

The following weightings are applied as a ratio (funding pot has not increased for eight years, so funding is redistributed dependent on overall performance)

- 1 point- observational studies with a sample size nationally of more than 10,000
- 3.5 points for observational studies
- 11 points for interventional studies

The funding model within South London flows funding to research active trusts using a model that is refreshed each year but currently is based on weighted recruitment with no caps and collars.

KCH CRN Funding Distribution 2019 / 20



Top slices

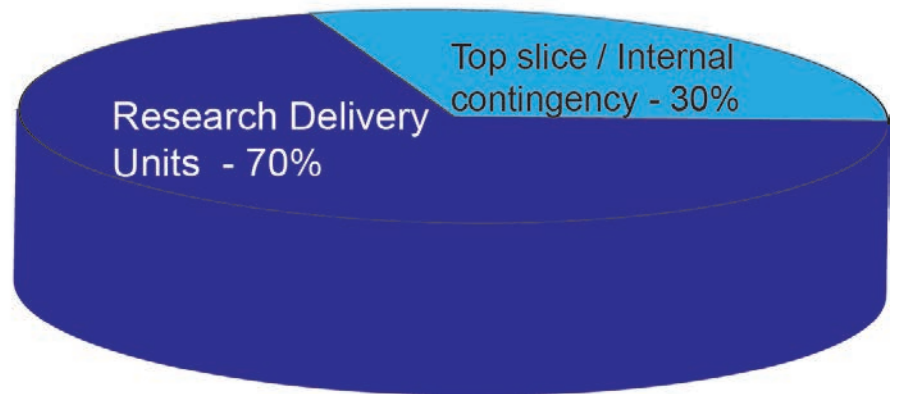
- > R&I Governance and Contracts Team
- > Trust Overhead - 8%
- > Information Team
- > R&I Finance Team
- > Key service support
- > Management and administration

Other sources of funding for research

- > Commercial
- > RCF
- > Grants
- > CRN Contingency



Activity based funding to Research Delivery Units
2 years average
1:3, 5:11 weighted allocation
5% cap and 10% collar
£250K internal contingency fund



For the first time in 2018 / 19 KCH will implement a transparent funding model that flows funding down to RDU's based on activity thus incentivising teams to perform. There is a 5% cap and 10% collar on this model as funding was not previously distributed based on activity.

Appendix 4 - Active ATMP Areas within KCH

Haematology- CAR-T cells and others are increasingly been introduced as either licenced products or as clinical trials. We aim to be preferred providers for the pharma for clinical trials as we have the right patient population in our clinical practice and the necessary expertise for delivering ATMPs trials in a safe and regulated environment.

Gene Therapies-This group has produced a range of Advanced Therapy Investigational Medicinal Products (ATMP), including the largest number of viral vectors for regulatory approved clinical trials in Europe. The production of these cell and gene based therapies on such a large scale has led to a large number of collaborations with multiple centres in UK and Europe, including several high profile clinical trials here at KCH. The latter include, for example, two immune gene therapy studies in patients with acute myeloid leukaemia, several CAR-T cell based therapies for a range of haematological malignancies and dendritic cell based vaccination for treatment of glioblastoma. The continued expansion of cell and gene therapy at KCL / KCH, enabling the production of ATMPs, will continue to underpin the development of such ground-breaking cell and gene therapy based clinical studies at KCH.

Islet cell therapies – King’s is the first and the oldest Islet cell transplant facility that provides treatment for diabetes patients at Kings and at other sites by exporting high quality Islet cells. The group is ideally placed to carry out clinical trials using islet cell containing implantable devices and stem cell derived islet cells.

Mesenchymal Stromal Cell therapies - Mesenchymal group is based at Denmark Hill campus in the KCH cell therapy unit provides MSCs for clinical trials in UK for example GOSH and NIHR clinical trial on MSC co transplantation with hepatocytes for the treatment of acute liver failure , a world first study.

Human Hepatocyte Transplantation - We have been world leaders in providing hepatocyte transplantation for metabolic liver disorders and acute liver failure. The world first use of micro encapsulated human hepatocytes on named patient basis has led to a NIHR funded clinical trial to study this therapy further. The group has also been awarded funding by MRC to improve the engraftment of hepatocytes for metabolic disorders. The group is working on a commercialisation plan in collaboration with KCL Commercialisation Institute

Neurology - King’s hosts the largest programme for infusion therapies in Parkinson’s disease in the UK with several international clinical CRN based studies underpinning the clinical service.

Appendix 5 - Research Institutes

King's Health Partners Institutes programmes

We are fully engaged in the Kings Health Partners Institutes programmes, hosting the Haematology and Neurosciences programmes at Denmark Hill, and our research strengths and clinical peaks align well with these programmes.

The KHP Haematology Institute has a very strong portfolio of internationally leading research, among the top 10 in the world, and will be hosted at Denmark Hill. Across King's Health Partners there are currently nearly 200 clinical trials under way across all trial phases and covering all aspects of benign and malignant haematology. Sixty-seven of these studies have required KCH R&I support for governance and contracting as they involve KCH patients and over 770 haematology patients have been involved in haematology studies over the last 2.5 years. KCL have recently submitted a bid to UKRPIF for capital to support the Stage 1 Institute build, providing the research component of the planned global haematology institute.

In KHP Neurosciences, substantial research accommodation is hosted at Denmark Hill site. The Maurice Wohl Clinical Neuroscience Institute (the Wohl), which opened in June 2015, provides 6,500m² of state-of-the-art neuroscience laboratory space and translational research facilities. Since 2014, academic neurosciences across the campuses have been organised in a single Division of Neuroscience, which is the second largest academic neuroscience department in the UK. The aim is to continue to achieve and exceed global benchmarks for excellence, through better connecting academic research with clinical strengths in neurosciences, as well as with key related areas including psychiatry, trauma, and cancer.

In KHP Cardiovascular, KHP is at the international forefront in several fields of research, notably basic science discovery, heart failure, inherited heart disease, and the use of novel biomarkers for personalised precision medicine and imaging. Denmark Hill hosts the British Heart Foundation Centre of Research Excellence within the James Black Centre and the Institute aims to be a global leader in cardiovascular research and innovation, reaping the benefits of collaborative working across services and sites. Fifty-eight cardiovascular studies requiring access to KCH patients have been open in the last 2.5 years, resulting in 678 patients being recruited to these studies. Over twenty of these studies were commercially sponsored.

In Women & Children's we contribute our strengths in fetal medicine, paediatric respiratory physiology, children's liver disease, paediatric allergy, and women's health. The Variety Children's hospital is one of the very few children's hospitals in the country that have basic science laboratories available to its researchers with a dedicated space for clinical research team and access to clinical trials unit. International peaks are in the fields of hepatocyte transplantation, clinical trials of gene therapy, neonatal and respiratory medicine, neurosurgery and haematology. Variety Children's hospital researchers are key partners in the newly established Women's and Children Institute by KHP and has been awarded first of the PhD studentships from this institute. There have been fifty-two research studies within the Children's portfolio in the last 2.5 years, with close to 700 KCH paediatric patients participating in these clinical studies.

Fetal medicine is the major recruiter to CRN portfolio studies through the Fetal Medicine Research Institute and the fetal medicine continues to lead the world in new and novel techniques to treat foetal defects and introduce new diagnostic tests for the early non-invasive detection of foetal anomalies. Fetal medicine studies have recruited over 30,000 patients to non-commercial research studies over the last 2.5 years. Significantly more than any other research delivery unit.

The KHP Diabetes, Obesity and Endocrinology programme encompasses a number of distinctive academic international strengths across the spectrum of diabetes and obesity research with clinicians and researchers across sites contributing to the substantial and high-impact research outputs. The Institute aim is to build on these successes with an aspiration to be a major UK centre in the field of diabetes and obesity research. Key links on the Denmark Hill site are with work on surgical cures for diabetes (metabolic surgery), understanding metabolic liver disease, islet and gut physiology, islet transplant, cell replacement and transplant. Six hundred patients have been enrolled in diabetes studies since January 2016.

Cicely Saunders Institute of Palliative Care, Policy and Rehabilitation is the first purpose built institute for research into palliative care. The Institute brings together academics, healthcare professionals, community organisations, patients and carers in one centre and acts as the hub for a network of international research. It offers high quality palliative care solutions to patients, as well as providing education, patient information and support. Current research priorities for the DH relate to primary and social care, long-term conditions and multiple morbidities, as well as a drive to ensure research is carried out where the patients are based. Many of the patients recruited into palliative care studies are in hospices or at home, the R&I office assist with navigating the complex governance required to undertake research in an independent provider setting. The South London CRN provide two full time palliative research staff, outside of the core funding allocations to Trusts in recognition that most of the research is not carried out on trust premises.

The Foundation for Liver Research, London was founded in 1973 and has supported research programmes into liver disease for more than thirty years. In June 2016 the Institute relocated to a new facility on the Denmark Hill campus of KCH as part of an agreement with KCL and KCH to maximise the opportunities on campus for clinical translational research into liver disease.

