King's College Hospital
NHS Foundation Trust

# Research & Innovation Strategy:
## One year on

**Excellence in patient care underpinned by research and innovation**

Dear Colleagues,

**Welcome to the 2020 Annual Research Strategy review produced by the Research and Innovation (R&I) team at King's College Hospital (KCH).**

R&I is one of KCH's defining characteristics. It is a central part of the offer of research that underpins quality care, a core principle of the NHS that we make to our patients and their families, and our staff. The Trust-wide R&I five year Strategy was published in April 2019 and significant progress has already been made in meeting the three main aims:

**Aim 1** - Increase commercial and academic research activity ensuring equity of access for all patients and staff.

**Aim 2** - Develop an Advanced Therapies and Biomedical Sciences hub to develop and deliver therapies that are based on cells, genes and small molecules

**Aim 3** - Develop a Trust-wide, supportive research culture including a workforce who appreciates and are skilled in the conduct and use of research and innovation outputs.

This review, 'One Year On', aims to highlight some of the exciting research achievements made by KCH over the last year. This includes recruiting over 19,000 patients into research studies or trials during 2019/20, making KCH the second highest recruiting Trust in the UK.

In the past year, patients have had the opportunity to participate in 835 studies across 30 different research-active specialties within the Trust. Commercially, KCH has also had a successful year, with over 320 patients enrolled into 74 trials sponsored by and partnered with stakeholders such as industrial pharmaceutical companies, generating income exceeding £15.8 million. Innovations have included support in the form of the "Breaking the Boundaries" programme for emerging NHS researchers, consolidation of our Trust-wide PPI programmes as well as high esteem factor publications and grants.

This encouraging performance has only been possible due to the hard work and dedication of the Trust's clinical researchers and research teams, as well as the R&I support staff who handle governance, finance, data, quality assurance and contracts related to research. We would therefore like to extend our considerable thanks to these teams.

Kind regards

Professor K. Ray Chaudhuri
Director of Research & Innovation

Ann-Marie Murtagh
Director of Research & Innovation, Head of Nursing

Professor Anil Dhawan
Director of Research & Innovation

# Contents

# Aim 1

The first aim of the R&I strategy is to increase commercial and academic research activity, ensuring equity of access for all patients and staff.

## Here, we show what we have accomplished in order to achieve this aim, and showcase research from around KCH that highlights this.

- ✔ Consistently be in the top ten recruiting Trusts in the UK for Clinical Research Network (CRN) portfolio studies.
- ✔ Put a fair and transparent funding model in place to support the delivery of both portfolio and commercial research.
- ✔ Funding for R&I Lead roles secured, including a new lead role for the Princess Royal University Hospital (PRUH).
- ✔ Exhibit growth in commercial contract income.
- ✔ Agree routes, and publicise, for all research contracts
- ● Implement data mining platform Cogstack and the electronic records interface KERRI for research purposes

# Stroke

## KCH's stroke research has increased commercial and academic research activity over the past year, reflecting the key aims of the R&I strategy. The portfolio currently consists of 15 studies that cover the entire continuum of care while ensuring equity of access for all patients.

The stroke research team at KCH is currently recruiting for an exciting pilot trial called PROHIBIT-ICH. Sponsored by University College London (UCL), PROHIBIT-ICH aims to prevent blood pressure-related injury after intra-cerebral haemorrhage (ICH), a highly fatal type of stroke which accounts for 10-15% of all strokes in the Western world.

The main objective of PROHIBIT-ICH is to determine whether frequent blood pressure measurements, using novel technology that sends readings automatically to the UCL's research team via Bluetooth (called "telemetric" monitoring), can be used to safely guide medication alteration to intensively lower blood pressure, reducing damage to the small blood vessels in the brain after spontaneous ICH.

KCH has recruited six patients to date, making them the most active recruiting site for the trial. KCH's stroke research team hope to build on this recruitment success in the year ahead, with the aim of paving the way for new and innovative treatments that improve patient care in the future.

*The Stroke research team*

# Neuroradiology

## In April 2019, the Neuroradiology team at KCH and researchers at King's College London (KCL)'s School of Biomedical Engineering & Imaging Sciences launched the MIDI study.

This exciting collaboration and National Institute for Health Research (NIHR) CRN Portfolio study aims to train and test a computer algorithm via Deep Learning in order to detect abnormalities in head MRI scans faster and more efficiently than current methods.

If successful, this innovative new method could allow us to faster identify and prioritise those with abnormalities, in turn reducing diagnosis times and improving patient outcomes.

Over five years, they aim to recruit over 30,000 patients undergoing head MRIs: in the past year 700 participants have been enrolled at KCH, Guy's and St Thomas' NHS Trust and St George's University Hospitals NHS Trust. Due to its clinical potential and relevance, the team are hoping to expand and create national collaborations. Using these partnerships, they hope to both achieve the study recruitment target as well as embed and develop a clinical research culture within NHS radiology departments, paving the way for improved patient care and further imaging research.

**"This system is designed to bring any abnormality to the front of the queue for reporting and improve patient morbidity and mortality rates."**
Dr Tom Booth, Consultant Neuro-radiologist at KCH and MIDI study lead.

*Consultant Neuroradiologist Dr Tom Booth and post-doctoral researcher Dr David Wood analysing King's College Hospital Trust patients' brain scans.*

# Gerontology

## Since the launch of the R&I strategy in 2019, the Gerontology Research Delivery Unit (RDU) has increased their collaboration across the different sites in the Trust. To support this, the team have been holding regular RDU performance and governance meetings at the PRUH.

Further increasing their multisite collaboration, the Gerontology team have been recruiting to two observational studies spanning Denmark Hill, the Princess Royal University Hospital (PRUH) and Orpington. Called DLBgenes and ADgenes, the two studies aim to reveal genetic factors associated with certain types of dementia. To do this, they are recruiting people with either Alzheimer's disease or dementia with Lewy Bodies (DLB) as well as a member of their family. The team will then take blood or saliva samples and analyse their DNA and look for genes which could explain the development of these conditions.

Additionally, the team have recently opened an interventional trial evaluating the potential effects of a new drug on agitation in dementia. Agitation is a very distressing symptom of dementia yet there are very few safe pharmacological methods to treat it. This study is recruiting from Orpington and is thought to be the first clinical trial of an investigational medicinal product (CTIMP) to operate from Orpington. Study lead Dr. Nike Dare and her research nurses Shaula Candido and Fabio Speranza - as well as the pharmacy team at Orpington - have worked very hard to make this happen and the team looks forward to the preliminary results.

# Renal

## The Renal research team is made up of 14 research delivery staff who support lead researchers from Renal, Urology and Diabetes teams across KCH. In 2019-2020, the Renal Research team ran 25 commercial and 20 non-commercial NIHR portfolio studies.

A key success from the Renal team was the completion and positive results from the trial of certain type of drug could improve renal and cardiovascular health in people with type 2 diabetes. Called CREDENCE, the trial showed that 100mg/day of the drug canagliflozin reduced the risk of end-stage kidney disease or death by 30%. They are now investigating the renal and cardiovascular health benefits of similar drugs in two other clinical trials.

For 2020-2021, the team hope to get 13 studies, that are currently in set-up, up and running. They shall also continue to work closely with the Urology and Diabetes Foot Ulcer team and help deliver their studies to completion and also to grow their portfolio. The team will also be looking to reactivate their research activity at the PRUH site and will work across sites once again.

*The Renal team*

# Renal Exercise and Rehabilitation

## Led by Consultant Nephrologist Dr Kate Bramham and Renal Consultant Physiotherapist Dr Sharlene Greenwood, the Renal Exercise and Rehabilitation team is committed to raising the research profile of the department as evidenced by its growing research activity and output year on year.

In the last year the Renal Exercise and Rehabilitation team have had two multicentre studies funded by Kidney Research UK: the now-completed PEDAL study, which was investigating the potential benefits of exercise in between kidney dialysis session for those with chronic kidney disease, and the ongoing Iron and Muscle study which is looking into the potential benefits of iron supplements on a person with kidney disease's capacity for exercise.

Dr Bramham has also paved the way for the setting up of five new NIHR portfolio investigator-led studies with KCH as lead site that address various issues within renal research. For example, the recently completed RADAR-ANCHOR study focused on creating and maintaining a detailed clinical database to facilitate research into rare kidney diseases, whereas the COAG-KD study, which recently finished recruiting ahead of schedule, aims to assess the role of new coagulation tests in identifying people with kidney disease who are at risk of bleeding. The Renal Exercise and Rehabilitation nurses are also actively engaged in research and Research Delivery Unit Manager, nurse Danilo Nebres, has successfully received a British Renal Society grant to help set up and be the primary investigator for the RAPID study. This study will compare rapid 'Point of Care' capillary blood testing of protein to traditional methods as a way to measure kidney function in people of different ethnicities.

The team's hard work has been publicly recognised as in the last year alone, they represented KCH at the 2019 UK Kidney Week conference, where six submitted abstracts were accepted and presented. Also in 2019, Renal Exercise and Rehabilitation team leader Dr Sharlene Greenwood was inducted as the President of the British Renal Society – the second female and the first non-medic to hold this position. She was also given a double accolade at the King's Awards by winning the Inspirational Leader of the Year and Chair's Awards.

*Members of the Renal Exercise and Rehabilitation research team showcasing their research at the UK Kidney Week conference in 2019.*

# Ophthalmology

## The Ophthalmology research team at KCH is a dynamic team led by Professor Tim Jackson, Mr Haralabos Eleftheriadis and Mr Gerassimos Lascaratos.

The Ophthalmology team's research areas include three leading causes of sight loss: age-related macular degeneration (AMD), glaucoma and diabetic retinopathy. Reflecting this, the research team at KCH is at the forefront of several cutting-edge eye research trials.

The team is currently recruiting to the DERBY study, a trial of a novel therapeutic agent for a type of AMD called dry AMD, for which there is currently no established treatment.

In June 2019, they were awarded a €2m joint-grant from the European Society of Retina Specialists and the charity Fight for Sight to lead a pan-European study comparing surgical with non-surgical treatment of submacular haemorrhage in AMD. Called the TIGER study, this is currently in the process of being set up and recruited to at KCH.

Towards the end of 2019, the team at KCH finished recruiting for the STAR study, one of the largest investigator-led multicentre clinical trials in Ophthalmology. It investigates the use of a type of radiotherapy called stereotactic radiotherapy (SRT) as a treatment for a different type of AMD – wet AMD. SRT uses precision-focused X-ray beams to target the leaking areas in the retina that cause the condition.

Finally, in December 2019, the Opthalmology team completed the PEACE study. This was the first ever randomised controlled trial which compared different surgical approaches to treat progressive glaucoma in Afro-Caribbean patients.


*IRay Stereotactic Radiotherapy System used in the STAR Study*

# Paediatric

## The Paediatric research team aim to improve the lives of children and young people through research and innovation. Their mission is to advance healthcare and develop new and improved treatments for children and young people while maintaining high standards of excellence in research practice.

*The Paediatric research team*


*Some of the Paediatric research team at KCH's Clinical Trials Day*

The Paediatric research team consists of a study coordinator, both junior and senior research nurses and an R&I Lead. Their study areas are extremely varied; spanning hepatitis C, sickle cell anaemia, epilepsy, asthma and type 2 diabetes – as well as rare genetic conditions such as cystic fibrosis. Reflecting this, in the last year the team have set up and run over forty innovative early and late phase studies with great success.

One study they conducted was a successful trial of new combinations of licenced drugs for chronic hepatitis C infection in children. They found that combining licenced hepatitis C drugs sofosbuvir and velpatasvir dramatically decreased the level of hepatitis C infection to the point where it was undetectable. This has the potential to be life-changing for children with hepatitis C. These studies are now in their final stages, and we are expecting combinations of sofosbuvir and velpatasvir to be licenced soon.

The team are also hosting the first paediatric trial of the anti-inflammatory therapy mepolizumab in children with a particular type of asthma. In two papers published at the end of last year – with KCH Paediatrics R&I lead Atul Gupta as lead author - they showed that mepolizumab was safe and beneficial in children aged six to eleven. It is hoped that this study will lead to mepolizumab being licenced for use in children, leading to better asthma control and improved quality of life.

# Cardiology

## The Cardiology research team consists of eight research nurses, one research facilitator and one research physiologist. They also fund one echocardiographer. The team cover a range of studies across all cardiac sub-specialities, from translational research to first-in-man device trials.

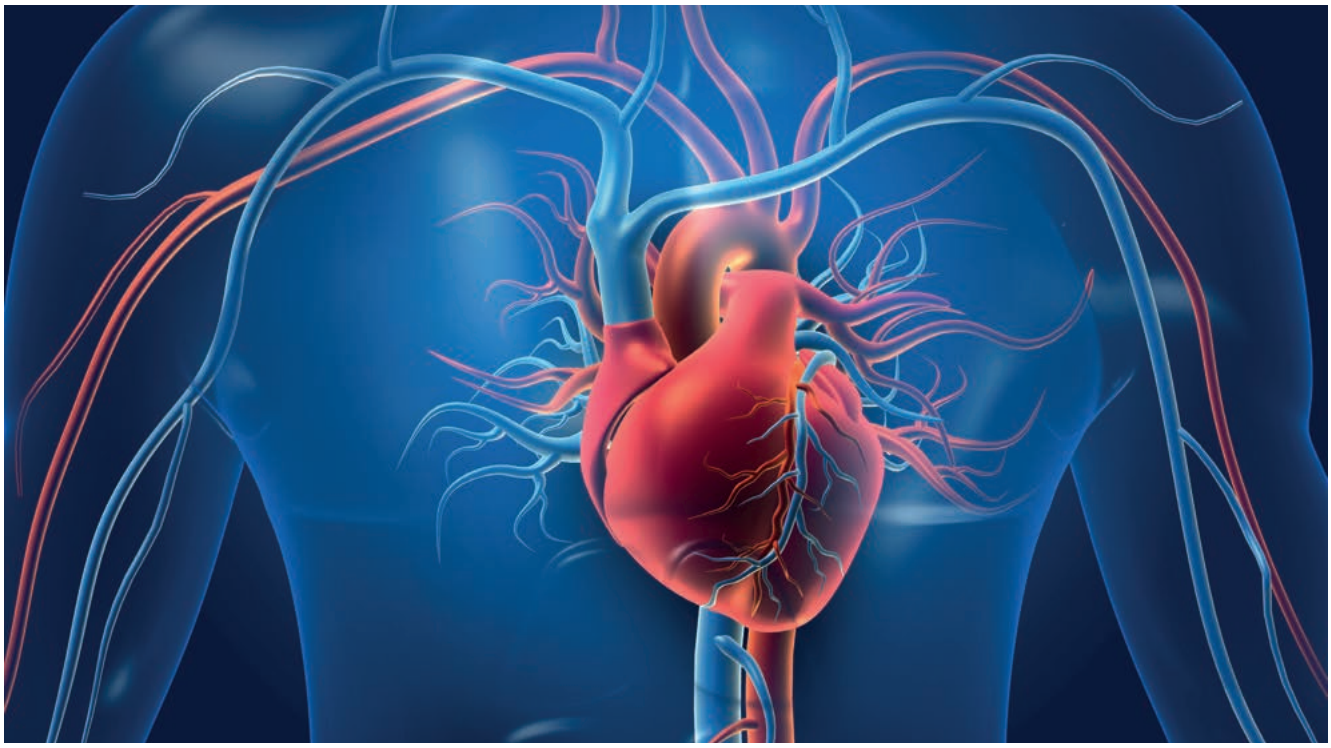
Cardiogenic shock is a condition in which the heart can't pump enough blood to meet the body's needs. Affecting over 50,000 people in Europe each year, it is most often caused by a severe heart attack, although not everyone who has a heart attack has cardiogenic shock. Currently, if a person is still in cardiogenic shock after the heart attack has been treated, there is a 50% chance they will not survive.

An extracorporeal mechanical oxygen machine (ECMO), which pumps and oxygenates a patient's blood outside of the body, is used as short-term support if the heart is failing following a heart attack and cardiogenic shock. Currently, the ECMO machine is only started once it has been established that a patient isn't improving.

The EURO SHOCK trial, a European collaborative project led in the UK by the Cardiology research team KCH, aims to challenge this approach by testing the efficacy and cost-benefit of very early ECMO machine use in cardiogenic shock. More specifically, the trial will investigate whether using an ECMO machine immediately after treating a heart attack has any short and/or long-term benefits for the patient. If the results are positive and this practice is incorporated into standard clinical care for heart attacks, this could save a number of lives.

This study will foster collaboration across KCH, drawing on expertise from various departments, with Dr Sameer Patel, Consultant in Intensive Care, Liver Intensive Care & ECMO acting as Principal Investigator and Sheetal Patale, Cardiac Research Nurse, supporting as the study coordinator. Furthermore, cardiologists, cardiac physiologists, anaesthetists and more - as well as the research team – will all work together to trial the study on participants.

The trial aims to recruit 428 patients from 44 EU centres: in early February this year, KCH recruited the first patient in the UK and the second in the world.



# Palliative Care

## The need for palliative care and rehabilitation is increasing rapidly. At the Cicely Saunders Institute, cutting-edge research is continuously being developed. Some of their studies trial new models of care and services to improve care for patients and their families.

The Palliative Care research team also conduct research focused on interventions and treatments so that symptoms such as breathlessness can be managed more effectively. The BETTER-B study, for example, is a major international programme to test treatments for severe breathlessness in advanced lung disease and to produce guidance for health professionals and patients.

Following a successful feasibility trial led by the research team, the results of which were published this year the journal Thorax (http://dx.doi.org/10.1136/thoraxjnl-2019-213879), Palliative Care are now currently leading a team involving collaborators across England, Germany, Switzerland, Ireland, Poland and Italy. This world-first study will evaluate a new 're-purposed' medicine – one that has already been licenced for use in a different disease - for breathlessness. They have already established a dedicated website (www.betterbreathe.eu) with resources for clinicians and patients, links to a home toolkit, E-Learning and newsletters. In November 2019, they also ran a half day workshop with over 100 professionals at KCH to help them learn how to manage breathlessness better.

Patient reported outcome measures ensure that patients are always at the centre of the team's research. The Institute is therefore at the forefront of developing patient-centred measures of outcomes. The Palliative Care Outcome Scale Workshop 2020 took place on the 13th and 14th February 2020 at the Cicely Saunders Institute with 200 national and international attendees.

During the workshop, the Outcomes Action Collaborative (OAC) was launched. Working through the NIHR Applied Research Collaborative and through local and national leadership, the OAC aims to mobilise partnerships, support efforts of all involved in the care of seriously ill people to respond to local and national challenges secondary to multimorbidity, support the introduction of outcome measures into routine practice and provide training and support on outcome measurement.

Patients, carers, family and members of the public are central to all the Palliative Care team's research. In November 2019, they re-launched their online forum for patient and public involvement (PPI) in palliative care and rehabilitation research (www.csipublicinvolvment.co.uk). The online forum provides a flexible method of involvement which increases the number and diversity of people contributing to palliative care and rehabilitation research.


*The Cicely Saunders Institute at KCH*

Visit the team's webpages for information about projects, open seminars, free resources in outcome measurement, education and training: http://www.kcl.ac.uk/palliative.

Follow the Cicely Saunders Institute on Twitter: @CSI_KCL

The Cicely Saunders Institute is a World Health Organisation Collaborating Centre: https://www.kcl.ac.uk/nursing/departments/cicelysaunders/about/partners.aspx

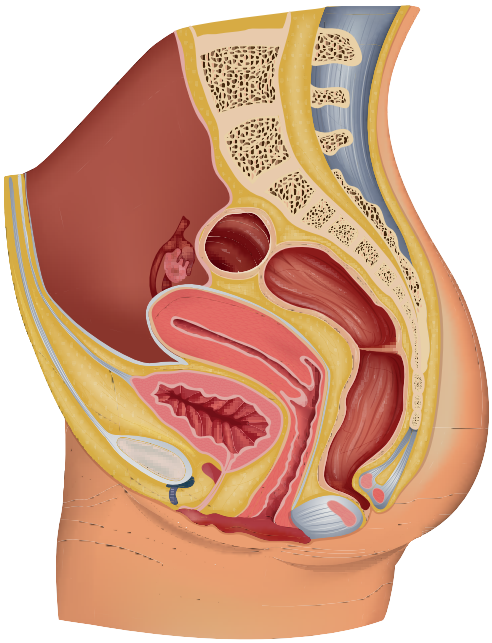
# Women's Health

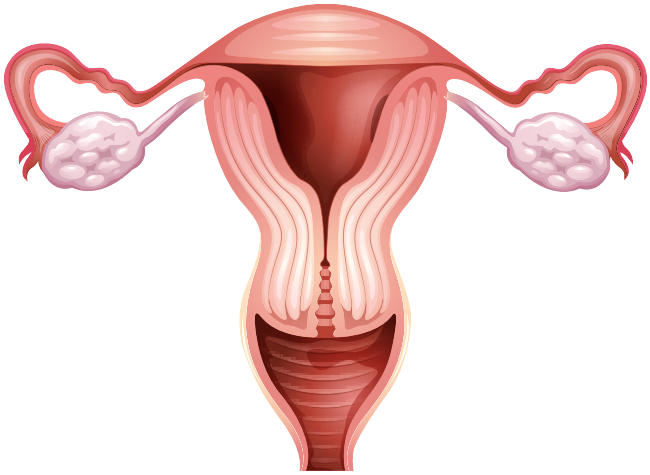
## Nursing and Midwifery Research

This year, the Women's Health research team have demonstrated substantial success within nursing and midwifery research. Lead urogynaecology nurse Angie Rantell was awarded her PhD titled 'The impact of overactive bladder symptoms on women's sexual activity'. Additionally, urogynaecology Clinical Nurse Specialist Cathy Davis won the 'Best Overall Presenter Award' at the Urology Conference for Nurses for her work, 'Patient perceptions of and compliance with bladder diaries' and Katherine Clark, specialist midwife, was awarded a Kidney Research UK Stoneygate Allied Health Professionals Fellowship, as well as a place on the NIHR 70@70 Senior Nurse and Midwife Research Leadership Programme.

## Urogynaecology

Linda Cardozo, KCH's Professor of Urogynaecology, and her team have published over 20 papers in peer-reviewed journals over the last year including work on the impact of patient behaviour on the risk and prevalence of recurrent urinary tract infections. The team also recently published the protocol for an innovative randomised controlled trial of laser therapy for the management of genitourinary syndrome of menopause, an umbrella term for the multiple genital, sexual and urinary symptoms associated with menopause and urinary incontinence.





## Pregnancy

In the last year, consultant in Maternal-Foetal medicine Dr Nick Kametas and his team have published over ten papers in peer-reviewed journals focused on the prediction of pre-eclampsia, a potentially fatal condition that affects some women during pregnancy. Close collaboration with teams from Fetal Medicine and Liver have continued to promote a holistic approach to this prediction work.

Also this year, the Renal team, led by consultant nephrologist Dr Kate Bramham, have been hugely successful in grant applications, receiving three separate project grants from Kidney Research UK. One of the projects is focusing on the prediction of deterioration in kidney function during pregnancy in women with chronic kidney disease. Additionally, the commercial company PerkinElmer are supporting the team to validate an innovative pre-eclampsia testing kit and finally the MRC have awarded funding for the team to carry out an acute kidney injury and pre-eclampsia prediction study in Africa.

# HIV & Sexual Health

## The HIV & Sexual Health research team is made up of two doctors, a research manager, research nurse and three research assistants from KCH. Their research programme comprises interventional trials and observational cohort studies focused on kidney and bone disease in the setting of HIV and the effects of HIV treatments on kidney and bone. The team's ultimate aim is to improve efficacy and safety of the life-long treatments for people with HIV.

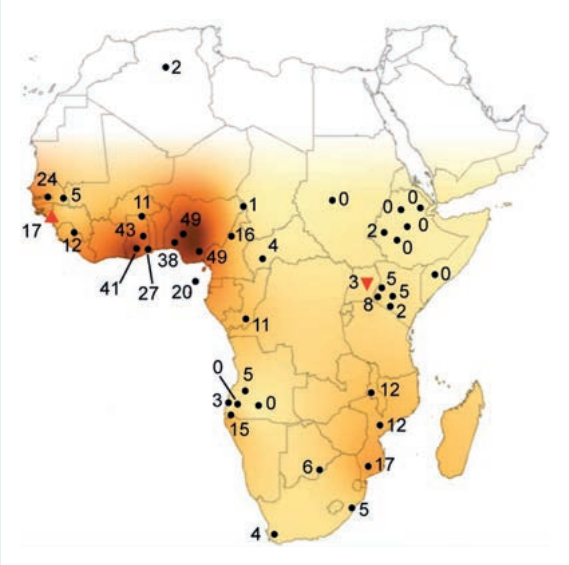
Severe kidney disease requiring dialysis or transplantation is common in people of African ancestry with HIV, and has been linked to genetic evolution in African populations to better withstand infections such as malaria and sleeping sickness.

In 2018, the HIV & Sexual Health research team at KCH initiated the GEN-AFRICA study to investigate these genetic risk factors further. The study also investigates other conditions that are relevant to African populations: hypertension, diabetes, obesity and stroke.

GEN-AFRICA was originally conceived as a single-centre study supported by a small KHP Challenge Fund grant. The study was portfolio adopted and a further 15 centres country-wide joined forces to recruit about 3,000 people, including over 1,000 from KCH alone, by February 2020.

In the past year, the team has successfully used the GEN-AFRICA study to apply for additional funding for further studies. For example, they are now embarking on the CKD Africa study which is further investigating the genetic determinants of multiple long-term conditions in Black African communities with HIV.

The HIV & Sexual Health research team have submitted further applications to investigate obesity in African populations, and for a PhD studentship focused on the role of the APOL1 gene in the development of kidney disease in African people with HIV. They are also exploring collaborations with an industry partner to study other genetic and epigenetic determinants of kidney disease in populations of African descent and evaluate novel medications to slow kidney disease progression in this population.


*Distribution of the APOL1 variants in Africa**

**Used with permission from Cooper et al. eLife 2017; APOL1 renal risk variants have contrasting resistance and susceptibility associations with African trypanosomiasis 24;6 doi:10.7554/eLife.25461.*

# Anaesthetics, Critical Care, Emergency Medicine and Trauma (ACET)

## The ACET research team was established in 2012 to deliver coordinated clinical research across their four clinical areas in order to develop clinical care and improve patient outcomes.

The team integrated their service to overcome the unique and distinct challenges of delivering clinical research common within our clinical areas including; criticality of illness, time-urgency to recruit to studies, 24 hour and unplanned patient admissions, enabling informed consent for incapacitated patients and delivery of clinical protocol to different departments throughout the hospital.

The ACET team currently run over 45 commercial and NIHR-supported research projects and have recruited thousands of patients. They deliver internationally important clinical research trials that best enhance care for their patients. These cover a diverse range of clinical sub-specialities including paediatrics, haemorrhage in major trauma, elderly care in the emergency setting, septic shock and acute respiratory distress syndrome, as well as to determining best practice for delivering sedation to patients whilst in theatre.

One recent example of how the team's work improves patient care is the Crash 3 trial. This trial, the results of which were published in the Lancet in 2019, demonstrated that the administration of tranexamic acid to adult patients after head injury due to major trauma can significantly increase rates of survival.

ACET are also a multi-award winning clinical research team with an academic focus. For example, last year ACET RDU lead Dr Phil Hopkins won the Faculty of Intensive Care Medicine NIHR Clinical Research Network Award for his research within the team. Also, many of the ACET research nurses are completing PhDs and pre-PhD programmes with a focus on the specific needs of patients and families at KCH and its new critical care unit. ACET are grateful to their clinical teams for all their help to ensure they can deliver clinical research to their patients.

*Members of the ACET research team*

# Aim 2

Aim two of the R&I strategy is to develop the Advanced Therapy (investigational) Medicinal Products (AT(I)MP) and Biomedical Sciences Hub to develop and deliver therapies that are based on cells genes and small molecules.

## Here, we highlight what we have achieved so far and discuss the new initiatives and research that will help us achieve future goals within this aim.

- ✔ Establish a Trust-level AT(I)MP oversight group.
- ✔ Appoint a Biological Safety Officer and set up a Trust-wide Biological Safety Committee for research.
- ✔ Establish closer links with Guy's and St Thomas' Biomedical Research Centre.
- ✔ Fund and appoint a Research Quality Manager.
- ✔ Establish an AT(I)MP Academy and hold first workshop
- Fund and appoint a Clinical Biological Safety Lead for research

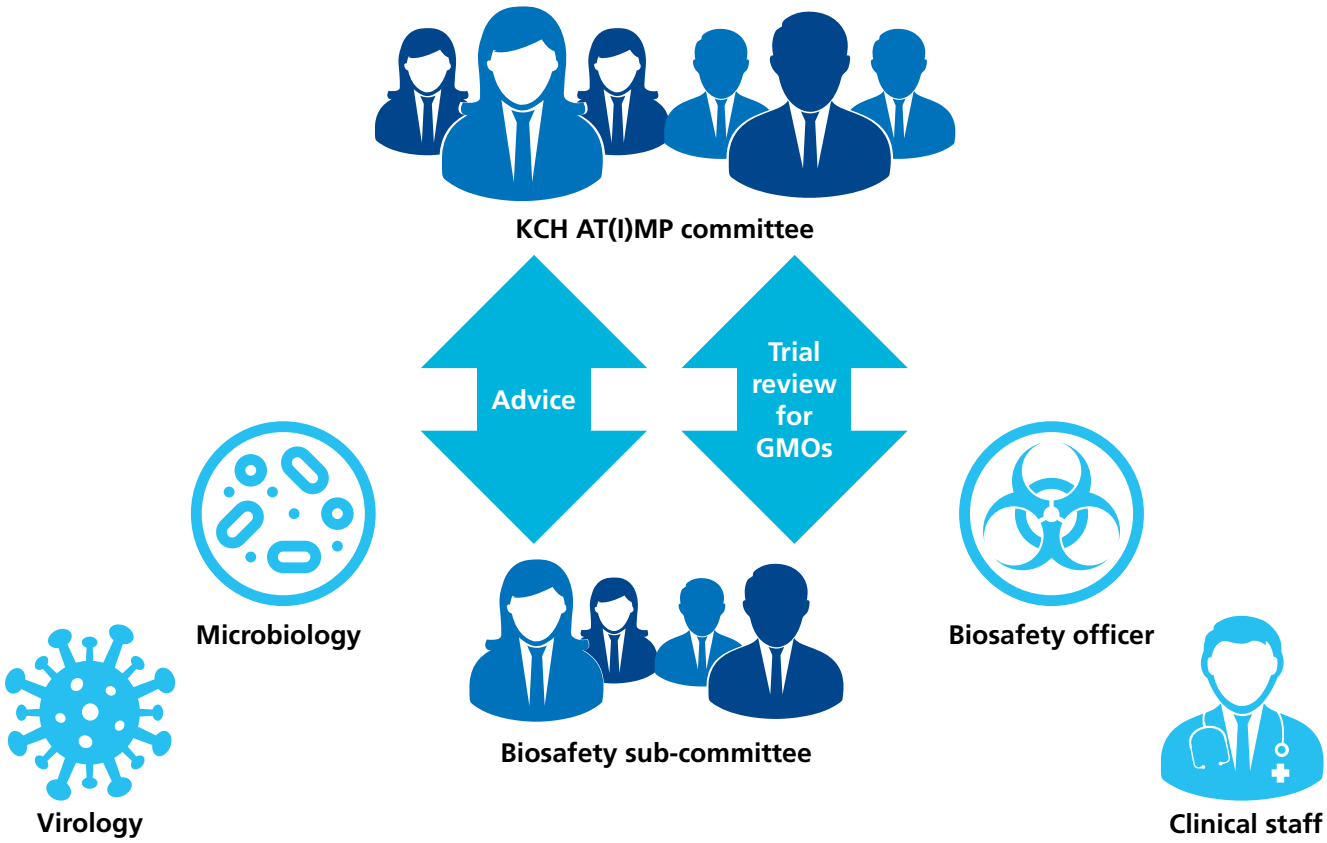
# AT(I)MPs and Biosafety

## The R&I strategy aims to increase the number of advanced therapy trials carried out within the Trust. To do this, work is being undertaken to create an academy for Advanced Therapy (Investigational) Medicinal Products (AT(I)MPs) which will be led by Professor Anil Dhawan.

The Trust currently has a portfolio of trials and treatments using AT(I)MPs in Haematology, Gene Therapy, Mesenchymal Stem Cells, as well as hepatocyte and islet cell transplantation. To increase this portfolio, the R&I department are organising an AT(I)MPs academy composed of a one day symposium with lectures from experts as well as a three day workshop for a smaller number of delegates. The aim is to give an in-depth understanding of the processes maintained in an accredited Good Manufacturing Practice (GMP) laboratory such as the Cell Therapy Unit on the 2nd floor of the CRF, as well as KCH quality assurance systems, regulatory perspectives, inspections processes and audits. The workshop will be conducted by our existing GMP lab scientists, quality managers, Qualified Persons (QPs), Designated Individuals (DIs) and licence holders. Representatives from Cardiology, Orthopaedics and Rheumatology, Ophthalmology and Dermatology are also invited to contribute and be involved.

To ensure the safety of staff and trial participants while working with and trialling AT(I)MPs, KCH has set up a Biological Safety Sub-committee which will meet on a regular basis and report into the Trust's designated committee for AT(I)MPs. Providing advice from both a clinical and laboratory perspective, the Biological Safety Sub-committee will consist of representatives form virology, microbiology, senior clinical staff as well as a Biological Safety Officer provided by the CRF. The committee will adhere to the legal requirement to review trials using Genetically Modified Organisms (GMO's) which may need HSE notification if they are categorised as a risk to the environment or staff.

For any enquiries regarding AT(I)MPs, the AT(I)MP committee or the AT(I)MPs academy, please contact Prof Anil Dhawan at anil.dhawan@nhs.net

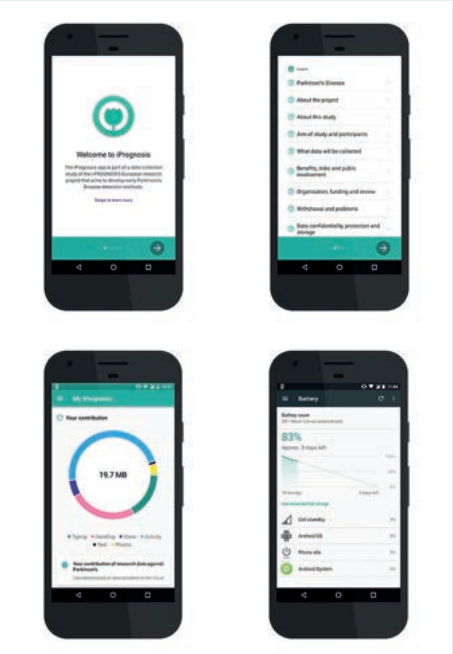


# Neuroscience

## Neuroscience is a vital arm of KCH research and spans multiple disciplines. Here, the Neuroscience research team discuss two key areas of research within Neuroscience – Parkinson's disease and Epilepsy.

The EUROPAR team, led by Professor K Ray Chaudhuri, is a team that has been driving research and engagement activities as well as recruitment across several sites in South London. With focus on the Princess Royal University Hospital (PRUH) and with a dedicated Movement Disorders Service, over the past year the team have successfully recruited and engaged a number of patients in various research activities, as well as educating neurologists on their research portfolio. One example of a EUROPAR project is the Non-Motor International Longitudinal Study (NILS), which holistically assesses the natural history of non-motor symptoms during the disease course. Overall, these efforts with engagement and collaboration have contributed to the PRUH becoming more research-active.

KCH Neuroscience researchers are also developing i-Prognosis, an experimental, pioneering app which captures movements, sleep patterns, breathing, voice and emotional contents to predict the development of Parkinson's disease. Overall, they have recruited more than 400 people into the study, with over 200 recruited in 2019 alone.




*The i-Prognosis app*

Epilepsy research at KCH comprises two world class research groups led by Professor Mark Richardson for adult epilepsy and Professor Deb Pal for paediatric epilepsy. One example of a KCL/KCH multicentre study currently recruiting is the CASTLE programme.

Funded by the NIHR, the CASTLE (Changing Agendas on Sleep, Treatment & Learning in Epilepsy) programme is focused on rolandic epilepsy, which is the most common type of childhood epilepsy and affects about one sixth of all children with epilepsy in the UK. Throughout the CASTLE study, the team will work with children, parents, doctors and nurses to choose the best ways to measure health and quality of life for children with epilepsy. The research will also include talking to parents and children about their experiences in relation to sleep, taking medication, learning and how taking part in the study has impacted on them.

CHANGING AGENDAS ON SLEEP, TREATMENT & LEARNING IN EPILEPSY
CASTLE

# Haematology

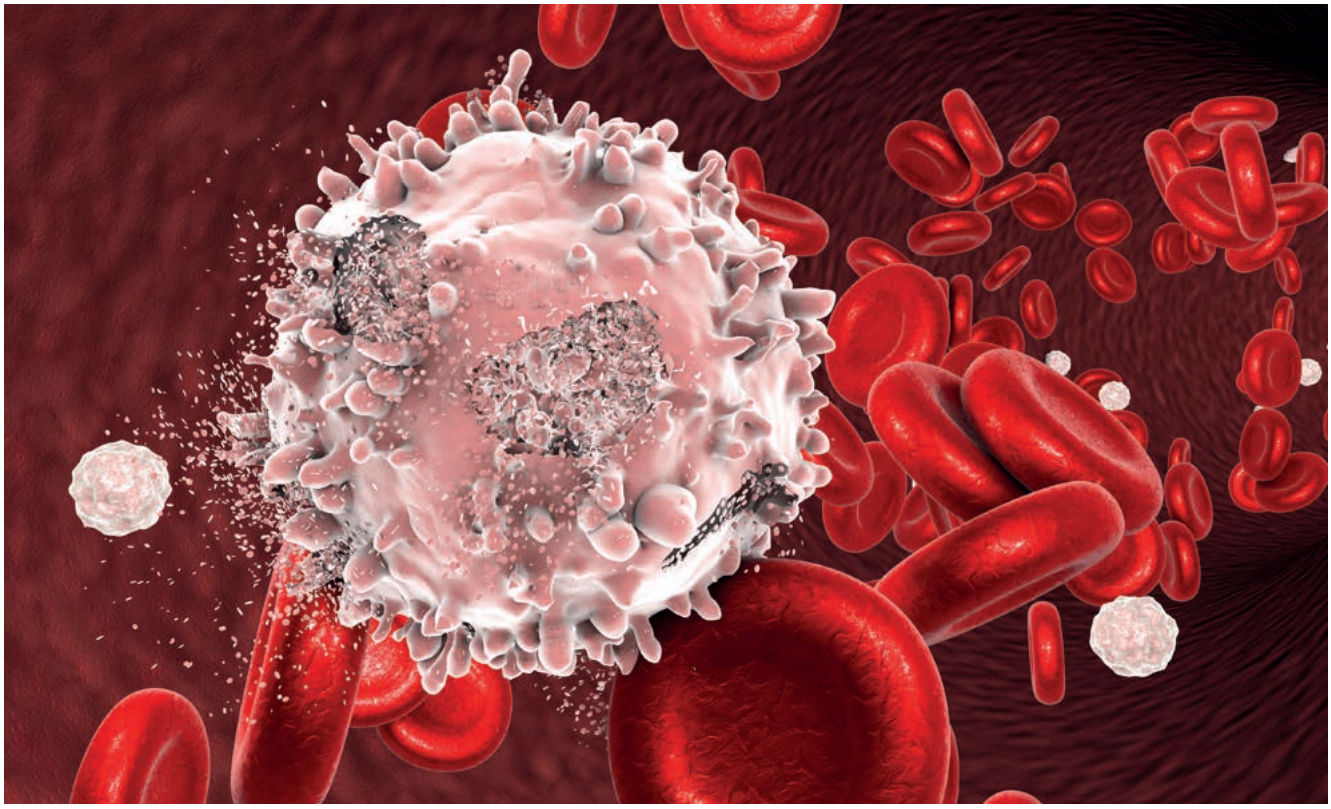
## The Haematology research team at KCH has a large portfolio of commercial and non-commercial Phase I-IV clinical trials focusing on blood cancers and non-cancer related blood diseases. They have a number of successful KCH-sponsored clinical trials, as well as a growing portfolio of trials at the PRUH.

At KCH, one of the Haematology research team's current sponsored trials is the 'Pro-DLI' trial. This is a Phase II clinical trial investigating whether the addition of donor immune cells into patients who have recently received a stem cell transplant (as part of their treatment for certain types of blood cancers) can prevent relapse and increase their chances of a successful, sustained remission. Pro-DLI is the first national randomised transplant trial with KCH coordinating the study and being the largest recruiter in the UK.

The team has a proven track record in recruiting to other nationally important clinical trials and have been the highest recruiting centre in the UK and globally in several studies, spanning disease areas such as Chronic Lymphocytic Leukaemia, Acute Lymphoblastic Leukaemia and Paroxysmal Nocturnal Haemoglobinuria.

The Haematology research team also has a key focus on cell and gene therapy. This is demonstrated by a new academic partnership with biopharma company Celgene (recently acquired by Bristol-Myers Squibb) involving a unique collaboration with the Orthopaedics Research Team. The team also has a growing cellular therapy clinical trial portfolio in B-cell Acute Lymphoblastic Leukaemia, Multiple Myeloma, Post-Transplant Lymphoproliferative Disorders (PTLD, a type of cancer arising from a transplant procedure) and Follicular Lymphoma that offers cutting-edge novel treatments for patients.

Finally, recognising the need to work seamlessly alongside clinical practice at KCH, they have recently introduced two Clinical Trial Link Nurse Practitioner roles. These nurse practitioners are based on the Haematology wards and are tasked with building relationships and improving research culture.



# King's NIHR Wellcome Trust Clinical Research Facility

## Opened in 2014, the NIHR / Wellcome Trust King's Clinical Research Facility (CRF) is a collaborative research facility shared between King's College Hospital, South London and the Maudsley Hospital and King's Health Partners, supported by a successful NIHR award and Wellcome Trust funding.

Since opening, the King's CRF has supported over 460 CRF applications, have inducted over 800 users to access the facility and have currently over 140 active/ open trials. Sixty-eight per cent of their commercial studies and 71% of our academic studies were badged as early phase or experimental medicine studies.


*The entrance to the CRF at KCH*

# Recent highlights from the CRF

## Haematology

The CRF is actively supporting studies on a rare blood disease that causes red blood cells to break apart, Paroxysmal Nocturnal Haemoglobinuria (PNH). Following 2018's successful Phase II trials of a new biological therapy for the condition, rapid translation and patient enrolment into Phase III trials of the therapy can be attributed to the CRF's expertise in this area.

Furthermore, the current cost of treatment for PNH patients is approximately £300,000 per year yet through the current clinical trial, the CRF is receiving these drugs free of charge.

# Neurology

*EEG technology in action.*

**Epilepsy**
Professor Mark Richardson has been the PI of two related studies of a first-in-human Phase I clinical trial to evaluate the safety, tolerability and mechanistic effects of a new anti-epileptic drug. Sponsored by Xenon Pharmaceuticals Inc., Phase I trials of the drug on healthy volunteers were conducted at the CRF by Dr. Isabella Premoli and Dr. Eugenio Abela. The Transcranial Magnetic Stimulation (TMS) and electroencephalography (EEG) technology at King's CRF, along with the required academic and technological expertise available at the Facility, were central to the analysis of the drug's mechanisms of action. In turn, this provided the basis for further progression and since last year the CRF has been recruiting for participants with epilepsy to enter further clinical trials of this drug.

*Participants in trials such as those for ALS are monitored and cared for by the CRF's experienced research staff.*

**Amyotrophic Lateral Scelrosis (ALS)**
ALS is a rare neurodegenerative disease resulting in loss of motor neurons and their axons within the brain cortex, brainstem and spinal cord. Patients suffer from progressive loss of muscle mass, strength and loss of function of respiratory, voluntary and involuntary muscles. Decline is inevitable, with death from respiratory failure following two to five years after diagnosis for most patients. Since August 2019 the CRF has supported a first-in-human Phase I study evaluating a new medicinal compound in people with ALS.

*The state-of-the-art ward where clinical trials such as those for ALS can take place safely and efficiently.*

**Migraine**
This year, a new preventive treatment has been developed and approved for the most common and disabling neurological disorder in the UK - Migraine. Following a collaboration between CRF Director Professor Peter Goadsby, Professor of Neurology, and Professor Lars Edvisson, Professor of Medicine at the University of Lund, Sweden, the new preventative drug – an antibody therapy called erenumab - was discovered, transforming patient care and improving quality of life by significantly reducing the number of migraine episodes patients experience. After completing clinical trials, the therapy is now available in Scotland, with hope for its availability to spread nationwide.

*Prof Peter Goadsby, CRF Director and erenumab study lead.*

# Diabetes

## KCH is at the forefront of diabetes research. Led by Dr Pratik Choudhary, KCH's Diabetes research team is active in various areas of both type 1 and type 2 diabetes - in particular hypoglycaemia.

Hypoglycaemia is a key barrier to optimal glucose control in those with diabetes, and recurrent or severe hypoglycaemia can lead to vascular and neurological complications as well as death. Hypoglycaemia unawareness also affects around a quarter of people with type 1 diabetes. This is when a person is no longer able to recognise the signs of hypoglycaemia and therefore risks more frequent severe hypoglycaemic episodes.

HYPO RESOLVE

KCH's Diabetes research team are part of a €27m European collaborative project called the Hypo-RESOLVE study. This is a collaborative study between KCH and King's College London which aims to reduce the burdens and consequences associated with hypoglycaemia by better understanding the clinical mechanisms of the condition and better defining its predictors and the consequences. At KCH, the Diabetes team are about to start a 600-patient multicentre study as part of this project.

As part of King's Health Partners (KHP), the Diabetes research team are helping to set up T1DE, a 15-month pilot service for people with type 1 diabetes and disordered eating – sometimes called Diabulimia. Bringing together professionals across diabetes and mental health, the pilot aims to investigate the effectiveness of integrated diabetes and mental health care for a cohort of 40 patients with type 1 diabetes who experience disordered eating.

Additionally, the Diabetes team at KCH are continuously working to improve and discover new effective therapies and technological advancements for people with type 1 diabetes. In January this year, they facilitated the use of a new type of insulin pump for people with type 1 diabetes.

# Liver

## 2019 has been the busiest year yet for liver research at KCH. In the last year alone, the Liver research team has opened 31 new commercial studies, 20 of which have been either Phase I or II studies.

The team's portfolio has moved toward early phase as they explore the various pipelines and combination therapies in development with the aim of Hepatitis B virus (HBV) cure.

The team's hard work has meant that they have been the first global recruiter and top global recruiter in an international multicentre HBV study, as well as being the lead recruiter in a study focusing on Non-Alcoholic Fatty Liver Disease. KCH's Liver department was also the only UK site selected this year for early phase HBV studies with two global sponsors, and a Phase II study – of which consultant hepatologist Dr Kosh Agarwal was a National Coordinating Investigator – navigated regulatory approval and contracting in just seven weeks.

In the last year, Dr Vish Patel from the Liver team received £2.2 million in funding from the NIHR Health Technology Assessment programme to deliver the BOPPP (Beta-blockers or placebo for portal hypertension in patients with small oesophageal varices) study. BOPPP will establish the effects of beta-blockers in the treatment of oesophageal bleeding, which is a key complication of liver cirrhosis. This is one of the largest NIHR awards made to liver research at KCH and establishes the hospital as a leader in portal hypertension research.

Advanced therapies are at the core of KCH's research strategy. The Adaptimmune-sponsored study in hepatocellular carcinoma trial is a Phase I first-in-human study of genetically engineered immune cells in people with advanced hepatocellular carcinoma – primary liver cancer. At KCH, the team will take specific immune cells from eligible patients and send them to the USA to be genetically altered to attack the liver cancer cells. Collaborating with Guy's and Thomas' Hospital, the team will administer these cells to the same patient and monitor their response to the cancer. The study is being overseen at both sites by KCH Consultant and Senior Lecturer in Medical Oncology, Dr Debashis Sarker, leveraging on the largest service for patients with primary liver cancer in the UK based at KCH.


*The Liver research team*

# Aim 3

Aim 3 of the R&I strategy is to 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.

## Here, we highlight what we have achieved so far and discuss the new initiatives and research that will help us achieve future goals within this aim.

- ✔ Put into place robust data systems for accurate data collection (EDGE)
- ✔ Establish a Quality Assurance system backed by an appropriate suite of Standard Operating Procedures
- ✔ Ensure that information regarding research is part of the Trust induction
- ✔ Tailor reports to each Research Development Unit on a monthly basis to aid performance
- ✔ Establish PRUH and R&I Leads meetings
- Raise the profile of R&I with a strong communication strategy
- Seek patient input into the setting up of research priorities via a network of patient groups

# Patient and Public Involvement and Engagement (PPIE)

Over the past year, KCH have been developing a roadmap of PPIE initiatives within the Trust as part of the R&I strategy. In this section, some of the fantastic work which has gone into involving public and patient groups in research is highlighted.

**KCH Patient Engagement**
KCH has an in-house Patient Engagement Team who, using their Patient Engagement and Experience Strategy, focus on delivering the Trust's commitment to ensuring that the voices of patients, carers and service users are heard and acted upon. The team are committed to ensuring they provide an excellent patient experience and engage with patients and the public in the design and evaluation of our services. This work is funded by the Trust.

The Patient Engagement Team currently has three key areas of work. The first is the delivery of local and national patient experience feedback surveys. These include the Care Quality Commission and Department of Health national patient surveys, the national Friends and Family Test Survey and the internal Trust 'How are we doing?' survey. The surveys cover all of the Trust's core services and, in addition, they support individual services to gather bespoke feedback on their service and to inform service development and improvements. This includes working closely with staff groups to support them in service improvement including providing training and guidance on 'listening' to patients.

Secondly, the team engages with patients, carers, relatives and the public in line with the legal duty to consult and, more generally, to ensure that patients inform the work that the Patient Engagement Team and the Trust does.

Lastly, the team also manage their Foundation Trust membership, of whom 99% are patients or relatives of patients and are an important part of their engagement activity. Two years ago, they developed an Associate Membership made up of voluntary sector and community groups to widen access to feedback and enhance the support available to patients through these groups.

The Patient Engagement Team's current priorities are focussed on a Patient Experience Improvement Plan, which is tackling key areas that need improvement, as evidenced by patient feedback survey data. For example, this includes specific improvements to the delivery of good nutrition and hydration for patients as well as improving the experience of patients visiting KCH's Emergency and Outpatient Departments.

**Clinical Trials Day at the PRUH**
International Clinical Trials Day is celebrated around the world on the 20th of May to mark the day James Lind began his famous trial into the deadly disease scurvy in 1747. The trial led to the discovery that citrus fruits high in vitamin C could prevent the disease – paving the way for the development of specific vaccines to prevent diseases such as smallpox in the late 18th century.

Last year, KCH celebrated International Clinical Trials Day at the Denmark Hill site on the 17th of May and at the PRUH on the 31st of May to raise awareness of the importance of research to healthcare, and highlight how partnerships between patients and healthcare practitioners are vital to high quality, relevant research.

More than 15 teams showcased their work and hundreds of patients, staff and visitors attended both of these events. Visitors explored how clinical trials, which are responsible for the most significant medical advances, are conducted and gained an insight into the extraordinary work carried out by the Trust's research teams. There were lots of interesting quizzes and games organised to raise awareness of the incredible research happening at our hospitals to help find new treatments for patients now, and in the future.

**KHP Summer School at the Clinical Research Facility**

Following on from the success of the KCL K+ Programme in 2018 where the King's Clinical Research Facility (CRF) hosted 40 students to attend events at the facility, in summer 2019 the CRF hosted the Reach Out For Healthcare Science Week sponsored by Health Education England. Organised by King's Health Partners, this programme is run in South London and aims to allow students to get a real feel for what a career in healthcare science might look like, together with other scientific careers outside of medicine.

The Science Week gave 100 GCSE students from non-fee paying schools the opportunity to attend a week of careers talks and activities in order to provide an insight into several different aspects of healthcare science. Activities were run by different departments across Guy's and St Thomas' and KCH, and the CRF was one such department.

Over five days the students met with scientists working in healthcare, discovered how science is an essential part of life in a busy London hospital, took part in a wide range of activities in different areas of healthcare science and gained confidence in their ability to enter a career in healthcare science. The CRF offered an opportunity to get involved in the Virtual Reality Lab where students tested the equipment and were immersed in a virtual reality world. They also observed live MRI and EEG scanning and were given information about how MRI and EEG can 'see into the brain'. They met with research scientists and assistants, PhD students, doctors and nurses, each of whom discussed either career advice or provided information about the research taking place in the CRF.

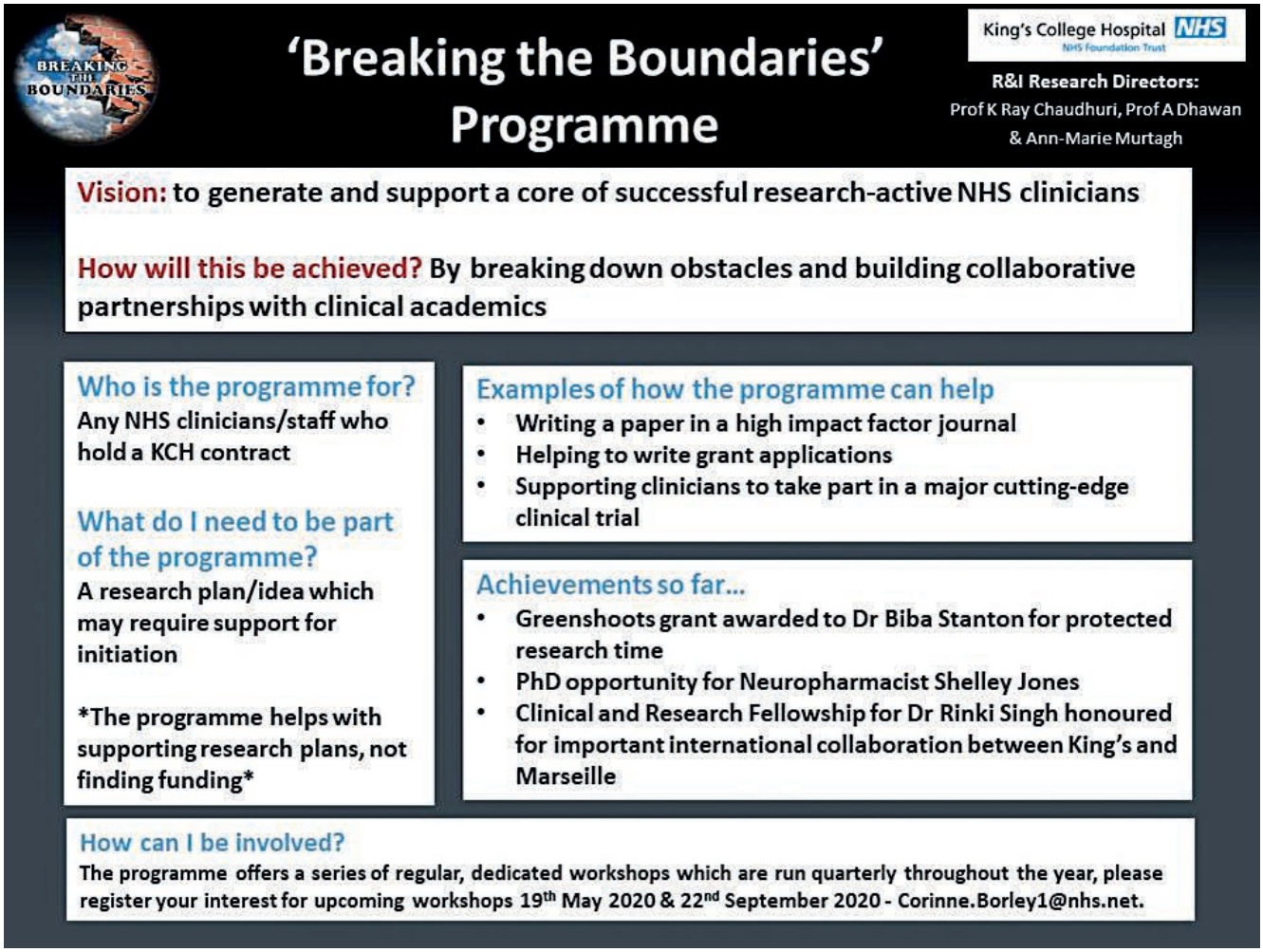
Reach Out for Healthcare Science gives young people a chance to see for themselves what exciting opportunities there are in science careers in the NHS. With more than 50 different specialist options, there was something for every interest and at every level of entry. The King's CRF was proud to host and support this event and will continue to so in the future.

*R&I staff and Research Development Units at 2019's Clinical Trials Day*

# Breaking the Boundaries Programme

## The R&I Directors at KCH have been championing a new initiative called the 'Breaking the Boundaries' programme.

The programme aims to support and develop research-based aspects of the roles of NHS clinicians and Health Care Professionals (HCPs), helping to overcome challenges and barriers to setting up research projects.



# NIHR 70@70 Senior Nurse and Midwife Research Leadership Programme

## This year, KCH were very fortunate to have two successful applicants to the competitive NIHR 70@70 Senior Nurse and Midwife Research Leadership Programme. Daniel Hadfield is a critical care nurse and post-doctoral research fellow and Katherine Clark is a specialist midwife and PhD student.

The programme funds Katherine and Dan's time for two days per week for three years allowing them to focus on project work promoting research culture, activity and engagement within nursing and midwifery across all trust sites. They are working with the national cohort on projects including promotion of clinical academic careers.

Locally, they have a number of ongoing workstreams. The team are organising research workshops that are designed to share skills and knowledge, develop research ideas and provide one-to-one mentorship. They are also increasing their website and kwiki presence to improve access to research information and enhance collaborations. Katherine and Dan will improve research engagement with patients and visitors by running an events and poster campaign while promoting evidence-based practice among clinical staff by facilitating access to research experts and delivering a staff survey to investigate the barriers and pathways to their involvement in research. Furthermore, by enhancing links with local universities, they will promote clinical academic career pathways and, working with new research link nurses and midwives, assist in the creation of research projects.

*Critical care nurse Dr Dan Hadfield and specialist midwife Katherine Clark.*

Katherine and Dan are happy to be contacted by anyone considering applying for a research fellowship or grant or considering engaging in research.

# The Princess Royal University Hospital (PRUH)

## As part of the R&I strategic aims one of the important objectives is to increase the number of patients participating in clinical research at the PRUH and the South Sites (Orpington Hospital, Queen Mary's Hospital Sidcup and Beckenham Beacon).


*Some of the research team from the PRUH*

The lead research facilitators covering the PRUH and South Sites, Nyma Sikondari and Riti Desai along with the joint R&I leads Dr Deepak Rao and Mr John Bladen, have strived hard to increase opportunities in a number of research areas and deliver equitable access to clinical research to patients at PRUH and South Sites.

In the last year, the team at the PRUH have consolidated and built upon their research capacity by achieving a successful pre-assessment for their accredited clinical laboratories and invested in a -80°C freezer for sample storage. They also helped to secure funding for a full-time generic research nurse and research delivery staff for a range of research areas as well as Greenshoots funding for new investigators. Improvements to the EDGE software allowed the team to record and capture PRUH-specific activity in the database.

The PRUH team are actively encouraging the initiation and continuation of research projects by engaging with and supporting new consultants starting at the PRUH. They have facilitated networking between specialities and made a concerted effort to bring more research awareness at the site through; posters, regular communication via emails, meetings and attending teaching or training events. To ensure that clinical staff undertaking research are aware of and comfortable with the requirements for conducting clinical trials, they held a research advice surgery as well as a Good Clinical Practice (GCP) training session.

The PRUH continues to recruit to clinical trials across many specialities. In the Respiratory department, they had a successful internal bid for a research nurse and have successfully completed recruitment to the trial OPTIMUM. This is a nationwide trial comparing outpatient methods to current inpatient methods for the treatment Malignant Pleural Effusion, a complication arising from many different types of cancer.

The Ophthalmology team at PRUH are coordinating and recruiting into a UK wide, NIHR portfolio study looking into the incidence and management of eyelid melanoma, a type of skin cancer. At Queen Mary's Hospital in Sidcup, they are successfully recruiting to a commercial study MERCURY-3, which compares the safety and efficacy of two ophthalmic solutions in subjects with elevated intraocular pressure – a key risk factor for glaucoma.

The Maternity and Midwifery unit also obtained funding for a research midwife who works across sites. Currently, the unit has two studies ongoing and are setting up their first randomised control trial. The Blood Pressure in the Postnatal Period (BPIPP) trial has exceeded the recruitment target at the PRUH a number of months early!

KCH's Haematology Research Unit have a Senior Trials Coordinator who works between Denmark Hill and the PRUH. Two Haematology studies which are recruited for by the PRUH are RUDY (Rare and Undiagnosed Diseases StudY) and TEAMM (Tackling Early Morbidity and Mortality in Myeloma). Both studies involve patients diagnosed with the blood cancer Myeloma. RUDY is a study looking at a national cohort of patients with rare diseases – such as Myeloma - in order to develop new therapies, whereas TEAMM aims to test the prophylactic use of an antibiotic to prevent infections and related morbidity in people with Myeloma.

Both studies were nationally recognised as high recruiting studies at PRUH and the results of TEAMM, which were published at the end of 2019 in Lancet Oncology, have helped to change national practice and will be considered in National Institute for Health and Care Excellence (NICE) guidelines.

Finally, as patient input and engagement is central to the research at the PRUH and across the Trust, the team at the PRUH celebrated International Clinical Trials Day in May last year by holding a range of engagement activities for staff, patients and visitors to the hospital.

For further information on clinical research in PRUH & South sites please contact **Nicola Griffiths** on *nicola.griffiths20@nhs.net* or call 0168 9865335.

*The team at the PRUH celebrating Clinical Trials Day in 2019*

# Congratulations Corner

## A snapshot of the achievements made by KCH R&I staff in the past year

*Dr Phil Hopkins accepting his award*

At June 2019's Faculty of Intensive Care Medicine and NIHR CRN Awards, KCH R&I Lead for Critical Care and CRN South London Critical Care Speciality Group Lead Dr Phil Hopkins won a national award for his research activity. Dr Hopkins was awarded the Established Investigator Award at the event to recognise his work in completing over fifty portfolio studies - the output of which has transformed clinical care for critically ill patients – although he emphasised the importance of teamwork in his achievement by stating "I am accepting the award on behalf of the entire Anaesthetics, Critical Care, Emergency Medicine and Trauma (ACET) Team, and my two collaborating leads Jeff Keep and Gudrun Kunst. This achievement is the culmination of ten years of very hard work across this team".

*Dr Gudrun Kunst*

In December 2019, Dr Gudrun Kunst, Consultant Anaesthetist and R&I Lead for Anaesthetics at KCH won the prestigious Macintosh Professorship, awarded by the Royal College of Anaesthetists, for her local, national and international contribution to the field of anaesthesia. Commenting on the award, Gudrun said, "This award recognises the excellent opportunities for cross-disciplinary clinical research at KCH and across south London, and I feel truly honoured to represent the School of Cardiovascular Medicine and Sciences and KCH as the RCoA Macintosh Professor."

In January 2020, the KCH Trauma & Orthopaedic Surgery Research Team won the National Top Recruiter Award at the 8th NIHR Musculoskeletal Trauma Trials Day - for the second year running! The team, led by Ms Ines Reichert, Consultant Orthopaedic Surgeon and R&I Lead for Trauma & Orthopaedic Surgery and Rheumatology, has gradually increased the number of orthopaedic researchers and multiplied the number of recruiting studies from just two open trials in 2016 to fourteen in 2019.

Research Manager, Kerim Gokturk said: "This has been down to solid teamwork. Without the engagement of the surgeons and our dedicated research team, this would not have been possible. We are a unit where everybody is on board and every patient gets considered for participation in a national study. Each patient with musculoskeletal trauma suffers significant impact on their quality of life and should have the benefit of participating in clinically relevant studies."


*The KCH Trauma & Orthopaedic Surgery research team accepting their award*

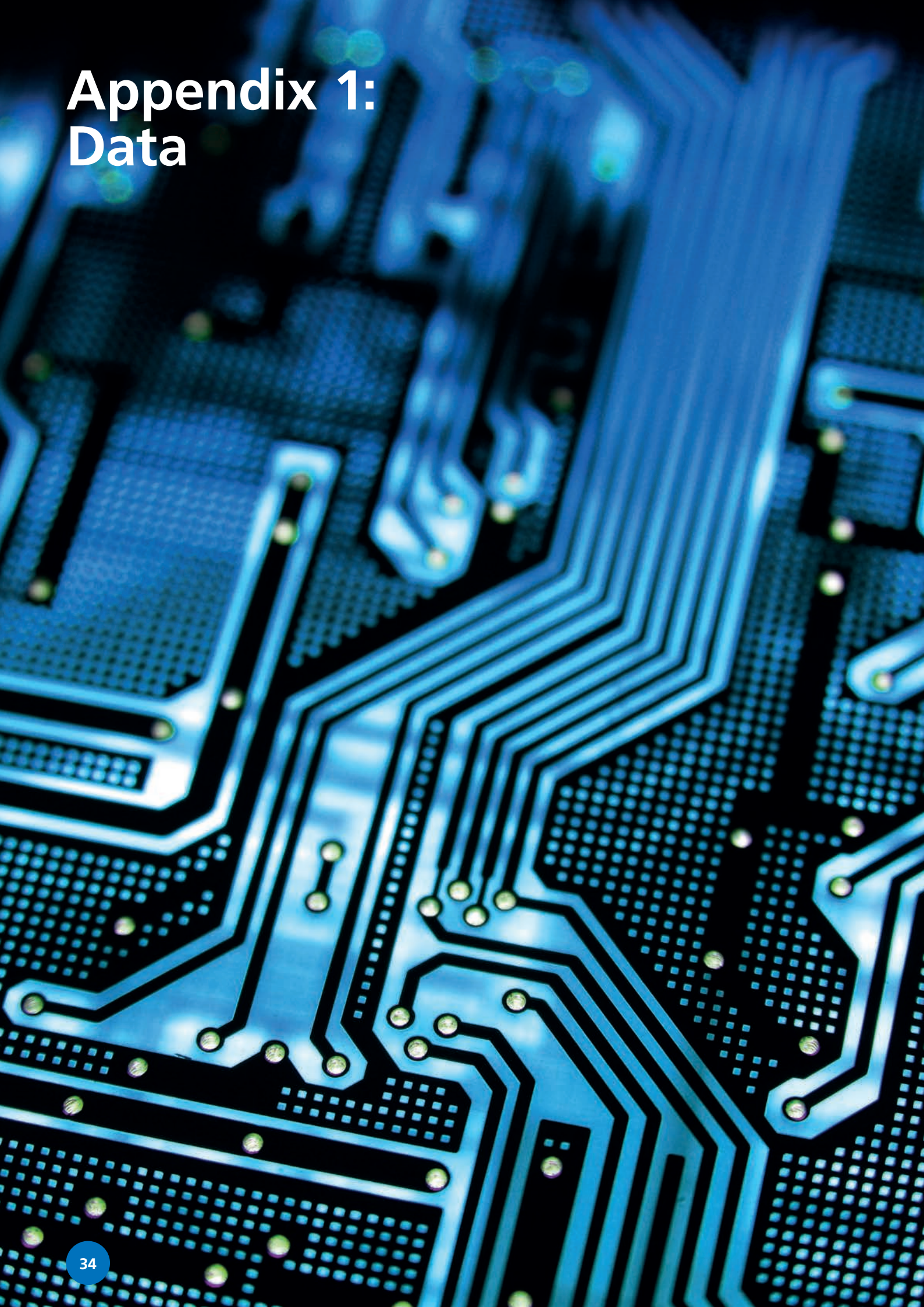
The ACET research team was nominated for the Nursing Times 2019 award in the clinical research nursing category by the critical care leads. Of the 48 nominations in their category, the team were delighted to be one of the eight finalists.

The ACET team was nominated for their commitment to patient focused clinical research, expanding the integration of the research delivery services within their four research areas and their development of nurse-led research. They presented the work and achievements of the ACET team to the Nursing Times assessment panel and attended a wonderful evening at a Mayfair hotel where the winner was announced.

The ACET team were delighted to represent KCH in the clinical research category and would like to thank all the patients, family members, clinical teams and all other supporting departments for helping them to provide their clinical research service to improve patient care and outcomes.


*The Nursing Times awards ceremony*

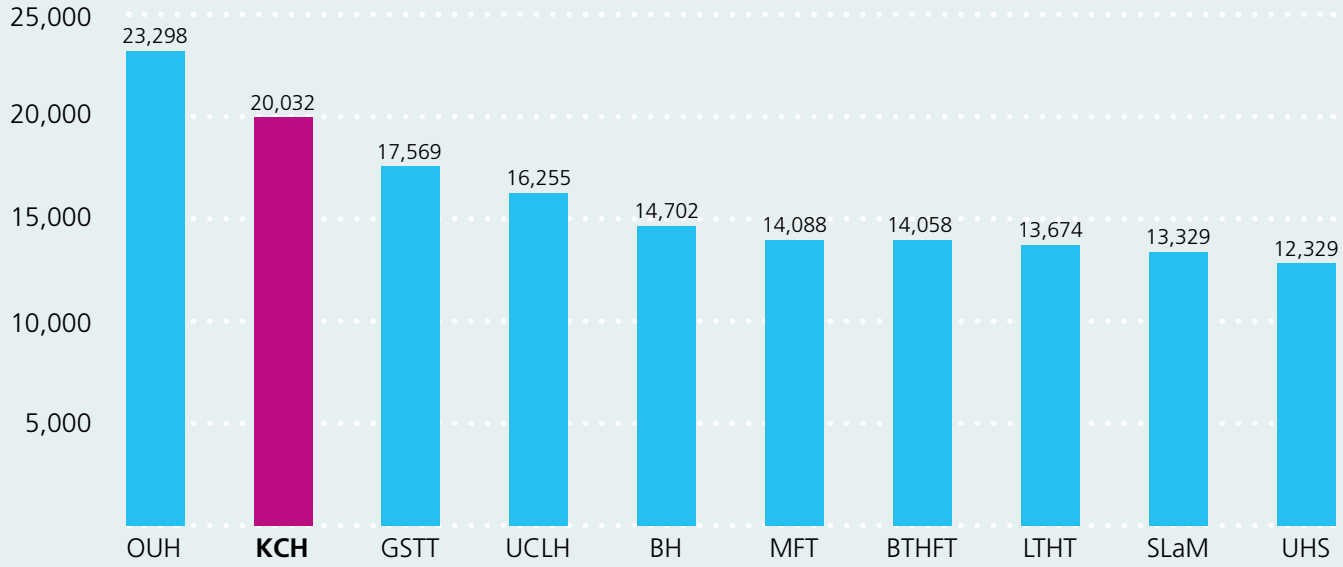
# Appendix 1: Data



# The year in numbers

## Recruitment by Trust in England (top 10), FY19/20

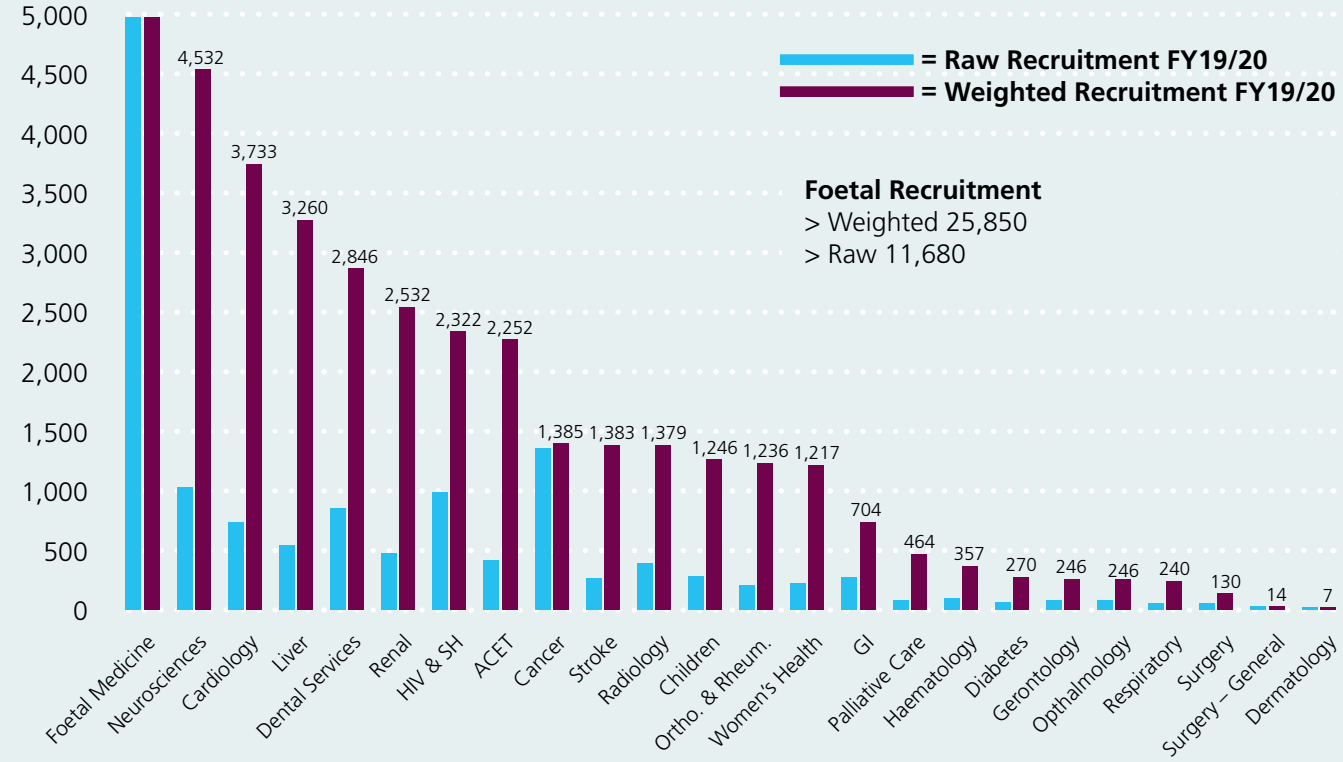
Demonstrating that KCH is the second highest recruiting Trust in the UK to NIHR Portfolio studies




| | | | |
|---|---|---|---|
| OUH | Oxford University Hospitals NHS Foundation Trust | MFT | Manchester University NHS Foundation Trust |
| **KCH** | **King's College Hospital NHS Foundation Trust** | BTHFT | Bradford Teaching Hospitals NHS Foundation Trust |
| GSTT | Guy's and St Thomas' NHS Foundation Trust | LTHT | Leeds Teaching Hospitals NHS Trust |
| UCLH | University College London Hospitals NHS Foundation Trust | SLaM | South London and Maudsley NHS Foundation Trust |
| BH | Barts Health NHS Trust | UHS | University Hospital Southampton NHS Foundation Trust |

## Recruitment by Research Delivery Unit

April 2019 – February 2020 Portfolio Raw vs. Weighted Recruitment



## R&I non Commercial Performance

**114**
**Non-Commercial portfolio studies approved**

**41**
**Non-portfolio studies approved**

**260**
**Substantial amendments**

**101**
**Co/sponsored studies approved**

**262**
**Contracts executed (average review 59 days)**

**118**
**Non-substantial amendments**

## KCH Commercial Performance 2019

**Approved Recruiting Active / in Follow Up**
**309**

**Trials in Feasibily or Set Up**
**107**

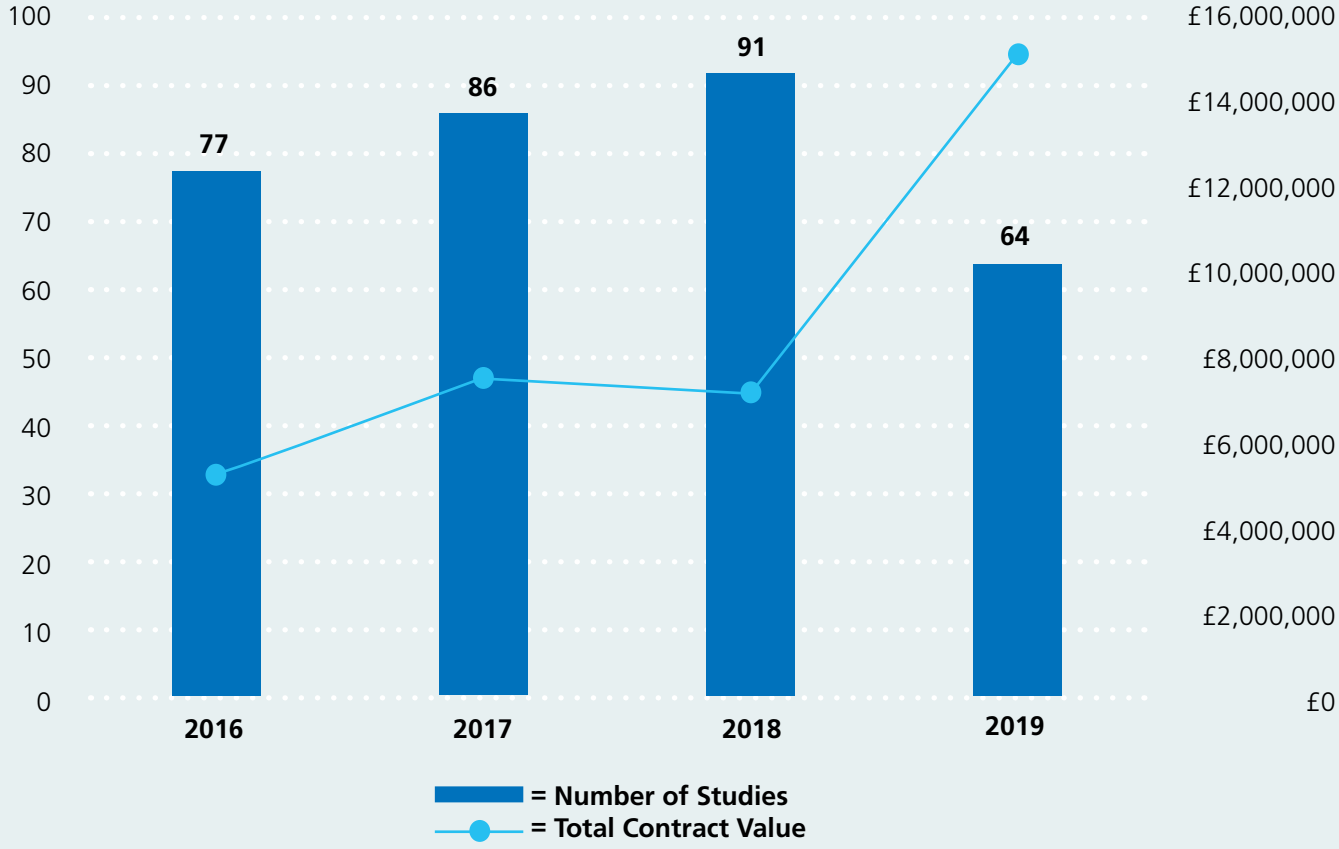
**In 2019: 74 commercial trials were opened – of which 31 were early phase trials**

**Number of Participants currently in Open Trials**
**1652**

**Number of Investigators**
**101**

**Highest number of PIs working on commercial trials in feasibility / set up and approved**

# Number of Commercial Contracts and Total Contracts Value 2019



# Appendix 2: Useful information

# KCH Research Delivery Unit (RDU) Leads

**Anaesthetics**
Dr Gudrun Kunst
*gudrun.kunst@nhs.net*
*kch-tr.acetresearch@nhs.net*

**Critical care**
Dr Phil Hopkins
*p.hopkins@nhs.net*
*kch-tr.acetresearch@nhs.net*

**Trauma**
Dr Fleur Cantle
*fleur.cantle@nhs.net*
*kch-tr.acetresearch@nhs.net*

**Anaesthetics**
Prof Theresa McDonagh
*t.mcdonagh@nhs.net*

**Neurosciences**
Prof K Ray Chaudhuri
*ray.chaudhuri@nhs.net*

**Child Health**
Dr Atul Gupta
*atulgupta1@nhs.net*

**Diabetes**
Dr Pratik Choudhary
*pratik.choudhary@nhs.net*

**Foetal Medicine**
Prof Kypros Nicolaides
*k.nicolaides@nhs.net*

**Gastroenterology**
Dr Alexandra Kent
*alexandra.kent@nhs.net*

**Gerontology**
Dr Julie Whitney
*julie.whitney@nhs.net*

**Haematology**
Dr Piers Patten
*piers.patten1@nhs.net*

**HIV (Sexual Health)**
Prof Frank Post
*frank.post@nhs.net*

**Liver**
Dr Mark McPhail
*mmcphail@nhs.net*

**Neuroradiology**
Dr Thomas Booth
*thomasbooth@nhs.net*

**Palliative Care**
Dr Sabrina Bajwah
*sbajwah@nhs.net*

**PRUH R&I Lead**
Dr John Bladen
*john.bladen1@nhs.net*

**PRUH R&I Lead**
Dr Deepak Rao
*deepak.rao@nhs.net*

**Radiology**
Prof Paul Sidhu
*paulsidhu@nhs.net*

**Renal**
Dr Sapna Shah
*sapna.shah@nhs.net*

**Physiotherapy**
Dr Sharlene Greenwood
*sharlene.greenwood@nhs.net*

**Stroke**
Dr Laszlo Sztriha
*laszlo.sztriha@nhs.net*

**Surgery - Orthapaedics & Rheumatology**
Dr Ines Reichert
*i.reichert@nhs.net*

**Women's health**
Dr Dudley Robinson
*dudley.robinson@nhs.net*

# Research Delivery Managers & Matrons (RDMs)

**ACET**
John Smith
*john.smith27@nhs.net*

**Diabetes**
Andrew Pernet
*andrewpernet@nhs.net*

**Gastroenterology**
Lee Meng Choong
*leemeng.choong@nhs.net*

**HIV & Sexual Health**
Maria Liskova
*maria.liskova@nhs.net*

**Neuroscience**
Alexandra Rizos
*a.rizos@nhs.net*

**Paediatrics**
Eniola Nsirim
*ensirim@nhs.net*

**Renal**
Leela Goldstein
*leela.goldstein@nhs.net*

**Stroke**
Jonnie Aeron-Thomas
*j.aeron-thomas@nhs.net*

**Women's health**
Katherine Clark
*katherineclark1@nhs.net*

**Cardiology**
Jonathan Breeze
*jonathan.breeze@nhs.net*

**Foetal medicine**
Argyro Syngelaki
*argyro.syngelaki@nhs.net*

**Haematology**
Jen Lewis
*jen.lewis2@nhs.net*
Lorraine Catt
*lorraine.catt@nhs.net*

**Liver**
Vernie Ramalingam
*vernie.ramalingam@nhs.net*

**Ophthalmology**
Riti Desai
*ritidesai@nhs.net*

**PRUH**
Nyma Sikondari
*nyma.sikondari@nhs.net*

**Surgery, Orthopaedics and Rheumatology**
Kerim Gokturk
*agokturk@nhs.net*

# South London Clinical Research Network Speciality Research Leads (SRLs) and RDMs

SRLS in black / RDMs in red

**Ageing**
Julie Whitney *julie.whitney@nhs.net*
Andra Cosma *andra.cosma@nihr.ac.uk*

**Cancer**
Sanjay Popat *sanjay.popat@rmh.nhs.uk*
Sarah Rudman *sarah.rudman@gstt.nhs.uk*
Frances Doyle *frances.doyle@nihr.ac.uk*

**Children**
Paul Health *pheath@sgul.ac.uk*
Robert Pleass *robert.pleass@nihr.ac.uk*

**DeNDRoN**
Jeremy Isaacs *jeremy.isaacs@nhs.net*
Andra Cosma *andra.cosma@nihr.ac.uk*

**Diabetes**
Kirsty Winkley *kirsty.1.winkley@kcl.ac.uk*
Elisabeth Sullivan *elisabeth.sullivan@nihr.ac.uk*

**Gastroenterology**
Richard Pollock *rpollok@sgul.ac.uk*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Haematology**
Lara Roberts *lara.roberts@nhs.net*
Robert Pleass *robert.pleass@nihr.ac.uk*

**Hepatology**
Deepak Joshi *d.joshi@nhs.net*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Infection**
Julie Fox *julie.fox@gstt.nhs.uk*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Mental Heatlh**
Paul Stokes *paul.r.stokes@kcl.ac.uk*
Andra Cosma *andra.cosma@nihr.ac.uk*

**Neurological Disorders**
Jeremy Isaacs *jeremy.isaacs@nhs.net*
Andra Cosma *andra.cosma@nihr.ac.uk*

**Oral & Dental Health**
Tara Renton *tara.renton@kcl.ac.uk*
Robert Pleass *robert.pleass@nihr.ac.uk*

**Respiratory Disorder**
Patrick Murphy *Patrick.Murphy@gstt.nhs.uk*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Surgery**
Joydeep Sinha *joydeepsinha@nhs.net*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Anaesthetics, peri-operative medicine & pain management**
Gudrun Kunst *gudrun.kunst@nhs.net*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Cardiovascular Diseases**
Ronak Rajani *Ronak.Rajani@gstt.nhs.uk*
Elisabeth Sullivan *elisabeth.sullivan@nihr.ac.uk*

**Critical care**
Phil Hopkins *p.hopkins@nhs.net*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Dermatology**
Carsten Flohr *Carsten.Flohr@kcl.ac.uk*
Robert Pleass *robert.pleass@nihr.ac.uk*

**ENT**
Louisa Murdin *Louisa.Murdin@gstt.nhs.uk*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Genetics**
Nayana Lahiri *nayana.lahiri@nhs.net*
Louise Izatt *Louise.Izatt@gstt.nhs.uk*
Robert Pleass *robert.pleass@nihr.ac.uk*

**Health Services Reseach**
Mark Ashworth *mark.ashworth@kcl.ac.uk*
Ana Guerra *Ana.Guerra@nihr.ac.uk*

**Imaging**
Vicky Goh *vicky.goh@kcl.ac.uk*

**Metabolic & Endocrine**
Barbara McGowan *Barbara.McGowan@gstt.nhs.uk*
Elisabeth Sullivan *elisabeth.sullivan@nihr.ac.uk*

**Musculoskeletal disorder**
Louise Pollard *louisepollard@nhs.net*
Caroline Hing *Caroline.Hing@stgeorges.nhs.uk*
Robert Pleass *robert.pleass@nihr.ac.uk*

**Ophthalmology**
Chris Hammond *chris.hammond@kcl.ac.uk*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

**Palliative Care**
Sabrina Bajwah *sabrina.bajwah@kcl.ac.uk*
Ana Guerra *Ana.Guerra@nihr.ac.uk*

**Public Health**
Mark Ashworth *mark.ashworth@kcl.ac.uk*
Ana Guerra *Ana.Guerra@nihr.ac.uk*

**Reproductive & Child Health**
Laura McGee *laura.a.magee@kcl.ac.uk*
Robert Pleass *robert.pleass@nihr.ac.uk*

**Stroke**
Ajay Bhalla *ajay.bhalla@gstt.nhs.uk*
Elisabeth Sullivan *elisabeth.sullivan@nihr.ac.uk*

**Trauma & Emergency Care**
Heather Jarman *heather.jarman@stgeorges.nhs.uk*
Nhlanhla Mguni *nhlanhla.mguni@nhs.net*

# King's Health Partners Clinical Trials Office

## The King's Health Partners Clinical Trials Office (KHP CTO) was set up to formalise the pre-existing collaborations between partner organisations, to develop their clinical trials potential and to increase the quality and delivery of clinical trials.

The KHP CTO has two sections: the Commercial Team which provides a single interface for those wishing to conduct trials sponsored by the pharmaceutical and allied healthcare industries and the Quality Team that supports investigators at KHP's institutions who undertake clinical trials where KHP are the sponsor or co-sponsor, to ensure delivery of the statutory obligations contingent on sponsorship of drug trials.

## KHP-CTO partner Organisations

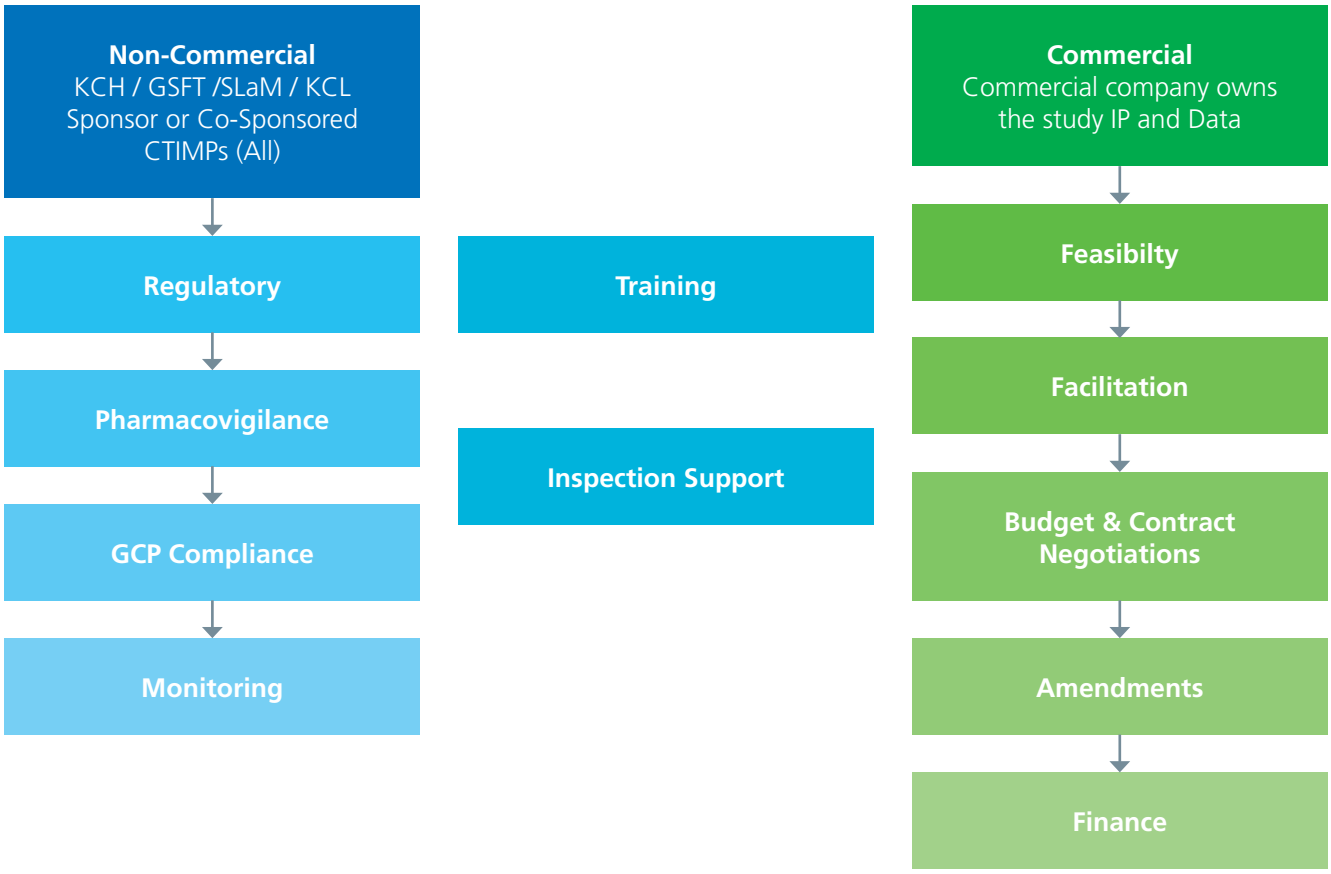
NHS
King's College Hospital
NHS Foundation Trust

NHS
South London and Maudsley
NHS Foundation Trust

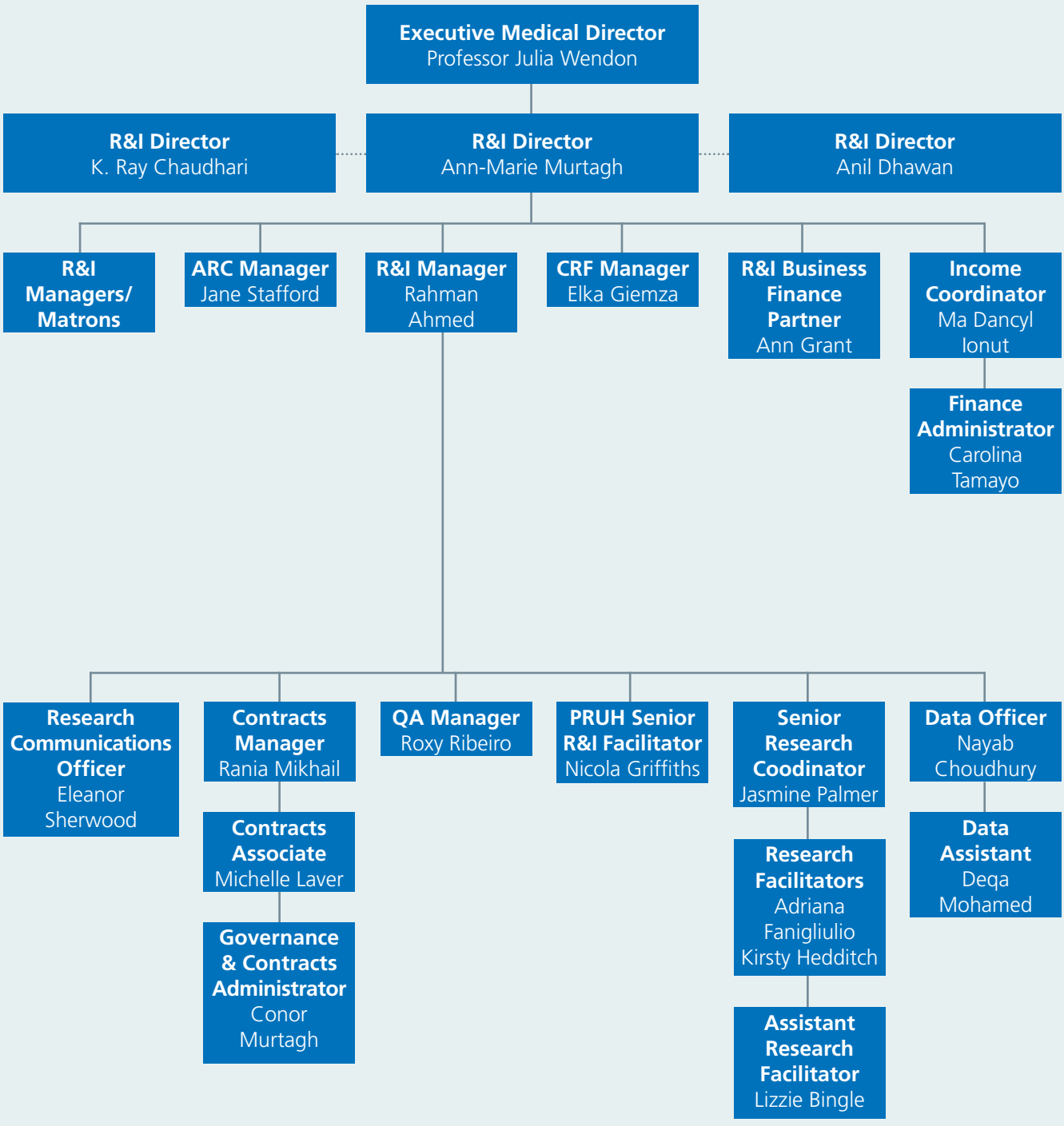
NHS
Guy's and St Thomas'
NHS Foundation Trust

King's College London

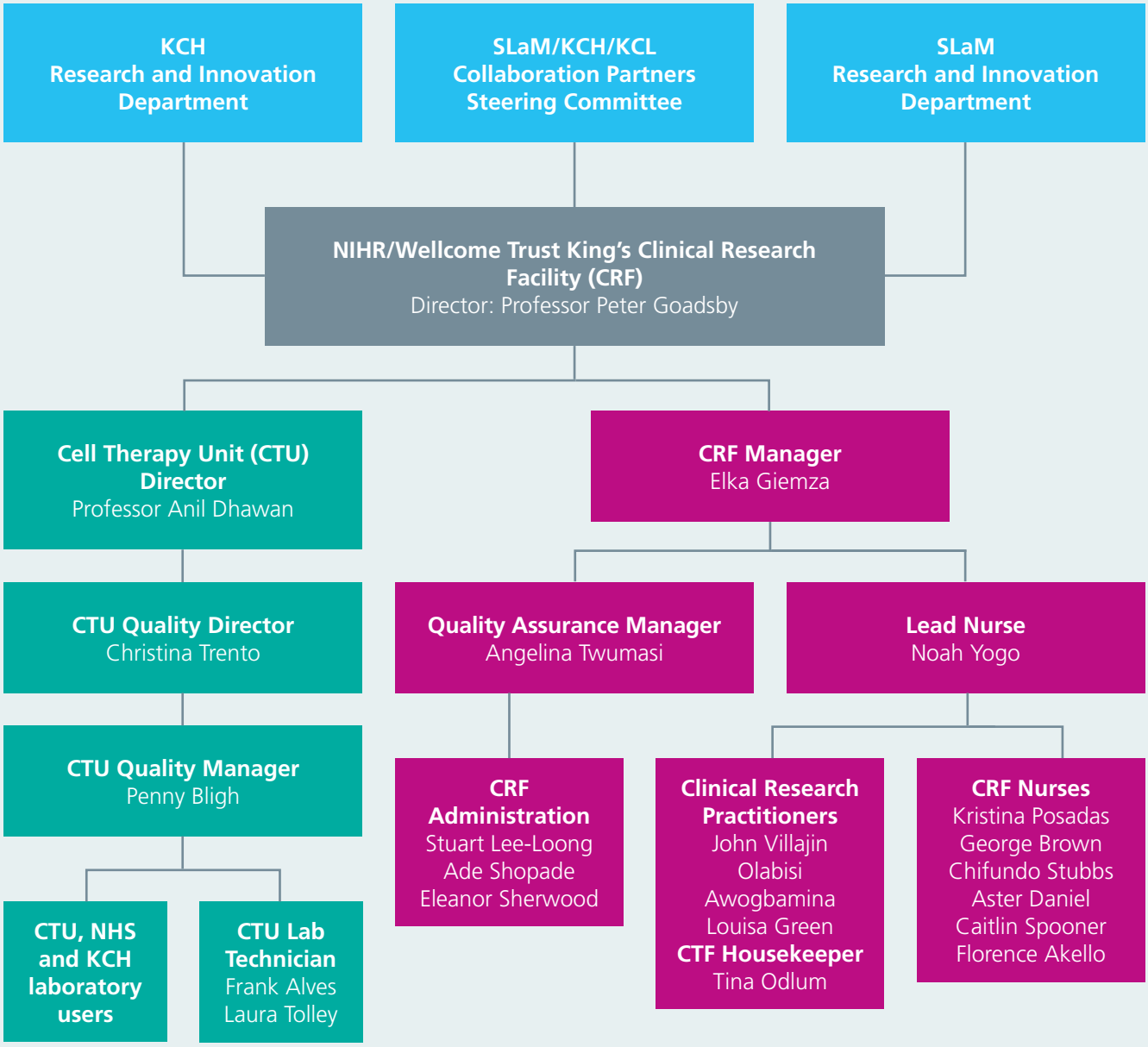
## The functional set up of the KHP CTO



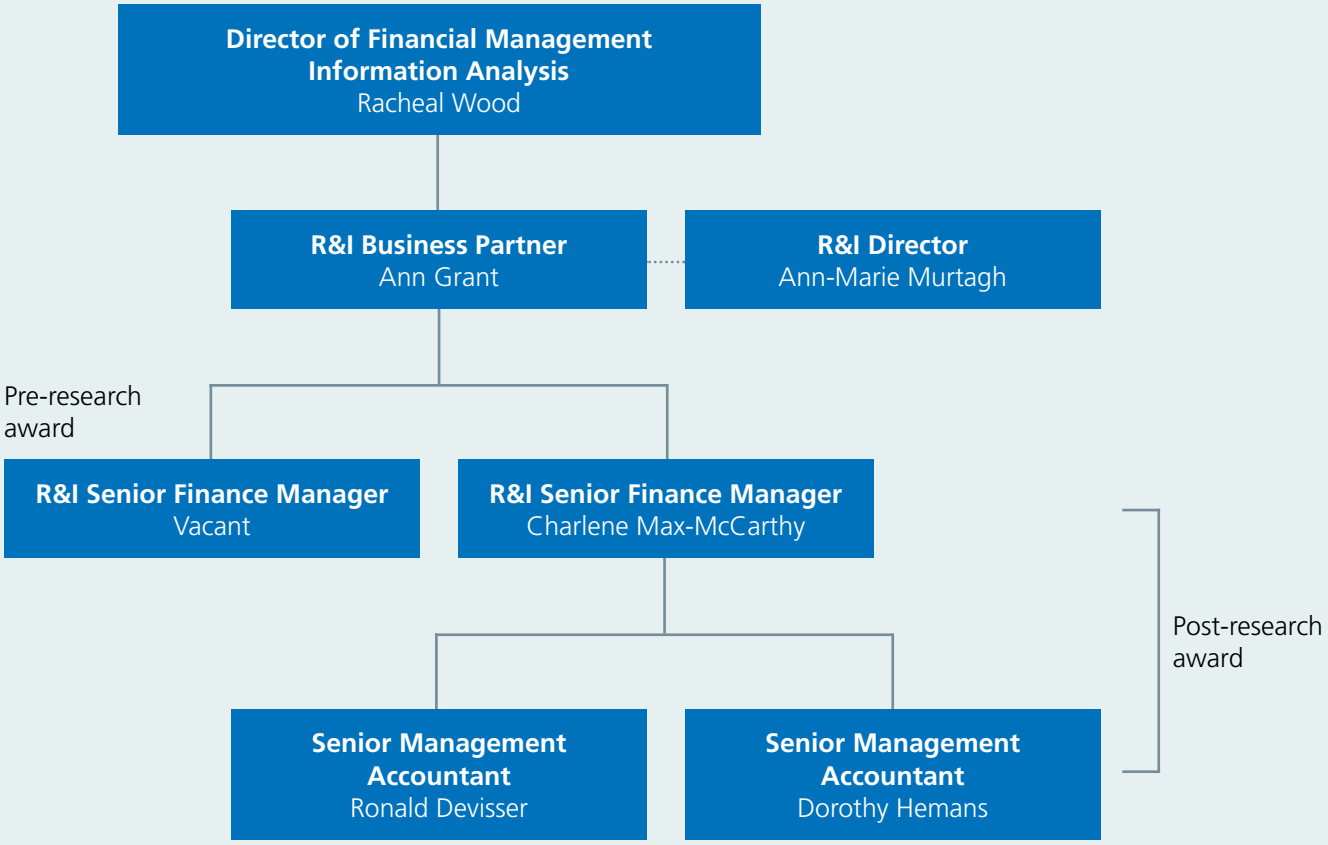
# Research & Innovation Organisational Structure



# Clinical Research Facility Organisational Structure

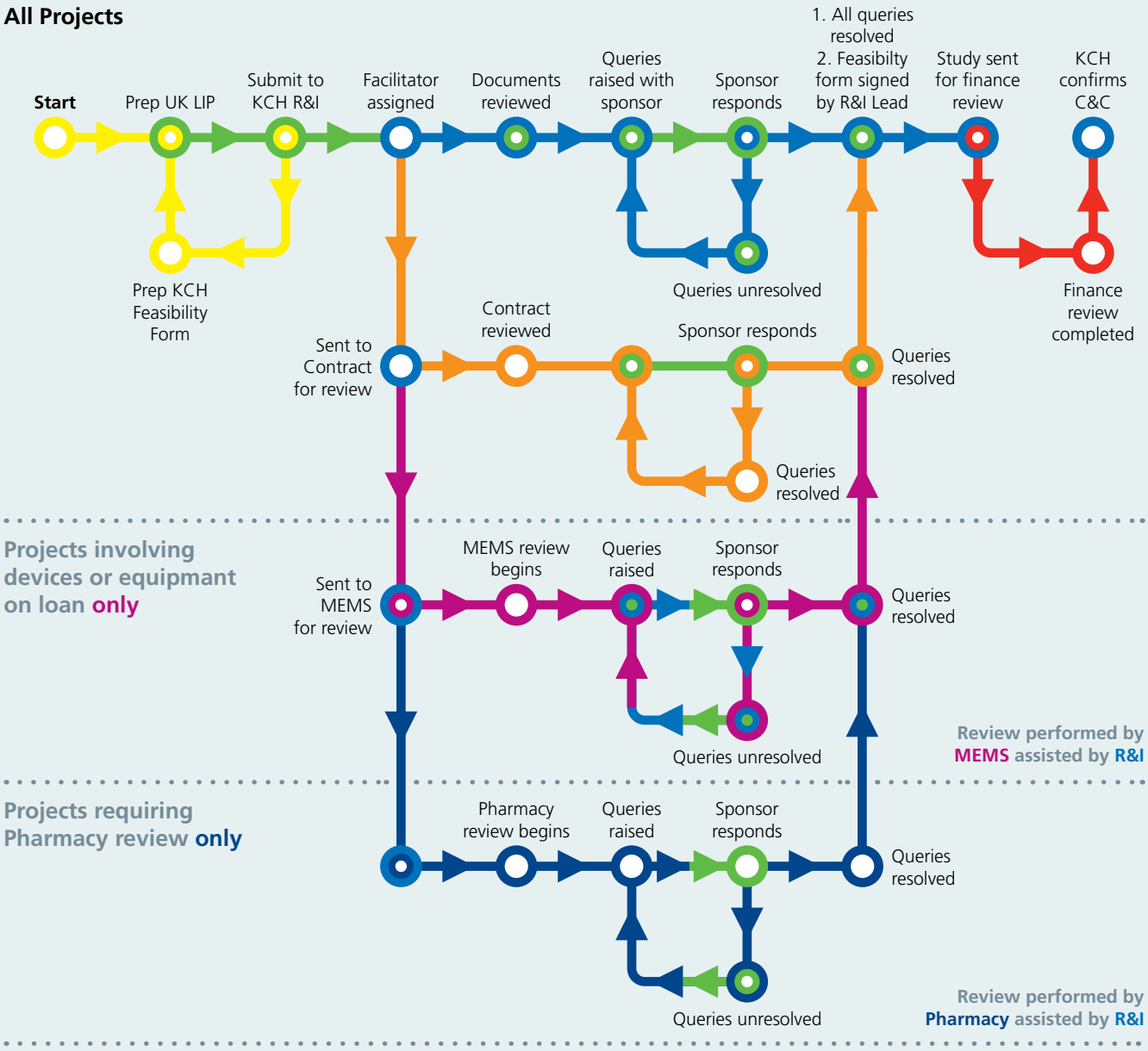


# R&I Finance Organisational Structure



# Project Approval 'Tube Map'

This map details the complete approval pathway for site only studies at KCH. If you are unsure if your study is a 'site only study' and eligible to use this pathway, please refer to the decision tool at http://www.hra-decisiontools.org.uk/research/.



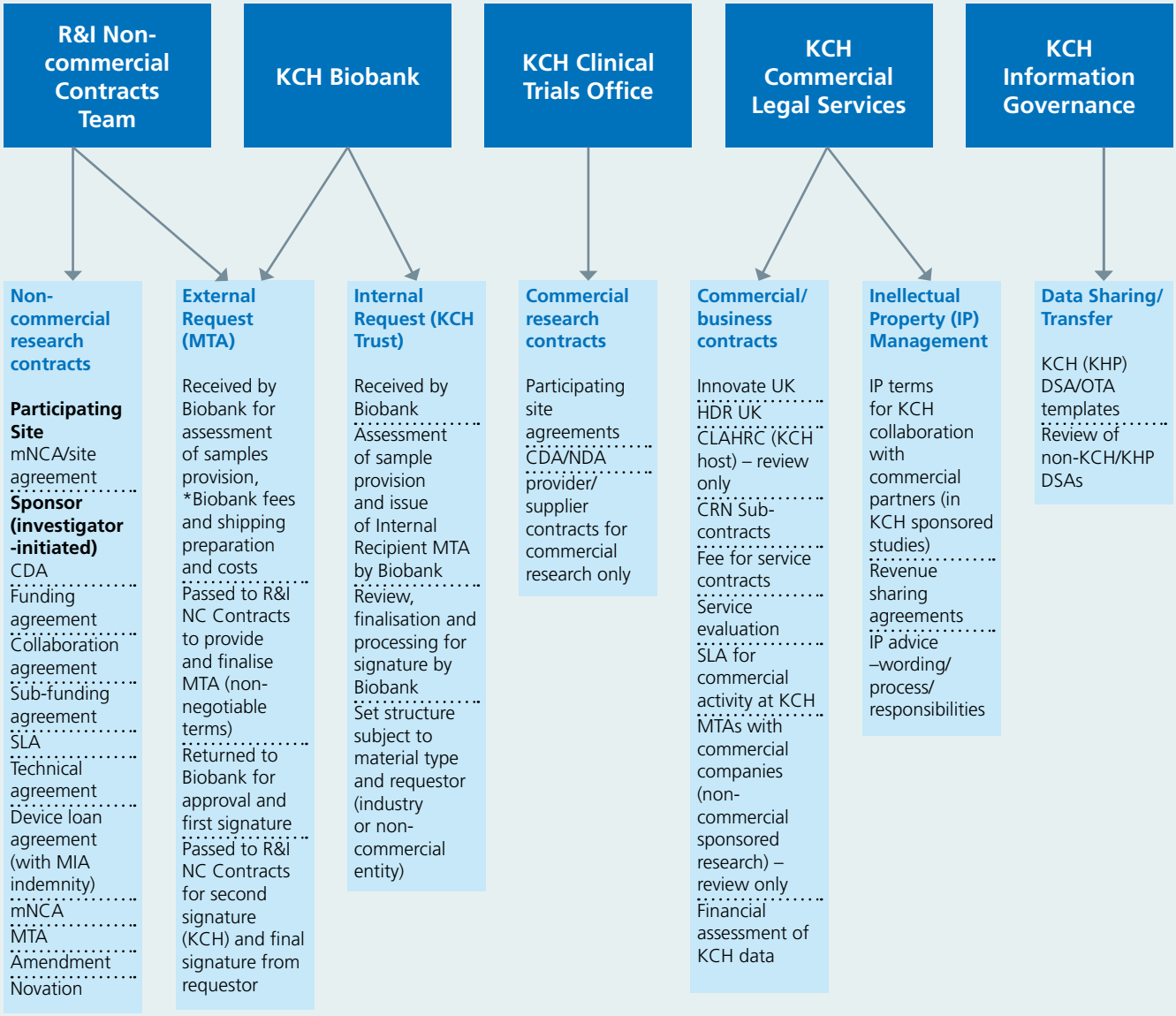

**Key**

Lines = *pathway information flow*
Circles = *an event without which the application cannot progress*
Colour = *party responsible for information flow/event*

Where two or more parties are involved this will be represented by concentric circles:

**= Sponsor**
**= KCH PI**
**= KCH R&I**
**= KCH Contracts**
**= MEMS**
**= Pharmacy**

# Examples of R&I Contracts




**Key**

CDA = Confidential Disclosure Agreement
CLAHRC = Collaboration for Leadership in Applied Health and Research Care
CRN = Clinical Research Network
DSA = Data Sharing Agreement
DTA = Data Transfer Agreement
HDR UK = Health Data Research UK
MIA = Master Indemnity Agreement
mNCA = Model Non-Commercial Agreement
MTA = Materials Transfer Agreement
NC = Non-Commercial
NDA = Non-Disclosure Agreement

# EDGE and Real Time Performance

EDGE is KCH Trust's trial management software. It manages, reports and tracks the activity of the clinical trials that are held across the Trust. Developed in 2000, it is used in across 80% of the NHS trusts in England Scotland and Northern Ireland. EDGE provides a constantly updated view of clinical research activity which allows for real-time data analyses and reporting in multiple locations and organisations. This enables research managers, data analysts and research nurses and clinicians to make the most of their information and streamlines the research process.

The R&I office also use EDGE to produce a monthly Real Time Performance (RTP) report. This measures the expected performance for active studies within the Trust using actual, planned, end date and target recruitment from EDGE. The report gives a summary of performance for each Research Delivery Unit (RDU).

## Real Time Performance Report

**Real Time Performance – % of expected recruitment to date**

*Real time performance is a measure of expected to date for active using the actual recruitment, planned recruitment end*

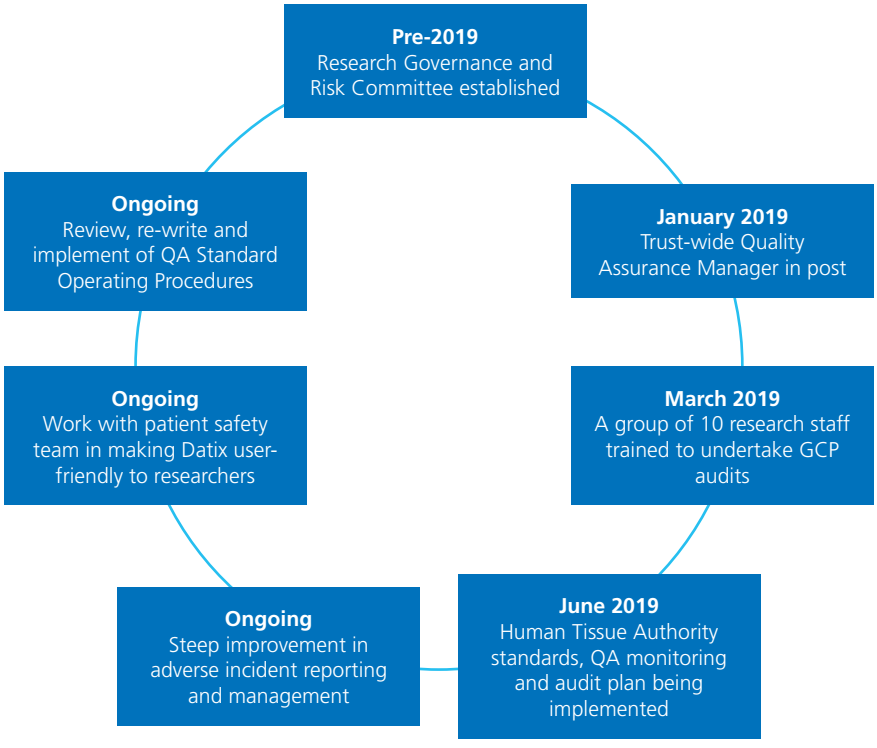
| Real Time Performance | Number Open Studies | Number Studies in Follow Up |
|---|---|---|
| 0-9%: Performance below expectation* | 117 | 58 |
| 10-69%: Performance below expectation | 88 | 77 |
| 70-99%: Performance average | 39 | 27 |
| 100+%: Studies meeting/exceeding recruitment target | 284 | 166 |
| Not reportable - Data missing | 20 | 19 |

As you can see on the image above, studies shown in grey have recruited less than 10% of their target recruitment, studies in red have recruited 10-69% of their target, and studies shown in green have recruited 100% or more of their target.

# Quality Assurance at KCH

As part of KCH's commitment to the continuous improvement of clinical research across all sites, the R&I department is supporting research teams to ensure that their work is conducted to the highest level of quality. To do this, a Quality Assurance (QA) plan was developed and implemented in 2019, led by QA Manager Roxy Ribeiro.

A QA plan is a key element of a Good Clinical Practice (GCP) quality system, which is one of the most important pillars in research. Its objective is to provide research teams with the support to ensure trial conduct and data quality are compliant.



# Abbreviations and Acronyms

| | |
|---|---|
| AHSN | Academic Health Science Network |
| ALBs | Arms Length Bodies |
| AMRC | Association of Medical Research Charities |
| ARC | Applied Research Collaboration |
| 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 |
| CTU | Cell Therapy Unit |
| GCP | Good Clinical Practice |
| HSMR | Hospital Standardised Mortality Ratio |
| HTA | Human Tissue Authority |
| 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 Indicators |
| LHS | Learning Health System |
| MRC | Medical Research Council |
| NHS | National Health Service |
| NIHR | National Institute for Health Research |
| PIN | Patient Involvement Network |
| PPIE | Patient and Public Involvement and Engagement |
| PRUH | Princess Royal University Hospital |
| R&I | Research & Innovation |
| RCF | Research Capability Funding |
| RDM | Research Delivery Manager |
| RDU | Research Delivery Unit |
| SLaM | South London and Maudsley Hospital |
| SOP | Standard Operating Procedure |
| SRL | Speciality Research Lead |

# Notes

# Notes

# Contacts list

**Research & Innovation Office**
The R&I Office
Kings College Hospital NHS Foundation Trust
161 Denmark Hill
London SE5 8EF
*kch-tr.research@nhs.net*
020 3299 1980

**R&I Contracts**
*kch-tr.researchcontracts@nhs.net*

**R&I Quality Assurance**
*kch-tr.researchqualityassurance@nhs.net*

**R&I Data**
*kch-tr.data@nhs.net*

**R&I Finance**
*kch-tr.researchcosting@nhs.net*

**R&I Costing**
*kch-tr.rd-researchcosting@nhs.net*

**Clinical Trials Pharmacy**
*kch-tr.ClinicalTrialsPharmacy@nhs.net*

**KHP CTO Feasibility**
*khpctofeasibility@kcl.ac.uk*

**KHP CTO Study Approvals**
*khpctofacilitator@kcl.ac.uk*

**KHP CTO Protocol Amendments**
*khpctoamendments@kcl.ac.uk*

**KHP CTO Commercial Finances and Invoicing**
*finance-khpcto@kcl.ac.uk*

**KHP CTO Data**
*khpcto.CommercialData@kcl.ac.uk*

**Clinical Research Associate Team**
*khpcto.crateam@kcl.ac.uk*

**KHP CTO Training Team**
*KHP-CTOTrainingTeam@kcl.ac.uk*

**ACET**
*kch-tr.acetresearch@nhs.net*

**Haematology**
*kch-tr.hrutrialsetup@nhs.net*

**Liver**
*kch-tr.liverresearchgov@nhs.net*

**Ophthalmology**
*kch-tr.ophthalmologyresearch@nhs.net*

**Paediatrics**
*kch-tr.paediatricresearch@nhs.net*

**Stroke**
*kch-tr.kingsresearch@nhs.net*

**Rheumatology**
*rheumatology-ctg@kcl.ac.uk*

**Clinical Research Facility**
*kingscrf@kcl.ac.uk*