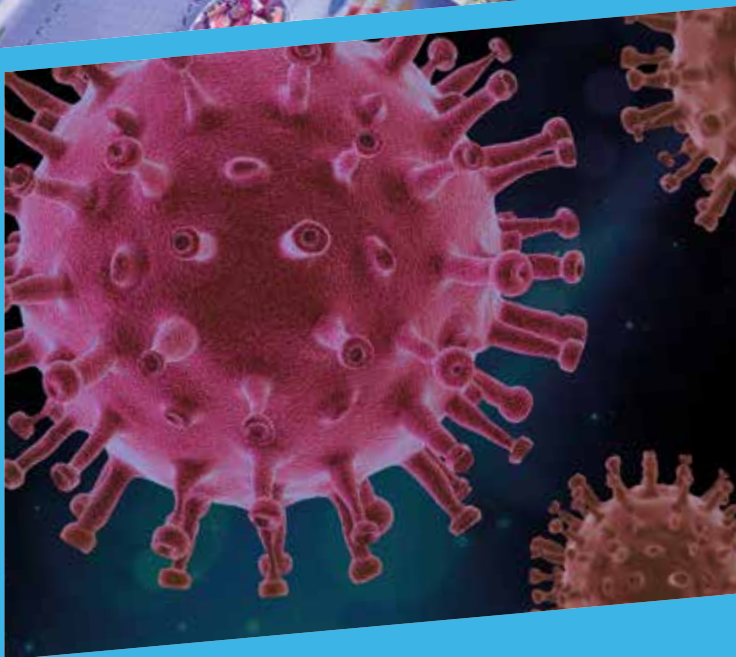


Research & Innovation Strategy: Three years on



Excellence in patient care
underpinned by research and innovation

Welcome

Dear colleagues,

Welcome to the third instalment of the Research and Innovation (R&I) Strategy update. The Research and Innovation Five-Year Strategy was launched in 2019 in order to demonstrate and guide how we align with and support the Trust's Strong Roots, Global Reach strategy, of which research underpins a key part of its BOLD vision. Since then, the R&I team have released yearly Research and Innovation Strategy updates in order to highlight our successes and show how our teams have achieved key milestones set out in the Five-Year Strategy.

Since the last update, where we focused on the vast number of COVID-19 clinical trials and research studies that were initiated from March 2020 onwards, we are now – within the Trust and wider society – beginning to settle into our 'new normal'. This could only have been achieved through the aforementioned trials and studies; those which brought us vaccines that could prevent severe COVID-19 as well as those which brought about novel treatments for the disease and informed infection control policies. Our 'new normal' also means that, while many COVID-19 studies are still ongoing at the Trust, our research teams have been able to shift more focus back to their specialities, resulting in us opening more commercial trials this financial year than ever before and recruiting more participants to either commercial or non-commercial studies than last year.

Looking back over our third year, we have remained on track to achieve the three aims of the Research and Innovation Five Year Strategy; (i) to increase commercial and academic research activity, (ii) to develop an Advanced Therapies and Biomedical Sciences Hub and (iii) to develop a supportive Trust-wide research culture. As previously mentioned, we have increased the number of participants enrolled into trials and studies compared to last year. We are also assisting prospective clinical researchers along their career path through Pre-Doctoral Clinical Academic Fellowship scheme and our Greenshoots programme and have just held our first Advanced Therapy Medicinal Products (ATMPs) symposium, where attendees learned about the possibilities of clinical research involving this type of therapy.

As a testament to the quality of our research at King's College Hospital NHS Foundation Trust, many of our staff have won awards for exceptional achievements within their fields. For example, consultant neurologist and director of the NIHR Wellcome King's Clinical Research Facility Professor Peter Goadsby was elected to the prestigious Fellowship of the Royal Society.

We, the directors of Research and Innovation at King's College Hospital (KCH), are immensely proud of our research teams and what they have achieved in the last year. Following what was the most challenging period in the history of the NHS, our teams have regrouped and pushed forward to recruit to and deliver vital clinical trials and studies in a wide range of disease areas that will enable us to continue to provide the best care possible for our patients.

With warm regards,



Professor K. Ray Chaudhuri
Director of Research
& Innovation



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



Professor Anil Dhawan
Director of Research
& Innovation

Research Strategy Aims: where are we now?

It has been three years since the launch of the Research and Innovation Strategy. This document set out three key aims and the steps we, as the R&I community, would take to achieve those aims. So how are we doing?

Aim 1: Increase commercial and academic research activity

- ✓ In the top ten recruiting Trusts in the UK for CRN portfolio studies
- ✓ Fair and transparent funding model in place to support delivery of portfolio and commercial research
- ✓ Funding for R&I Lead roles secured, including two co-lead roles for PRUH
- ✓ Growth in commercial contract income (despite COVID-19 "pause")
- ✓ Recruit >18,000 patients annually
- ✓ Seek patient input into setting of research priorities via a network of patient groups
- ✓ Implementation of KERRI/COGSTACK for research purposes
- ✓ Baseline metrics for recruitment at site level implemented

Aim 2: Development of the Advanced Therapies Medicinal Products (ATMPs) and Biomedical Sciences Hub

- ✔ Establish trust level ATMP oversight group (Chair – Anil Dhawan)
- ✔ Appoint Biological Safety Officer(s) and set up Trust-wide Biological Safety Committee for research
- ✔ Fund and appoint Research Quality Facilitator for R&I
- ✔ Fund and appoint a Clinical Biological Safety Lead
- Implement consent to contact for all KCH patients (via Apollo Due 2023)
- ✔ Establish ATIMP Academy and hold first workshop
- ✔ Baseline metrics for recruitment at site level implemented

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

- ✔ Ensure robust systems for accurate central data collection (EDGE) in place
- ✔ Quality Assurance system in place backed by appropriate suite of research Standard Operating Procedures (SOPs)
- ✔ Information regarding research is part of Trust induction
- ✔ Tailored reports to each RDU on monthly basis to aid performance
- ✔ PRUH R&I Leads meeting established
- ✔ R&I housed on a main Trust site (Coldharbour Works)
- ✔ R&I training implemented (R&I Academy programmes and workshops)

Contents

RDU 1 - Neurosciences, Stroke, Neurology, Age and Ageing	7	RDU 8 - Anaesthetics, Critical Care, Emergency Department and Trauma (ACET), Pain, Respiratory and Orthopaedics	28
Neuroscience	8	ACET	29
Neuroradiology	9		
Stroke	10	RDU 9 - Children	30
		Paediatrics	31
RDU 2 - Cardiology and Breast Cancer	11		
Cardiology	12	King's Clinical Research Facility	32
RDU 3 - Women's Health and Fetal Medicine	13	Princess Royal University Hospital (PRUH)	36
Women's Health	14	Supporting Services	38
Fetal Medicine	15	Pharmacy	39
		Radiology	40
RDU 4 - Haematology, Precision Science, Palliative Care	16	Pathology	41
Haematology	17		
Palliative Care	18	Research & Innovation	42
RDU 5 - Liver, Gastroenterology and Rheumatology	19	ATMP	47
Liver	20		
Gastroenterology	21	Congratulations Corner	48
RDU 6 - Renal, Diabetes and Endocrine, Urology	22	Useful Information	51
Renal, Diabetes and Endocrine, Urology	23	Outreach & Engagement	52
Therapies	24	The year in numbers....	55
		KCH Research Delivery Unit (RDU) Leads	56
RDU 7 - HIV & Sexual Health, Ophthalmology, Dermatology and Dental	25	King's Health Partners Clinical Trials Office	60
HIV, Sexual Health and The Havens	26	Abbreviations and Acronyms	63
Ophthalmology	27		

RDU Structure



RDU 1 – Neurosciences, Stroke, Neuroradiology, Age and Aging



RDU 2 – Cardiovascular and Breast Cancer



RDU 3 – Women's Health and Fetal Medicine



RDU 4 – Haematology, Precision Science and Palliative Care



RDU 5 – Liver, Gastroenterology and Rheumatology



RDU 6 – Renal, Urology, Diabetes and Endocrinology



RDU 7 – HIV & Sexual Health, Ophthalmology, Dermatology and Dental



RDU 8 – Anaesthetics, Critical Care, Emergency Department and Trauma (ACET), Pain, Respiratory and Orthopaedics



RDU 9 – Children



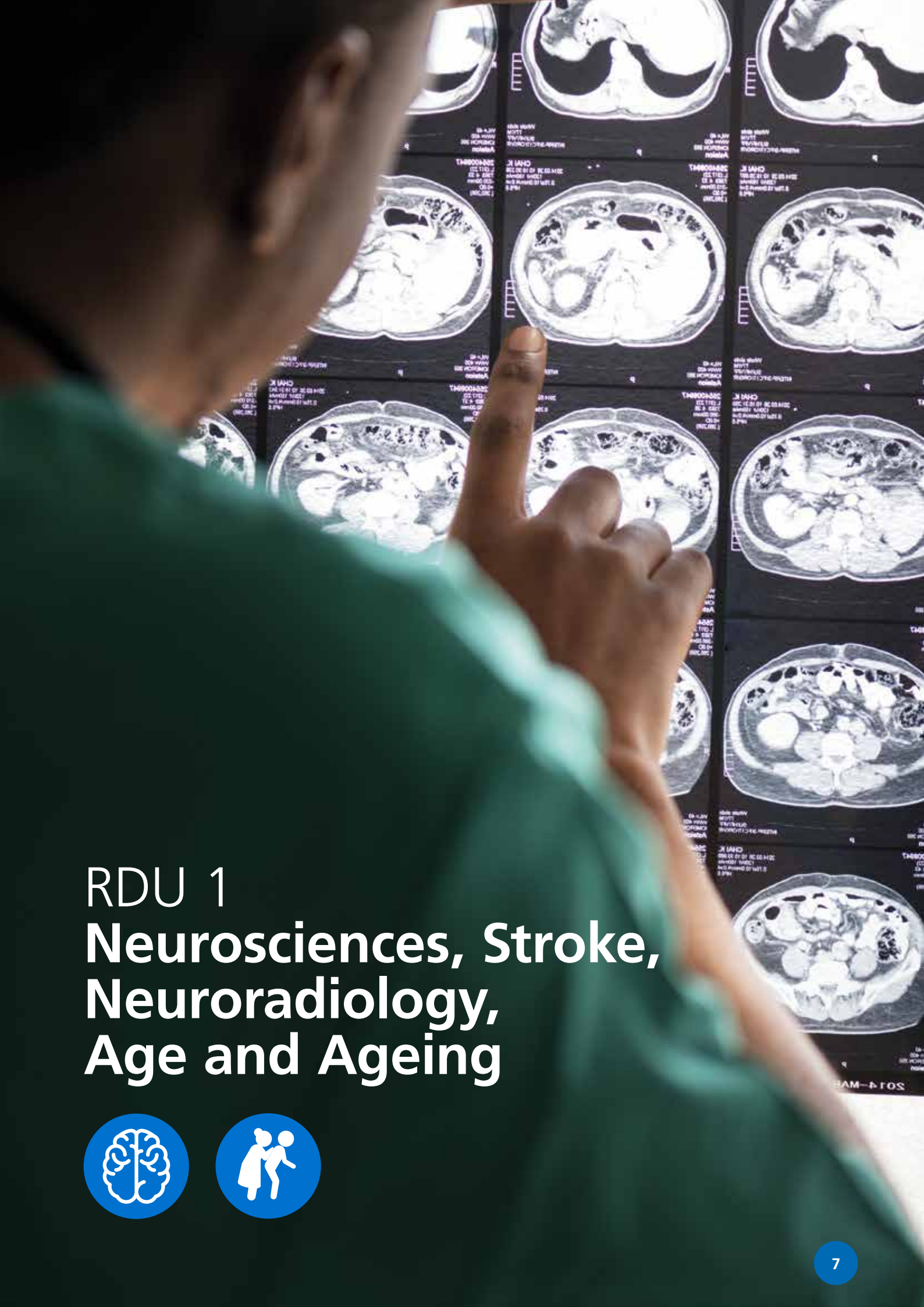
NIHR Wellcome King's Clinical Research Facility



The Princess Royal University Hospital (PRUH)



Cross-cutting areas of Research



RDU 1 Neurosciences, Stroke, Neuroradiology, Age and Ageing



Neuroscience

The Parkinson's research team consists of research manager Alexandra Rizos, seven neurologists and clinical research fellows, five research coordinators and a research administrator, all of whom are led by RDU1 lead and neuroscience consultant Professor Ray Chaudhuri.

The Parkinson's team, which sits within the Neuroscience research team, is currently running over 20 studies of which seven are commercial. Our commercial studies focus on improving treatment of Parkinson's disease (PD) by exploring novel delivery of medication and development of new treatment options.

We have had incredibly successful recruitment in cutting-edge commercial trials, such as the ORCHESTRA trial. Sponsored by UCB Biopharma and led by Professor Chaudhuri both at KCH and nationally, ORCHESTRA aims to explore whether a novel drug can help slow down the progression of PD, specifically by targeting the misfolded protein α -synuclein, which plays a role in the pathology of the disease.

Our team continually drive to offer a diverse range of people access to research. In doing so, we strive to capture a representative picture of the ethnically diverse population of South London in our recruitment across our studies, both observational and interventional. For example, over half of the participants recruited to the COVID-CNS study, which is led by Parkinson's research team member Dr Daniel van Wamelen and explores the neurological and psychiatric complications of COVID-19, are from a Black or minority ethnic background.

Since the beginning of 2021 we have published over 90 research papers across many high impact journals, with a focus on exploring and highlighting the non-motor symptoms of PD. In response to the COVID-19 pandemic, many of these papers addressed the impact of COVID-19 on people with PD. In particular, 'Outcome of Parkinson's Disease Patients Affected by COVID-19' was the first paper to be published specifically exploring mortality of Parkinson's patients with COVID-19. With our international collaborators we have written

and published a comprehensive book, titled "COVID-19 and Parkinsonism", which focuses on the impact of COVID-19 on people with PD and Parkinsonism and covers a wide range of COVID-19-related effects from both a motor and non-motor perspective, as well as the effect on healthcare delivery across the globe.

The outstanding level of care – underpinned by our pioneering research – has been recognised this year in multiple ways. For example, we have again been awarded the title of Parkinson's Foundation Centre of Excellence, one of only two in the UK, and of only 14 worldwide (outside of the US). Professor Chaudhuri was named one of the top experts in PD in the world by Expertscape – this is based upon the number peer-reviewed research articles published in the last nine years. Furthermore, last year our team celebrated the 10-year anniversary of our expert patient group, CRISP (led by Research Manager, Alexandra Rizos). The group provides invaluable insight and advice into our new and upcoming studies, ensuring that we continue to conduct research into areas most valued by people with PD and serve our community in the best way that we can.



Members of the Neuroscience research team, with RDU Lead and Neuroscience Lead Professor K Ray Chaudhuri at the far left.

Neuroradiology

The Neuroradiology Team is led by Dr Thomas Booth and has three neuroradiologists, one trainee radiologist, one physician and a chief data scientist. Critical to the team are three clinical study assistants, two research managers as well as neuroradiographers and radiography assistants. The team at KCH are the leading recruiters to the Magnetic Resonance Imaging Abnormality Deep Learning Identification (MIDI) study amongst 38 UK sites.

The MIDI study is an NIHR portfolio-adopted non-commercial study. Our main goal is to improve patient care and outcomes by making faster MRI diagnoses with the help of Artificial Intelligence (AI) and Deep Learning-based (DL) algorithms. DL is a rapidly developing field with great potential in all aspects of healthcare – in particular radiology. This pioneering method can transform healthcare by deriving new and important insights from the vast amount of data generated every day in healthcare settings. DL excels in image pattern recognition and can learn complex representations from raw MRI data.

A national increase in demand for brain MRI scans as a diagnostic tool used has increased the waiting time for MRI patients to receive results. This problem is compounded further by a shortage of radiologists to review these scans.

The MIDI study aims to develop an automated triaging tool which could immediately flag and identify abnormalities at the time of imaging, allowing radiology departments to prioritise limited resources for reporting abnormal scans and expediting early intervention from the referring clinical team. This would vastly improve clinical outcomes and also lower healthcare costs.

The overall performance of DL-based algorithms relies on the availability of large-scale annotated data with diverse, high-quality images from various institutions in different geographic areas. This ensures the generalisability of a model for clinical use.

Our team are in the process of

collecting a large dataset of MRI scans from across the UK which will be used to train the DL-based algorithm to distinguish normal MRI scans from abnormal MRI scans. Currently, there are 38 participating NHS sites across the UK and, overall, the study has enrolled nearly 12,000 patients making it the top-recruiting study within the Neurological Disorders speciality.

The study aims to recruit 30,000 participants by March 2025, whose MRI scans will be used to further train and test the DL-based algorithms. Once trained, the DL-based algorithm will be tested in a clinical setting to determine its validity in analysing radiological images to suggest clinically relevant findings and aid diagnostic decisions.



Dr Tom Booth, Neuroradiology research team

Stroke

Led by consultant neurologist Dr Laszlo Sztriha, the Stroke research team consists of one research manager, two research nurses, two research coordinators and a research administrator. Working across Denmark Hill and the Princess Royal University Hospital, Stroke research offer a broad portfolio of commercial and non-commercial interventional trials and observational studies. These range from hyper-acute treatment in A&E to secondary prevention and observational studies designed to address fundamental knowledge gaps in Stroke.

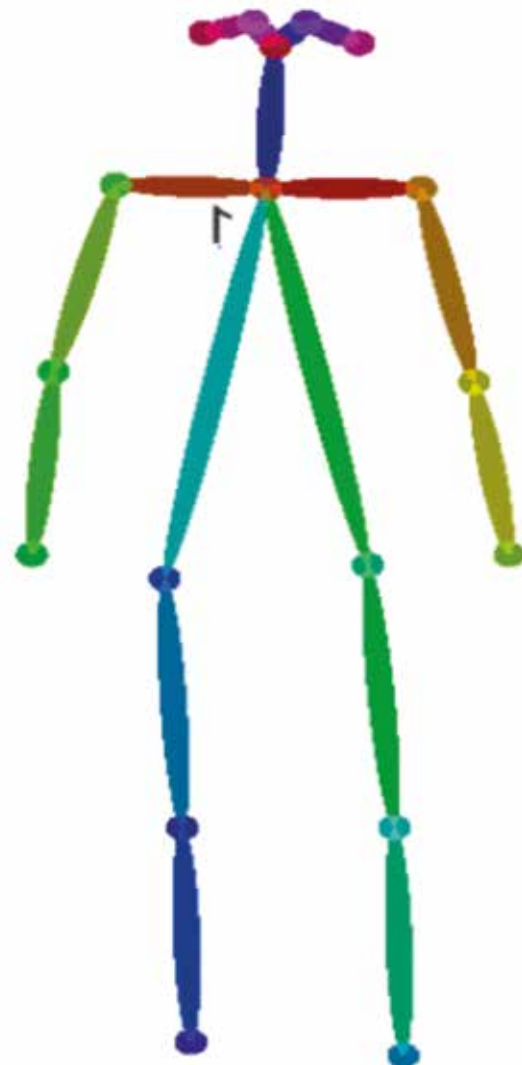
In the last year, the KCH Stroke research team recruited over 1,400 patients – making them the highest recruiting trust for Stroke across the UK. Amongst other trials, KCH's recruitment success was driven by a Trust-sponsored observational study titled Clinical Outcome Modelling of Rapid Dynamics (also known as 'Stickman').

The brainchild of consultant neurologist Dr Yee Mah, Stickman aims to see how patients on the ward recover after a stroke. Stroke commonly presents with weakness or complete paralysis. Predicting recovery and choosing an appropriate treatment depends on our ability to track a patient's movement – however this is currently recorded subjectively in words and diagrams.

Stickman aspires to improve our ability to monitor the health of patients by using a motion categorisation device and artificial intelligence (AI) to characterise the movement of a patient's arms, torso and legs in the form of an anonymous "stickman".

Using movement data in combination with routinely-collected clinical information, the study aims to quantify a patient's impairment of motor skills over time. Overall, Stickman should produce mathematical models that predict the evolution of the illness and indicate the best treatment options.

In addition to developing predictive models that support clinical management, the technology in Stickman presents a unique opportunity. More detailed characterisation of patients' clinical picture enables research to test new and innovative treatments in the future. Stroke research hopes the fruit of Stickman's labour will feed the research of tomorrow!



'Stickman': AI-generated representation of a stroke patient.

RDU 2 Cardiology and Breast Cancer



Cardiology

The Cardiac research team, made up of lead research nurse Jonathan Breeze, research nurses, Michelle, Abi, Sheetal, Katherine, Sarah, Rita, Victoria and Javier, and research facilitator/practitioner Hosanna, have had another exceptional year of high-quality research supporting studies across the range of cardiology subspecialties. With over 50 studies running at any one time, more than 1000 patients have either enrolled or been followed up over the past 12 months.

There have been many highlights this year, from reaching the '100 patients recruited' mark to two important national studies – the British Heart Foundation PROTECT-TAVI study (brain protection during aortic valve replacement) and the QUACS study (Quality of Life After Cardiac Surgery), to recruiting and following up 250 participants to the PHOSP-COVID (The Post-hospitalisation COVID-19) study, which has already given unique insight into the symptoms and prevalence of long COVID.

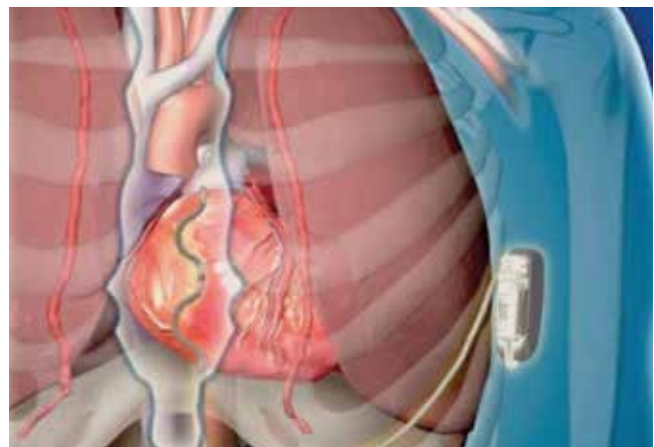
One of the key strengths of KCH Cardiology is the willingness of the clinical team to offer novel, cutting-edge treatments to our local population. That could be in the form of a new drug, a cardiac imaging technology that is in its infancy, or a minimally-invasive surgical technique. In the case of the EV ICD Study, sponsored by Medtronic and led at KCH by Dr Francis Murgatroyd, we were able to offer participants the opportunity to receive a new type of implantable cardioverter defibrillator (ICD).

An ICD is a small battery-powered device placed in the chest which detects and stops irregular heartbeats (arrhythmias). It continuously monitors the heartbeat and delivers electric shocks, when needed, to restore a regular heart rhythm. This device is recommended to those with conditions that put them at the highest risk of life-threatening arrhythmias and to those that have survived cardiac arrest. Traditionally the device is placed beneath the skin, under the collarbone and attached to wires that thread through veins into the heart.



An illustration of the Medtronic EV ICD

A newer device (subcutaneous ICD), developed around 15 years ago, can be implanted under the armpit and attached to a lead that is threaded under the skin and above the ribcage. Both devices are effective but have some limitations.



An illustration of the placement of the new EV ICD

An Extravascular ICD (EV ICD) uses a similar technique to the subcutaneous device but positions a lead underneath the sternum so that it is closer to the heart allowing more detailed heart rhythm monitoring, less energy to effectively shock the heart back to normal, and is a smaller device. The UK's first EV ICD implant took place at KCH in June 2021 and, over the course of late 2021, seven further patients were successfully implanted with this innovative device. The pivotal study reports at the European Society of Cardiology Congress in August 2022 and we can't wait to hear the results.

2022/23 promises more innovation and opportunity for our local patients, and you can be sure that the Cardiac research team will be ready to support and deliver when called upon!

RDU 3

Women's Health and Fetal Medicine



Women's Health

The Women's Health research team continues to grow in strength and size. The team is now led by the Lead Midwife for Research, Katherine Clark, which is a new substantive role to integrate research within clinical practice, and Senior Clinical Research Midwife Sophie Webster, with three research midwives also in the team. We have a growing number of PIs across the multi-disciplinary team including Alice-Amanda Hinton who is a midwife PI on the associate PI scheme.

Early Pregnancy Unit

The team in the Early Pregnancy Unit, led by Miss Jackie Ross and Miss Jemma Johns, are participating in the CERM study – a multicentre study looking at the use of antibiotics for women with recurrent miscarriages and endometritis. We have also started a prospective study looking at the use of ultrasound in excluding molar pregnancy and facilitating non-invasive treatments for early miscarriage. In the last year we have co-authored papers on medical treatment for miscarriage, Caesarean scar pregnancies and heterotopic pregnancies.



Sophie Webster, PRUH Research Midwife on the PRUH Labour Ward

Maternity

Supported by our Intrapartum Research Champions across sites who enable research to be undertaken during labour care, in the last financial year we successfully opened the GBS3 and iGBS studies. These are large multi-centre studies striving to improve care in the prevention of Group B Streptococcus infection in newborn babies. There are a further ten studies running in maternity.



New fridges to enable research on the labour wards

Our research capacity has improved as we have been able to procure a freezer and centrifuge to process and store samples. This has been thanks to collaboration with Fetal Medicine and Nicola Griffiths' support at the PRUH.

Urogynaecology

The Urogynaecology team, led by Professor Linda Cardozo with Mr Dudley Robinson and Dr Angie Rantell, initiated a new study looking at the impact of wearable technology on symptom control, quality of life and physiological changes associated with clean intermittent self-catheterisation.

The study will use a survey to compare anxiety and quality of life between using an existing catheter and using the new GentleCath™ Air catheter, with an Apple iPhone and watch being used throughout the study to measure associated heart rate variability and as a new method of data collection as questionnaire data are completed on the smart watch.

Fetal Medicine

The Harris Birthright Research Centre for Fetal Medicine, located within the Fetal Medicine Research Institute, provides a high-quality service to thousands of pregnant women every year. The Institute allows for the combined delivery of KCH NHS services with world-class research, teaching and practice in foetal medicine, and provides a range of services such as ultrasound scanning, consulting and treatment rooms as well as diagnostic and research laboratories.

Research at the Institute is spearheaded by RDU co-lead and Fetal Medicine research lead Argyro Syngelaki and has one of the highest rates of recruitment by KCH for CRN portfolio studies, ensuring that cutting-edge research is continually being delivered. The Centre continues to play a major role in education and research. In the last financial year, the team at the Fetal Medicine Institute have recruited over 7,000 participants to 16 research projects.

In FY21/22, the Fetal Medicine Research team recruited over 5,000 participants to the Advanced Cardiovascular Imaging in Pregnancy Study, led by KCL's Dr Marietta Charakida and Professor Kypros Nicolaides at KCH. Cardiovascular (CV) disease is the number one cause of death among women from all countries and while this is in decline, mortality in younger women has plateaued. Pregnancy and pregnancy-associated hypertensive disorders such as pre-eclampsia may lead to physiological and metabolic changes that could in turn increase the risk or trigger the onset of CV disease, going some way to explain the levelling-off of CV-related mortality in younger women. Therefore, understanding the structure and function of the heart in pregnancy is vital to recognising abnormalities at an early stage and planning interventions to avoid adverse maternal and foetal outcomes.

Modern ultrasound technology can demonstrate subtle changes in cardiac anatomy and performance and reveal any heart function impairment in hypertensive disorders of pregnancy both for mother and the foetus. In the Advanced Cardiovascular Imaging in Pregnancy Study, the team at the Fetal Medicine Institute are using ultrasound combined with various computer software to analyse subtle changes in heart function as well as non-invasive machines to assess the hardness of arteries. These methods will be used antenatally to determine participants' risk of CV-related pregnancy complications. Participants will also be assessed six weeks to five years after birth in order to flag any persistent cardiac functional changes and

inform clinicians of those that are at an increased risk of CV complications.

Another project is aiming to improve treatment options for women with polycystic ovary syndrome (PCOS) who wish to get pregnant. PCOS is thought to affect 1 in 10 women in the UK and can prevent eggs from being released from the ovary, affecting fertility. Current treatment with clomifene – with or without metformin – only results in pregnancy in 30% of women and is associated with various side effects and a 10-fold increase in the risk of multiple pregnancy. A recent review of the drugs available for PCOS suggested letrozole could be more effective than clomifene – and that its effects could be enhanced with metformin. As such, the current LOCI (Letrozole Or Clomifene for Ovulation Induction) study, which opened at KCH at the end of 2021 and is led at KCH by Dr Sesh Sunkara, aims to compare the efficacy of letrozole taken with or without metformin to clomifene taken with or without metformin.



RDU 4

Haematology, Precision Science, Palliative Care



Haematology

The Haematology Research team comprises a mix of research nurses, clinical trial coordinators and data managers led by Dr Piers Patten. As part of Kings Health Partners Haematology we are working to improve collaborations between King's College Hospital, Guy's and St. Thomas' Hospital and King's College London, taking advantage of their collective strength. This strategy has allowed for several collaborations with commercial partners to be developed.

We continue to run the following clinical trials in cutting edge areas such as Chimeric Antigen Receptor T (CAR-T) cell therapy and bispecific antibody therapies that target a range of blood cancers. For example the CARTITUDE 4 study, led by Dr Reuben Benjamin, is a Phase 3 trial which aims to see whether inclusion of myeloma cell-specific CAR-T cell therapy improves outcomes for patients with multiple myeloma in comparison to those receiving standard, non-myeloma cell-specific therapy.

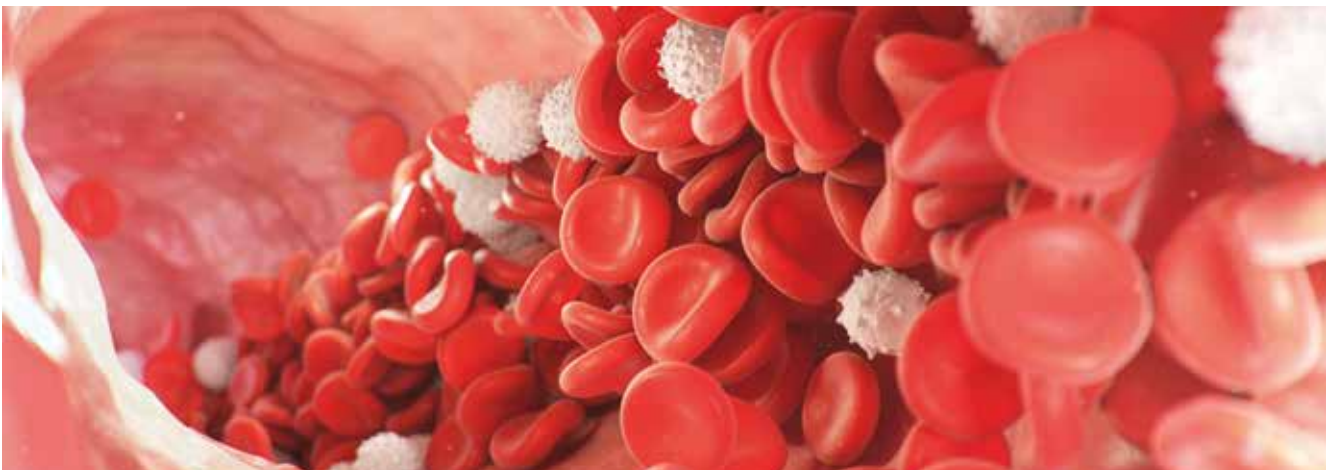
The global VOYAGE trial, led by Dr Victoria Potter, aims to test the safety and pharmacokinetics of the bispecific antibody MGD006 in patients with Acute Myeloid Leukaemia or Myelodysplastic Syndromes. MGD006 is designed to target and attach to both tumour cell-killing T cells and cancerous B cells, facilitating T cell-mediated elimination of cancer cells. Our research team are currently the highest recruiter in the UK for this trial.

IMPACT is a clinical trials partnership involving the Anthony Nolan Foundation, Leukaemia UK and NHS Blood and Transport, which is dedicated to improving the outcomes of stem cell transplant patients. Our team are the top recruiter to IMPACT trials and this year we

contributed to recruitment of the 1000th patient in the UK to an IMPACT portfolio.

Current IMPACT trials being held at KCH include MoTD, a Phase 2 clinical trial comparing the current prophylactic anti-rejection treatment of thymoglobulin for patients requiring stem cell transplants with two new treatments: either calcineurin inhibitors or sirolimus-based post-transplant cyclophosphamide. If successful, this could result in a more effective treatment for the prevention of stem cell donor rejection.

Other key highlights from the last financial year include the availability on the NHS of pioneering new therapies: acalabrutinib for the treatment of Chronic Lymphoid Leukaemia, ravalizumab for the treatment of Paroxysmal Nocturnal Haemoglobinuria and crizanlizumab for the treatment of Sickle Cell Disease (SCD). Furthermore, the team have just opened the Natural History Sickle Cell Disease study in collaboration with Guy's and St. Thomas NHS Foundation Trust. This will establish a cohort of adults with SCD and allow for data collection regarding the natural history of the disease to improve SCD patient care in the future.



Palliative Care

The KCH Palliative Care research team comprises three research nurses (Stefi Stegner, Laura Sharp and Param Kaler) and is led by Dr Sabrina Bajwah. For the second year running, KCH was the highest recruiting NHS Trust in the country for palliative care. In financial year 2021/2022, we successfully recruited to two respiratory studies, the BETTER-B trial and SELF-BREATHE.



Chronic or refractory breathlessness is a very common and distressing symptom of advanced chronic respiratory diseases. In 2020, KCH successfully opened the King's College London-led BETTER-B trial. This EU-funded project for which Professor Irene Higginson is Chief Investigator (led at KCH by Dr Sabrina Bajwah) is testing whether an established antidepressant - mirtazapine - could be used to treat chronic breathlessness in patients with advanced chronic respiratory diseases.

This randomised double-blind clinical trial will test the clinical and cost-effectiveness of mirtazapine compared with placebo in patients with chronic obstructive pulmonary disease or interstitial lung disease. The trial is currently recruiting patients as well as their informal caregivers across the UK, Ireland, Germany, Italy and Poland. We have recruited 47 out of our local target of 60 patients at KCH. Remote consenting and data collection has ensured vulnerable patients are given the opportunity to participate in this trial.



Professor Irene Higginson



Dr Sabrina Bajwah

For more information, please visit the project website here:
www.betterbreathe.eu



A proactive approach to tackle breathlessness is required to build capacity and resilience within health systems, especially given rising health and social care costs and workforce challenges. SELF-BREATHE, an innovative digital app developed by Dr Charles Reilly, aims to support those living with breathlessness and is one potential solution.



Dr Charles Reilly,
consultant physiotherapist

Over the last year, Dr Reilly and colleagues have tested SELF-BREATHE in a feasibility randomised controlled trial, comparing usage of the SELF-BREATHE app in addition to standard NHS healthcare for breathlessness versus NHS healthcare alone. Fifty-two patients were recruited from specialist out-patient clinics and services across KCH over 12 months.

The Palliative Care research team are now analysing the data. By the end of the study, the researchers expect to deliver:

- the first UK digital intervention specifically for chronic breathlessness
- essential feasibility data on delivering and evaluating this digital intervention
- an optimised protocol for a randomised controlled trial of clinical and cost effectiveness.



Going forward, we are now recruiting to the national MABEL trial, led at KCH by Dr Sabrina Bajwah. Currently, clinical guidelines support the use of morphine for the relief of chronic breathlessness in common long-term conditions, but questions remain around clinical effectiveness, safety and longer-term administration. The MABEL trial is a multicentre, parallel group, double-blind, randomised, placebo-controlled trial which will evaluate the effectiveness of low-dose oral modified release morphine in chronic breathlessness.

RDU 5

Liver, Gastroenterology and Rheumatology



Liver

The Liver research team has expanded significantly over the past two years; it now includes a team of 13 research nurses, two trials practitioners, five lab technicians and ten administrators, all supported by a team of nine clinical research fellows. Led by consultant hepatologist Dr Vishal C. Patel, the team focuses on facilitating the delivery of studies across the spectrum of liver diseases and transplants, with a portfolio of over 100 active studies.

The portfolio of research council-funded and investigator-initiated studies focusing on patients with cirrhosis, portal hypertension and complications of advanced chronic liver disease continues to grow within the Trust. The national NIHR-funded BOPPP trial, led by Drs Vishal C. Patel and Mark McPhail, recruited over 350 patients and will be pivotal to the future management of portal hypertension, preventing bleeding of varices in patients with liver cirrhosis.

The Hepatitis research team, led by Dr Kosh Agarwal, continues to deliver a high-quality service and are often the first point of contact for many clinical research organisations and pharmaceutical partners running studies in hepatitis B (HBV), Non-Alcoholic Steatohepatitis (NASH) and Non-Alcoholic Fatty Liver Disease (NAFLD). The team are global leaders in numerous early phase HBV and NASH clinical trials and in early 2022, they welcomed the first global recruits to the Antisense Oligonucleotide for HBV treatment (ALIGOS) clinical trial, which investigates the safety and efficacy of a new type of antiviral to prevent HBV replication.

The Liver research team is also involved in various AI projects, collaborating on NIHR-funded projects with industry as well as national organisations. Prof Will Bernal's £1.1 million MAP-CLD project looks at emergency admissions in chronic liver disease. Working with the London School of Hygiene and Tropical Medicine and NHS Digital (among others), this collaborative project looks at reality and lived experience of patients and clinicians within liver ICUs with a view to mapping pathways that will influence future planning of services. Aside from focusing on liver disease, in the last financial year the Hepatocellular carcinoma (HCC) and transplant clinicians within the Liver research team have enhanced existent relationships with industry partners Kinomica Ltd, obtaining a MRC/Innovate UK Biomedical Catalyst grant that will allow them to assist Kinomica to innovate their propriety KScan device which will aid the discovery of biomarkers for treatment response in HCC.

Finally, the portfolio of activity around Wilson's Disease, a rare genetic disorder where excess copper storage in the liver can lead to liver disease, has also expanded significantly under the guidance of Prof Aftab Alla. Research focuses on uncoupling the unmet needs of this rare disease population, improvements in diagnosis and monitoring, establishing a registry to facilitate insight into the disease, establishing the needs of at-risk populations and increased translational activity around chelation therapies and copper monitoring. The KCH team were also involved in developing the 2021 British Association for the Study of the Liver (BASL) guidelines for management of this rare disease population.



Gastroenterology

The Gastroenterology research team consists of consultants, clinical fellows and research nurses from Gastroenterology and Colorectal Surgery, led by Consultant Gastroenterologist Dr Alexandra Kent.

The team support the delivery of multiple research projects across Gastroenterology, Endoscopy and Colorectal Surgery. Over the last year, we have recruited-to-target for eight commercial and 10 non-commercial studies spanning local, national, and international trials. Over 170 patients have signed up to take part in these studies and seven patients are currently on long term extension studies.

The interests of the Gastroenterology team include a range of clinical studies in Inflammatory Bowel Disease (IBD), Coeliac disease, Irritable Bowel Syndrome (IBS), Diverticular Disease (DD) and Advanced Therapeutic Endoscopy.

Inflammatory Bowel Disease (IBD) research

There has been an expansion in the number of IBD commercial studies, in particular those which aim to modulate pathogenic inflammatory immune responses in IBD. In 2021 we opened recruitment to the SEQUENCE trial which, sponsored by Abbvie and led at KCH by Dr Kent, aims to compare the efficacy of new potential antibody therapy risankizumab in people with moderate to severe Crohn's disease with the current standard immunotherapy of ustekinumab. While this trial is yet to yield significant data, other researchers in the field have published encouraging results regarding risankinimumab in Crohn's disease.

Another series of studies, also sponsored by Abbvie, testing the efficacy of another potential immunotherapy in people with moderate to severe Crohn's disease has been ongoing at the Trust for the past few years. Recent results from Phase 3 of the latest of these studies have found the new therapy to be effective in achieving clinical and endoscopic remission. These and other studies have enabled KCH IBD patients to access potentially novel, effective therapies, improving patient care at the Trust. Additionally, some biomarker studies are also in the pipeline aiming to optimise IBD management and we are developing research to investigate e-health and apps to support self-directed management in IBD and Patient Initiated Follow-Up.

Endoscopy research

The Gastroenterology research team is one of the UK's leading recruiters to studies relating to state-of-the-art endoscopic imaging technology, artificial

intelligence (AI) and computer-aided diagnosis systems. The team is currently pursuing novel areas including robotic endoscopy and remote systems. We are also actively recruiting for the Fast Track Study, led by Dr Sukhdev Chatu. Piloted by the NHS and supported by NHS England, the aim of the study is to determine the diagnostic accuracy of colon capsule endoscopy for significant colorectal polyps and organic enteric disease in patients with suspected colorectal cancer as well as patients undergoing post-polypectomy bowel surveillance. Information will be collected to compare how effective colonoscopy, CT colonography and colon capsule endoscopy tests are at identifying bowel disease.

The future

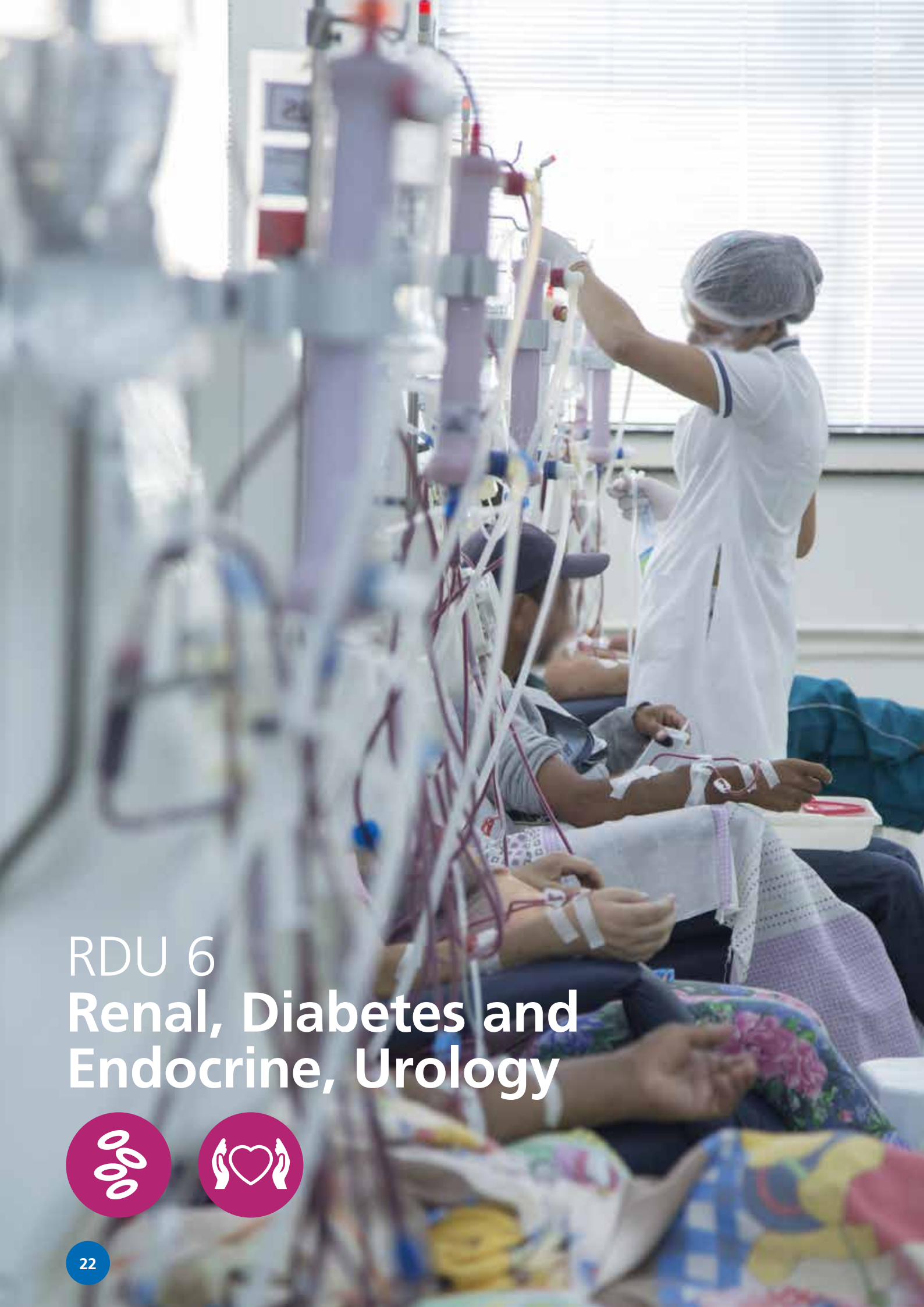
Going forward, the Gastroenterology team aim to complete recruitment to their major studies and intend to present details of their work at local and international seminars and conferences.



Doctors performing an endoscopy



An example of a Pill Cam used in capsule endoscopy



RDU 6 Renal, Diabetes and Endocrine, Urology



Renal, Diabetes and Endocrine, Urology

RDU 6 is led by Dr Sapna Shah who is also the Clinical Lead for the Renal research team. The unit is supported by Dr Kate Bramham and Dr Sharlene Greenwood, Clinical Leads for Renal Exercise and Rehabilitation, Mr Gordon Muir, Clinical Lead for Urology, Dr Prash Vas, Clinical Lead for Diabetes and Dr Georgios K Dimitriadis, Clinical Lead for Endocrinology and Obesity. Twenty-four research delivery staff support the team of 20 primary investigators (PIs) who have a portfolio of approximately 70 studies with 14 PhD / Master's students.



Dr Sapna Shah

Renal

Dr Sapna Shah's research interests include kidney transplantation, anaemia of renal disease and IgA nephropathy. Over the last year, she has supported the delivery of 10 new commercial and non-commercial clinical trials in the Renal team. Notably, 22 patients were recruited to the UNPACK Study (PI Dr Katie Vinen) which aims to understand treatment

preferences of older patients and their families deciding between dialysis and comprehensive conservative care for kidney failure. We also have the highest recruitment of all the south London renal units of CRN-supported studies with RADAR (PI Dr Sui Phin Kon), a registry study of rare kidney diseases recruiting 396 patients in 2021/2022, and PROTECT V (PI Prof Claire Sharpe), which studied the use of nasal niclosamide to prevent COVID 19 infection in extremely vulnerable patients with kidney disease, recruiting 32 patients. Our team are currently setting up the second part of the PROTECT V study.

Renal exercise and rehabilitation

Dr Kate Bramham has a diverse research portfolio including NIHR, Kidney Research UK, UKRI and industry-funded investigator-led studies. Her research interests include chronic and acute kidney disease in pregnancy in the UK and Africa, and improving kidney disease outcomes for people of African ancestry through community-based approaches and novel therapies. She works closely with Dr Sharlene Greenwood, whose research is focussed around the theme of exercise and lifestyle medicine in kidney disease. She has led on several NIHR and Kidney Research UK investigator-led studies - the most recent of which is the Kidney Beam Trial, a multi-centre randomised trial which aims to evaluate the clinical value and cost-effectiveness of a 12-week virtual exercise programme in people with chronic kidney disease. Developed by KCH and a commercial technology company, the trial aims to recruit 304 participants and the results will inform its implementation and roll-out across the UK.



Members of the Renal exercise and Rehabilitation research team (also known as Renal Rehab) led by Drs Kate Bramham and Sharlene Greenwood.



Dr Gordon Muir

Urology

In 2021, the Urology research group, supported by Dr Gordon Muir, have recruited to a variety of commercial and non-commercial studies. These include CATHETER II, a randomised controlled trial comparing the efficacy of rinsing the urinary catheters with either saline (as standard) or citric acid, and MIND-P, a prospective and longitudinal cohort study assessing mental wellbeing and quality of life in prostate cancer.

pump in order to automatically deliver the correct amount of insulin needed. The team have also recruited to Hypo-METRICS, an observational study looking at impact and factors that influence symptomatic and asymptomatic episodes of hypoglycaemia on a variety of clinical, patient-related and health economic outcomes such as mood, quality of sleep and productivity. The STEADY project, led by NIHR Clinical Scientist Dr Stadler is currently in its early stages within the Diabetes team. STEADY is a five-year research project which aims to develop a complex intervention for people with type 1 diabetes and disordered eating together with a multidisciplinary team of diabetes and mental health care professionals.



Dr Prashanth Vas

Diabetes

Dr Prashanth Vas leads the wide portfolio of clinical research spanning experimental medicine, clinical trials and commercial research across type 1 and type 2 diabetes and diabetes foot complications.

This year, the Diabetes research team, led by Dr Katharine Hunt, have recruited to AiDAPT. An open-label, randomised, two-arm parallel group trial AiDAPT will compare blood glucose control in

pregnant women who either use standard measurement and insulin delivery to automated closed-loop (Artificial Pancreas) insulin delivery, whereby a computer algorithm is linked to a continuous glucose monitor and insulin



Dr Georgios Dimitriadis

Endocrinology and Obesity

Dr Georgios K Dimitriadis has supported the delivery of multiple research projects across Endocrinology and Metabolism/Obesity. Over the last year, the team has recruited-to-target for four non-commercial studies including local, national, and international trials.

Over the next year we plan to continue recruiting to our portfolio of studies, for example Long Limb 2 (evaluating the impact of a modified Roux-en-Y-gastric bypass operation on people with type 2 diabetes mellitus) and look forward to opening further studies including GAMECHANGER (Improving kidney transplant outcomes in patients sensitised to HLA antigens), PREPARED (integrated primary care-based programme of pre-pregnancy care to improve outcomes in women with type 2 diabetes) as well as PROSAIC (Evaluation of an AI platform per personalised, evidence based treatment in multidisciplinary prostate cancer care).





RDU 7
HIV & Sexual Health,
Ophthalmology,
Dermatology and Dental



HIV, Sexual Health and The Havens

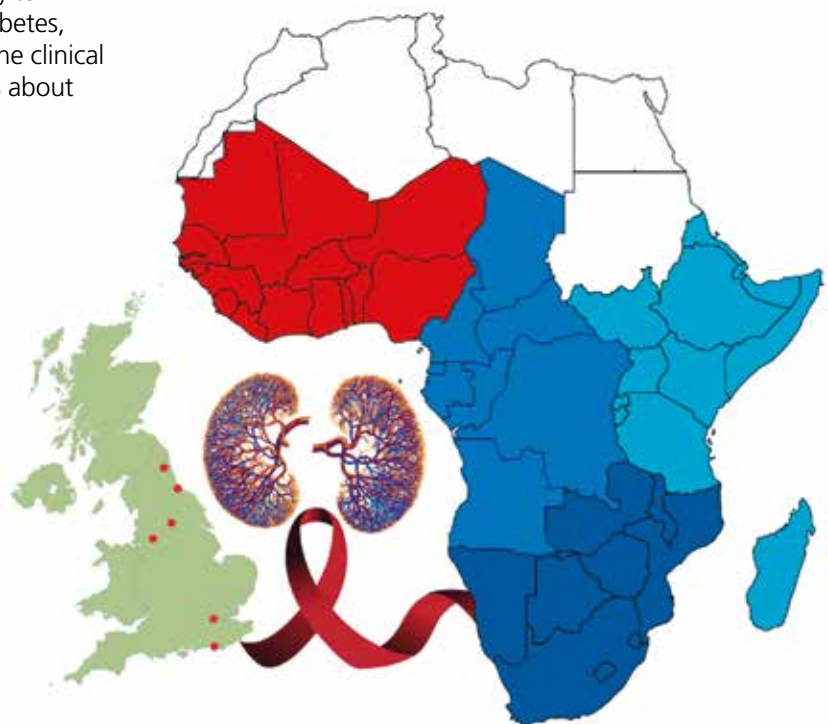
The HIV, Sexual Health and The Havens research team is headed by Professor Frank Post, leading clinical research fellows, PhD students, research delivery staff and a research manager. They come from a diverse background including clinical trials, nursing, quantitative and qualitative experience and allow us to deliver on a varied range of studies.

The HIV research team is currently delivering several clinical trials of new medications for the treatment of HIV. In addition, the team manages one of the largest cohorts of people of African ancestry with HIV in the UK. This population is disproportionately affected by obesity, hypertension, diabetes, and kidney disease. Supported by 15 sites across the UK, they enrolled over 3,000 participants in 2018-2020 to the GEN-AFRICA study and have since reported that about 60% of kidney failure in black people with HIV is attributable to variants of the *Apolipoprotein L1* gene or sickle cell trait. This genetic susceptibility is particularly common among people of West African and Caribbean descent.

The team has since initiated several GEN-AFRICA sub-studies to explore the role of social determinants of health in the development of multiple long-term conditions such as cardiovascular disease, diabetes, and chronic kidney disease, and to describe the clinical epidemiology of COVID-19 - including beliefs about vaccination in this population.

The Sexual Health research group is exploring the sexual health needs of Trans and Non-Binary people. The Trans & Non-Binary Reference Intervals While on Hormone Therapy Study (TransRIHTS) aims to identify a new reference range for blood tests which are affected by sex, as it is unclear what intervals should be used for transgender people who are on hormone therapy. Additional studies focus on screening for human papillomavirus-associated cancers in this population and the contraceptive needs of trans-men and non-binary people.

The Havens have a research programme focused on sexual assault, looking at ways of maximising the chances of prosecution of the perpetrators while improving the support provided to and experiences of the victims.



Ophthalmology

The King's Ophthalmology Research Unit (KORU) is based at King's College Hospital and led by Professor Tim Jackson. Principal investigators include Mr Haralabos Eleftheriadis, Mr Gerassimos Lascaratos, Ms Anna Grabowska, and Mr Mohammed Abu-Bakra, working with two clinical research fellows, two research coordinators, one research manager, one trial manager, two ophthalmic imaging technicians, and one research optometrist. Other clinical and non-clinical research fellows work off-site in Biomedical Engineering and Imaging Sciences at the King's College London campus.

The KORU team are responsible for a large portfolio of both investigator-initiated and industry-sponsored clinical trials. We support other non-ophthalmic trials being undertaken at KCH, and have particular expertise in the fields of age-related macular degeneration (AMD), diabetic retinopathy (DR), glaucoma, and ophthalmic devices, covering all of the leading causes of sight loss in the UK. Additionally, our team have experience setting up and leading large, multicentre, national and international clinical trials including pioneering technologies such as retinal implants and robotically-controlled precision radiotherapy for AMD.

The team is currently responsible for two large, multicentre randomised controlled trials (RCTs) with cumulative funding of over £4 million – the STAR study and the TIGER study. STAR is a UK-based, NIHR-funded RCT of 411 patients and investigates the benefit of low-voltage X-ray ocular irradiation in the treatment of neovascular AMD and is currently in final patient safety follow up, with primary outcome data undergoing analysis. TIGER is a pan-European surgical RCT joint-funded by the European Society of Retina Specialists (EURETINA) and Fight for Sight, which investigates the optimal surgical management of submacular haemorrhage, a rare but devastating complication of neovascular AMD caused by bleeding below the retina, and is currently recruiting patients and undertaking site set-up.

The team is also involved in the recruitment and assessment of several industry-sponsored studies of novel therapies for AMD, DR and glaucoma. One current AMD study is the Phase 3 SHORE study, which investigates a novel monoclonal antibody to vascular endothelial growth factor (anti-VEGF), which is hoped to

block the growth of abnormal blood vessels in patients newly diagnosed with neovascular AMD. Additionally, the Phase 3 VELODROME and DIAGRID studies investigate a novel intraocular implant that delivers sustained-release of an existing gold-standard anti-VEGF therapy for neovascular AMD, decreasing the need for monthly hospital visits for injections.

Currently active DR studies include the Phase 2b NEON-NPDR study, which investigates runcaciguat, a novel oral therapy for severe diabetic retinopathy, and the Phase 2 BARDENAS study, which investigates the first injectable ocular Interleukin-6 inhibitor medication for diabetic macular oedema in combination with anti-VEGF therapy. The glaucoma team is also recruiting for the TRITON study, which investigates a slow-release, intraocular bimatoprost implant – a medication for glaucoma which lowers the pressure in the eye - for open-angle glaucoma and ocular hypertension as an alternative to topical drop therapy.



The Ophthalmology research team

RDU 8

Anaesthetics, Critical Care, Emergency Department and Trauma (ACET), Pain, Respiratory and Orthopaedics



ACET

ACET (Anaesthetics, Critical Care, Emergency medicine and Trauma) is led by three specialist consultants: Dr Fleur Cantele (Emergency Department), Dr Philip Hopkins (Critical Care and RDU 8 Lead) and Prof Gudrun Kunst (Anaesthetics and RDU 8 Deputy Lead). ACET is supported by a team of research nurses led by ACET Lead Research Nurse John Smith.

ACET has recently seen much more interest in research opportunities and has supported clinical staff to uptake these. In addition to the 19 pharmacists and consultants as principal investigators (PIs), this year we have also welcomed five associate PIs, utilising the NIHR associate PI scheme, as well as having the support of more than 25 trainees in the clinical areas and eight research nurses within the team itself.



Members of the ACET research team (L-R):
Research nurses Sian Saha, Hannah Cotton, Maria Depante, Eleanor Corcoran, Kevin O'Reilly, ACET Lead Research Nurse John Smith and Critical Care and RDU8 Lead Dr Phil Hopkins.

The ACET team has made its mark both internationally and nationally with 14 observational and 16 interventional studies as well as one commercial study. Over the last year, we have further strengthened our ties with the PRUH and Orpington research teams who have provided great support on the Sprint National Anaesthesia Project (SNAP). SNAP3 was the third Sprint National Anaesthesia Project looking to describe the impact and management of frailty, multi-morbidity and delirium on post-surgery outcomes. As well as cutting-edge research, we have also developed a portfolio of in-house studies in each area of ACET.

INSIGHT

Previous research has shown the use of ultrasound as an initial assessment tool to be a quick, non-invasive

and effective method of diagnosis. It reduces the need for more extensive nuclear imaging which can be harmful to the patient and disruptive to their intensive care. Nurses do not currently use ultrasound in their routine assessment. The INSIGHT pilot study, led by PhD student Eleanor Corcoran from Critical Care, aims to see if nurse-led ultrasound assessment is feasible as a nurse-led intervention and whether it is an effective intervention within the Intensive Care Unit (ICU).

PIM-COVID & Recovery FU clinics

The PIM-COVID study, led by senior ACET research nurse Sian Saha, was supported by the King's ICU Recovery group. The study used questionnaires to assess peoples' experience on ICU during the COVID pandemic and how their recovery is going. When a patient was discharged from being in ICU due to COVID-19, they were invited to participate in the study and also informed that King's ICU has an online recovery support group, run with psychologist support. This group further assesses the short and long-term psychological needs of the patients and helps to provide emotional support to aid recovery.



BIAS-ED

The BiasED study is building on work published in the US which suggests that people from different ethnic groups receive different care in emergency departments.

There is very little evidence in this country to show whether the pressures faced by staff in emergency departments lead them to rely on cognitive shortcuts, such as stereotyping and biases. Work from the US has highlighted that this unconscious bias does exist and leads to suboptimal care for ethnic minorities. This multi-centre study, led by Dr Fleur Cantele, aims to explore if UK healthcare workers display a similar bias using a validated tool. The study is currently running in four emergency departments with plans in place to open another four. Longer-term aims involve using the results to inform future discussion and research efforts to combat structural racism in healthcare – in particular the emergency department setting.

RDU 9 Children



Paediatrics

The Paediatric research team has been through many challenges in the last year yet are ready to take on trials that are more multi-disciplinary and be more involved in shaping the future of research in children towards better health outcomes. Our team consists of research nurses and a clinical trial coordinator led Dr. Atul Gupta.

Our team is running several respiratory studies led by consultant in paediatric respiratory medicine and RDU lead Dr. Atul Gupta. A particular focus is on asthma, with around one in 11 children and young people living with asthma in the UK.

The TREAT study aims to create a unified, national approach in treating children who have Severe Therapy Resistant Asthma (STRA). Current therapies for children with STRA are high dose steroids (which can have severe side effects) and omalizumab which, while effective, is only viable for use in around 60% of children with STRA – and then only works in half of those children. Mepolizumab was licenced for use in children with STRA in 2018, however there have been no studies to determine whether it improves their symptoms. TREAT will aim to determine whether this drug is as effective as omalizumab, in the hope that it will present a viable treatment option for those children who cannot take omalizumab.

Another trial, The BLIPA (Bacterial Lysate in Preventing Asthma) study, hopes to prevent asthma and wheeze in patients who had bronchiolitis as infants. Previous studies have shown that bronchiolitis in infancy can increase the risk of developing preschool wheeze and school-age asthma. The BLIPA trial will treat infants with either bacterial lysate (a medicine made from broken-down bacterial cells which can boost the immune system) or placebo following severe bronchiolitis and see if the lysate can prevent the development of asthma. KCH is the third hospital around the world to open this study.

Aside from asthma studies, the Paediatric research team will soon be taking part in study focusing on a novel treatment for acute liver failure in children. The HELP study, sponsored by the Medical Research Council and led by KCH R&I Director Professor Anil Dhawan, aims to evaluate the safety, biological activity and tolerability of transplantation microbeads comprising a protein and alginate (a gel-like substance found in algae) 'shell', which then deliver mesenchymal stromal cells and hepatocytes to in paediatric patients with acute liver

failure. It is hoped that the hepatocytes and stromal cells will act as a temporary liver until a donor is found, buying the patient much-needed time.



Members of the Paediatric research team

King's Clinical Research Facility (CRF)





NIHR Wellcome King's Clinical Research Facility

The NIHR Wellcome King's Clinical Research Facility (CRF) is a collaborative research facility shared between KCH, South London and the Maudsley Hospital and King's Health Partners. Opened in 2014 at the Trust's Denmark Hill site, the Facility is supported by a successful NIHR award and Wellcome Trust funding. Neurology professor and recent Royal Society elected fellow Peter Goadsby is the Facility's director and the in-house research staff are managed by Elka Giemza.

In the last financial year, the King's CRF has recruited 60 patients to a wide range of commercial and non-commercial early phase clinical studies trialling pioneering new therapies for the treatment of diverse disease areas including headache and migraine, rheumatology, mental health and COVID-19. Our facility is also the site of many promising trials investigating the use of psychedelic compounds in the treatment of a range of neurological and psychological conditions. We have also installed new equipment to enable us to prepare in-house pharmaceuticals and Investigational Medical Products (IMPs) as well as continuing to improve public and patient engagement through in-person and online outreach activities.

Rheumatology

In August 2021, the King's CRF started recruiting to a global Phase 2 clinical trial of novel immunotherapy nipocalimab for the treatment of active rheumatoid arthritis. Affecting over 400,000 people in the UK, rheumatoid arthritis is an autoinflammatory condition where the body's immune system attacks the joints causing pain, swelling and loss of function. Nipocalimab is a monoclonal antibody which can block the binding site of a key antibody involved in the autoimmune attack, and therefore has the potential to control the condition. In the current study, sponsored by Janssen, participants with active rheumatoid arthritis who have not responded to standard therapy will receive intravenous nipocalimab or placebo over the course of 12 weeks along with standard therapy. Trial researchers based at the King's CRF will analyse whether the drug reduces inflammation and relieves symptoms following the 12 weeks of treatment.

Another study being delivered at the King's CRF is the Inflammatory Response In Schizophrenia (IRIS) study. Previous studies that suggest that brain inflammation, driven in particular by brain immune cells known as microglia, could be a mechanism for the development of schizophrenia. To this end, the IRIS study is investigating the effect of immunotherapy natalizumab, which blocks the migration of certain immune cells including microglia, on the reduction of microglia activity in patients with first episode psychosis. Researchers will assess this by using positron emission tomography (PET), and whether any reduction is associated with improvement in symptoms of psychosis.

COVID-19 vaccine trials

Since the start of the COVID-19 pandemic, the King's CRF has been at the forefront of global clinical trials of novel COVID-19 vaccines. Phase 3 trials of Novavax's Nuvaxovid COVID-19 vaccine were successful; the vaccine was found to be 90% effective in preventing mild to severe COVID-19 and in February this year, the vaccine was approved for use in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA). The last financial year also saw the launch of Moderna's multivalent COVID-19 booster vaccine trial at the King's CRF. Led by Dr James Galloway and recruiting 100 participants, the trial aims to assess the



A participant on the Novavax Nuvaxovid trial

safety and efficacy of a tweaked booster vaccine which is designed to immunise a person against multiple variants of the Sars-CoV-2 virus – rather than just one variant as with previous vaccines.

Psychedelic trials

In Financial Year 21/22, the King's CRF began recruiting to a cutting-edge study which is exploring the effects of psilocybin, a psychedelic compound isolated from a



certain species of mushroom, on cognition in patients with Chronic Short-lasting Unilateral Neuralgiform Headache (SUNHA), a rare but debilitating headache disorder. The Phase 1b study, led by Dr James Rucker from King's College London and sponsored by Beckley Psytech, will examine the safety and effectiveness of psilocybin when given to 12 patients with chronic SUNHA. It will also explore the change in frequency, duration, and intensity of headache attacks with escalating doses of psilocybin treatment, as well as the drug's effects on cognition in people with chronic SUNHA.

Another study which started recruitment in FY21/22 is assessing the safety and pharmacokinetic profile of Intranasal 5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) in healthy participants. 5-MEO-DMT, also known more simply as DMT, is a psychedelic compound found in a range of plants and can cause marked alterations in consciousness, with potential long-term benefits to mental health and well-being. The current study, also led by Dr James Rucker and sponsored by Beckley Psytech, aims to determine its safety in a controlled environment in healthy participants in order to build a platform upon which the drug may be studied in people with Treatment Resistant Depression (TRD) - a type of depression which is not improved by at least two commonly available therapies.

Laminar flow cabinet

A laminar flow cabinet was installed in the King's CRF annex in the last year and is now ready for use by trained staff at the King's CRF.

The cabinet is designed to provide a 'clean air' particle-free environment to allow for the preparation of pharmaceuticals such as Investigational Medical Products (IMPs) used in clinical trials. It does this by circulating air through a filtration system which can filter out 99.9998% of particles $>0.12\mu\text{m}$ in size, meaning that most airborne fungi and bacteria are eliminated. King's CRF research nurses have now been trained in broth culture, aseptic technique and disinfection procedures, allowing for the on-site and in-house preparation of IMPs.

The flow cabinet will allow for rapid, efficient in-house and delivery of early phase therapeutics that will be trialled on-site. Initially it will be used to make IMPs for the WAVE study, which will use a type of treatment called antisense therapy which uses synthetic strands of DNA – a type of IMP which will be made in-house in the Laminar Flow Cabinet – to silence mutated genes that can lead to diseases such as Amyloid Lateral Sclerosis (ALS). In this early-phase study, researchers will initially test the safety of using the IMP in people with ALS and also how long it remains in the body.



The Princess Royal University Hospital (PRUH)

The PRUH and South Sites (Orpington Hospital, Beckenham Beacon and Queen Mary's Hospital Sidcup) have contributed greatly to research participant numbers and enrolment, particularly throughout the pandemic.

We have developed a local governance team to support research staff of all levels working across all sites. Key members are PRUH research lead Dr Deepak Rao, lead research facilitator Nicola Griffiths and deputy research leads Dr Georgios Dimitriadis and Dr Mohammad Albarjas. We hope to identify and prioritise local issues or barriers for research at the four sites, to enable the service to grow and integrate into patient treatment pathways.

Study highlights

As COVID-19 research has reduced in FY21/22, we have used this time to open studies that focus on treatments which specifically benefit the local patient population. These include studies in Cardiology, Respiratory medicine, Haematology, ACET, and the Maternity portfolio, with just a snapshot of key studies highlighted here.

Cardiology

This year we have successfully opened and randomised participants to the ORION-4 study, and are on track to meet our site target of 75 patients. Led by Dr Mohammad Albarjas, ORION-4 aims to find out if a new cholesterol-lowering injection (inclisiran) safely reduces the risk of heart attacks and strokes in people who have already had one of these conditions, or who have had an operation or procedure to unblock their arteries. It is expected that about 15,000 people aged 55 years or older will take part in this study around the world.

Liver and hepatobiliary research

The research team based at the PRUH have been continually supported by the Liver research department prior to and throughout the pandemic and, as such, we have increased our portfolio of studies in the area of liver and hepatobiliary research, with high recruitment rates into pancreatic cancer trials. One current study, 'Precision-Panc: Advancing personalised medicine treatment strategies for pancreatic cancer', aims to identify, test and implement tailored therapeutic approaches for people with pancreatic cancer and so far our team have helped to recruited double the initial site target for the study.

Haematology

The Haematology department have many trials open across the PRUH and Denmark Hill sites and Dr Stella Bowcock leads on two of these. PRUH consultant Dr Bowcock is a haematologist with a special interest in multiple myeloma; she is an active member of the UK Myeloma Research Alliance and is on the trial management group for two national trials. Alongside PRUH senior clinical trial practitioner Rachel Ryan, Dr Bowcock exceeded the recruitment target for the Fitness study and the PRUH is a high-recruiting site nationally. This Phase 3 clinical trial aims to see whether dose adjustments to treatment for multiple myeloma, dependent on a patient's level of frailty, can improve their ability to remain on treatment, reduce toxicity and improve outcomes.

Dr Bowcock and Rachel have also started to recruit patients to the newly-opened OXPLORED study. This observational study will identify pre-cancerous markers in people with potentially-malignant blood disorders who are at the highest risk of going on to develop malignant disease. Researchers will then follow up participants for up to five years while identifying novel biological markers that indicate whether a participant will develop malignant disease, as well as defining which markers may determine whether they are cured or not.



Rachel Ryan (L) and Dr Stella Bowcock (R)



Anaesthetics

Anaesthetist Dr Karthick Duraisamy led a team of medics at the PRUH and Orpington Hospitals to recruit 55 patients, over a one-week period, onto the SNAP3 project (3rd Sprint National Anaesthesia Project). Joint-led by the Health Services Research Centre and the University of Nottingham with support from the Royal College of Anaesthetists, SNAP3 aims to determine which patients are frail and at risk of developing delirium, as well as investigating care given before, during and after surgery. Recruitment was more than triple of the initial target thanks to a huge collaborative effect between anaesthetists across the PRUH and Orpington.

Respiratory medicine

Currently, we are in the process of opening an interventional respiratory study at the PRUH led by PRUH respiratory consultant Dr Lynette Linkson. The MucAct COPD Study is co-sponsored by the NIHR and NHS

Lothian and is open solely at the PRUH site. It will assess the clinical and cost-effectiveness of nebulised sodium chloride – or salty water - plus Active Cycle Breathing Technique (ACBT) in patients with chronic obstructive pulmonary disease, when compared with the current standard treatment which is carbocysteine (a chemical which breaks down mucus) plus ACBT.

Outreach and engagement

Finally, in an effort to raise research awareness and engagement at the PRUH, we presented a research governance session at the joint medical/surgical grand rounds in August 2021 and held further informal 'drop in' research surgery sessions in the following March. Going forward, currently-active PIs from the PRUH are being invited to present a short talk around their projects at the Research Grand Rounds in November and there are plans to grow engagement sessions, with R&I staff attending the PRUH for advice around research.



PRUH research staff (L-R): Consultant gastroenterologist Dr Mayur Kumar, lead research facilitator Nicola Griffiths, deputy research leads Dr Mohammad Albarjas and Dr Georgios Dimitriadis, PRUH research lead Dr Deepak Rao and research nurse Anna Posada.

Supporting Services

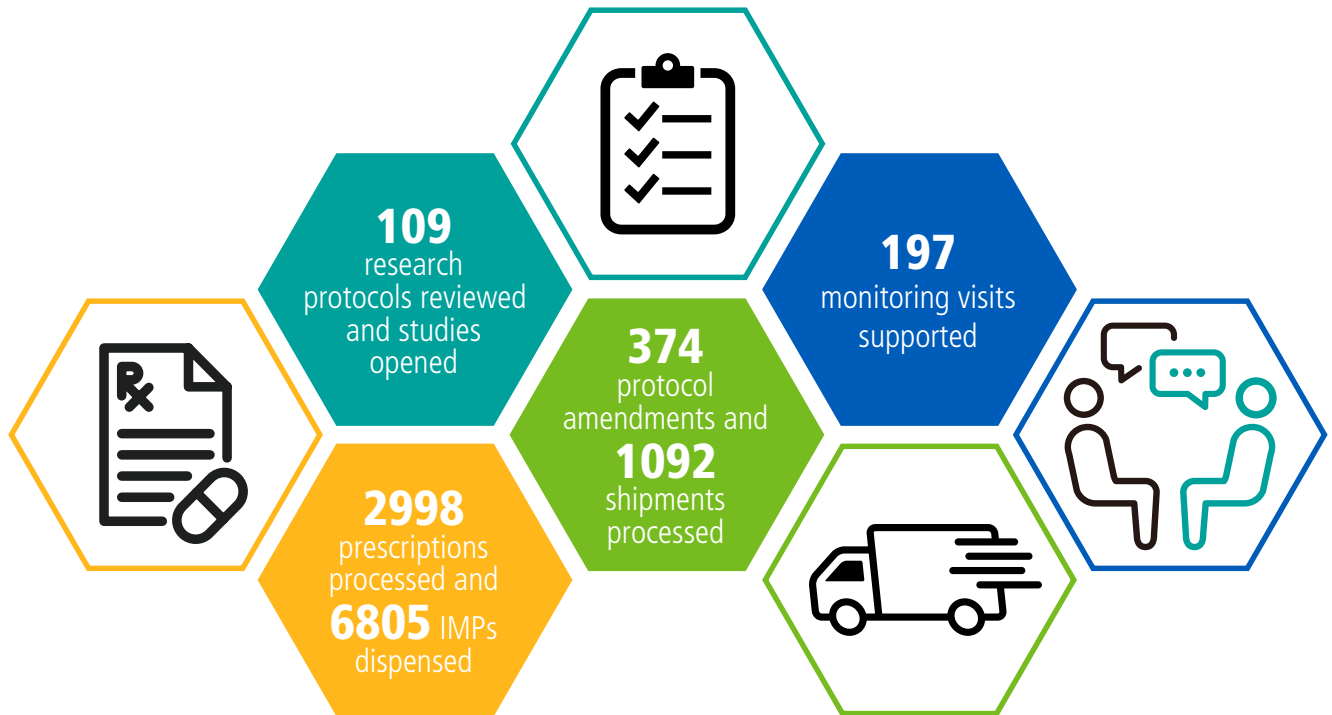


Pharmacy

Pharmacy Clinical Trials Team

The Pharmacy Clinical Trials team continues to collaborate across all RDUs in the delivery of innovative research across the Trust. Our team takes overall responsibility for centralising all pharmacological processes such as procurement, safe handling, preparation, administration and dispensation, ensuring all products are handled safely in compliance with current legislations.

Over the last five years there has been a significant increase in the demand and complexity of clinical trials of which the Pharmacy Clinical Trials team play a vital role. Our aim is to continue to support the delivery of innovative research across the Trust as we return to 'business as usual' following the pandemic. A summary of the wide range of activities that the Pharmacy Clinical Trials team have been involved with in the last year in is provided below.



Pharmacy Academic Research Unit

The Academic Research Unit (ARU) was established in 2020 and works in partnership with the Pharmacy Clinical Trials team. As a key component of the Pharmaceutical Sciences Clinical Academic Group (PSCAG), the aim of the ARU is to embed academic excellence over the entirety of the pharmacy department. Some of the highlights of academic achievements in 2021 to 2022 include one PhD completion, 20 peer-reviewed publications, four research funding awards, two predoctoral fellowships (one NIHR-supported and one via the Health and Social Care Research and Development Division Northern Ireland scheme), one book (Critical Illness – Essential medicines information to support complex decision-making and dynamic prescribing in critical care) and the appointment of pharmacist principal and associate principal investigators.

We would like to thank our collaborators and mentors across KCH and indeed King's Health Partners for continuing to support us 2021 to 2022.

Our plans for 2022 to 2023 include higher impact publications, honorary clinical academic appointments with KCL, greater integration with PSCAG, NIHR clinical doctoral applications and a major funding award.

To contact the Pharmacy Clinical Trials team email Esther Makanju at Esther.Makanju1@nhs.net
To contact the ARU, email Dr Cathrine McKenzie at Cathrine.Mckenzie@nhs.net

Radiology

The Department of Radiology, comprising General and Breast Radiology, Neuroimaging and Nuclear Medicine, remains an active participant in Research at the Denmark Hill and PRUH sites. At Denmark Hill, the department provides imaging support to other departments in more than 140 active commercial clinical trials and more than 50 non-commercial portfolio studies. Besides providing imaging support, the department maintains an active research program that encompasses a wide range of projects.

In 2021, King's College London (KCL) was ranked in the top three in the world for its academic research in the field of Radiology, Nuclear Medicine, and Medical Imaging. Many of KCL's radiology and imaging academics have a key role in clinical practice and research at KCH. For example, Professor Paul Sidhu, a consultant radiologist at KCH and Professor of Imaging Sciences at KCL, has published extensively in the field of ultrasound and is known for pioneering the introduction of contrast-enhanced ultrasound (CEUS) and ultrasound elastography in the United Kingdom. In recognition of his enormous contribution to diagnostic ultrasound, Professor Sidhu was recently awarded the Gold Medal by the Royal College of Radiologists. In addition, KCH and KCL Neuroradiologist Dr Tom Booth and fellow consultant neuroradiologists are particularly active in the development of an artificial intelligence (AI) software tool to automatically identify abnormalities on brain MRI scans, also known as the MIDI study. In this regard, Dr Booth was recently awarded a £1 million grant from the Medical Research Council to further develop this AI brain abnormality tool. Finally, the Department's clinical

director Dr Keshthra Satchithananda is the PI of the KCH-led multicentre NIHR portfolio PROSPECTS trial involving 100,000 female volunteers to compare the use of traditional 2D mammograms with new 3D breast imaging technology in primary breast screening.

In addition to these individual accomplishments, we remain active in self-funded projects ranging from evaluation of various AI imaging algorithms, assessment of different ultrasound liver elastography (which assesses the severity of fibrosis) and liver fat quantification techniques to the evaluation of CEUS for the detection of various solid organ tumours) and innovative techniques in Nuclear Medicine. Each year, the Radiology Department publishes around 60 articles/studies in peer-reviewed journals. In view of the importance attached to research, we will soon appoint a fulltime Imaging Research Manager. We have also recently installed three state-of-the-art MRI scanners that will provide invaluable support for research studies at KCH that require this important imaging modality.



CEUS example: A liver tumour (arrow) at 25 seconds following injection of contrast agent. The corresponding b-mode US image is shown on the right

Pathology

Viapath Analytics is an NHS partnership with SynLab and is the preferred pathology provider for Guy's and St Thomas and King's College Hospital NHS Foundation trusts.

Viapath supports research across King's Health Partners (KHP), encompassing the pathology disciplines of Blood Sciences, Clinical Biochemistry, Reference Chemistry, Reference Haematology, Clinical Transplantation, Diagnostic Immunology and Allergy, Genetics, Tissue Sciences, Haemostasis and Thrombosis, Nutristasis, Infection Sciences and Contract Research. Viapath laboratories are accredited to the UKAS ISO15189 standards for medical laboratory quality and competence.

Both NIHR portfolio and commercial studies are supported by Viapath, as well as providing a specialist service to staff within KHP. It also supports wider NHS organisations, national academic faculties, international collaborators and commercial institutions. This is achieved through the development of new tests and supporting Trust speciality trainees in FRCPath and higher research degrees (MSc, PhD) by providing the technical expertise in delivering in-house research projects.

Viapath supports many research studies with the investigation of routine pathology endpoints and also by designing bespoke biomarker pathology exploratory endpoints, using multiple analytical platforms as well as manual set-up and pre-analytical processing requirements.

During FY2021/22, Viapath supported 122 new studies and implemented 17 new research-specific tests. The team also assisted with the analysis of insulin, C-peptide and Cystatin C on stored samples for the CKD study, led by Prof Frank Post, which is investigating the factors associated with cardiovascular disease, chronic kidney disease and diabetes in people of African ancestry with HIV. We also validated two new tests for serum biomarkers for a study which will assess the utility of these markers in patients with osteoporosis in stage 4 & 5 Chronic Kidney Disease and comparing them to current routine markers obtained in the osteoporosis assessment and the bone density (DEXA) scan.



Research & Innovation



Research & Innovation

The Research and Innovation (R&I) Office is part of the Corporate Division of King's College Hospital NHS Foundation Trust, reporting via the Director of Research and Innovation, Ann-Marie Murtagh, to the Trust Executive Medical Director. The R&I team is split into seven smaller teams – Research Governance, Contracts, Finance, Data, Quality Assurance, Communications and Research Office Administration – who work both individually and collectively to support researchers from King's College Hospital NHS Foundation Trust and King's College London in the planning, set-up, delivery and completion of non-commercial clinical trials and studies at the Trust.

Research Governance

The Research Governance team is made up of assistant research facilitators Amelia Turrell and Louisa Freemantle and three research facilitators; Kirsty Hedditch, Adriana Fanigliulo and Lizzie Bingle. They are overseen by Research Governance Specialist Danielle Lyon and the team report to R&I Operations Manager Jasmine Palmer.

The team play a key role in coordinating and facilitating research, acting to ensure that new and ongoing research across King's Health Partners is supported and developed to the highest ethical, legal and scientific standards. This varies from early contact and engagement with researchers regarding their research idea, to the feasibility, funding of the trial and how the study can be conducted at NHS sites with patients' rights, safety and wellbeing upheld



Danielle Lyon



Adriana Fanigliulo



Lizzie Bingle



Kirsty Hedditch



Louisa Freemantle



Amelia Turrell

Contracts

The majority of research studies rely to some extent on involvement from external organisations, whether in the preliminary phase (securing funding, arranging collaborations, database set-up), or at a later stage (sample analysis, statistical support, site engagement). Every interaction with an external organisation requires a contract, which accurately reflects what the parties have agreed, and to protect the interests of patients, staff and the Trust when conducting research.

The R&I Contracts team consists of Senior Contracts Associate Michelle Laver led by Contracts Manager Rania Mikhail, with a further Senior Contracts Associate to be appointed. The team supports Trust investigators and study teams by providing advice and processing contracts to facilitate KCH-sponsored/co-sponsored and non-commercial collaborative or site-only research. Regular engagement with the Governance, Costings and R&I Finance teams, in addition to liaising with



Rania Mikhail



Michelle Laver

numerous other teams across the Trust and externally, ensure that contracts effectively support research from a legal, regulatory and ethical standpoint and limit the risk to patients, staff and the Trust.

Finance

The R&I Finance Team is led by R&I Finance Facilitator Dancyl Ionut, alongside Research Costing Officer Deqa Mohamed and Finance Administrator Steve Baker. The team's key focuses are on cost attributions and income facilitation of site payments for non-commercial studies, as well as liaising regularly with RDUs and sponsors for finance-related support. The team also deal with requisition and purchase order queries, reconcile fiscal year activities and supporting finance management as necessary.



Dancyl Ionut



Deqa Mohamed

Data

A key aim for the government's Life Science Industrial Strategy is for providers of NHS services to have a dramatic and sustained improvement in the initiation and delivery of clinical research. The Data team, led by Data Officer Nayab Chaudhury uses data from research conducted at KCH to evidence the Trust's portfolio of research and how it is benchmarked against other organisations in order to track the Trust's progress on this aim.

The main roles of the Data team include national and local metric management and reporting for KCH R&I. The team also monitor at the performance of studies, research teams and R&I in order to identify areas of improvement. Clinical trial and study management is done by the team through the online database Edge as well as the clinical trials database ClinicalTrials.gov.



Nayab Chaudhury

Quality Assurance

The R&I Operations Manager Jasmine Palmer and Quality Assurance (QA) Facilitator Niamh Finnegan play a key role in the co-ordination of working practices and policy implementation to ensure that the Trust is at all times compliant with both internal policies and external regulatory frameworks. They have an expert knowledge of regulatory frameworks and will be able to liaise at a high level with all stakeholders within KHP.

The support provided varies from safety reporting, adverse incident reporting, information governance and human tissue samples arrangements for studies,

Each RDU has designated QA links to help support the research on the ground to identify and mitigate any shortfalls when conducting research at KCH.



Niamh Finnegan

Research Communications

The R&I Communications Officer, Eleanor Sherwood, is involved with both the internal and external communication of research-related information in order to boost the visibility of and celebrate the research being delivered at the Trust, as well as facilitating recruitment into clinical trials and studies. For example, Eleanor works closely with the Trust Corporate Communications team to disseminate research achievements to local and national news outlets as well as the Trust website and social media outlets. She is also instrumental in promoting research-related news and Trust and NIHR-led research opportunities to staff at the Trust - for example through a regular Research Newsletter - and helps to organise multiple internal and external research outreach events such as the regular Research Grand Rounds, International Clinical Trials Day and the annual R&I Research Strategy Meeting.



Eleanor Sherwood

Research Office Administration

The R&I Administration team is led by Research Office Coordinator Laura Freer and supported by two business support assistant apprentices. The team's focus is on supporting the R&I team and the wider research teams when required.

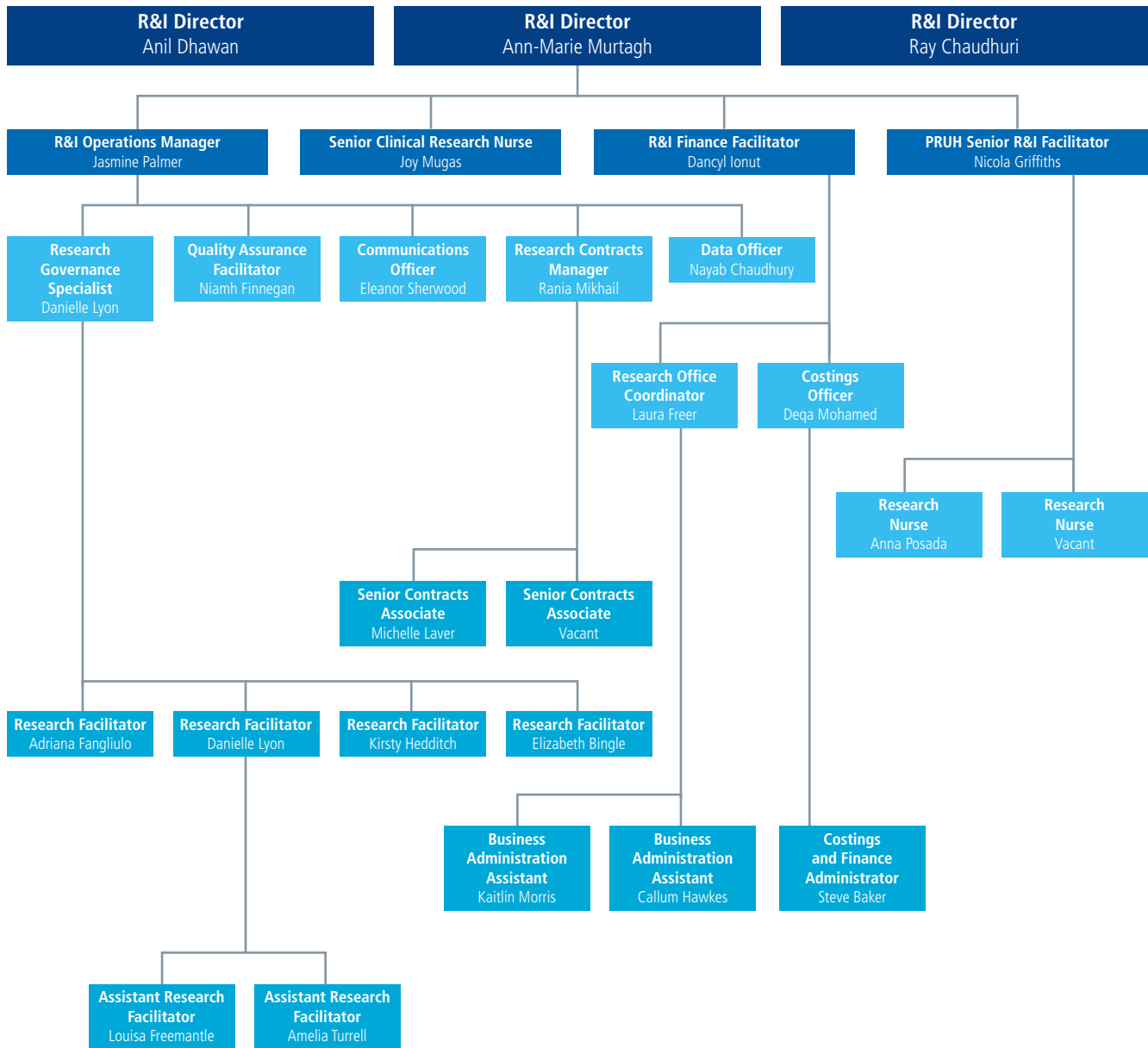
The Administration team cover a wide variety of areas, ranging from supporting recruitment and HR issues, organising and taking minutes of meetings, supporting the finance team with raising purchase orders and supporting the data team using Edge and clinicaltrials.gov.

Separately, Laura also provides Executive support to R&I Director, assisting with any tasks or projects that may arise.



Laura Freer

R&I Organisational Chart



ATMP Academy launch and symposium

Aim 3 of the R&I strategy is to increase the number of advanced therapy trials carried out within the Trust. Advanced Therapy Medicinal Products (ATMPs) present an exciting and pioneering area of research into new treatments for a wide range of diseases.

The Trust currently has a portfolio of both ATMP and Advanced Therapy Investigational Medicinal Product (ATIMP) clinical trials and treatments in areas such as Haematology, Gene Therapy and hepatocyte and islet cell transplantation. To ensure the safety of staff, participants and the public while working with and trialling ATIMPS, KCH has an ATMP committee and a Biological Safety Sub-committee who meet on a regular basis to discuss and review Genetically Modified Organisms (GMOs) used in trials at the Trust (see Box 1).

To highlight the use of ATMPs across the Trust and to increase the portfolio of work in this area, the KCH R&I department is launching King's ATMP Academy, led by KCH R&I Director Professor Anil Dhawan. The academy will provide training, education and hands-on experience to create future workforce for ATMP and ATIMP activities for whole UK and abroad. Professor Dhawan and Dr Reuben Benjamin also organised an all-day ATMP symposium where researchers from KCH and across King's Health Partners (KHP) discussed their work in this area.

Opening with a welcome and introduction to KCH ATMP academy from Professor Dhawan, the morning session saw the audience of over 150 people from across KHP

hear about the setting up and use of advanced therapies from KCL's Professor Ajay Shah and KCH haematologist Dr Victoria Potter. KCH's Dr Reuben Benjamin and Prof John Maher from KCL both discussed the use of CAR-T cells, a type of ATMP that has driven important advances in cancer treatment. In a similar vein, KCH neurosurgeon Professor Keyoumars Ashkan discussed the use of vaccinated immune cells in tackling glioblastoma, an aggressive form of brain cancer.

After a networking lunch, where attendees could discuss their questions and ideas with speakers, Dr Potter discussed the possibilities of ATMPs as a cure of Sickle Cell Disease. This was followed by two talks, one by Professor Dhawan and another by KCL's Professor David Hopkins, on the role of ATMPs in liver cell and insulin-producing islet cell transplantation. This was followed by further exploration of the use of ATMPs in transplantation, this time by using regulatory T cells – those which dampen down immune responses – in liver transplants. Towards the end of the symposium, professors Michael Heneghan and Ghulam Mufti discussed KCH's ATMP strategy as well as the interaction between pharmaceutical companies and academia in the ATMP sphere, before the day was rounded off with a Q&A session chaired by Dr Reuben Benjamin.

Box 1

The KCH Biological Safety Sub-committee meets regularly with the Trust's ATMP committee. Providing advice from both a clinical and laboratory perspective, the Biological Safety Sub-committee has representatives from virology and microbiology as well as senior clinical staff and a Biological Safety Officer provided by the King's CRF. The committee will adhere to the legal requirement to review trials using Genetically Modified Organisms (GMO's) which may need Health and Safety Executive notification if they are categorised as a risk to the environment or staff.



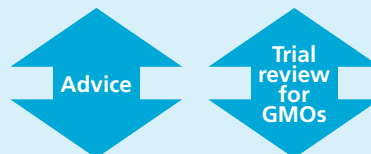
Microbiology



Virology



KCH AT(I)MP committee



Biosafety sub-committee



Clinical staff



Biosafety officer

Congratulations Corner



Congratulations Corner

In the last year there have been numerous important achievements made by KCH staff. Below is a snapshot of the highlights!



Professor Stephanie Amiel

Professor Stephanie Amiel wins Robert Turner Award

In May 2021 Stephanie Amiel, Professor of Diabetes Research at KCH, won the prestigious Robert Turner Award for Research Impact. Professor Amiel has been at the forefront of diabetes research for a number of years, leading the team that performed the first

successful islet cell transplantation in 2005 and more recently spearheading the HARPdoc trial, a method of improving hypoglycaemia awareness in order to reduce severe hypoglycaemia in people with type 1 diabetes.

The Robert Turner Award for Research Impact honours her significant role in revolutionising our understanding of hypoglycaemia and improving diabetes education.

CogStack wins Artificial Intelligence in Health and Care award

In June 2021, CogStack won the Artificial Intelligence in Health and Care Award for their innovative use of Natural Language Processing (NLP) to transform and improve research, planning and care.

CogStack is an information retrieval, extraction and natural language processing platform developed by researchers at the NIHR Maudsley BRC and King's College Hospital NHS Foundation Trust in partnership with the University College London Hospitals NHS Foundation Trust BRC.

The platform uses artificial intelligence (AI) to unlock important patient data in order to support clinical decision making and healthcare research.



KCH's neurosurgery team amongst most productive in UK

In August 2021, analysis of academic and research output found that the KCH Neurosurgery team, led by Professor Keyoumars Ashkan, were amongst the most productive team in the UK. KCH is a major centre for neurosurgery and treats thousands of patients a year. As well as this, the team frequently undertake academic research projects to improve clinical practice and care. The analysis using data from Web of Science, showed that between 2011 and 2020, the KCH Neurosurgery team ranked third out of thirty centres for their academic and research output.



The Neurosurgery team in action: Prof Ashkan (left) is operating on a woman while she plays the violin to ensure that the surgery does not affect her fine motor skills.



Professor K Ray Chaudhuri

Professor K Ray Chaudhuri wins Honorary Membership Award

In September 2021, KCH Research Director and Consultant Neurologist, Professor K Ray Chaudhuri, received the Honorary Membership Award from the International Parkinson and Movement

Disorders Society (MDS), in recognition of his world-leading research on defining the non-motor symptoms and genetic characteristics of Parkinson's disease. He is first clinician from the Trust to have received this honour since the awards started.



Dr Jennifer Vidler

Dr Jennifer Vidler wins joint NIHR CRN RCP Award

In October 2021, haematology registrar Dr Jennifer Vidler won the joint NIHR Clinical Research Network (CRN) and Royal College of Physicians' Award for outstanding contribution to research – becoming the only trainee doctor in

London to do so. Dr Vidler won the award after being redeployed to the PRUH during the pandemic and playing an important role in recruiting patients to the RECOVERY trial. This urgent public health platform trial resulted in the licencing of low-cost dexamethasone for use for people with severe COVID-19. In March 2021, it was estimated that it had already saved 22,000 lives in the UK and 1 million lives globally.

KCH Parkinson's PPI group celebrates ten years since formation

In December 2021, the CRISP (Community for Research Involvement and Support by people with Parkinson's) Patient Participation and Involvement (PPI) group, founded and based at KCH, celebrated their tenth anniversary since launching in 2011.

CRISP is the first PPI group in the UK that assists scientists in Parkinson's disease-related research and has played a key role in the initiation and development of many clinical research projects, including the now-globally used King's PD Pain Scale.

The anniversary was celebrated with an evening of insightful talks from both Parkinson's researchers and patients, followed by presentation of commemorative plaques.



Professor Peter Goadsby

Professor Peter Goadsby elected to Royal Society Fellowship

In May, consultant neurologist and Director of the NIHR Wellcome King's CRF Professor Peter Goadsby was elected to the prestigious fellowship of the Royal Society.

The Fellowship of the Royal Society is made up of the most eminent scientists, engineers and technologists from the UK and the Commonwealth. Each year, the Royal Society elects up to 52 new fellows and up to 10 Foreign Members in recognition of their exceptional contributions to science and medicine.

Professor Goadsby is one of the world's leading researchers exploring the science behind migraine and cluster headache research. In a career that has spanned four decades, his work has been central to the development of many novel, effective migraine treatments. As well as his role at KCH, Professor Goadsby is the Theme lead for Pain at the NIHR Maudsley Biomedical Research Centre and Professor of Neurology in the School of Neuroscience at King's College London.

KCH researchers' success in PCAF applications

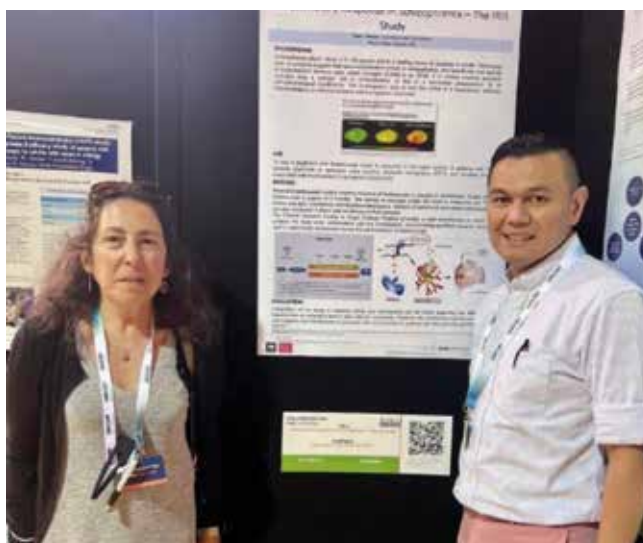
In June, pharmacists Ashraf Mumin and Rachel Clapham from the Pharmacy research team and research nurse Hannah Cotton from the ACET research team secured places on the highly prestigious and competitive NIHR Pre-doctoral Clinical Academic Fellowship (PCAF) scheme.

The scheme is designed to prepare non-medical clinical healthcare practitioners such as nurses and midwives for a clinically relevant PhD by supporting them to carry out a research project of their choice.

In addition, consultant pharmacist in paediatrics Joanne Crook secured a Bridging Fellowship, which enables clinical academics to build on their previous academic training and develop proposals for a pre- or post-doctoral award, taking the next step on their clinical academic pathway.

King's CRF researchers win poster competition

At this year's annual UKCRF Network conference, Negar Tadayon, Dani Nebres and Yuya Mizuno from the NIHR Wellcome King's CRF won best poster in the Clinical and Medical Science category. Their poster focused on the Inflammatory Response In Schizophrenia (IRIS) study, which aims to determine the role of brain immune cells in schizophrenia, and how symptoms may be reduced through immunotherapy.



Negar Tadayon (L) and Dani Nebres (R) with their winning poster

Useful Information



Outreach and engagement

Research Grand Rounds

At the beginning of the pandemic, Professor Ray Chaudhuri and research communications officer Eleanor Sherwood teamed up to organise the delivery of monthly Research Grand Rounds sessions. With a key aim to increase research awareness across both clinical and non-clinical staff at the Trust, the Research Grand Rounds have taken the form of a series of regular virtual symposia where a nominated member of a research team shares recent research updates to a wide and varied audience.

Recent highlights have included “COVID-19: Adventures in Clinical Trials” by Dr James Galloway, Rheumatology research team lead. Attended by over 100 staff members, this fascinating seminar involved a whistle-stop tour through key clinical trials delivered at the Trust which resulted in key breakthroughs in the treatment and prevention of COVID-19. For example, he highlighted platform trials such as RECOVERY and REMAP-CAP, which allowed for the efficient removal and addition of ineffective/effective treatments and allowed patients to receive the best care as quickly as possible. These trials have since brought about the use of a number of life-saving treatments. He also discussed various vaccine trials, including the huge cross-departmental collaborative effort that went into successfully delivering the clinical trial of the Novavax COVID-19 vaccine, of which he was the PI. Novavax’s ‘Nuvaxovid’ vaccine was subsequently found to provide 90% protection against severe COVID-19 and has been approved by the MHRA for use in the UK.

Emergency Department (ED) research team leader Dr Fleur Cantle also provided a unique insight into how research takes place within the busy ED and her team’s current projects. She discussed how while carrying out research in the ED had its challenges – mainly time, space and patient-associated factors – the ED had recruited over 1,000 patients to research studies in the last few years.

One such study was the Halt-it study, which found that while tranexamic acid could reduce head injury-related death in those with Traumatic Brain Injury, it was not effective in stopping intestinal bleeding and shouldn’t be given to patients in this situation.

She also discussed local and national COVID-19 studies that were carried out in the ED from the start of the pandemic. She described how early studies were crucial to determining the care pathway of patients entering the ED with COVID-19. Risk scores for severe COVID-19, such as NEWS2, came from national studies which ran at KCH were crucial in triaging patients



Rheumatology research team lead and Novavax clinical trial PI Dr James Galloway



Emergency Department research lead Dr Fleur Cantle

so that they could receive the most appropriate care based on their score. Other national trials held in the ED, such as FALCON-C19 and CONDOR, evaluated important new diagnostics tests for COVID-19. Since their inception, the Research Grand Rounds have continued to be popular among clinical and non-clinical staff and are a useful and accessible way to disseminate and highlight the wide variety of research projects across the Trust.

CRISP ten-year anniversary

In December last year, the CRISP (Community for Research Involvement and Support by people with Parkinson's) Patient Participation and Involvement (PPI) group, founded by and based at KCH celebrated their tenth anniversary since launching in 2011.



Members of the CRISP group alongside KCH and KCL Parkinson's disease researchers

CRISP is the first PPI group in the UK that assists scientists in Parkinson's disease-related research. CRISP has played a key role in the initiation and development of many clinical research projects, including the now-globally used King's PD Pain Scale.

To mark their tenth anniversary, CRISP members were joined by researchers from KCH and King's College London for an evening of talks.

CRISP clinical lead and KCH Neuroscience Research Manager, Alex Rizos and Professor K Ray Chaudhuri, Neurologist at KCH and Professor in Movement Disorders at King's College London, provided a whistle-stop tour of CRISP's involvement in Parkinson's research. They highlighted CRISP's advisory role in research that has investigated Parkinson's effect on the gastrointestinal system and how activities such as ballet can support people to live well with the condition.

CRISP members also shared their personal stories of Parkinson's disease and how involvement with research and CRISP had impacted their lives. CRISP member John discussed the trauma of his mother's diagnosis of Parkinson's disease when he was young yet. John

was invited to join CRISP due to his previous career in academia and has since participated in a number of studies. He concluded his talk by stating that he was on a happier journey than the one he had envisioned based on his childhood experiences.

To conclude the talks, KCH Head of Research & Innovation Ann-Marie Murtagh and Clinical Research Network PPI manager Neha Modha both emphasised the importance of the patient voice for informing the direction of research and inspiring researchers to continue improving patients' lives.

Afterwards, CRISP members Eros and Karen spoke to guests about their reasons for getting involved and how it had impacted their lives. Eros was diagnosed with Parkinson's disease in 2004 and is a founding member of CRISP:

"I was honoured when Professor Chaudhuri asked me if I'd like to join the group, explaining it was like a sounding board for new developments and research. The most exciting thing we've done is working on the Parkinson's Pain Scale. It's used all over the world! If you're interested in getting involved in research projects in this way, it's never too late."

Like Eros, Karen also found out about the CRISP group from Professor Chaudhuri. Diagnosed in 2010, Karen has now been part of CRISP for nine years and said:

"I was interested in research as you find out much more about the disease. Researchers often ask us to look at their research and ask us for ideas, for example to help make a questionnaire more user-friendly for participants. Being part of CRISP gives you hope for the future and what may come about – that's the main thing. Personally, I'm excited about genetic research and individual therapies."

International Clinical Trials Day

Earlier this year, research teams from across the Trust celebrated International Clinical Trials Day with by holding the first in-person public event since 2019.

The awareness day is held partially in commemoration of what is believed to be the first clinical trial where, in 1747, James Lind investigated the treatment of scurvy above the HMS Salisbury, ultimately revealing the link between citrus fruits and scurvy prevention. Now, International Clinical Trials Day is a chance to celebrate life-changing clinical trials and the researchers and participants that make them possible.

At KCH, eleven research teams from across the Trust filled two marquees and part of the Golden Jubilee Wing used posters, interactive activities and even a dialysis machine to celebrate and discuss their research with staff, patients and members of the public.

The King's CRF team ran a blinded study to determine which diet cola drink was the favourite of the day – all



KCH research teams joining forces for International Clinical Trials Day

while highlighting the importance of removing bias in clinical trials - while the Viapath team tested visitors' pipetting skills with goody bags available to those with the most accurate and neatest results.

Towards the back of the marquee, the Cardiology team demonstrated the use of stents in treating heart attacks and discussed their current trial which aims to determine the best treatment for cardiac arrest, whereas the ACET team were positioned at the front of the tent enticing passers-by in with a chance to test their CPR skills on a dummy.

Also, due to inclement weather seen in the morning, the Liver research team took over the Golden Jubilee wing where they provided on-the-spot liver scans which, using their FibroScan technology, checks for fibrosis of the liver - an early sign of cirrhosis.

At around lunchtime, Chief Nurse Nicola Ranger visited the marquees to hand out 'Covid Stars' to all research nurses who had worked tirelessly during the pandemic to treat patients and enrol over 30,000 patients into clinical trials and studies.

Overall, the event was well-attended by staff and the public alike, with many members of the public coming away having learnt a bit more about clinical trials at KCH – and some even signing up to participate!

South Asian Heritage Month

In July, staff across the Trust celebrated South Asian Heritage Month and highlighted the numerous people who hail from a range of South Asian countries that are key to the research workforce at KCH.

Devised by senior research nurse Chifundo Stubbs and launched by consultant neurologist and Director of Research Professor Ray Chaudhuri, who hails from India, the awareness month kicked off with an all-day engagement stand which involved learning common research phrases, such as 'would you like to participate in a clinical trial?' in a number of South Asian languages. The month continued with an interview with King's CRF administrator Pratik Solanki being published on the CRN South London website, as well as further learning of important country-related and cultural facts. Language cards will be used by Prof Chaudhuri in clinics and some wards around the hospital have expressed interest in using them.

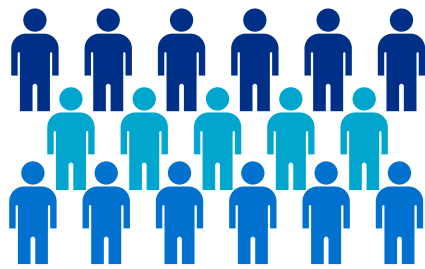


Researchers at KCH launching South Asian Heritage Month

The year in numbers....

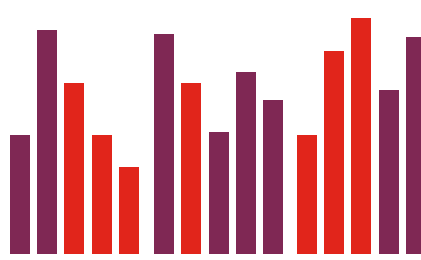
Here we look back at FY2021/2022's research output in numbers, from the number of participants in research studies to value of commercial contracts.

NUMBER OF PARTICIPANTS IN RESEARCH STUDIES 2021/22



20,642

NUMBER OF RESEARCH STUDIES OPEN IN 2021/22



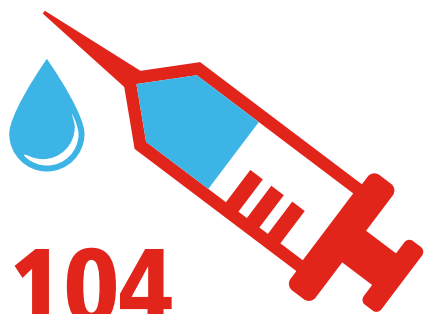
684

NUMBER OF NEW NON - COMMERCIAL PORTFOLIO STUDIES APPROVED 2021/22



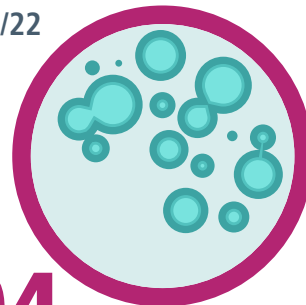
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NUMBER OF NEW COMMERCIAL STUDIES OPENED IN 2021/22



104

NUMBER OF NON-COMMERCIAL RESEARCH CONTRACTS FULLY EXECUTED IN 2021/22



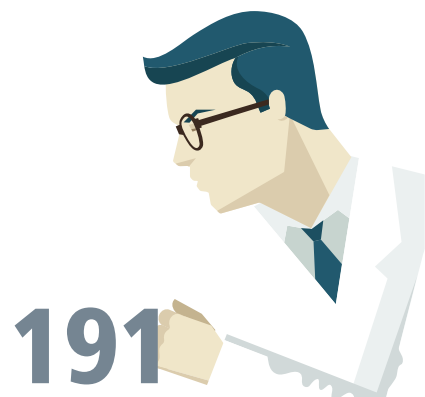
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NUMBER OF AMENDMENTS PROCESSED IN 2021/22



577

NUMBER OF FULL TIME RESEARCH STAFF



191

COMMERCIAL CONTRACT VALUE OF RESEARCH STUDIES IN 2021/22



£12 million

Research Delivery Unit Leads

RDU 1



Prof K Ray Chaudhuri
RDU 1 Lead
Speciality Lead:
Neurosciences
ray.chaudhuri@nhs.net



Prof Keyoumars Ashkan
RDU 1 Co-Lead
Speciality Lead: Neurosurgery
k.ashkan@nhs.net



Dr Thomas Booth
Speciality Lead:
Neuroradiology
thomasbooth@nhs.net



Dr Laszlo Sztriha
Speciality Lead:
Stroke
laszlo.sztriha@nhs.net

RDU 2



Dr Julie Whitney
Speciality Lead:
Age and Ageing
julie.whitney@nhs.net



Prof Theresa McDonagh
RDU 2 Lead
Speciality Lead:
Cardiovascular
t.mcdonagh@nhs.net



Jonathan Breeze
RDU 2 Co Lead
Speciality Lead: Cardiology
jonathan.breeze@nhs.net

RDU 3



Argyro Syngelaki
RDU 3 Co-Lead
Speciality Lead: Fetal
Medicine
argyro.syngelaki@nhs.net



Katherine Clark
RDU 3 Co-Lead
Speciality Lead: Women's
Health
katherineclark1@nhs.net



Dr Piers Patten
RDU 4 Lead
Speciality Lead: Haematology
and Precision Science
piers.patten1@nhs.net



Dr Sabrina Bajwah
RDU 4 Co-Lead
Speciality Lead:
Palliative Care
sbajwah@nhs.net

RDU 5



Dr Vishal C. Patel
RDU 5 Lead
Speciality Lead: Liver
vishal.patel@nhs.net



Dr Alexandra Kent
RDU 5 Co-Lead
Speciality Lead:
Gastroenterology
alexandra.kent@nhs.net



Mr Wayel Jassem
Speciality Lead:
Liver Surgery
wayel.jassem@nhs.net



Dr James Galloway
Speciality Lead:
Rheumatology
james.galloway@nhs.net

RDU 6



Dr Sapna Shah
RDU 6 Lead
Speciality Lead: Renal
sapna.shah@nhs.net



Dr Georgios Dimitriadis
RDU 6 Co-Lead
Speciality Lead: Endocrine &
Obesity
g.dimitriadis@nhs.net



Dr Prashanth Vas
RDU 6 Co-Lead
Speciality Lead: Diabetes
prashanth.vas@nhs.net



Dr Gordon Muir
Speciality Lead: Urology
gordon.muir@nhs.net

RDU 7



Prof Frank Post
RDU 7 Lead
Speciality Lead:
HIV and Sexual Health
frank.post@nhs.net



Prof Timothy Jackson
Speciality Lead:
Ophthalmology
t.jackson1@nhs.net



Prof Tara Renton
Speciality Lead:
Dental
t.renton@nhs.net

RDU 8



Dr Phil Hopkins
RDU 8 Lead
Speciality Lead: Critical Care
p.hopkins@nhs.net



Dr Gudrun Kunst
RDU 8 Co-Lead
Speciality Lead: Anaesthetics
gudrun.kunst@nhs.net



Dr Fleur Cattle
Speciality Lead: Emergency
Department
fleur.cattle@nhs.net



Prof Surinder Biring
Speciality Lead: Respiratory
surinder.biring@nhs.net

RDU 9



Dr Atul Gupta
RDU 9 Lead
Speciality Lead: Children
atulgupta1@nhs.net



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



Dr Georgios Dimitriadis
PRUH R&I Co-Lead
g.dimitriadis@nhs.net



Dr Mohammad Albarjas
PRUH R&I Co-Lead
mohammadalbarjas@nhs.net

Supporting services



Esther Makanju
Pharmacy Lead
esther.makanju1@nhs.net



Dr Mohammad Ibrahim
R&I Lead: General Pathology
mohammad.ibrahim@nhs.net



Dr Daniel Quinlan
R&I Lead: General Radiology
dan.quinlan@nhs.net



Dr Sharlene Greenwood
R&I Lead: Therapies
sharlene.greenwood@nhs.net

Research Delivery Managers and Matrons (RDMs)

RDU 1



Alex Rizos
Neuroscience
a.rizos@nhs.net



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

RDU 2



Jonathan Breeze
Cardiology
jonathan.breeze@nhs.net

RDU 3



Argyro Syngelaki
Fetal Medicine
argyro.syngelaki@nhs.net



Katherine Clark
Women's Health
katherineclark1@nhs.net

RDU 4



Lorraine Catt
Haematology
lorraine.catt@nhs.net



Maria Liskova
Haematology
maria.liskova@nhs.net

RDU 5



Vernie Ramalingam
Liver
vernie.ramalingam@nhs.net



Lee Meng Choong
Gastroenterology
leemeng.choong@nhs.net

RDU 6



Leela Goldstein
Renal
leela.goldstein@nhs.net



Andrew Pernet
Diabetes
andrewpernet@nhs.net

RDU 7



Riti Desai
Ophthalmology
ritidesai@nhs.net



Lucy Campbell
HIV/Sexual Health
lucy.campbell1@nhs.net

RDU 8



John Smith
ACET
john.smith27@nhs.net



Kerim Gokturk
Orthopaedics
agokturk@nhs.net

RDU 9



Katie Tupper
Paediatrics (On maternity leave)
katietupper@nhs.net



Ivan Caro
Paediatrics (Maternity cover)
ivancaro@nhs.net

King's Health Partners Clinical Trials Office

The King's Health Partners Clinical Trials Office (KHP-CTO) was set up as a joint initiative between King's College London and three NHS Foundation Trusts; Guy's and St Thomas', King's College Hospital and South London & Maudsley. The key aim was to formalise the pre-existing collaborations between the partners and develop the potential of their clinical trials as well as increasing the quality and delivery of clinical trials.

KHP-CTO partner Organisations



Quality Team

Support investigators of Clinical Trials of Investigational Medicinal Products (CTIMPs), where KHP partner organisations are the sponsor or co-sponsor, to ensure delivery of the statutory obligations contingent on sponsorship of drug trials.

Team led by Rebecca Newton
Rebecca.Newton@kcl.ac.uk

Key focuses

- Regulatory
- Pharmacovigilance
- GCP compliance
- Monitoring
- Training
- Inspection Support



Commercial Team

Set up and administration of commercial clinical trials sponsored by the pharmaceutical and allied healthcare industries hosted by a KHP partner organisation.

Team led by Kirsty Hough
Kirsty.Hough@kcl.ac.uk

Key focuses

- Feasibility
- Facilitation
- Budget & contract negotiations
- Amendments
- Finance

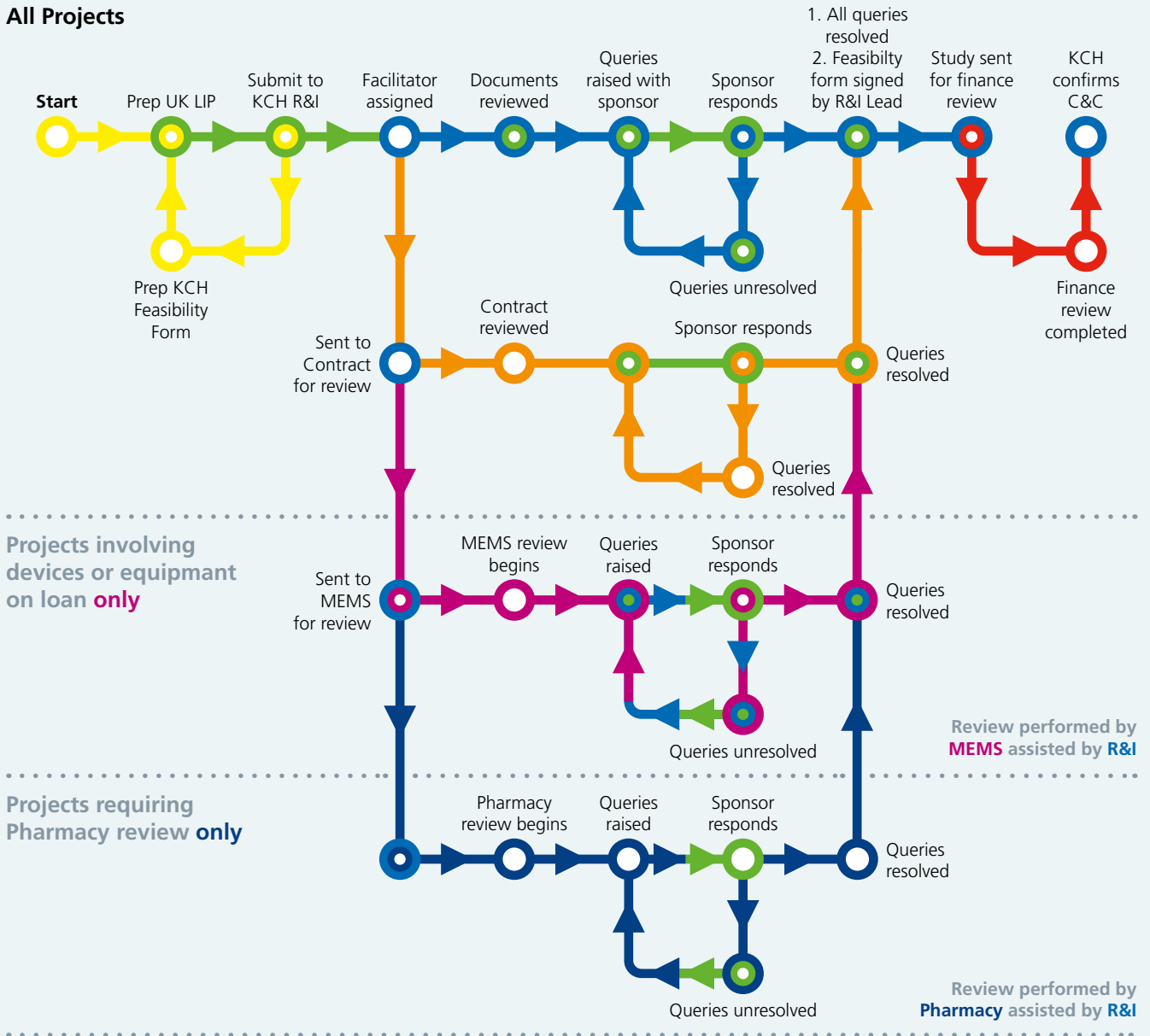


Project Approval 'Tube Map'

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/>.



All Projects



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 R&I
- = MEMS
- = KCH PI
- = KCH Contracts
- = Pharmacy

Examples of R&I Contracts

R&I NON-COMMERCIAL CONTRACTS TEAM

NON-COMMERCIAL RESEARCH CONTRACTS		
mNCA/site agreement	Technical agreement	Termination agreement
CDA	Device loan agreement (with MIA indemnity)	Data sharing agreement
Funding agreement	MTA	MoU
Collaboration agreement	Amendment	PiC agreement
Sub-funding agreement	Novation	
SLA		

KCH BIOBANK

EXTERNAL REQUEST (MTA)		
Received by Biobank for assessment of samples provision, *Biobank fees and shipping preparation and costs	Passed to R&I NC Contracts to provide and finalise MTA (non-negotiable terms)	and first signature
	Returned to Biobank for approval	Passed to R&I NC Contracts for second signature (KCH) and final signature from requestor

INTERNAL REQUEST (KCH TRUST)		*BIOBANK FEES
Received by Biobank	MTA by Biobank	Set structure subject to material type and requestor (industry or non-commercial entity)
Assessment of sample provision and issue of Internal Recipient	Review, finalisation and processing for signature by Biobank	

KHP-CTO

COMMERCIAL RESEARCH CONTRACTS	
mCTA/mCIA'	commercial research only
CDA/NDA	SLA
provider/supplier contracts for	

KCH COMMERCIAL LEGAL SERVICES

COMMERCIAL/BUSINESS CONTRACTS		
Innovate UK	Consortium agreements	SLA for commercial activity at KCH
HDR UK	Data sharing agreements	MTAs with commercial companies
ARC (KCH host) – review only	Chief investigator agreements	(non-commercial sponsored research) – review only
CRF contract	Consultation agreements	Financial assessment of KCH data
Fee for service contracts	CRN Sub-contracts	
	Service evaluation	

INTELLECTUAL PROPERTY (IP) MANAGEMENT	
IP terms for KCH collaboration with commercial partners	IP advice –wording/process/ responsibilities
Revenue sharing agreements	

Key

ARC = *Applied Research Collaboration*
 CDA = *Confidential Disclosure Agreement*
 CRN = *Clinical Research Network*
 CRF – *Clinical Research Facility*
 DSA = *Data Sharing Agreement*
 DTA = *Data Transfer Agreement*
 HDR UK = *Health Data Research UK*
 MIA = *Master Indemnity Agreement*

mCIA = *Clinical Investigation Agreement*
 mCTA = *Clinical Trials Agreement*
 mNCA = *Model Non-Commercial Agreement*
 MTA = *Materials Transfer Agreement*
 NC = *Non-Commercial*
 NDA = *Non-Disclosure Agreement*
 PIC – *Patient Identification Centre*

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
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 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

Contacts list

Research & Innovation Office

The R&I Office
King's College Hospital NHS Foundation Trust
First Floor Coldharbour Works
245A Coldharbour Lane
Brixton SW9 8RR
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.finrl@nhs.net

R&I Invoices

kch-tr.ncsiteincome@nhs.net

R&I Costing

kch-tr.rd-researchcosting@nhs.net

R&I Purchase Orders

kch-tr.researchpurchaseorders@nhs.net

Clinical Trials Pharmacy

kch-tr.ClinicalTrialsPharmacy@nhs.net

ACET Team

kch-tr.acetresearch@nhs.net

Haematology

kch-tr.hrutrialsetup@nhs.net

Liver

kch-tr.liverresearchgov@nhs.net

Ophthalmology

kch-tr.ophthalmologyresearch@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

Clinical Research Facility

kingscrf@kcl.ac.uk

Clinical Trials Pharmacy

kch-tr.clinicaltrialspharmacy@nhs.net

Rheumatology

rheumatology-ctg@kcl.ac.uk

Stroke

kch-tr.kingsresearch@nhs.net

Paediatrics

kch-tr.paediatricresearch@nhs.net