

Research & Development Strategy: Four years on



Welcome

Dear colleagues,

Welcome to our Annual Research and Development Strategy meeting. It is wonderful to hold this meeting face-to-face after the challenges of the past few years due to COVID-19. Our Five-Year Strategy for Research and Development was launched in 2019 to guide and showcase our alignment with the Trust's Strong Roots, Global Reach strategy, with research being a vital component of its BOLD vision. The R&D team has released yearly Research and Development Strategy updates since then to highlight our successes and demonstrate how our teams have reached key milestones in the Five-Year Strategy.

Following our last update, where we focused on opening more commercial and non-commercial studies post-COVID-19, our research teams have concentrated more on their specialty areas and have recruited more participants for commercial and non-commercial studies than last year. This year, we also changed the department name from Research and Innovation to Research and Development, with the innovation aspect now under the Quality Improvement team.

As we look back at our fourth year, we are on track to achieve the three objectives of the Research and Development Five-Year Strategy: (i) to increase commercial and academic research activity, (ii) to establish an Advanced Therapies and Biomedical Sciences Hub and (iii) to create a supportive research culture throughout the Trust. We also support prospective clinical researchers through NIHR Senior Research Leadership programmes and Pre- and Post-Doctoral Clinical Academic Fellowship schemes.

Our staff have received numerous awards for their exceptional achievements in their respective fields, demonstrating the quality of our research at King's College Hospital NHS Foundation Trust. For example, Professor Anil Dhawan received the Honouring the Greats award from the International Liver Transplantation Society (ILTS) for his 30-year global impact in the liver transplantation field.

Today, at our Annual Research and Development Strategy meeting we celebrate and review the fantastic achievements made since March 2022, which have only been possible due to our research staff's hard work and dedication. We also recognise the importance of patient experiences and participation in research. We extend a special thank you to our patients who are attending today; without your participation and support, none of this would have been possible.

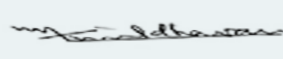
With warm regards,



Professor K. Ray Chaudhuri
Director of Research
& Development



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



Professor Anil Dhawan
Director of Research
& Development

Research and Development Annual Research Meeting

Fetal Medicine Research Institute Lecture Theatre, 16 – 20 Windsor Walk, SE5 8BB

20 October 2023, 12 – 5pm

Agenda

12.00 - 13.00 **Registration and Lunch**

13.00 - 13.15 Welcome address – Dr Leonie Penna

13.15 - 13.30 R&D Directors' Annual Review – Ann-Marie Murtagh

Session 1: Research highlights

Chaired by Professor Anil Dhawan

13:30 - 13:40 Update on studies at Princess Royal University Hospital (PRUH) and South sides services - Dr Deepak Rao and Nicola Griffiths

13:40 - 13:50 ORION study - Dr Mo Albarjas

13:50 - 14:00 Redefine update - Dr Georgios Dimitriadis

14:00 - 14:25 Nurse, Midwife and AHP-led Research at King's College Hospital - Dan Hadfield

14:25 – 14:45 King's Clinical Research Facility Highlights 2023 and Beyond
- Professor Peter Goadsby

14:45 - 15:15 Panel discussion

15.15 - 15.45 **Coffee Break & Poster Viewing (Presenters stand by posters)**

Session 2 Patient Voices

Chaired by Professor K Ray Chaudhuri

15.45 - 16.15 Participation in research – why me? - Community champions

16.15 - 16.30 Advanced therapy in Parkinson's: King's leading the way
- Professor K Ray Chaudhuri

16.30 - 16.45 Panel discussion

16.45 - 17.00 Vote of thanks, poster competition outcome and closing remarks

Research Strategy Aims: where are we now?

It has been four years since the launch of the Research and Development Strategy. This document sets out three key aims and the steps the R&D community has taken to achieve them. 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&D 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: Develop the Advanced Therapies Medicinal Products (ATMPs) and Biomedical Sciences Hub

- ✓ Establish trust-level ATMP oversight group (Chair – Professor 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&D
- ✓ Fund and appoint a Clinical Biological Safety Lead
- ✓ Implement consent to contact for all KCH patients
- ✓ Establish ATIMP Academy and hold first workshop

Aim 3: Develop a supportive Trust-wide research culture including a workforce that appreciates and is skilled in the conduct and use of research and development 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&D leads meeting established
- ✓ R&D housed on a main trust site (Coldharbour Works)
- ✓ R&D training implemented (R&D Academy programmes and workshops)

Contents

Abbreviations and Acronyms	7	RDU 8 - Anaesthetics, Critical Care, Emergency Department and Trauma (ACET), Pain, Respiratory and Orthopaedics	38
RDU 1 - Neurosciences, Stroke, Neurology, Age and Ageing	9	ACET	39
Neuroscience	10	Respiratory	41
Motor Neurone Disease and Amyotrophic Lateral Sclerosis (ALS)	12	Trauma and Orthopaedic Surgery	43
Neurosurgery	13	RDU 9 - Children	45
Stroke	14	Paediatrics	46
Neuroradiology	15	NIHR King's Clinical Research Facility	48
RDU 2 - Cardiology and Breast Cancer	16	Mental Health Studies	50
Cardiology	17	Rheumatology	50
RDU 3 - Women's Health and Fetal Medicine	18	Neurological Studies	51
Women's Health	19	Princess Royal University Hospital (PRUH)	53
Fetal Medicine	20	Supporting Services	55
RDU 4 - Haematology, Precision Science AND Palliative Care	21	Pharmacy	56
Haematology	22	Pathology	59
Palliative Care	24	Radiology	60
RDU 5 - Liver and Gastroenterology	26	King's Liver Biobanks	61
Liver	27	Research & Development	62
RDU 6 - Renal, Diabetes and Endocrine, Urology	29	Congratulations Corner	64
Renal, Urology, Diabetes and Endocrinology	30	Useful Information	67
RDU 7 - HIV & Sexual Health, Ophthalmology, Dermatology and Dental	34	Outreach & Engagement	68
HIV and Sexual Health	35	The year in numbers....	70
Ophthalmology	36	The year in pictures	72
Dental	37	KCH Research Delivery Unit (RDU) Leads	74
		King's Health Partners Clinical Trials Office	78
		KCH Research and Development Finance Team	79
		Equality, Diversity and Inclusion	81
		Glossary	83

Abbreviations and Acronyms

AHSN	Academic Health Science Network
ALBs	Arm's 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
EDI	Equality, Diversity and Inclusion
GCP	Good Clinical Practice
GSTT	Guy's and St Thomas' NHS Foundation Trust
HSMR	Hospital Standardised Mortality Ratio
HTA	Human Tissue Authority
IfLS	Institute of Life Sciences
IoPPN	Institute of Psychiatry, Psychology & Neuro-science
KCH	King's College Hospital
KCL	King's College London
KHP	King's Health Partners
KHP CTO	King's Health Partners Clinical Trials Office
KPI	Key Performance Indicator
LHS	Learning Health System
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health and Care Research
PIN	Patient Involvement Network
PPIE	Patient and Public Involvement and Engagement
PRUH	Princess Royal University Hospital
R&D	Research and Development
RCF	Research Capability Funding
RDM	Research Delivery Manager
RDU	Research Delivery Unit
SLaM	South London & Maudsley NHS Foundation Trust
SOP	Standard Operating Procedure
SRL	Specialty Research Lead

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 and Gastroenterology



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



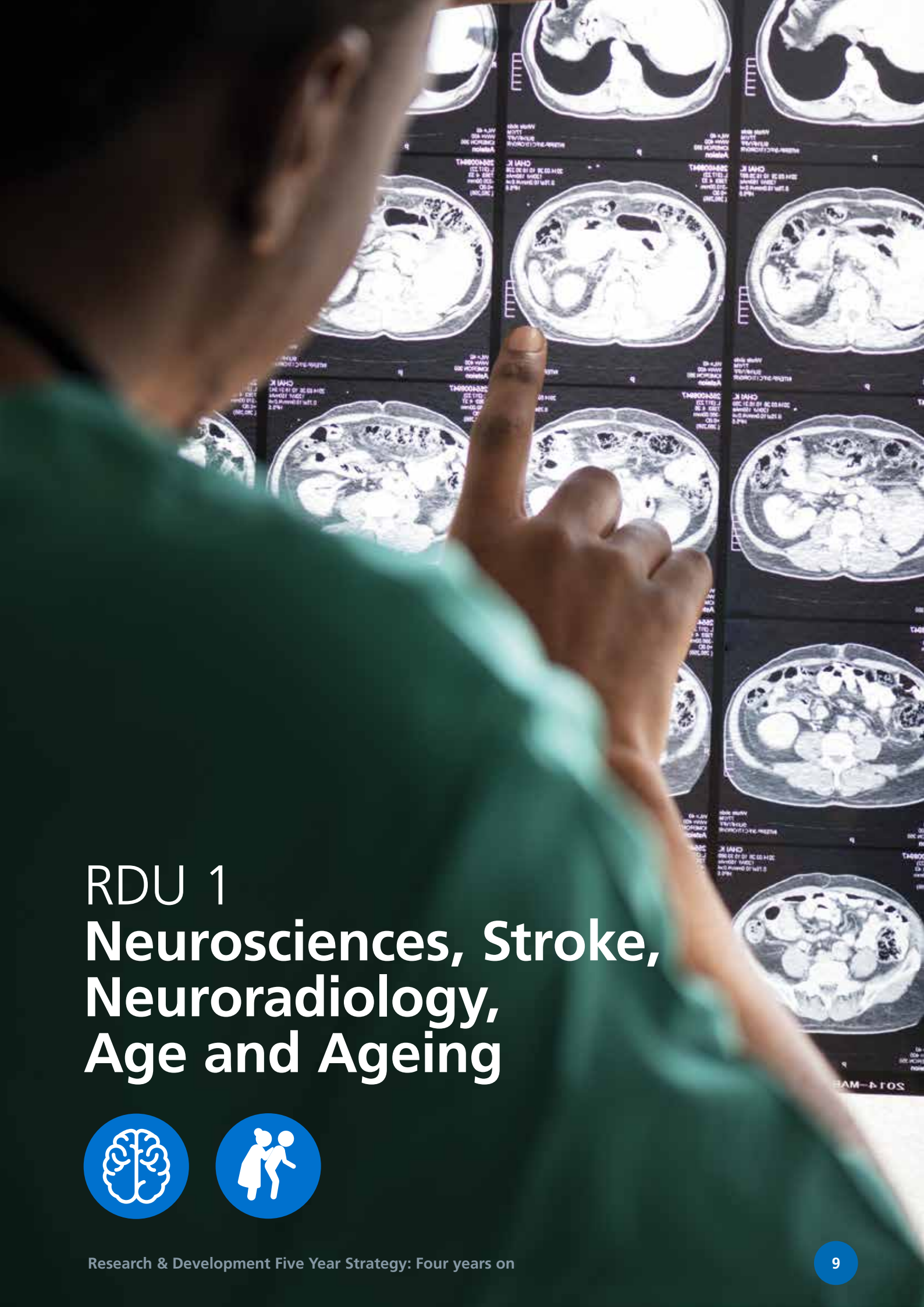
NIHR King's Clinical Research Facility – Mental Health, Rheumatology and Neurology



The Princess Royal University Hospital (PRUH)



Cross-cutting areas of Research



RDU 1 Neurosciences, Stroke, Neuroradiology, Age and Ageing



Neuroscience

The King's Parkinson's Foundation Centre of Excellence is led by Professor K Ray Chaudhuri. Our team comprises one research manager, five research coordinators, five PhD fellows, two neurologist and movement disorder clinical research fellows and two research nurse specialists. We conduct research on all stages of the disease, from prevention to advanced therapies.

We are a leading world-class research centre conducting over 20 commercial and non-commercial studies. Non-commercial studies include a Wellcome Trust-funded collaboration with the English National Ballet to assess the effectiveness of ballet on Parkinson's symptoms. PhD Fellow Alexandra Podlewska leads the study. We are also one of the key centres of understanding of how to improve palliative care delivery for Parkinson's through PD-PAL, a Horizon 2020-funded project in Europe. We are conducting trials on drugs such as Exenatide (anti-diabetic drug) and Ambroxol (mucolytic) to slow Parkinson's progression. We are the highest recruiter for the COVID CNS study, part of a national biobank study that aims to understand COVID-19 better. Furthermore, we have completed a study on the effects of Symprove probiotics on the quality of life of individuals with Parkinson's (Sym-PD) and are currently conducting analyses.

We are contributing to developing digital technology in Parkinson's and Neuroscience. Our centre is a leader in prognosis with a Horizon 2020-funded project, the EU Horizon-funded successor study AI-PROGNOSIS, and the Parkinson's KinetiGraph registry, the first of its kind in the world to collect objective data on movement

in Parkinson's. Our commercial trials cover early interventions to advanced therapies, serving patients with Parkinson's at all stages. We conducted the first-in-human Phase 1 drug trial of a new medication for early PD diagnosis (UCB Pharmaceuticals). Another trial includes a Phase 4 RCT on an available new drug, OCEAN and ADOPTION (Bial Pharmaceuticals).

We are hosting the development of a new drug that targets alpha-synuclein, a protein found primarily in neurons. This protein accumulates to form Lewy bodies in people affected by Parkinson's disease and some forms of dementia. Additionally, we are the only European centre hosting a trial for a device-based technology called STEM-PD. This uses neuromodulation (a technology that acts directly on nerves) to improve non-motor symptoms such as depression and anxiety in Parkinson's patients.

Furthermore, we are one of the lead centres for advanced therapies in Parkinson's and, as such, are currently working with several commercial sponsors on alternative delivery devices. Our centre is home to accomplished fellows and observers. Dr V Leta won the Movement Disorder Society LEAP Award for young neurologists. Associate Professor A Sauerbier spent six years with our

team and is now an Associate Professor in Movement Disorders in Germany. Our Director, Professor K Ray Chaudhuri, is ranked first in the UK and fourth globally for Parkinson's disease and is building relationships for collaboration with sites worldwide. We receive two – three observers a month from around the world.

King's Parkinson's Centre of Excellence

PARKINSON'S at KING'S
King's Parkinson's Centre of Excellence in Research and Care is a diverse and international group of researchers. Clinical Director, Professor K Ray Chaudhuri is a world renowned professor in Parkinson's disease.

1st Ranked UK expert on PD Expertise

4th Ranked WORLD expert on PD Expertise

10 PhD Fellows

2 Neurology Fellows

6 Research Coordinators & Research Nurse

2 PD Nurse Specialists

Global collaboration with over 25 countries!

Largest clinical research group at King's College London

Over 100 publications, cited over 40,000 times

Host to international researchers & neurologists

First UK PhD student from Pharmacy!

First in-kind international patient-led training clinic

UK first post-graduate patient-led training clinic

www.parkinsons.london.kcl.ac.uk
#KingsParkinsons

Logos: King's College Hospital NHS Foundation Trust, NHS, King's College London, Parkinson's Foundation Centre of Excellence, EPDA

Interactive page

This is an interactive page, please scan the QR code



<https://bit.ly/3qcETRa>

Motor Neurone Disease and Amyotrophic lateral sclerosis (ALS)

Our clinical trials team at King's College London for Motor Neurone Disease (MND) consists of four neurologists, a senior research fellow, three clinical research fellows, a senior ALS clinical trials manager, an MND research coordinator, an ALS clinical research practitioner, an ALS clinical trials manager, an ALS operation assistant and two PhD candidates. We aim to allow MND patients to participate in commercial and non-commercial clinical trials.

Under the leadership of Professor Chris Shaw and Professor Ammar Al-Chalabi, the clinical trial delivery is divided into two teams. Professor Shaw's team focuses on commercial anti-sense oligonucleotide (ASO) gene (small pieces of DNA or RNA that can bind to specific molecules of RNA) therapy trials for patients with specific gene mutations that cause MND, such as FUS, SOD1 and C9ORF72. These therapies are delivered by injecting the spinal fluid at the bottom of the back.

We are currently running the FUSION trial which uses ASO therapy to block the production of a faulty FUS protein to slow or stop MND progression. We are also part of the VALOR trial, which concentrates on MND patients with a SOD1 mutation. The medication – Tofersen/Qualsody – has already been licensed in the USA and is expected to be available in the UK in 2024. King's is also one of the few locations in the country that offers treatment with Tofersen as part of an Early Access Programme (EAP) in partnership with the pharmaceutical company Biogen, providing the medication free of charge to patients outside of a clinical trial.

Dr James Bashford's team is also conducting studies using neurophysiological techniques such as non-invasive surface EMG (SEMG) to better understand environmental influences on disease progression and develop novel biomarkers to advance drug discovery. This includes the RHAALS study and the Exploration of TMS study, which uses magnetic brain stimulation, electroencephalogram (measurement of brain electrical activity using small metal discs attached to the scalp) and surface muscle recording to explore potential electro-diagnostic markers of MND, particularly in the early stages of the disease.

Professor Al-Chalabi's team is conducting commercial and non-commercial trials of oral therapies for patients with sporadic and familial ALS. Key trials include Lighthouse II, MAGNET, PHOENIX and MND Smart. Lighthouse II is investigating the use of an antiretroviral drug combination (previously licensed in the treatment of HIV) to slow down the progression of MND. MND Smart is a platform trial that allows existing medicines to be quickly tested for use in MND through a shared placebo arm, reducing the number of patients on placebo, which is always a concern in a rapidly progressive condition such as MND.



Neurosurgery

Our Neurosurgery research team at King's is headed by Professor Keyoumars Ashkan, who is a Lead Clinician for Neuro-oncology and Functional Neurosurgery, as well as Co-Chair of King's RDU 1. Our team includes a clinical trials coordinator, a clinical research fellow in neuro-oncology and a senior clinical research fellow in functional neurosurgery. We are currently running eight neuro-oncology and three functional non-commercial studies.

Most of our neuro-oncological studies are centred on glioblastoma, an orphan disease and the most lethal form of primary brain cancer, with a median patient survival of over a year. Of the neuro-oncology studies, ROAM (Radiation vs Observation in Patients with Atypical Meningioma) is the longest study and designed to test the efficacy of radiotherapy versus standard of care (SOC) in preventing the recurrence of atypical meningioma. We are also one of the main recruitment centres for the Tessa Jowell Brain Matrix study, a platform study for patients with gliomas grade 2 – 4 using tissue samples for whole genome sequencing (WGS) and imaging data to assess and validate standard operating procedures (SOPs) for collection, processing and storage of the bio-samples and imaging data.

Our centre is among the top UK recruiting sites for FUTURE-GB (Functional and Ultrasound guided Resection of Glioblastoma), a trial designed to assess if maximal resection of glioblastoma can be improved using extra tools such as intra-operative ultrasound and diffusion tensor imaging (DTI) added to the standard ones, to increase patients' quality of life and progression-free survival. Our research activities involve close collaboration with the multidisciplinary Neuro-oncology team, designated a Centre of Excellence by the Tessa Jowell Brain Cancer Mission.

Among the functional neurosurgical studies, ADROIT is a multi-centre international study designed to collect short- and long-term safety and effectiveness data on various populations implanted with Abbott's deep brain stimulator (DBS) systems, including patients with Parkinson's disease and with disabling tremors, including essential tremor and dystonia.

Patients with refractory essential tremors can also participate in novel modes of DBS, a prospective double-blinded crossover study, which compares the clinical effects of novel versus conventional stimulation. Our studies are highly supported by the DBS team, who are involved in



the screening and follow-up of patients eligible for DBS treatment.

Over the past 10 years, we have been the biggest European recruiting site in the Phase 3 trial of the international Autologous Tumor Lysate-Loaded Dendritic Cell Vaccination in Patients with Newly Diagnosed and Recurrent Glioblastoma trial. A trial compared overall survival in patients with newly diagnosed and recurrent glioblastoma treated with DCVax-L plus SOC versus matched external control patients treated with SOC. The study showed that adding DCVax-L to SOC resulted in a clinically meaningful and statistically significant survival extension for patients with newly diagnosed and recurrent GBM compared with controls (JAMA Oncology Nov 2022).

Stroke

King's Stroke research team has made its mark over the past two years, remaining the highest recruiting Trust for Stroke research across the country, with 1,200 patients recruited last year. This is made possible by Consultant Neurologist Dr Yee Mah's innovative study, Clinical Outcome Modelling of Rapid Dynamics in Acute Stroke (also called Stickman), which uses artificial intelligence (AI) and high-performance computing to study the dynamics of acute stroke. Led by Dr Mah and under the management of Con Tibajia, our Stroke research team comprises two research nurses, two research coordinators and a research administrator working across the Trust's Denmark Hill and PRUH sites.

During the 2022/2023 financial year, we have experienced a big transition in our team. We welcomed former team Research Coordinator Con as our new Research Manager, two new research nurses and two research coordinators. Unfortunately, this transition left us working at a reduced capacity for a couple of months; however, it did not prevent us from going beyond our recruitment targets and opening new studies. Indeed, now that we have closed the COVID-19 studies, we have focused on broadening our stroke portfolio with commercial and non-commercial studies ranging from hyper-acute studies for potentially life-saving interventions, to prevention, rehabilitation and observational studies.

Our 2022/2023 portfolio consisted of 19 studies and seven studies in set up, including two big Phase 3 commercial studies for preventing stroke sponsored by BAYER. We have also managed to recruit participants for ESCAPE-MEVO, an important hyper-acute trial looking at mechanical thrombectomy (surgery to remove a blood clot) for patients with medium vessel occlusions (the obstruction of cerebral arteries). With Dr Thomas Booth as our Principal Investigator for this study, we had our first successful recruit in February 2023, and to date, we are second top recruiter in the country.

In addition, we have increased our resources at the PRUH to improve our recruitment at this site.

In the new financial year, we aim to keep increasing our portfolio at Denmark Hill and the PRUH, maintaining our position as the highest recruiting Trust for stroke.



Stroke Research Team

Neuroradiology

Dr Thomas Booth leads the Neuroradiology research team, which includes three neuroradiologists, four trainee radiologists and a chief data scientist. Our team also includes three clinical study assistants, a research manager, neuro-radiographers, and radiography assistants, all vital to our team's success. Our KCH neuroradiology research team is the top recruiter for Magnetic Resonance Imaging Abnormality Deep Learning Identification (MIDI) among the 41 NHS sites across the UK.

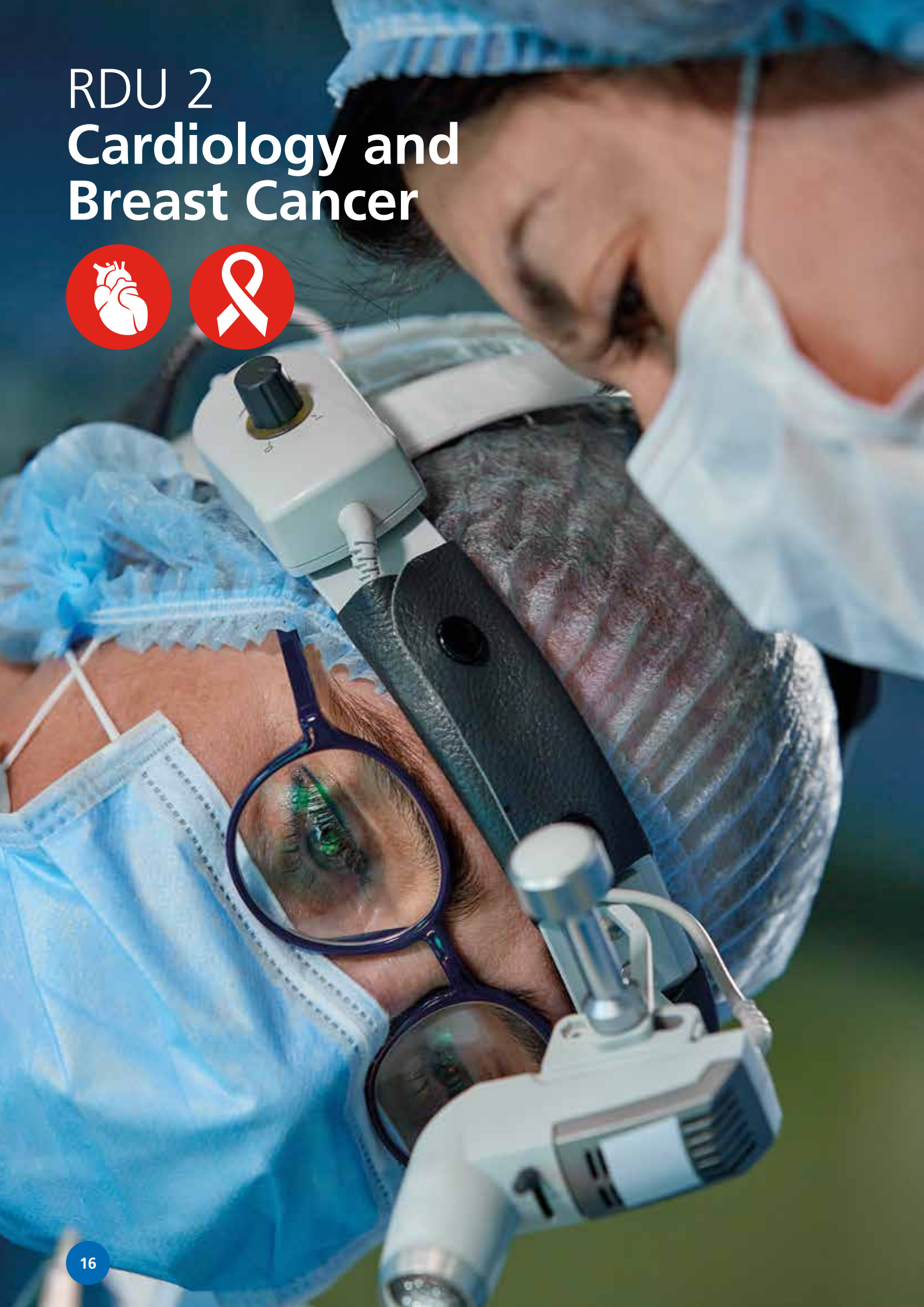
The MIDI study, an NIHR portfolio-adopted non-commercial study, aims to improve patient care and outcomes using AI and deep learning (DL)-based algorithms to make faster MRI diagnoses. DL is a rapidly developing field with great potential in all aspects of healthcare, particularly radiology. It can transform healthcare by deriving new and important insights from the vast data generated daily in healthcare settings. DL excels in image pattern recognition and can learn complex representations from raw MRI data.

The demand for brain MRI scans as a diagnostic tool has increased, leading to patients having to wait longer for the results. Additionally, there is a need for more radiologists able to review these scans. Therefore, the MIDI study aims to develop an automated triaging tool that flags and identifies abnormalities during imaging, allowing radiology departments to prioritise limited resources for reporting abnormal scans and facilitating early intervention from the referring clinical team. This would improve clinical outcomes and lower healthcare costs.

The performance of DL-based algorithms depends on the availability of large-scale annotated data with diverse, high-quality images from various institutions in different geographic areas. This ensures that the model is generalisable for clinical use. We are 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 ones. The study aims to recruit 30,000 participants by March 2025. The MRI scans of these participants will be used to train and test the DL-based algorithms further. Once trained, the algorithm will be tested in a clinical setting to determine its validity in analysing radiological images to suggest clinically relevant findings and aid in diagnostic decisions.



RDU 2 Cardiology and Breast Cancer



Cardiology

Our Cardiac research team, consisting of Lead Research Nurse Jonathan Breeze, Research Nurses Michelle, Abi, Sheetal, Katherine, Sarah, Rita, Victoria and Maria, along with Research Facilitator/Practitioner Hosanna, has had an exceptional year supporting cardiology studies. With over 50 studies ongoing at any given time, more than 1,500 patients have enrolled or been followed up over the past 12 months.

We remain committed to offering King's cardiac patients the opportunity to participate in research, by maintaining a complex portfolio of studies from simple blood tests to novel drug and device trials. Our partnerships with device and pharmaceutical companies continue to grow, with commercial trials in heart failure, imaging, cardiac surgery, structural heart, electrophysiology and interventional cardiology flourishing.

In 2022/23, the first cardiac research study was exclusively conducted at the PRUH. ORION-4, led by Dr Mohammed Albarjas, examined the lipid-lowering effects of Inclisiran and its effects on individuals with raised cholesterol and a history of cardiovascular disease. Coordinated by the PRUH Cardiac research team, led by Nicola Griffiths, ORION-4 has been a great success, enrolling close to 100 patients and leading to a request by the sponsor to increase the site's recruitment target.

CH-STEMI (Chief Investigator Professor Ajay Shah, PI Dr Dan Bromage) – a non-commercial, single centre study – investigates the body's inflammatory response to an acute heart attack and establishes if some individuals are more prone to heart damage than others. By characterising, at the genetic, cellular and molecular level, changes that occur in the phenotype and function of circulating blood cells it is hoped this will help identify novel therapeutic targets leading to new treatments; early results are highly promising.

CH-STEMI is a collaboration between KCH, KCL, the British Heart Foundation Centre of Research Excellence and The Social, Genetic & Developmental Psychiatry Centre.

More recently, the study has extended its collaboration to Professor Mufti's CHIP research programme, exploring the relationship between the immune system, clonal hemopoiesis and Myelodysplastic Syndrome (MDS) disease progression. As a combined force the Cardiac and CHIP research teams have driven CH-STEMI forward at exceptional speed and the future for the study is looking very bright indeed.

2023/24 looks even more exciting, with breast cancer research at King's taking centre stage and the start of/ completion of RDU2's first Phase 1 drug study, supported by the exceptional Clinical Research Facility (CRF) team. The past year has shown that we work with outstanding teams across the Trust and that by working together, we are stronger and can provide an even better service to our patients.



RDU 3 Women's Health and Fetal Medicine



Women's Health

Our Women's Health team is led by Research and Development Lead Katherine Clark and Senior Clinical Research Midwife Sophie Webster and includes five research midwives. Our research on Women's Health has been integrated into the clinical service, resulting in significant growth in recruitment.

We take pride in our increased research activity in intrapartum care settings at Denmark Hill and the PRUH, providing women and birthing individuals the chance to enhance care during labour. Additionally, we are expanding our research delivery provision in gynaecology and early pregnancy care and enjoying the benefits of collaborative relationships with the Fetal Medicine and Assisted Conception Units.

In 2022, we had 19 maternity studies that were actively recruiting. Of these, 11 were led by Midwife Principal Investigators at King's. Our productivity has also benefitted from freezer space and centrifuges that can spin samples on the labour wards at the PRUH and DH. Also, our Research Delivery Unit opened two studies that are looking at ways to improve care and management of Group B Strep in pregnancy. These have enabled all women receiving maternity care at King's to participate in research and helped embed research in our clinical areas.

Consultant Gynaecologist and Professor of Urogynaecology Professor Linda Cardozo was the Lead Editor of the 7th Edition of Incontinence. She worked alongside several other members of the RDU. Consultant Nurse Dr Angie Rantell was the publication's author. Additionally, Miss Jemma Johns and Miss Jackie Ross led the PERIOD study in collaboration with King's Thrombosis Centre. This aimed to investigate the impact of anticoagulants on menstruating women.

APRICOTS

Midwife Katherine Clark is Chief Investigator of the Acute Kidney Injury Prediction in Pregnancy using Point of Care testing study (APRICOTS) which is part of her PhD. This is recruiting women and birthing people who are giving birth and investigating the acceptability and feasibility of a finger-prick blood test that checks kidney function as a method of predicting and preventing acute kidney injury, a complication that can cause severe morbidity and mortality for mothers and their babies. Over the past six months 52 participants have been recruited.



COPE is a Phase 4 double-anonymised trial comparing Carboprost to Oxytocin for first-line treatment for primary postpartum haemorrhage. Led by Mr Kametas at King's, it is the first clinical trial of an investigational medicinal product (CTIMP) that we opened in Maternity. We are pleased to be reopening it to recruitment and have lots of the multidisciplinary team keen to be involved in this trial.

Fetal Medicine

The Fetal Medicine Research Institute's Harris Birthright Research Centre offers high-quality services, including ultrasound scanning, consulting and treatment rooms, and diagnostic and research laboratories to thousands of pregnant women annually. It combines Trust NHS services with world-class research, teaching, and practice in fetal medicine.

Professor Kypros Nicolaidis leads the research at the institute, alongside Consultant Research Midwife Argyro Syngelaki (co-lead of RDU 3) with one of the highest recruitment rates by KCH for Clinical Research Network (CRN) portfolio studies, ensuring cutting-edge research is continually delivered. We are major players in education and research, recruiting 19,396 participants for 16 research projects in the last financial year.

This year, we are conducting a trial to determine if delivering at term based on the risk of developing pre-eclampsia can reduce the condition's incidence and prevent associated complications. Pre-eclampsia affects about 3% of pregnancies and is characterised by high blood pressure, protein in the urine or abnormal blood tests. It can lead to serious complications for both the mother and the baby. Consultant Midwife in Fetal Medicine Dr Argyro Syngelaki and Professor Nicolaidis are leading the trial at KCH.

At 35-36 weeks of pregnancy, all women at the institute are offered an ultrasound scan to determine their risk of developing pre-eclampsia using the FMF competing-risks model, which combines their medical history, blood pressure and blood test results. It is not yet clear if having this information improves pregnancy outcomes.

In this proposed trial, pregnant women who are 35-36 weeks gestation and having a routine fetal ultrasound will be randomly assigned to one of two groups: pre-eclampsia screening by the FMF competing-risks model and planned risk-informed early-term birth, or usual care (waiting for spontaneous labour onset unless birth is medically necessary). The primary outcome will be to compare pre-eclampsia between the two groups. Pre-eclampsia rates are expected to decrease in the intervention group without increasing caesarean section or neonatal morbidity rates. Caesarean section rates may decrease based on previous studies.

Similarly, early-term deliveries may reduce gestational hypertension and neonatal morbidity as babies are born in better conditions. In this proposed trial, pregnant women who are 35-36 weeks gestation and having a routine fetal ultrasound will be randomly assigned to one of two groups: preeclampsia screening by the FMF competing-risks model and planned risk-informed early-term birth, or usual care (waiting for spontaneous labour onset unless birth is medically necessary).

The primary outcome will be to compare pre-eclampsia between the two groups. Pre-eclampsia rates are expected to decrease in the intervention group without increasing caesarean section or neonatal morbidity rates. Caesarean section rates may decrease based on previous studies. Similarly, early-term deliveries may reduce gestational hypertension and neonatal morbidity as babies are born in better conditions.



RDU 4 Haematology, Precision Science, Palliative Care

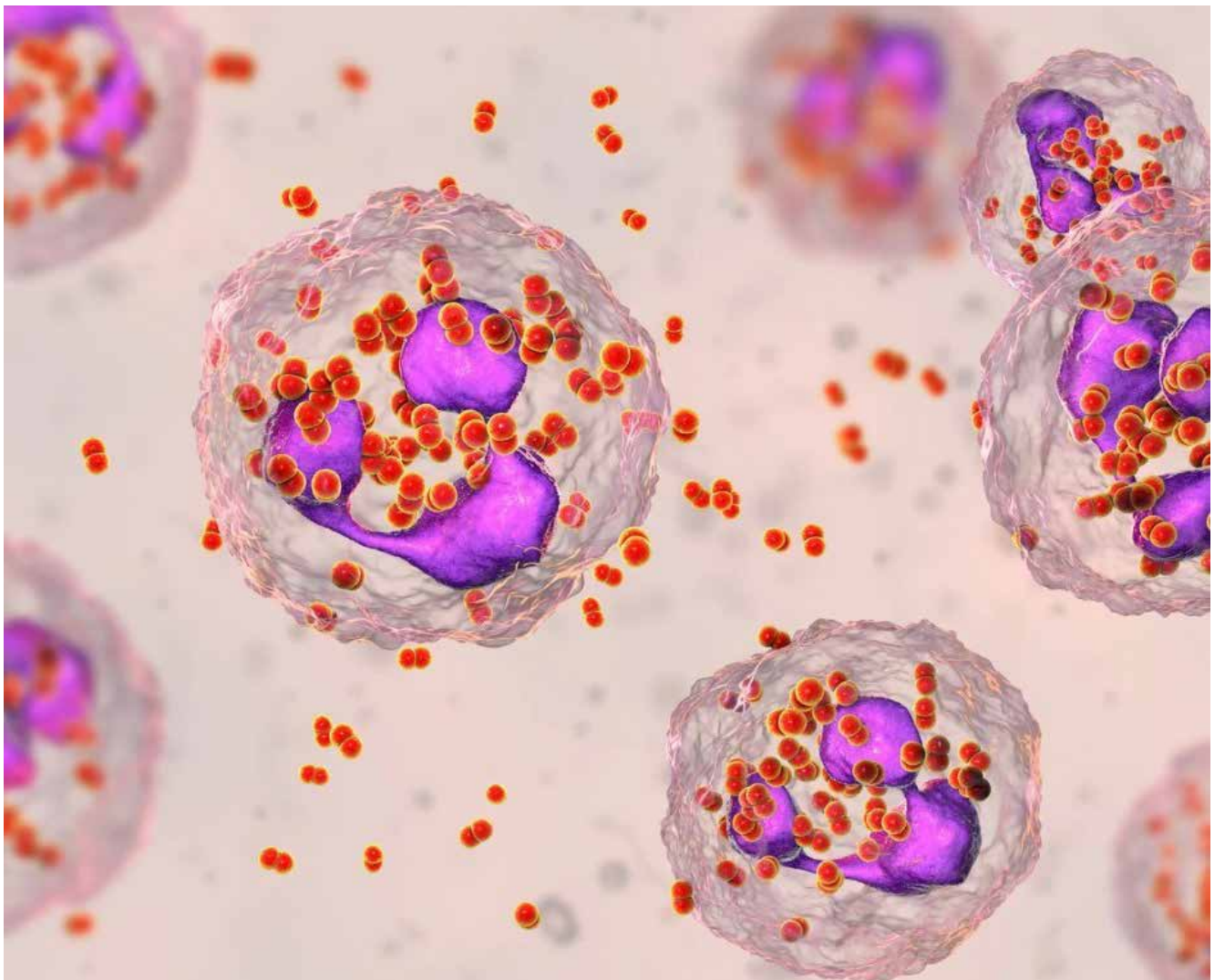


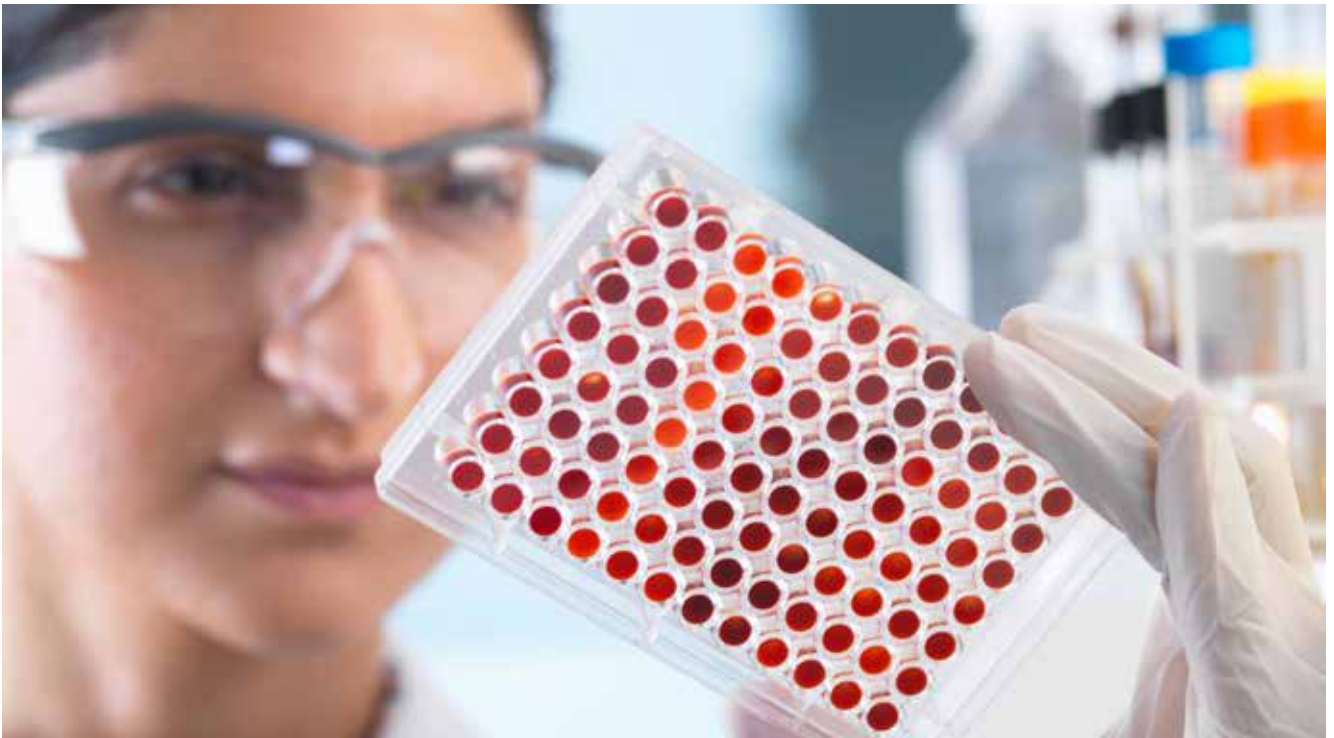
Haematology

Our Haematology research team is led by Dr Piers Patten and comprises research nurses, clinical trial coordinators and data managers. Our PIs lead and belong to the National Cancer Research Trial Institute (NCRI) programme, which is integral to our strategy. We collaborate with King's College Hospital, Guy's and St Thomas's Hospital and King's College London as part of King's Health Partners Haematology to enhance our collective strength. This strategy has allowed for several collaborations with commercial partners to be developed.

Our research focuses on cutting-edge areas such as Chimeric Antigen Receptor T (CAR-T) cell therapy and bispecific antibody therapies targeting various blood

cancers, including lymphomas, myeloma (a type of bone marrow cancer), and lymphoid and myeloid leukaemias.





Our team have contributed significantly to the ZUMA and CARTITUDE studies in the past year. For example, we participated in CARTITUDE 5, a Phase 3 trial led by Dr Reuben Benjamin, which aims to determine whether myeloma cell-specific CAR-T cell therapy improves outcomes for patients with multiple myeloma compared with those who receive standard, non-myeloma cell-specific therapy.

Led by Dr Victoria Potter, the global VOYAGE trial is a first-in-human study that 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 team is currently the highest recruiter in the UK for this trial.

Some recent publications on the work being carried out by the infection and fungal team include Letermovir prophylaxis in T-cell depleted transplants: breakthrough and rebound infections in the post-marketing setting. It is also successfully running a Phase 3 Respect Study which focuses on the efficacy and safety of rezafungin versus the Standard Antimicrobial Regimen to prevent invasive fungal diseases in adults undergoing allogeneic blood and marrow transplantation.

As the national strategy for haemato-oncology trials continues to evolve, we were able to renew both our TAP and IMPACT status for a further three years. This means we are part of an integral network incorporating specialised haematologists leading trials, many of whom are King's Investigators, with Deputy Medical Director of TAP Dr Pramila Krishnamurthy and Deputy Director of IMPACT Dr Victoria Potter. In addition, we continue

our 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.

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

The REDRESS study of haploidentical stem cell transplants in sickle cell disorders is run by a collaboration between the transplant team and the red cell team. This new study was launched in May 2023 to assess the effectiveness and feasibility of haploidentical stem cell transplants in sickle cell disorders (SCD).

Finally, we have successfully recruited to target an SCD HIBISUS study, an orally bio-available and small-molecule activator of pyruvate kinase activation which can reduce the rate of sickle cell polymerisation and improve red blood cell membrane function.

Trials performed at King's continue to be pivotal in future licensing and funding of drugs for all haematological diseases.

Palliative Care

Our Palliative Care research team comprises Research Nurses Paramjote Kaler and Stefania Stegner and is led by PI Dr Sabrina Bajwah.



Morphine and Breathlessness trial (MABEL)

A parallel-group trial comparing the effectiveness and cost-effectiveness of low-dose oral modified release morphine versus placebo on patient-reported worst breathlessness in people with chronic breathlessness.

We are recruiting patients with chronic breathlessness, cardiac disease, respiratory disease, post-COVID-19 chronic breathlessness or cancer. Participants will take the investigational medicinal product (IMP)/placebo for 56 days with regular follow-ups during and after the trial. The recruitment target for KCH is 20.

Currently, we have recruited 12 patients for the study. Recruitment will end on 30 September 2023. For further information, please contact the research team of Dr Sabrina Bajwah, Paramjote Kaler or Stefania Stegner.



An EU-funded project of 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.

We recruited patients and their informal caregivers across the UK, Ireland, Germany, Italy and Poland. When we closed recruitment on 31 December 2022, 205 patients and 70 caregivers had been enrolled. The trial is now in follow-up till 30 June 2023. We exceeded our target numbers for the trial locally at KCH by recruiting 67 patients (out of our local target of 60) and 27 caregivers.

This is now the largest trial of mirtazapine for chronic breathlessness in our patient population. Our findings will be useful for informing clinical practice in our patient population, including those with breathlessness post-COVID. We enrolled a further 17 patients and 5 caregivers who participated in the trial in interviews, to understand their experiences of the trial medication

across different cultures and socio-economic groups, considering gender, cultural and personal beliefs.

For more information, please visit the project website using this QR code:



Professor Irene Higginson



Dr Sabrina Bajwah

Dr Sabrina Bajwah has been awarded £40,000 for her Breathlessness Support: addressing the Ethnicity and health literacy imbalance by Q exchange study.



Dr Charles Reilly, consultant physiotherapist

Breathlessness Support Services provide resources to promote self-management of breathlessness. We will develop these resources better to meet the needs of those from ethnically diverse groups.

Current breathlessness support resources need to meet the needs of our local population as they are all in English and require high levels of health literacy. We urgently need to develop resources that meet the needs of these groups. By providing easy-to-understand resources in accessible formats that patients can relate to, ethnically diverse patients can have equitable access to breathlessness support resources. This will reduce health inequality, improve health literacy and reduce hospital admissions.

SELF breathe

SELF-BREATHE, an innovative digital app developed by Consultant Physiotherapist Dr Charles Reilly, aims to support those living with breathlessness and is one potential solution. In this study, patient-reported outcomes favoured SELF-BREATHE regarding breathlessness severity and health care utilisation. This provided a testable hypothesis and evidence to support the need for a fully powered efficacy trial of SELF-BREATHE.

Qualitative interviews demonstrated that SELF-BREATHE was acceptable and valued by users, proving them with interventions to improve their breathlessness during daily life and at the points of crisis.

“SELF-BREATHE was good... when you have a breathing attack you automatically just clam up and panic... having SELF-BREATHE to hand helped especially the breathing exercises and relaxation,”

Female with COPD, aged 41-50 years.

RDU 5 Liver and Gastroenterology



Liver

Over the past two years, we have grown significantly, adding more research nurses, trial coordinators, lab technicians and research administrators. Dr Vishal C Patel leads our team, with the support of Bernadette Solis and Anice Sundararaj and other research nursing, governance and administrative team members. There are currently 84 active studies in the portfolio, demonstrating collaboration with various stakeholders, including UK research councils, commercial sponsors, pharmaceutical companies, academic institutions, KCL Clinical Trials Office and other research organisations. We are committed to diversity, as evidenced by the opportunities for involvement in studies for people from all cultural and ethnic backgrounds.

The non-commercial study portfolio has expanded with multiple large projects funded by the NIHR, several of which are led by King's. One such project is the BOPPP trial, which aims to determine whether administering the beta-blocker carvedilol can prevent complications of chronic liver disease such as bleeding, fluid build-up, confusion and infections. The trial, which has been running at King's for four years, has recruited 570 patients across 55 UK sites as of June 2023, with King's contributing 15% of the total recruited cohort. The NIHR approved further funding for the trial in January 2023, bringing the total grant award to £2.5m and increasing the target number of participants to 740. We have received positive feedback from trial patients and the UK hepatology community and we currently have the largest primary prevention trial for portal hypertension worldwide. Ultimately, the BOPPP trial can potentially reduce disease progression rates and positively impact the treatment of patients with cirrhosis.

The PROMISE clinical trial began in June 2023, led by Professor Shawcross at KCL and funded by the NIHR. The trial seeks to enrol 300 patients with cirrhosis caused by alcohol or fatty liver from 16 medical centres across the UK. It aims to test if faecal microbiota transplantation (FMT) capsules – a 'poo transplant' – can reduce the risk of infection. This research provides hope for patients with limited treatment options for cirrhosis, with the goal of improving survival rates.

Another study, MAP-CLD, led by Professor William Bernal at King's and Professor Jan Van der Meulen from the London School of Hygiene and Tropical Medicine, is investigating the medical care given to people with chronic liver disease who are admitted to the hospital as an emergency. The project aims to understand how and why people's living conditions and available care affect their treatment and survival rates. Professor Bernal hopes that identifying the type of care linked to the best survival rates will provide access to better care for all people with liver disease, regardless of where they live.

The pursuit of new treatments for chronic hepatitis B, which could lead to a 'functional' cure, remains a major area of research due to the severity of the condition and its global impact. It is crucial to address the complications associated with the infection. The Hepatitis research team, led by Dr Kosh Agarwal, has successfully screened and recruited 45 patients in nine clinical trials. Chronic hepatitis delta (HDV) co-infection with HBV is a severe form of hepatitis that requires close monitoring and specialised care. The anticipated registration of the new antiviral drug Hepcludex® can potentially improve viral control and reduce disease progression, which is promising.

The low screen failure rate for NASH trials, led by a dedicated team overseen by Dr Agarwal, Dr Saima Ajaz and the patient support group NAFLD-LIVFIT reflects the team's commitment to patient advocacy and support.



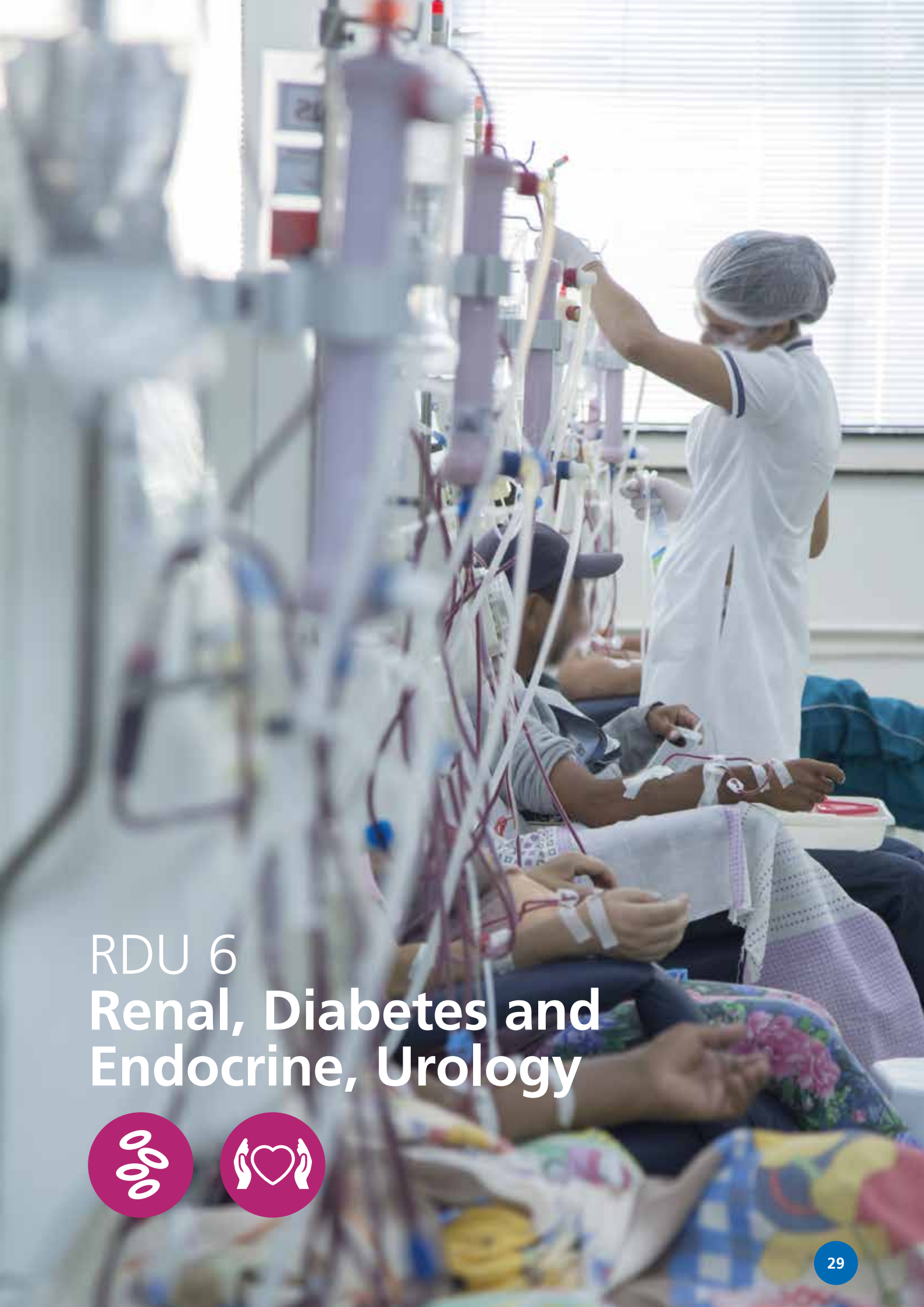
Liver Research Team

Dr Deepak Joshi is leading the way in supporting patients with primary sclerosing cholangitis (PSC), an autoimmune liver disease with no proven medical therapies. Patients with this condition often experience debilitating physical and psychological symptoms. Dr Joshi's team has developed a clinical trial portfolio to identify new therapies for PSC patients. They have four studies actively recruiting and hope to open future studies to support their patients' needs.

We are thrilled to hear about Professor Michael Heneghan's groundbreaking studies, especially the ELATIVE study for primary biliary cholangitis (PBC). The promising results and plans for licensing are exciting developments. Recently, our team's commitment to delivering high-quality trials was recognised when the MHRA inspected one of our studies with a positive outcome. These achievements demonstrate the quality of our research and ongoing dedication to improving patient outcomes.

Professor A Sanchez-Fueyo and colleagues have become world leaders in advanced therapies in liver transplantation, particularly regulatory T cells (Tregs) immunotherapy. Their research, supported by grants from the Medical Research Council (MRC) and the NIHR, has led to the establishment of the spin-off company Quell Therapeutics Ltd, which has raised more than £300m since 2019 and currently employs more than 100 staff. They are sponsoring a first-in-human clinical trial – LIBERATE – using chimeric antigen receptor (CAR) Tregs to induce tolerance in liver transplantation. The liver transplant team has also secured an MRC grant to investigate mechanisms of extracorporeal liver machine perfusion (iMAPS clinical trial). Additionally, Honorary Consultant Hepatologist Dr Niloufar Safinia, who is funded by the Wellcome Trust, is researching the role of Tregs in chronic liver disease and hepatocellular carcinoma as part of the CRUK Hunter Consortium.





RDU 6
Renal, Diabetes and
Endocrine, Urology



Renal, Urology, Diabetes and Endocrinology

Clinical Lead for Renal Dr Sapna Shah leads RDU 6. Our team is supported by Clinical Leads for Renal Exercise and Rehabilitation Dr Kate Bramham and Dr Sharlene Greenwood; Clinical Lead for Urology Mr Nicholas Faure Walker; Clinical Lead for Diabetes Dr Prash Vas; and Clinical Lead for Endocrinology and Obesity Dr Georgios Dimitriadis. The 20-strong PIs team, which has a portfolio of approximately 70 studies with 14 PhD/ MD students, is supported by 24 research delivery staff.

In 2022, we delivered commercial and non-commercial trials in kidney transplantation, glomerulonephritis (damage to the tiny filters in kidneys) and dialysis. Kidney transplantation is the gold standard treatment for patients with end-stage kidney disease, but it is

limited by the availability of suitable donors. Many of our patients form antibodies to their potential donors through pregnancy, blood transfusions or previous solid organ transplants, which then precludes further transplantation.



Renal, Urology, Diabetes and Endocrinology Team

Dr Sapna Shah has been the PI for the GAMECHANgER-1 trial and Sensitisation in Kidney Patients study, which evaluates sensitisation mechanisms to potential donors and T regulatory cellular therapy to reduce this. She has also recruited 15 patients to the international CARSK study, investigating how cardiovascular assessments should be undertaken while patients await kidney transplantation.

Glomerulonephritis is the second most important cause of end-stage kidney disease after diabetes and yet, historically, clinical trials in this area have been lacking.

Recently, there has been increasing interest as the molecular mechanism of the disease has been elucidated. Dr Jonathan Dick, Dr Sui Phin Kon and Dr Sapna Shah have recruited patients with IgA nephropathy, FSGS and lupus nephritis to several commercial Phase 2/Phase 3 clinical trials. We recruited the first patient to an IgA study evaluating AT-1501 in Europe. We also have a keen interest in patients receiving dialysis therapies. Dr Helen Alston, Dr Martin Ford and Dr Jonathan Dick recruit patients receiving haemodialysis and peritoneal dialysis to studies evaluating the benefits of vitamin D, phosphate and potassium binders.

The Renal Rehabilitation team, led by Dr Sharlene Greenwood and Dr Kate Bramham, has continued to lead a diverse portfolio of studies. The Kidney Beam Trial, which evaluates the clinical value and cost-effectiveness of a physical activity digital health intervention on mental health-related quality of life, completed recruitment in April this year. The initial results were presented in the late-breaking clinical trials session in UK Kidney Week in June 2023. Dr Greenwood was awarded a Health Education England Topol Digital Fellowship and is supervising a study evaluating the feasibility of providing digital health equipment and training on patient engagement with digital health interventions.

Dr Bramham has been awarded a £1.5m NIHR Advanced Fellowship to develop a remote feasibility trial for people from underserved communities at risk of cardiovascular disease. She is the Chief Investigator of several UK studies investigating the aetiology, treatment and experiences of people of African ancestry with kidney disease. She recently published a Phase 2 study of a novel therapy for APOL1-mediated kidney disease in the *New England Journal of Medicine*. She also works with the CogStack team and Kings Institute of Psychiatry, Psychology and Neuroscience and South London & Maudsley Hospital to explore and improve care pathways for people with severe mental illness and kidney disease.

In 2022, the Urology research group, supported by Mr Gordon Muir and Mr Faure Walker, recruited to a variety of commercial and non-commercial studies, including the E.Mbrace E.Coli vaccine trial for the over 60s; CATHETER II, a 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. In the UK alone, it is estimated that almost one in ten people aged 55 or over are affected by peripheral neuropathy. It is a serious complication affecting a third of people with diabetes mellitus. Since the start of the year, our team, led by Dr Prashanth Vas (as PI), and the NIHR grant co-applicant commenced recruitment for the Frequency-Modulated Electromagnetic Neural Stimulation (FREMS) study.

This study is looking at the utility of FREMS as a third-line treatment in patients with painful diabetes-related peripheral neuropathy (PDPN). PDPN can cause burning, deep aching and even 'electric shock' pains. Currently, the mainstay of treatment for PDPN is pharmacotherapy. The primary objective is to evaluate the efficacy of FREMS in reducing the seven-day mean pain score at three months. This study is also designed to evaluate the impact of FREMS treatment on sleep, quality of life, mood and medication use, in addition to assessing its safety and describing adverse and serious adverse events. A previous FREMS trial in the UK proved that it could improve pain, enhance microvascular function and promote cutaneous blood flow, as evidenced by laser Doppler measurements.

Reducing the Impact of Diabetic Foot Ulcers on Patients and the Health Service (REDUCE) is another innovative clinical trial our team recruits to. It is estimated nearly a third of individuals with diabetes will suffer a foot ulcer during their lifetime and this costs the NHS more than £1bn annually. Rates of recurrence are extremely high, reaching up to 60% at three years and preventing recurrence is now considered a vital aspect of ongoing care. The study explores psychological and behavioural modifications to reduce the recurrence of diabetic foot ulcers and promotes rapid self-referral and self-management.

Again, this is an NIHR funded study where the intervention arm consists of eight sessions of remote delivery psychological therapy/assistance, usually lasting for one hour, through a telephone conversation or online. A research participant said: "It is helpful to be acknowledged, to talk to somebody and to verbalise my concern with regards to the ulcer. It is life changing." The RDU 6 research team will continue to strive for the betterment and improvement of the lives of people with diabetes through well-designed clinical trials.

Dr Dimitriadis' research investigates the effects of medical, endoscopic and surgical interventions for managing obesity and related cardiometabolic and reproductive sequelae. Over the past year, he has supported delivering seven new commercial and non-commercial research projects across Endocrinology and Metabolism/Obesity. So far, more than 90 subjects have been recruited from KCH and the PRUH for the DAISy-PCOS phenome project. This is a Wellcome-funded/NIHR-adopted study using phenome and metabolome analysis with AI in predicting cardiometabolic risk in women with PCOS. King's has been the top recruiter nationally in this study.



Renal, Urology, Diabetes and Endocrinology Team

King's randomised first into REDEFINE-1 landmark commercial clinical trial programme investigating the effects of Semaglutide plus Cagrilintide vs placebo on weight loss. Dr James Crane is leading on "Is there a genotype-phenotype correlation in SDHB mutation carriers?" rare disease NIHR portfolio adopted non-commercial study, and Dr Ling Ling Chuah is the UK Chief Investigator on the SPARROW commercial clinical trial investigating the effects of a new treatment for hypercortisolism related to benign adrenal tumours.

Over the next year, we plan to continue recruiting to our portfolio of studies, such as Long Limb 2 RCT (evaluating the impact of a modified Roux-en-Y-gastric bypass in remission of T2DM), and setting up of further commercial and non-commercial studies, including the ALLEGRO study investigating the effects of a remote, digital and culturally sensitive, self-directed weight management intervention.

We look forward to 2023/24 when we plan to start exciting new clinical trials. Notably, a Phase 1 study in islet cell transplantation, trials in obesity, chronic kidney disease and improving outcomes for dialysis patients.



Interactive page

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



HIV and Sexual Health

Our HIV, Sexual Health and The Havens research team are headed by Professor Frank Post, leading a team of clinical research fellows, PhD students, research delivery staff and a research manager. We come from diverse backgrounds, including clinical trials, nursing, and quantitative and qualitative experience, allowing us to deliver various studies.

We are delivering several clinical trials of new medications for treating HIV. In addition, our 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, it enrolled more than 3,000 participants from 2018 – 2020 in the GEN-AFRICA study and has 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.

We have 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 affected by sex, as it is unclear what intervals should be used for transgender people on hormone therapy. Additional studies focus on screening for human papilloma virus-associated cancers in this population and the contraceptive needs of Trans men and non-binary people.

The Havens carries out research in areas related to sexual violence. The department will shortly commence a trial looking at the feasibility, acceptability and efficacy of group Enhanced-Eye Movement and Desensitization and Reprocessing (EMDR) therapy for adult women who have recently experienced a sexual assault. It is hoped that the project will provide new information that can be used to improve the availability of timely and effective psychological treatment for individuals who have experienced acute sexual assault. Work is also underway on a study exploring anal injuries in cases of non-consensual anal penetration. Research has shown that understanding the presence or absence of injuries

is associated with higher rates of charges, prosecutions and convictions in cases of sexual assault. However, little is known about the prevalence of anal injuries following non-consensual anal penetration. The project aims to add to the literature on this important topic.

The Havens, in collaboration with the Metropolitan Police and the Crown Prosecution Service (CPS), has led a pilot project to produce a Summary of Psychological Findings (SPF) report detailing psychological difficulties experienced by clients directly related to the sexual assault. Hopefully, this SPF report will build on medical and forensic evidence already considered by investigators and prosecutors when preparing a case for court. A qualitative study has recently been completed, exploring the impact of justice seeking on psychological recovery for survivors of sexual assault who have participated in this pilot project and how direct support from mental health professionals during this process may influence psychological recovery. Findings will shortly be available.



Ophthalmology

The King's Ophthalmology Research Unit (KORU) is based at King's College Hospital and led by Professor Timothy Jackson, with PIs for various studies including Mr Haralabos Eleftheriadis, Mr Gerassimos Lascaratos, Ms Anna Grabowska, Mr James McHugh, Mr Mohammed Abu-Bakra and Mr Obeda Kailani. Our team comprises research fellows, trial coordinators, research and trial managers, ophthalmic imaging technicians and research optometrists, research fellows and associates in other King's College London departments such as Biomedical Engineering and Imaging Sciences at the KCL campus.

We are responsible for an extensive portfolio of investigator-initiated and industry-sponsored clinical trials. We actively support other non-ophthalmic trials being undertaken at King's and has 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, we set up and lead large, multi-centre, national and international clinical trials, including pioneering technologies such as retinal implants and robotically controlled precision radiotherapy for AMD.

We are currently responsible for two active, large, multi-centre trials with cumulative funding of over £4m, both led by Professor Timothy Jackson – the STAR study (NCT02243878) and the TIGER study (NCT04663750). STAR is a multi-centre, UK-based, NIHR-funded surgical trial of 411 patients and investigates the benefit of low-voltage x-ray ocular irradiation in the treatment of neovascular AMD. STAR is currently in the final patient safety follow-up, with primary outcome data undergoing analysis and due for publication. TIGER is a pan-European surgical trial joint commissioned by the European Society of Retina Specialists (EURETINA) and funded by Fight for Sight, which investigates the optimal surgical management of submacular haemorrhage, a rare but potentially devastating complication of neovascular AMD caused by bleeding below the retina. TIGER is currently recruiting patients with most UK sites active and several European sites in setup.

We are also involved in recruiting and assessing several industry-sponsored studies of novel therapies for AMD, DR, glaucoma and neuro-ophthal. Some of the currently active AMD studies include: the Phase 3 SHORE study, which investigates a novel monoclonal antibody to

vascular endothelial growth factor (anti-VEGF) for patients newly diagnosed with neovascular AMD; the Phase 3 VELODROME study, which investigates a novel intraocular implant that delivers sustained-release of current gold-standard anti-VEGF therapy for neovascular AMD; and the Phase 3 ONWARD study, which examines the novel anti-complement medication danicopan to slow the progression of advanced dry AMD. 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 3 COMBO study, which explores a novel injectable medication to treat severe diabetic macular oedema. A neuro-ophthalmology study is currently set up for patients with idiopathic intracranial hypertension. The glaucoma team is setting up a large, multi-centre, NIHR-funded non-commercial trial called the NAMinG study, which investigates oral nicotinamide supplementation to slow the progression of glaucoma.



The Ophthalmology research team

Dental

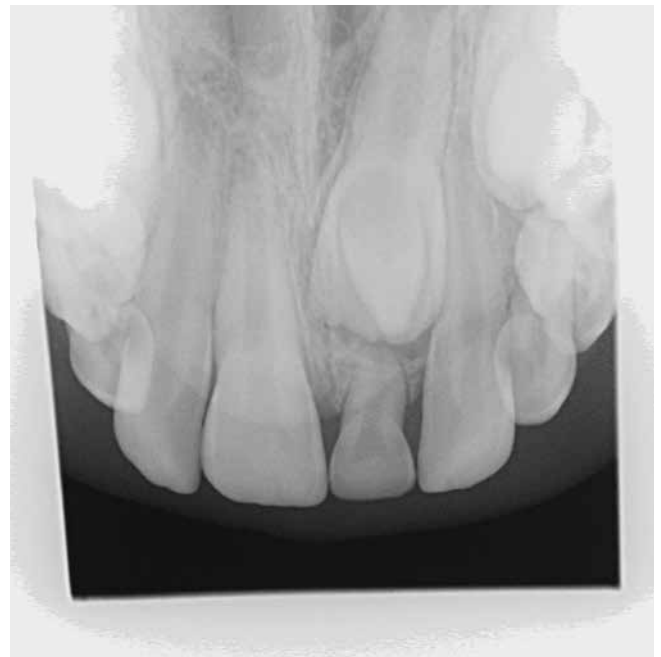
Our Dental Institute is a leading research facility headed by Professor Kathy Fan. It boasts a diverse team of dental specialists, including PhD and MSc students and undergraduate students who participate in The King's Undergraduate Research Fellowship (KURF) Programme. Our strength lies in our multidisciplinary collaboration, which includes experts in Maxillofacial, Orthodontics, Paediatric and Restorative Dentistry, Oral Surgery and Psychology.

As a major trauma unit in Southeast London, we have undertaken several projects to evaluate patient psychological well-being. We collaborate with the Integrating Mental and Physical Healthcare: Research, Training & Services IMPARTS team, a joint effort between KCH, KCL and SLAM. The IMPARTS team utilises screening tools to assess the risk of depression, anxiety and post-traumatic stress disorder, allowing for real-time assessment and intervention when necessary. Harmony Ubhi and Ashley Ferro studied 167 patients, identifying potential risk factors for adverse mental health outcomes, including interpersonal violence, previous mental health disorder and prolonged time to initial screening. The study found that 24% of facial trauma patients showed potential signs of PTSD. We are also conducting a funded national benchmarking project of outcome measures in Maxillofacial Surgery for facial trauma, skin cancer and orthognathic/facial deformity surgery.

In the field of Orthodontics, up to 15 trainees undertake MSc projects. Kishan Patel's recent project, supervised by Jadbinder Seehra, aimed to determine if randomised controlled trials in Orthodontics were appropriately justified with the citation of a systematic review. The meta-epidemiological study found that nearly 75% of orthodontic randomised controlled trials published in high-impact factor journals were appropriately justified. However, 25% were not, subjecting them to duplication and potential research waste.

Jadbinder Seehra also leads the iMAC multi-centre randomised clinical trial, which focuses on managing impacted maxillary central incisors. The study, funded by the British Orthodontic Association Foundation, aims to evaluate the most efficient clinical protocol for aligning impacted maxillary incisors in the presence of a supernumerary tooth. The findings of this study are anticipated to be presented in the future.

Our research efforts cover many specialties to advance knowledge and improve patient care within Dentistry and Maxillofacial Surgery.



An upper standard occlusal radiograph, showing an impacted upper left central incisor due to the presence of an overlying conical supernumerary tooth

RDU 8

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



ACET

Anaesthetics, Critical Care, Emergency Medicine and Trauma (ACET) has demonstrated strong performance in research delivery and academic aspiration this year. With more than 40 trials being managed, patients across our clinical specialties can access a diverse portfolio. We have consistently been one of the top three recruiting sites for TIGHT-K, which compares standard versus relaxed management of serum potassium to prevent dysrhythmias post-cardiac surgery. Moreover, we have been the highest recruiter in Europe – and fourth in the world – for the EFFORT trial, which investigates supplemental dietary protein in critically ill adults. Recently, we have seen a resurgence in recruitment to the REALIST study, which focuses on stromal stem cell infusion in treating acute respiratory distress syndrome (ARDS). As a result, KCH is now the top recruiter in the UK.

We are excited to announce that our relationship with the Respiratory Department has helped us establish two new trials, NIMBLE and ASPECT. NIMBLE focuses on developing a biomarker for early diagnosis of lung cancer. At the same time, ASPECT compares aspirin to standard care for reducing cardiovascular events in patients discharged from the hospital post-pneumonia. We could reinstate research coverage in the ACET areas at the PRUH and South Sites thanks to contingency funding.

Our team has grown with the addition of Anna Broderick, Annette Axalan and Burt Vergara. Their enthusiasm is a much-needed boost. We are proud to say that our academic pipeline continues to grow rapidly. Dr Dan Hadfield, our first-ever PhD graduate, has plenty to celebrate. He and Dr Phil Hopkins have been awarded a £2m Health Technology Assessment (HTA) grant to conduct a UK multi-centre RCT comparing neurally adjusted ventilation to standard ventilation in critically ill patients.

Ele Corcoran's NIHR-funded PhD is continuing to study inter-professional ultrasound training and its application to the critical care setting. Caitlin Spooner has begun a Marie Curie and Economic and Social Research Council (ESRC)-funded PhD to produce a core

outcome for measuring the impact of prognostication in palliative cancer care, with support from the University College London Marie Curie Palliative Care Department.

Sian Saha is working with Professor Louise Rose and has applied for a PhD to support a family peer support programme in Critical Care. Hannah Cotton recently joined the NIHR Pre-Doctoral Clinical and Practitioner Academic Fellowship (PCAF) alumni and is pursuing a PhD application focused on undiagnosed diabetes in the community. Hannah was awarded the 'Most Robust Research Question' by the University of San Francisco (UCSF). Harriet Noble's Freshair programme, which investigates the benefit of Intensive Care Unit roof gardens for critically ill patients, is scheduled to open in 2024. Harriet is collaborating with Professor Nigel Dunnett from Sheffield University. Kevin O'Reilly authored a paper published in the prestigious Lancet, reporting the findings of the EFFORT trial.

John Smith has been accepted into the NIHR Senior Research Leadership Programme. His task is to explore how informatics can be better used to support research capacity building, improve efficiency and recruitment, and facilitate research for clinical staff.

Working with Dr Phil Hopkins, a new collaboration between allied health professional's informatics and ACET has been established to build research screening and reporting tools and provide digital solutions to the perennial analogue problems of time and money.

We have also had a good year in terms of local investigator-led research. The Microwave Imaging in NeuroTrauma (MINT) research is led by Dr Malcolm Tunnicliffe. Despite the somewhat alarming name, this study aims to create a portable scanner using microwave technology that can detect intracranial bleeds in trauma and stroke patients during the very early stages. The hope is that this portable pseudo-neuro CT scanner could be used by ambulance or HEMS services.

EMERALD is led by Consultant Haematologist Dr Lara Roberts. This UK multi-centre research trial is focused on haemostasis in acutely ill patients with advanced chronic liver disease (CLD). It aims to develop an improved assay that can better reflect the haemostatic state of these patients. This is Dr Roberts' first multi-centre study as Chief Investigator and has been supported by a Medical Research Council and Clinical Academic Research Partnerships (CARP) award.

A trial led by Dr Sam Hutchings and supported by a grant from the European Society of Anaesthesiology and Intensive Care (ESAIC) aims to evaluate a new technology for assessing tissue and organ perfusion in critically ill patients. The technology incorporates plethysmography into a urinary catheter and is being compared with current techniques. Dr Hutchings hopes to determine whether this new technology is better at managing patients who are shocked or fluid depleted.

Another trial, led by Dr Daniel Hadfield, is a national RCT that has passed through the NIHR HTA funding application stages and is awaiting full funding approval. Dr Hadfield's trial aims to evaluate the clinical and cost-effectiveness of a novel ventilator technology called Neurally Adjusted Ventilatory Assist (NAVA). This automatically adjusts ventilator breaths based on breathing muscle activity. Dr Hadfield's primary question is whether NAVA is clinically and cost-effective for patients at risk of extended mechanical ventilation duration.



ACET Research Team

Respiratory

Our KCH Respiratory research team comprises doctors, research nurses, practitioners, administrators and students. We conduct studies on a wide range of chronic lung disorders. Here we present some examples of 2022/2023 studies.

New Understanding in the Treatment of Cough (N-EuroCough)

Professor Birring leads this study characterising the clinical phenotype of patients with chronic cough (including genetic profile) and their longitudinal outcomes. Professor Birring is also the chair of the scientific committee of this Europe-wide registry. KCH was the top recruiter of patients in Europe and has exceeded its target of 100 patients.



Left to Right: Dr Caroline Jolley, Dr Peter Cho, Professor Surinder Birring, Dr Barney Hirons, Katie Rhatigan and Harini Kesavan

Sleep and Ventilation

Dr Kai Lee and the Sleep and Ventilation team recently won funding from the QExchange programme for an innovative Home Ventilation Outreach project, exploring how to tackle health inequalities in patients with chronic respiratory failure. Their other projects include a study investigating physical activity levels in patients with sleep-disordered breathing undergoing treatment with Continuous Positive Airways Pressure (CPAP), building

on findings from their previous meta-analysis report that suggested a positive relationship between CPAP therapy and exercise capacity. The team is also focusing on patient-reported outcomes and is embarking on a study in obstructive sleep apnoea to examine whether current clinical assessment methods capture the issues that matter most to patients.



Members of the Sleep and Ventilation team: Tracey Mathieson, Claire Wood, Dr Kai Lee, Dr Amit Patel, Laura Elliott and Dr Rajiv Madula

Cystic fibrosis (CF) is a rare, genetic and life-shortening disorder primarily affecting the lungs and alimentary system. Approximately 10,500 people with CF live in the UK. Treatments to date have focused on managing disease complications (thick airway mucus, chronic airway infection, and malabsorption). Recent advances in CF therapies have seen the treatment of the underlying epithelial defect, with groundbreaking results in those eligible for such treatments. However, approximately 10% of the CF population remains ineligible or unable to tolerate these therapies, so the need for new drugs is urgent and paramount.



Left to Right: Dr Michael Waller, Dr Cara Bosley, Dr Dominic Hughes, Melanie Le Sayec and Dr Patricia Macedo

CF research at King's is formed by a strong collaboration between the adult (Dr Michael Waller and Patricia Macedo) and the paediatric (Dr Gary Ruiz, Dr Cara Bossley and Dr Dominic Hughes) CF teams and coordinated by Melanié Le Sayec. KCH is part of the UK CF Trust's Clinical Trials Accelerator Platform (CTAP), a network to improve access for all people living with CF into clinical trials, and a member of the European CF Society (ECFS) Clinical Trials Network (CTN). The KCH group meets twice a month – a local clinical trial meeting with members of R&D, the CRF and the London CTAP network, chaired by Dr Bossley.



Trauma and Orthopaedic Surgery

Our Trauma and Orthopaedic Surgery Research team is led by Consultant Trauma and Orthopaedic Surgeon Ms Ines Reichert, and Kerim Gokturk is the Clinical Research Manager. Ms Reichert is also Clinical Research Network South London Musculoskeletal Lead. We are committed to building inclusive research culture and collaborating with national and international stakeholders to conduct cutting-edge research.

Over the past two years, we have partnered with commercial trial programmes and new PIs have taken the initiative to advance Orthopaedic research at KCH. Our research portfolio encompasses a wide range of orthopaedic and trauma research, leading to numerous collaborations and partnerships and conducting many NIHR portfolio studies in Trauma and Orthopaedics.

KCH Haematology: the CHIP study led by Professor Ghulam Mufti, a multidisciplinary study aiming to understand clonal haemopoiesis and immune modulation in the healthy-ageing population and in people with myeloid neoplasms and bone marrow failure. The study is close to reaching its goal of recruiting 1,000 patients.



The KCH Cardiothoracic Surgery team is conducting the multi-centre ORIF study, which assesses the mortality, quality of life and cost-effectiveness of operative rib fixation along with supportive management. Our unit, led by local PI and Consultant Orthopaedic Trauma Surgeon Ash Vasireddy, is a high recruiting centre.

The Royal Veterinary College (RVC) awarded funding to Ms Reichert for her project entitled "Does small fibre neuropathy (SFN) predict the development and progression of Charcot Neuroarthropathy (CN) bone and joint destruction." The Orthopaedic Research UK (ORUK) Inspiration Fund peer reviewed this project. The project combines the clinic with basic science and collaborates with Professor Chantal Chenu at the RVC for the second time.

Imperial College is conducting an NIHR clinical trial funded by Health Technology Assessment (HTA) to determine the diagnostic performance of various index tests for diagnosing peripheral arterial disease (PAD) in diabetes patients. The study is conducted with the co-applicant, Consultant Trauma and Orthopaedic Surgeon and Hunterian Professor Raju Ahluwalia. The examined index tests include audible handheld Doppler, visual handheld Doppler, ABPI, exercise ABPI and TBPI. Another study being conducted internationally is the ZNN Bactiguard study, a commercial NHIR portfolio study. It is being conducted by local PI and Consultant Trauma and Orthopaedic Surgeon Aaron Saini. This post-market orthopaedic trauma study compares the fracture-related infection rates for ZNN Bactiguard Tibial nails to conventional uncoated titanium-alloy nails for tibial fractures.

The OBIC-1 Study is another international study initiated and led by Professor Ahluwalia. The study aims to evaluate the efficacy of a bone graft infused with antibiotics in orthopaedic surgical procedures. The study will investigate dead space management and the long-term value of osteointegration and infection control.



The Orthopaedic research team comprises various groups, including the CHIP study team, which screened and recruited patients for total hip replacement surgery. Ash Vasireddy leads a clinical Trauma and Orthopaedic Research Fellowship sponsored by industry partners, with secured funds year-on-year. Miss Sarah Phillips and Mr Graeme Groom lead the new Research and Data Coordinator post through the REBUILD Charity, supporting the IMPARTS programme, a KHP initiative that integrates mental and physical healthcare in general hospital settings.

The Orthopaedic research team hosts several training and meetings, inviting national research leaders in Trauma and Orthopaedic Surgery, such as Professor Xavier Griffin and internationally renowned guests such as Professor Heather Vallier, the first-ever female President of the Orthopaedic Trauma Association (OTA).



RDU 9 Children



Paediatrics

Our Paediatric research team is currently conducting innovative trials to improve the health outcomes of children. We conduct approximately 40 studies across various child health areas such as respiratory, haematology, gastroenterology, neurology, hepatology and neonatal care. Our team works diligently to establish clinical relationships between research and the wards and actively promotes and educates the paediatric multi-disciplinary team. Our team comprises research nurses, clinical trial coordinators and Research Lead Dr Atul Gupta.

In the Harmonie study, which ran from November 2022 to February 2023, we recruited 84 babies under 12 months old. The participants were randomly assigned to receive the Nirsevimab treatment via an injection or no intervention. Our goal was to assess the effectiveness of Nirsevimab in preventing hospitalisations due to a common contagious respiratory infection called respiratory syncytial virus in participants over 12 months. Participants were required to have monthly follow-ups for 12 months after their visit through a study app on parents' phones. They were to report any new health events or hospital visits. Our team at KCH was the top recruiting centre for South London and the fifth top recruiter for the UK.

Acute liver failure (ALF) in children is a multi-systemic disorder that has high mortality without a transplant. The HELP study, led by KCH Research and Development Director Professor Anil Dhawan and sponsored by the Medical Research Council, aims to evaluate the safety, biological activity and tolerability of single transplantation of hepatocytes and mesenchymal stromal cells co-encapsulated in microbeads to paediatric patients with ALF. The infusion, produced in the Institute of liver studies at KCH,



Members of the Paediatric Research Team



was meant to help bridge patients until an appropriate liver transplant becomes available or potentially aid in native liver recovery. Patients aged 0-16 years with ALF and without exclusion criteria such as instability or an impending transplant were eligible to enrol and receive the infusion. Close patient monitoring occurred during the infusion and the following hours and days. Patients had regular study visits and assessments for 52 weeks after the infusion to gather essential data about the long-term effects of the treatment.

The FORTIS study is a randomised trial assessing the safety and efficacy of ferric maltol oral suspension compared with ferrous sulphate oral liquid in children and adolescents aged two to 17 years with iron-deficiency anaemia. Iron-deficiency anaemia can cause symptoms such as tiredness, restlessness and irritability. There is a clear unmet medical need for an alternative oral treatment for anaemic children to avoid the need for IV treatment. This study aims to find an alternative for children intolerant to other iron medications.

The BEAR study is a respiratory study assessing the efficacy of Broncho-Vaxom in preventing respiratory tract infections in children aged six months to five years. Eligible patients will have had repeated infections and wheezy episodes 6 – 12 months before screening and require hospitalisations or medical assistance. Broncho-Vaxom has been approved for use across Europe since the 1970s, but its use in the UK has yet to be permitted. This randomised, double anonymised study has three treatment arms to aid assessment in determining the length of treatment, 3 vs 12 months, most effectively preventing illness and wheezing. Parents monitor their children's wheeziness and respiratory infections through daily e-Diary entries.

Our Paediatric research team was honoured to be nominated for the Leaders in Research, Innovation and Education category at the King's Stars Awards 2022. It was a great pleasure to receive recognition from the Trust and participate in such a remarkable event. Moreover, Child Health awarded our RDU, the team of the month in January 2023, which acknowledges our continuous efforts to enhance clinical care for paediatric patients.



King's Clinical Research Facility (CRF)





King's Clinical Research Facility

The NIHR King's Clinical Research Facility (CRF) is a collaborative research facility shared between KCH, SLaM and KCL. Opened in 2014 at King's College Hospital NHS Foundation Trust's Denmark Hill site, the facility is supported by another successful five-year NIHR award. Neurology Professor Peter J Goadsby is the CRF's Director and Elka Giemza manages the in-house nursing and research support staff.

More than 100 study applications were received in the last financial year and over 130 patients have been recruited to trials and seen at the CRF. The patients and healthy volunteers have participated in various commercial and non-commercial early-phase clinical studies testing pioneering new therapies for treating diverse disease areas. These include migraine, haematology, rheumatology, mental health, COVID-19 and many more. Our facility is the site of several promising trials investigating the use of psychedelic compounds in treating a range of neurological and psychological conditions.

Mental health studies

In 2022, we recruited our first participant in the multi-centre, double-anonymised Phase 2 trial that investigates the effectiveness of COMP360 psilocybin therapy in anorexia nervosa. Anorexia nervosa is a serious mental illness characterised by severe restriction of calorie intake and a preoccupation with weight and shape. Anorexia carries the highest mortality rate of all psychiatric disorders because of medical complications and suicide; approximately 20-40% of deaths in anorexia nervosa are thought to result from suicide. Currently, there are no approved pharmacological treatments. Globally, about 2.2% of women and 0.3% of men suffer from anorexia nervosa at some point. The Phase 2 clinical trial will compare the effects of 25mg and 1mg of investigational COMP360 psilocybin when

administered with psychological support. Changes in symptoms after COMP360 psilocybin therapy will be measured using the Eating Disorder Examination (EDE) interview and other measures. The trial aims to change the global baseline score of EDE after four weeks of COMP360 psilocybin therapy administration.

Rheumatology

This year, we commenced an early phase study, a multi-centre, double-anonymised study evaluating the efficacy and safety of Nipocalimab administered intravenously in participants with active rheumatoid arthritis despite standard therapy. This project resulted from working closely with our rheumatology research group during COVID-19, where Dr James Galloway, was PI for all our vaccine studies. This is the first of many rheumatology studies lined up for the next few years. We over-recruited this study and completed it before the target time. Results will be available when other sites have been completed.

In a collaborative project with Queen Mary University of London, we have supported a study investigating Phosphoproteomic profiling of Tofacitinib response in Rheumatoid Arthritis (RA). RA synovitis is highly heterogeneous, and a fundamental task is understanding how synovial pathobiology influences clinical evolution and response to therapy.



CRF Team



Previous studies, particularly cancer research, have demonstrated how tissue pathobiology plays a key role in diagnosing and treating conditions. Examining RA synovial tissue has enhanced our understanding of the disease pathogenesis and highlighted unique molecular targets for RA treatment.

More widespread access to RA synovial tissue has been facilitated by the development of minimally invasive biopsy procedures performed under local anaesthetic, such as ultrasound-guided synovial biopsy, which has been proven safe and well tolerated. This study's main focus is enhancing the ability to predict treatment response to tofacitinib to improve patient well-being, ensure rapid symptom reduction and minimise unnecessary side effects.

Neurological studies

We provide state-of-the-art facilities for neurological patients, which is a substantial focus of KCH developments, so mechanisms of these disabling problems will be better understood and new therapeutic avenues explored. Such facilities include a virtual reality room, an electroencephalogram suite (where brain activities are recorded), a 3T functional MRI scanner and several interview rooms that can record mental health assessment sessions.

Mr Ashkan Keyoumars and colleagues recently published study findings on the developments in brain mapping. A supplemental map of the clinically represented areas of the human body in the pre-central cortex and a novel subcortical corticospinal tract map has been made; this knowledge is essential for safe surgery in patients with eloquent brain lesions. The CRF was used to support this work.

The pain theme continues to deliver novel basic science studies. Professor Goadsby has led further experimental work to understand the role of calcitonin gene-related peptide (CGRP) in migraine and cluster headache, paving the way for the development of CGRP pathway-targeted preventive treatments undertaken by human brain imaging studies to understand and characterise the pathways crucial to the disorder, and has supported basic scientists and clinical scientists with career awards for their research. Professor Goadsby was elected a Fellow of the Royal Society for his achievements and contributions to human health last year.

Interactive page

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The Princess Royal University Hospital (PRUH) and South Sites

The Princess Royal University Hospital and its South Sites, including Orpington Hospital, Beckenham Beacon and Queen Mary's Hospital in Sidcup, have significantly contributed to the number of research participants and enrolment for the Trust. Our local governance team supports research staff at all levels across all sites. Key members of our PRUH team include PRUH Research Lead Dr Deepak Rao, Lead Research Nurse Facilitator Nicola Griffiths and Deputy Research Leads Dr Mohammad Albarjas and Georgios Dimitriadis. The Trust's aim to promote research across the KCH campus of hospitals is reflected in the expansion of the research portfolio at the PRUH, which now includes studies in Cardiology, Respiratory Medicine, Haematology, Oncology, Endocrinology, Hepatobiliary and Maternity.

Endocrinology

Our Endocrinology team at the PRUH has succeeded in opening the REDEFINE programme, a commercial programme of RCTs by Novo Nordisk. We have recruited the target of 20 patients in just seven months for the REDEFINE-1 study, which is led by Dr Dimitriadis and supported by Dr Lajeunesse-Trempe, Nicola Griffiths and Anna Posada. This study aims to investigate if combining peptide therapies with different modes of action can lead to better weight loss compared with placebo in endocrinology/obesity patients.

Our research team has recruited more than 90 patients for two non-commercial studies at King's Denmark Hill site. The first study, the Wellcome Trust-funded, NIHR-adopted DAISy-PCOS phenome/metabolome project, investigates the relationship between PCOS and metabolism. The second study, the Jon Moulton charity-funded, NIHR-adopted Long Limb 2 study, focuses on the effect of a modified Roux-en-Y gastric bypass (a weight loss procedure) on type-2 diabetes resolution after surgery. Our team plans to undertake several commercial and non-commercial studies in the coming months.



Cardiology

The PRUH is among the top recruiting sites in the UK for the ORION-4 study.

The ORION-4 study, led by Dr Mohammad Albarjas and run by Nurses Ewa Strak and Anna Posada, aims to determine whether a new cholesterol-lowering injection called inclisiran can safely reduce the risk of heart attacks and strokes in individuals who have experienced these conditions or who have had an operation or procedure to unblock their arteries. In 2022, following a successful opening and recruitment, the site recruitment target was increased from 75 to 185 patients. To achieve maximum recruitment, our team has screened more than 340 patients. This study is expected to involve around 15,000 individuals aged 55 years or older from all over the world.

Liver and hepatobiliary research

Our research team are actively supporting the liver trials portfolio with ongoing recruitment to the Beta-blockers Or Placebo for Primary Prophylaxis of oesophageal varices (BOPPP) study, and the Precision-Panc study: Advancing personalised medicine treatment strategies for pancreatic cancer, which aims to identify, test and implement tailored therapeutic approaches for people with pancreatic cancer. Thanks to Dr Mayur Kumar, who continues to provide local research oversight at the PRUH.

Haematology

Consultant Haematologist Stella Bowcock leads three studies across both locations. Rachel Ryan, a senior clinical trial practitioner at the PRUH, has increased the recruitment target for the Fitness study. This study has been successful in recruiting a high number of participants nationally. A Phase 3 clinical trial aims to see if adjusting the treatment dose for multiple myeloma based on a patient's level of frailty can improve their ability to remain on treatment, reduce toxicity and improve outcomes. Other haematology studies recruiting this year include RUDY, an online interventional study where multiple myeloma patients complete quality of life questionnaires on a website and manage their participation; OXPLORED, which aims to identify pre-cancerous markers in people with high-risk precursor plasma cell disorders and early-stage chronic lymphocytic leukaemia; and Advent, a trial of a new hand-held scanning device.



Left to right: Ewa Strak, Anna Posada, Dr Mayur Kumar (behind her), Dr Deepak Rao, Nicola Griffiths, Dr Stella Bowcock, Rachel Ryan.

Ongoing development includes: the opening of myeloid trials at the PRUH with Dr Gkreka leading; a qualitative study led by Consultant Musculoskeletal Physiotherapist Nicky Wilson at Denmark Hill; and Dr Stella Bowcock on the impact of myeloma spinal disease on QOL in patients with multiple myeloma. Dr Bowcock is also the PI for CSL-Behring, a multi-centre chart review study on the effectiveness of immunoglobulin replacement therapy in patients with secondary immune deficiency. Once again, the PRUH has proved to be one of the top national recruiters for this study.

Respiratory Medicine

This year, our respiratory department has successfully opened and recruited to the MucAct COPD Study, with Dr Lynette Linkson as PI. This interventional respiratory study is co-sponsored by the NIHR and NHS Lothian and is open solely at the PRUH. It aims to assess the clinical and cost-effectiveness of nebulised sodium chloride plus Active Cycle Breathing Technique (ACBT) in patients with chronic obstructive pulmonary disease when compared with the current standard treatment: carbocisteine (a chemical which breaks down mucus) plus ACBT.

Our respiratory department aims to increase the clinical research portfolio here. With the support of Dr Deepak Rao, we are looking to open the RASPER trial very shortly. A trial for primary pneumothorax early resolution, the aim is to understand whether using suction to treat people in a hospital with a lung collapse is safe and can shorten the time people need to have a chest tube in place.

Oncology

We are thrilled to announce the launch of new breast oncology studies in the past year, thanks to the continuous support from CRN-funded workforce staff. One is the MARECA national study, which focuses on managing breast cancer locoregional recurrence and oncological outcomes. Mr Doddi, the local PI, has already recruited more than eight patients to this study since its opening at the end of 2022, with the help of clinical research practitioner Terri Burchett. Terri has also successfully met the recruitment target for the SURECAN study, a multi-centre trial comparing enhanced acceptance and commitment therapy (plus) added to the usual aftercare versus usual aftercare only, focusing on survivors' rehabilitation evaluation after cancer trial.



Left to right: Nicola Griffiths, Dr Mo Albarjas, Ewa Strak, Anna Posada

Supporting Services



Pharmacy

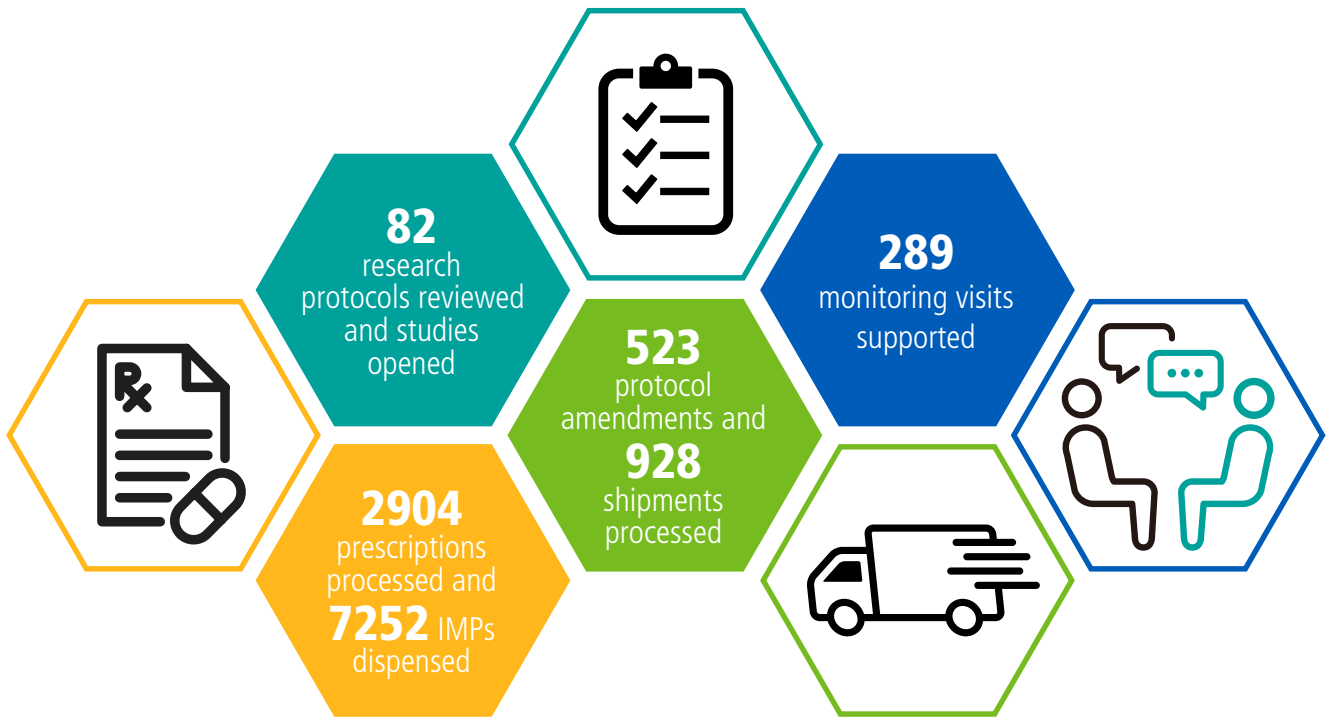
Our Pharmacy Clinical Trials team continues to work with the RDUs to ensure King’s is at the forefront of research by delivering innovative care to our local community and much wider. All studies that require pharmacy support undergo an in-depth review summarised below. This ensures we deliver research in a safe, diverse and equitable way in line with legislative guidance.

Pharmacy Review, Delivery and Completion Process for Clinical Trials



Key:

- Before a trial
- During a trial
- End of trial



Our focus for future years is to:

- Support the development of research across all sites.
- Advocate for Pharmacy-led trials in line with the Trust's BOLD strategy.
- Ensure we have a diverse team and an inclusive portfolio of research which will support and improve patient care.

The Pharmacy Academic Research Unit

Our Pharmacy Research and Audit Group (RAG) brings together the approval, monitoring and feedback process for research and audit activities undertaken by members of the Pharmacy Department across the Trust. Through monthly meetings, all proposed research, quality improvement (QI), service evaluation (SE) and audits undertaken by department members are reviewed and approved before data collection. A tracker of active and completed projects is kept for reference.



Interactive page

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Pathology

Synnovis is an NHS partnership between SYNLAB and Guy's and St Thomas' and King's College Hospital NHS Foundation Trusts.

Synnovis facilitates clinical trial research at King's Health Partners by providing pathology services through the Scientific Research and Innovation Services Department (SR&I). The pathology services available include Blood Sciences, Clinical Biochemistry, Reference Chemistry, Reference Haematology, Clinical Transplantation, Diagnostic Immunology and Allergy, Genetics, Tissue Sciences, Haemostasis and Thrombosis, Nutristasis and Infection Sciences, as well as specialist and customised tests provided by the SR&I. Synnovis laboratories are accredited to meet ISO 15189:2012 requirements for quality and competence in medical laboratories.

Synnovis supports commercial studies and the NIHR portfolio. Besides providing specialised services to King's Health Partners, Synnovis supports national academic organisations, NHS organisations, commercial institutions and international research collaborations. They do this by providing technical expertise for developing new tests and supporting FRCPath and higher research degree trainees (MSc, PhD).

Synnovis supports research by providing test results for research endpoints and safety parameters. This can be through routine pathology investigations or custom biomarkers, using multiple analytical platforms and manual and pre-analytical processing.

During the 2022-23 financial year, Synnovis supported 126 new studies and implemented 10 new research-specific tests (CY-25, GLP-1, acylated ghrelin, cytokeratin-18, CY-24, BDNF/NFL, ST2, IL-1R4 and glucagon-like peptide-1 & C-peptide). In recent years, the SR&I has developed a range of cytokine tests that have been translated into a clinical cytokine service. The cytokine panels (CY19, CY20, CY21 and CY23) were initially for research only. Still, they have been fully validated and utilised as routine clinical markers for cytokine release syndrome (cytokine storm), certain malignancies and sarcoidosis. Following its UKAS assessment in November 2022, the SR&I has received confirmation that its clinical cytokine service has been granted accreditation by UKAS to ISO 15189:2012.



Radiology

The Trust's Department of Radiology – comprising General Radiology, Breast Radiology, Neuroradiology and Nuclear Medicine – actively participates in research at the Denmark Hill, PRUH and South Sites. Radiology provides research support to a portfolio of more than 200 studies, some of which are led by KCH radiology consultants.

During the financial year 2022-2023, two multi-centre trials performed in General Radiology – ELATION and the CEUS LI-RADS – saw the final manuscripts submitted for publication.

ELATION (submitted for publication in Lancet Oncology) was a multi-centre UK-based trial evaluating the use of ultrasound elastography to diagnose thyroid nodules. This trial was supported by an NIHR grant and evaluated more than 900 patients, including 88 from KCH.

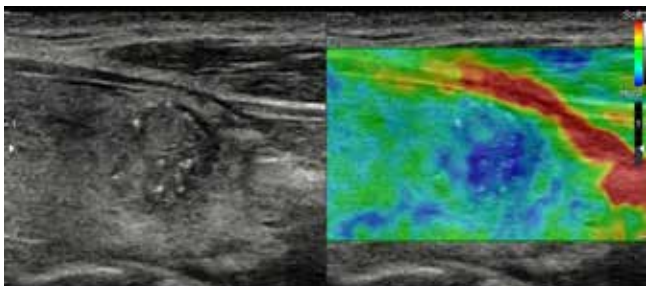


Figure B-mode (left) and elastography (right) ultrasound (US) images from the ELATION trial

CEUS LI-RADS (accepted for publication in Hepatology) was an international multi-centre trial that recruited more than 800 patients, supported by a grant from the NIH, Bethesda, USA. The study evaluated the diagnostic performance of contrast-enhanced ultrasound (CEUS) in patients at risk for hepatocellular carcinoma. At KCH, 44 patients were screened and recruited into the trial under the leadership of Professor Paul Sidhu.

In Breast Radiology, Dr Michael Michell, in collaboration with Dr Keshthra Satchithananda, continues to investigate the comparison between the traditional 2D mammograms with new 3D breast imaging technology in primary breast screening with the PROSPECTS trial. This study has recently undergone an amendment to allow for the development and evaluation of AI algorithms to analyse digital breast tomosynthesis (DBT) images.

One Nuclear Medicine-supported study – EPIC-Skin – has also recently made headlines in the media. This multi-centre trial aims to investigate a novel form of therapy



Figure Contrast-enhanced ultrasound (CEUS) image from the CEUS LI-RADS trial

that uses the radioactive agent Rhenium-SCT to treat non-melanoma skin cancer. KCH, under Dr Nicola Mulholland's leadership, became the UK's first institution to participate in a Phase 4 clinical trial to evaluate the efficacy of this new treatment.

Our Nuclear Medicine team also supports the ABATE study – a trial investigating the effects of a new vaccine in patients with prodromal Alzheimer's disease. This trial is part of Alzheimer Europe's Clinical Trials Watch database, a partnership developed in 2018 with funds from the European Union's Health Programme (2014-2020).

Radiology has also initiated processes to support a multinational study evaluating the use of Sonazoid. This contrast agent facilitates hepatic parenchyma-specific Kupffer phase imaging on CEUS to detect and characterise focal liver lesions in paediatric patients. This study should commence in October 2023. A grant application has also been submitted to the NIHR to support a UK-based multi-centre study of colour Doppler US imaging as a first-line investigation for acute testicular torsion.

King's Liver Biobanks

The King's Adult Liver and Paediatric Liver Research Biobanks had a very productive 2022-23, continuing to recruit donors throughout the adult and paediatric liver services here at King's. Through the generosity of our sample donors, we have collected, stored and distributed a wide variety of sample types to several new and ongoing research studies that we support across both Biobanks.



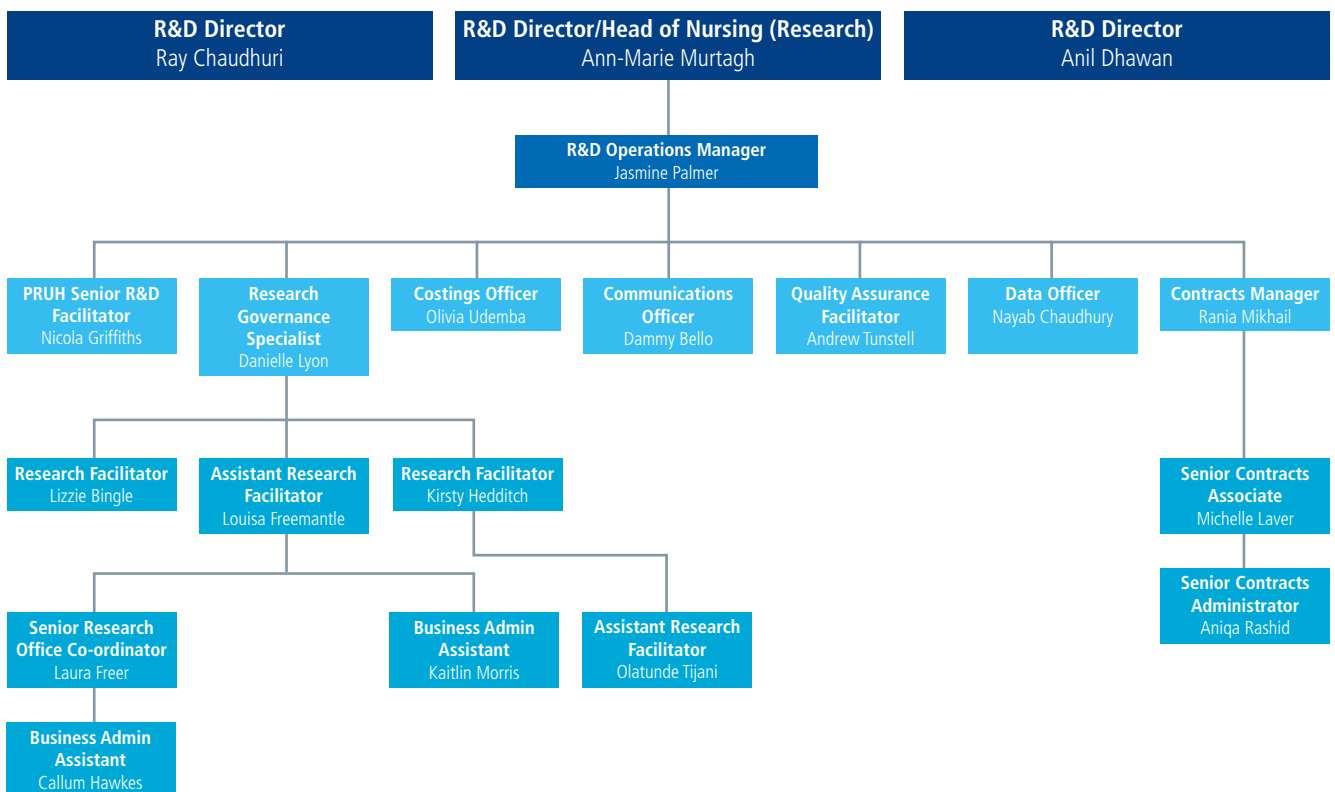
Research & Development



Research & Development

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

R&D Organisational Chart



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 Anil Dhawan receives Honouring the Greats award from the International Liver Transplantation Society



Professor Anil Dhawan, Consultant Paediatric Hepatologist, and Director of the Paediatric Liver, Gastroenterology, Nutrition and Mowat Labs at King's College Hospital, has received the Honouring the Greats award from the International Liver Transplantation Society (ILTS).

This prestigious award recognises medical professionals who have made outstanding contributions to the field of liver transplantation globally. Professor Dhawan was selected for his 30-years clinical, academic, leadership, mentorship and global impact in liver transplantation. He was also recognised for being the mentor with the most supported trainees and scientists in liver transplantation who has been honoured by the ILTS.

Professor Dhawan said: "This is a recognition of King's College Hospital, my colleagues and my wife, Dr Anita Verma, as without their support this would not have been possible. I feel fulfilled and honoured to receive the award as it demonstrates our commitment to providing excellent clinical outcomes, underpinned by good basic science and clinical research."

John Smith receives Senior Research Leadership Award



In January 2023, John Smith, Lead Nurse for Anaesthetics, Critical care, Emergency Medicine and Trauma (ACET), was one of only 15 nurses in the UK to be accepted onto a fully-funded scholarship from the NIHR to join its senior research leadership programme.

He said "King's already has a proven track record in attaining NIHR

awards and academic achievement, and I am genuinely humbled, yet super thrilled, to be joining this fraternity. The output of these initiatives really showcases what we do here at King's to support our colleagues caring for patients. More importantly, it continues to drive forward and evolve the care and treatment we give to our patients."

Dr Charles Reilly receives £1.2m Fellowship Award



In March 2023, Dr Charles Reilly, Consultant Physiotherapist in Chronic Respiratory Disease at King's College Hospital NHS Foundation Trust, was awarded £1.2m for a five-year advanced fellowship by the Health Education England/NIHR Integrated Clinical and Practitioner Academic Advanced Clinical and Practitioner Academic

Fellowship (ACAF) scheme. The NIHR ACAF fellowship allows Dr Reilly to advance his research and leadership expertise, develop his research team and fund his research project: "Improving the lives of people living with chronic breathlessness due to advance disease via a self-guided internet-based supportive intervention, SELF-BREATHE".

Neuro-Oncology team wins Professional Excellence award



In April 2023, the Brain Tumour Charity presented the Neuro-oncology team at King's College Hospital with an award for their dedication to treating patients with brain tumours and their patient-focused, pioneering research.

The team was announced the winners of the Professional Excellence Team Award at the charity's Celebrating You Awards on Tuesday 4 April 2023. The award recognises professionals who go above and beyond to provide the best standard of care and support to those affected by brain tumours. Keyoumars Ashkan, Professor of Neurosurgery and Lead for Neuro-oncology at King's College Hospital, said: "Our aim is to make sure every patient has the best chance of surviving a brain tumour diagnosis with the best quality of life. We are proud to work alongside the charity to help advance brain tumour treatments, and it is a huge honour to win the Professional Excellence Team award."

Team King's goes on Display at Hunterian Museum Exhibition

Dagmar Turner, who was able to play a violin while surgeons removed her brain tumour, has taken part in a film alongside Professor Keyoumars Ashkan, Professor of Neurosurgery at King's College Hospital, now on display at the Hunterian Museum. The museum's Transforming Lives digital display features a range of interviews recounting personal experiences of surgery, from both patients' and the surgeons' perspectives. It brings lifesaving and life enhancing surgery to life and focuses on the forging of unique personal and professional bonds between medical professionals and patients.

King's patient Sherrie Sharpe, who underwent a ground-breaking operation on her unborn baby with spina bifida, also features as part of the display, along with Professor of Fetal Medicine at the Trust Professor Kypros Nicolaidis. Professor of Fetal Medicine at the Trust. Professor Nicolaidis said: "I have been lucky in my career to have been involved in many of the major discoveries within fetal medicine. It has been extremely rewarding.

This field is constantly evolving as we learn more about how we can give unborn babies the very best start in life, and I hope this film will help inspire the next generation of health professionals to keep pushing the boundaries."



Professor Surinder Birring is elected a Fellow of the European Respiratory Society

Professor Surinder Birring was elected a Fellow of the European Respiratory Society in 2023. This is a prestigious award in recognition of outstanding research. Professor Birring and colleagues published in the Lancet in 2022 the findings of the Phase 3 clinical trial of Gefapixant, a novel antitussive

medication that inhibits a P2X3 sensory nerve receptor. Professor Birring, as Chief Investigator of the trial and was interviewed by and featured in The Guardian newspaper.

Useful Information



Outreach and engagement

Research Grand Rounds

The Research Grand Rounds, delivered on the first Wednesday of every month, is designed to increase research awareness across clinical and non-clinical trust staff. They take the form of a series of regular virtual symposia where a nominated research team member shares recent research updates with a wide and diverse audience, allowing research teams to foster collaboration and knowledge-sharing within the organisation. This year, we produced a booklet highlighting key presentations in the 2021 Research Grand Rounds.



International Clinical Trials Day

In May 2023, the research teams celebrated International Clinical Trials Day across Trust sites in collaboration with some of our partners from the Clinical Research Network South London and the NIHR Biomedical Research Centre (BRC). The teams hosted stalls at the entrance of the Denmark Hill site, the Hambleden wing boardroom and the Golden Jubilee Wing and at the Princess Royal University Hospital. One of these stalls was dedicated to Public and Patient Involvement Members, as public and patient members came to the event. As staff and patients passed by, teams spoke to them about our work and why it is important to involve and engage members of the community when conducting research.

A wonderful patient from the Parkinson's Research team shared her experience on the day.

"I got involved because I wanted to contribute something to Parkinson's research, and I ended up getting so much more back."

Catherine McLean, International Clinical Trials Day attendee



International Nurse's Day

In May 2023, the research team celebrated International Nurses Day. We held a public engagement event at King's College Hospital in collaboration with other teams across the Trust, including the Quality Improvement and King's academy teams. The research team hosted a stall in the boardroom at the Denmark Hill site. It was great to collaborate with other teams at the Trust and speak with them about the important work conducted in the research department.



Patient Experience Project

All year, we have conducted written and video interviews with our patients to capture their experiences of participating in research studies and clinical trials.

Following are short articles from a few of our brilliant patients.



Heather

"I received exceptional care at the Princess Royal University Hospital, making it the best hospital experience ever. Throughout my visits, the team consistently demonstrated professionalism and friendliness, with special recognition to Rachel for providing expert and personable care."

"I participate in research to aid future generations in understanding their medical conditions. I believe that research participation is crucial for the betterment of healthcare and to help individuals receive better care."



Lee

"I participated in the BOPP Trial to help others with similar conditions. Research trials aid in understanding diseases, creating hope for better treatment in the future. Participating makes me secure with the best people looking out for me."



Sarah

"I signed up to the Research programme for several reasons. First, the doctors caring for me asked me to do so, so I know it is a very important part of their care. I am also hopeful that it will result in more knowledge and more help for future patients with my and liver conditions. Thirdly, throughout the process, I am getting closely monitored with more

regular tests and checks, which also gives me a lot of comfort. Thank you, thank you for the bottom of my heart."



Joel

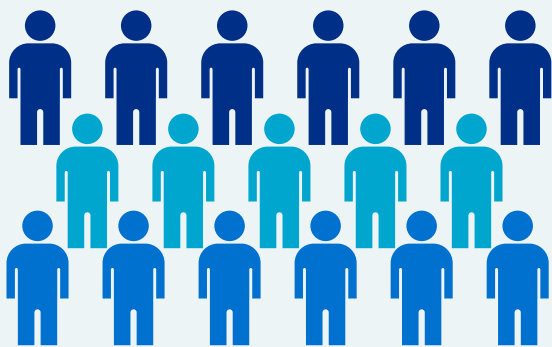
"As a black man, I understand the importance of people from my genetic and ethnic background participating in health and medical research. People like me should be included in research where possible so that we can increase representation of data from minority ethnic groups. I hope that this will allow the development of new technologies and medications to be made safe and accessible for

people of all backgrounds and varying genetic makeup. The treatment I receive for my conditions relied upon human subjects participating in their research, so I feel obligated to help with research where I can so that new medications can be made available for people who need them."

The year in numbers....

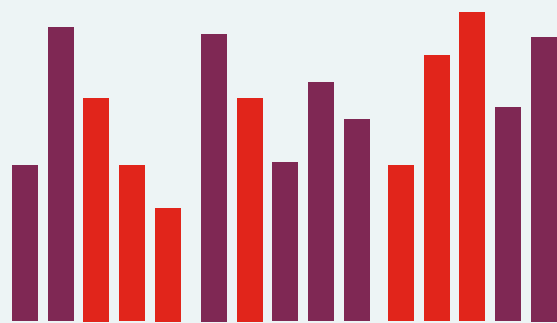
Here we look back at FY2022/2023's research output in numbers, from the number of participants in research studies to value of commercial contracts.

NUMBER OF PARTICIPANTS IN RESEARCH STUDIES 2022/23



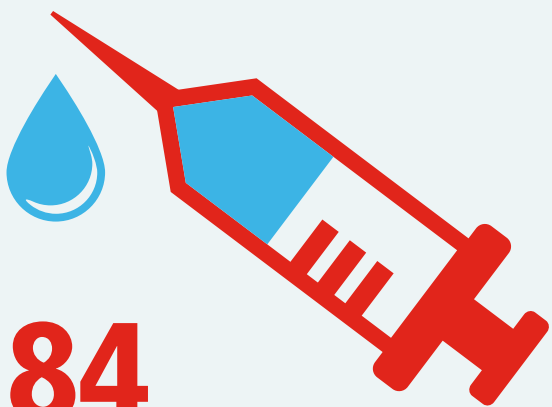
30,707

NUMBER OF RESEARCH STUDIES OPEN IN 2022/23



237

NUMBER OF NEW COMMERCIAL STUDIES OPENED IN 2022/23



84

NUMBER OF NEW NON - COMMERCIAL PORTFOLIO STUDIES APPROVED 2022/23

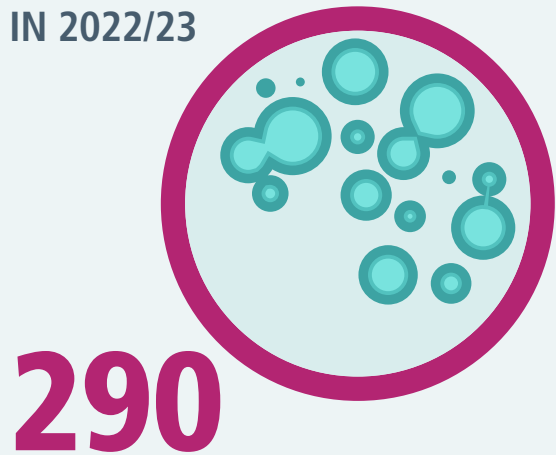


112

NUMBER OF NON-COMMERCIAL STUDIES OPENED IN 2022/23



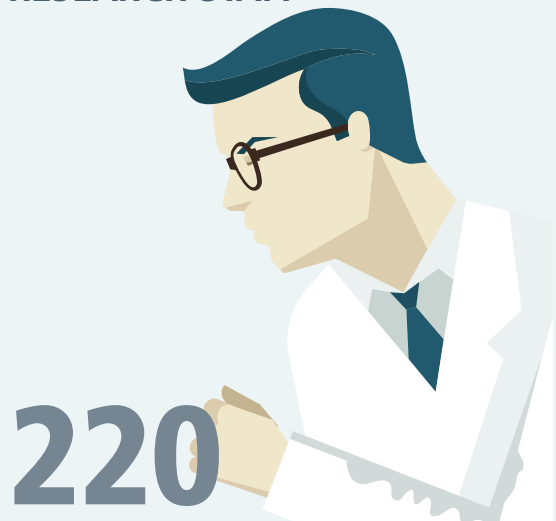
NUMBER OF NON-COMMERCIAL RESEARCH CONTRACTS FULLY EXECUTED IN 2022/23



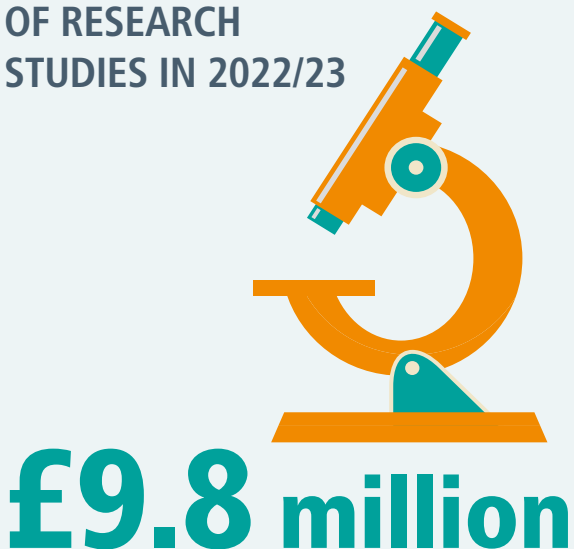
NUMBER OF AMENDMENTS PROCESSED IN 2022/23



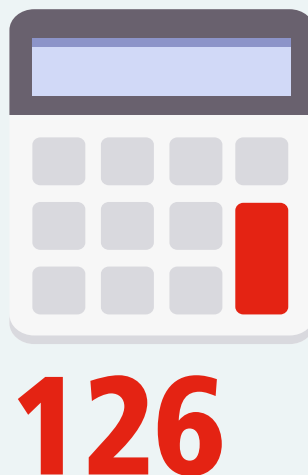
NUMBER OF FULL TIME RESEARCH STAFF



COMMERCIAL CONTRACT VALUE OF RESEARCH STUDIES IN 2022/23



NUMBER OF COSTINGS COMPLETED IN 2022/23



The year in pictures....

Here we look back at FY2022/2023's research output in numbers, from the number of participants in research studies to value of commercial contracts.



Jon Breeze and Hosanna Assefa-Kebede at the Clinical Research Network Conference



LivFIT (Liver Research) Patient and Public Involvement Engagement (PPIE) Members



Noeleen Bennett and Lucy Campbell at the HIV Testing Week Event at KCH



Danielle Lyon and Lizzie Bingle at the Annual Quality Improvement Conference

Red for Research Day



UK CRF Conference



Members of the CRF team

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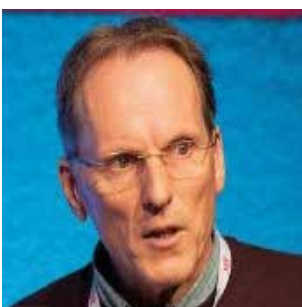


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King's Health Partners Clinical Trials Office

KHP-CTO



Collaboration between KHP Partner Organisations to develop their clinical trials potential and increase the quality and delivery of clinical trials.



Quality Team

Quality Assurance for all CTIMP's governed by relevant legislation and ensuring the delivery of Sponsor responsibilities for all clinical trials where one or more of the partners is Sponsor or co-Sponsor. Quality Team led by Amy Holton amy.holton@kcl.ac.uk

Key focuses

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



Commercial Team

Efficient, effective set up & administration of Commercial trials from feasibility to archive. Commercial Team led by Kirsty Hough kirsty.hough@kcl.ac.uk.

Key focuses

- Feasibility
- Facilitation
- National Contract Value Review
- Contract Negotiations
- Amendments
- Finance



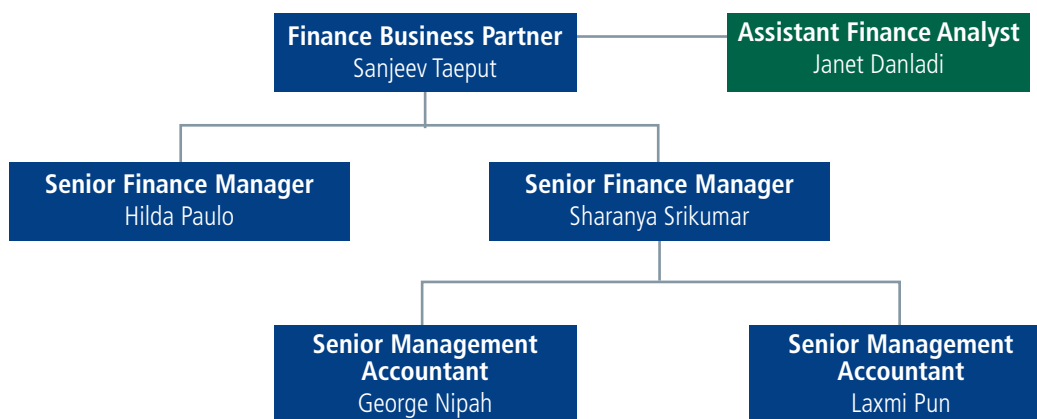
KCH Research and Development Finance Team

Our R&D finance team is on the second floor at the Coldharbour works office. We manage an annual research income budget of £15m, which consists of NIHR funding, EU grants, charity grants and commercial income received from the Clinical Trials Office (CTO).

We can help you with:

- salary research costings
- financial management of research study and PI accounts
- decision support and financial advice
- invoicing and transactional support.

R&D Finance Organisational Chart



R&D team areas of responsibility

Hilda Paulo	SharanyaSrikumar	George Nipah	Laxmi Pun	Janet Danladi	Sanjeev Taeput
NIHR ARC, CASTLE	RDU 1, 6 & 4	Therapies	RDU 5*	RDU 9	RDU 7
RDU 2 & 3		R&D Office inc RCF,CRF,CRN, Super Surplus & Rheumatology	RDU 8**	Service Support areas	

* RDU 5 (Sharanya in the interim) **RDU 8 (George in the interim)

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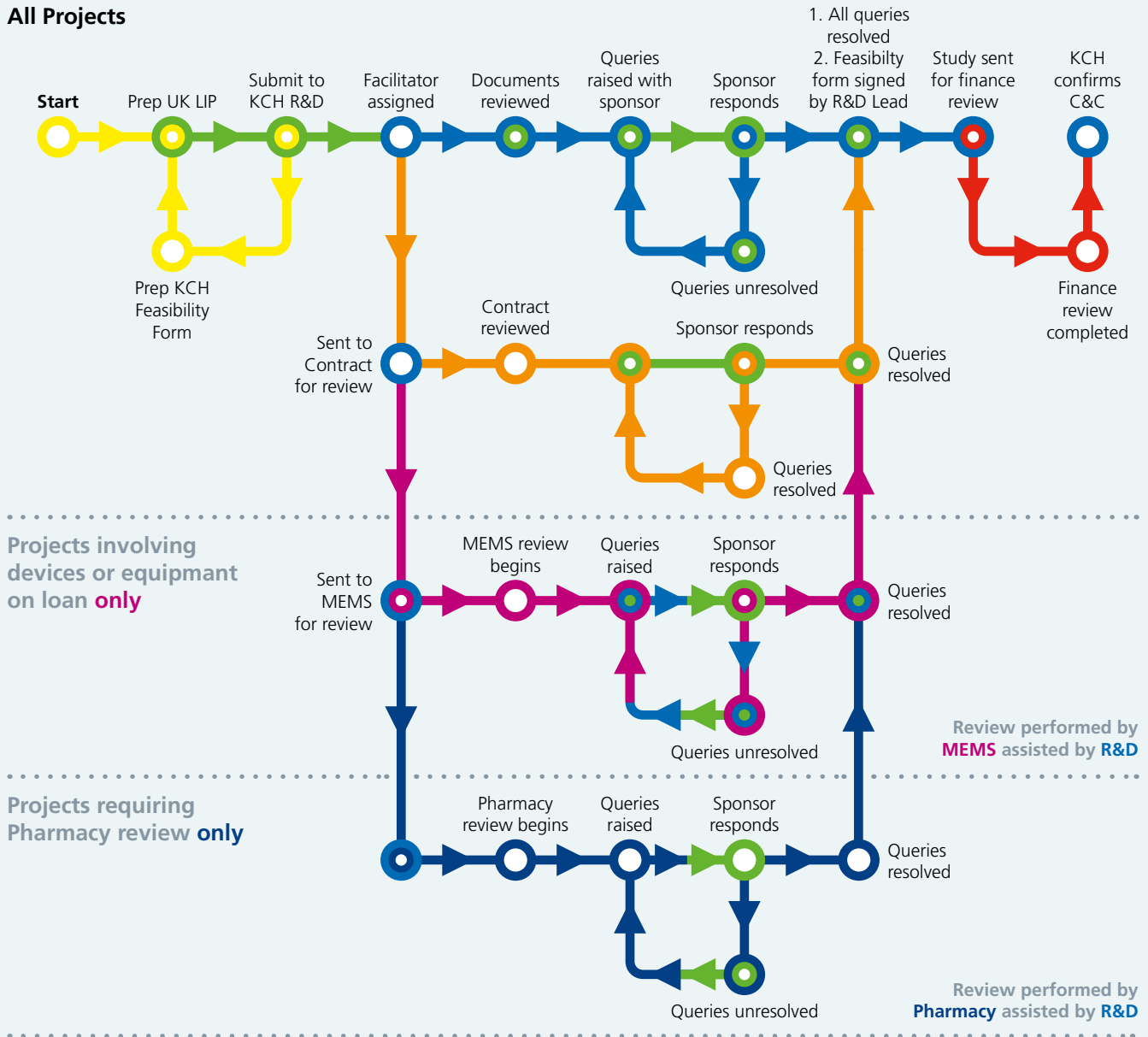
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Project Approval 'Tube Map'

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&D
- = MEMS
- = KCH PI
- = KCH Contracts
- = Pharmacy

Equality, Diversity and Inclusion

Professor K Ray Chaudhuri: our research participation is still lacking in diversity! And what are we doing to address this? The development of the world-first King's Model.

By K Ray Chaudhuri and A Podlewska

Lack of diversity in research participation was identified as a problem in the 1980s. Yet, 40-odd years later, we are nowhere nearer bridging this gap, with widespread recent reports in the British Medical Journal and other publications about racism in health service and clinical trials and lack of attention to diversity in recruiting patients in clinical trials by industry. The latest example is the recent TRAILBLAZER-ALZ 2 study, sponsored by Eli Lilly and hailed as the next breakthrough in Alzheimer's research. Out of the 1,736 participants, white populations comprised a **staggering 91.5%** of the study sample [1]. Further evidence of Parkinson's disease, the world's second most common neurodegenerative disorder, has recently been published based on clinical trial data in the last five years [2]. This begs the question of whether the results are applicable to non-white populations, given established evidence that tolerability, efficacy and metabolism of drugs may vary considerably among different ethnic groups.

And yet, most real-life data demonstrates that non-white populations demonstrate different symptomatology and have a different healthcare experience. For example, King's data shows ethnic disparities in analgesic use among people with Parkinson's with chronic pain living in the UK [2], with white people receiving more pain relief compared with non-white populations, despite a similar level of pain being experienced.

Despite wide literature outlining the barriers, enablers and recommendations for driving inclusion and diversity in research, there still needs to be more evidence for successful diversity in research participation, which directly impacts the quality of care provided to ethnically diverse individuals.

A new, comprehensive approach to recruitment strategies is therefore necessary.

The King's Model for Minority Ethnic Research Participant Recruitment, proposed in collaboration with the King's Research in Health Inequalities Working Group and tested out during the COVID-19 pandemic, proposes a series of actions to be taken within the hospital, as well as in the local community, to promote diverse research recruitment. We introduced these steps as part of the recruitment drive for our NOVAVAX study, COVID-CNS and, more recently, in the PD-Ballet study. In all cases, the non-white recruitment was higher than the national average and higher than the non-white recruitment in previous studies.

Given the positive results, we have approached the editors of Public Health in Practice to share our experiences and the King's Model with the wider research community. We propose the Model, along with the MAADE Scheme (Figure 1), a set of considerations to bear in mind for the long, effective implementation of the Model.

References

1. Sims JR, Zimmer JA, Evans CD, et al. Donanemab in Early Symptomatic Alzheimer Disease: The TRAILBLAZER-ALZ 2 Randomized Clinical Trial [published online ahead of print, 2023 Jul 17]. *JAMA*. 2023;e2313239. doi:10.1001/jama.2023.13239
2. Lau YH, Podlewska A, Ocloo J, et al. Does Ethnicity Influence Recruitment into Clinical Trials of Parkinson's Disease?. *J Parkinsons Dis*. 2022;12(3):975-981. doi:10.3233/JPD-213113
3. Rukavina K, Ocloo J, Skoric MK, ..., K Ray Chaudhuri. Ethnic Disparities in Treatment of Chronic Pain in Individuals with Parkinson's Disease Living in the United Kingdom. *MovDisordClinPract*. 2022;9(3):369-374. Published 2022 Mar 9. doi:10.1002/mdc3.13430

Approach	Specifications
Local (in hospital)	<p>Engagement of senior management in conversations</p> <p>Engage key professionals in meetings</p> <p>Engage all hospital stakeholders ranging from security and cleaning to consultants in seminars</p> <p>Video of management and clinical stakeholders to engage ethnic minorities</p>
Community Outreach	<p>Webinare for local population by a multi-specialist and disciplinary panel</p> <p>Communication with local champions</p> <p>Social media presence about vaccine facts and dispel fake news</p> <p>Engage with NIHR (South London ARC)</p> <p>Vaccine awareness day (modifiable for a specific research area)</p> <p>Video of ethnic minorities patient ambassadors</p>

The MAADE Scheme for effective implementation of the King's Model

M	<p>Monitor</p> <p>Monitoring ethnicities of participants in research studies</p>
A	<p>Acceptability</p> <p>Challenging flawed assumptions about research and making it more acceptable</p>
A	<p>Accessibility</p> <p>Ensuring access to research participation for all (including carers, full time/part time workers and parents)</p>
D	<p>Drive</p> <p>Trust-wide drive and initiatives for active engagement in research</p>
E	<p>Experience</p> <p>Ensuring satisfaction with research participation</p>

Glossary

Term	Definition
AHSC – Academic Health Science Centre	A partnership between a healthcare provider and a university.
Abstract	A brief summary of the study and its results. It should tell you what the study tried to show, how the researchers went about it and what they found.
Analysis	Data analysis involves examining and processing research data to address the study's questions.
Audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.
Blinding	The process of preventing those involved in a trial from knowing which comparison group a participant belongs to.
Case study	A report based on observations of a single individual, also known as an anecdote, case history or single case report.
Chief Investigator (CI)	The investigator with overall responsibility for the research.
Clinical research	Aims to find out the causes of human illness and how it can be treated or prevented.
Clinical trial	An experiment to compare the effects of two or more healthcare interventions. Clinical trial is an umbrella term for a variety of healthcare trial designs.
Clinical Research Network (CRN)	The NIHR CRN provides infrastructure that allows high-quality clinical research to take place in the NHS, so patients can benefit from new and better treatments.
CTIMP	Clinical trial of an investigational medicinal product. (Any other type of research is known as a non-CTIMP)
Double-blind	A trial where the investigators and the subjects included in the trial (healthy volunteers or patients) do not know which interventions / treatments have been assigned.
Intervention	The process of intervening on people, groups, entities or objects in an experimental study. In controlled trials, the word is sometimes used to describe the regimens in all comparison groups, including placebo and no-treatment arms.
Lead site	In the case of a multi-site study, the site for which the Chief Investigator is also the Principal Investigator.
Participant	Patient, service user, carer, relative of the deceased, professional carer, other employee, or member of the public, who consents to take part in a study.
Phase 1 trial	A clinical trial to study the pharmacology of an investigational medicinal product (IMP) when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial.
Placebo	A placebo is a fake or dummy treatment designed to be harmless and have no effect. It allows researchers to test for the placebo effect.
Principal Investigator (PI)	The investigator responsible for the research site. There should be one PI for each research site.
Randomised	Where people are randomly allocated to receive (or not receive) a particular intervention (this could be two different treatments or one treatment and a placebo).
Randomised controlled trial (RCT)	A type of clinical trial in which observations made during the trial are compared to a standard (called the control). The control may be a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a historical control).
Research	For the purposes of research governance, research means the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.
Research governance	Research governance is a process aimed at ensuring that research is high quality, safe and ethical.
Research funding	Research funding enables researchers to carry out a particular piece of research.

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