



Research & Innovation Department

Annual Report 2016-17

Foreword

It is always a pleasure to sit down to read (and edit!) this report because it reminds me just how much we've achieved in the past 12 months. We've launched a new strategy, rebranded ourselves, started work on our fantastic new webpages (expect a launch late 2017/early 2018), and have taken huge strides in our engagement work with patients, public and colleagues. Our lead research nurse, Ruth Hulbert, has been instrumental in driving this agenda, and I would like to thank her along with our growing band of Patient Ambassadors - Karen, Ian, David & Brent to name but a few – who have given much time and energy in support of this work.

At the same time our delivery teams, and those that support them in pharmacy, pathology, the R&I office and others, have recruited well over 2000 patients to 118 studies over 23 different disease areas. It is this latter statistic that I often tell people about, because it reflects how we are offering the opportunity to participate in research to as many people as we can.

There is no doubt that we continue to face some headwinds – financial, R&I estate, capacity within some support services – which in many respects mirror the challenges that face the organisation as a whole. However, what remains very evident to me is the immense enthusiasm and commitment of colleagues towards delivering our vision of “Making a difference to the experience and outcomes of health care to the people of Kent, the NHS and internationally through Research, Inquiry and Innovation”. No more so was this reflected than in the inaugural CRN:KSS awards, in which EKHUFT featured prominently with winners or highly commended in virtually all categories.

Dr Tim Doulton
Director of Research & Innovation
September 2017

(Front cover picture: R&I Delivery Team staff sporting our new uniform)

Contents

Foreword	2
Contents & acknowledgments	3
Executive summary	4
Key events during 2016-17 financial year	5
Public & Patient Involvement & Engagement	8
Key metrics	10
Overview of research activity (individual/team) during 2016-17 financial year	14
List of peer-reviewed publications from Trust researchers (April 2016 to March 2017)	26
Appendix: Finance Report	31

Acknowledgements

I would like to express my thanks to all those PIs, delivery team staff and other researchers who have contributed the content of this report, to Ruth Hulbert for the PPIE report, Jacky Douglas for the finance report and Art Ationu and Joanne Isaacs for assembling the first draft.

Dr Tim Doulton

1. Executive Summary

1. During the year a total number of 2128 patients were recruited by East Kent Hospitals University Foundation Trust (EKHUFT, hereinafter referred to as “the Trust”) researchers into National Institute for Health Research (NIHR) portfolio studies. This represents an increase of 59% on 2015-16.
2. During 2016-17 there were 64 studies given NHS R&D approval by the Trust of which 45 were NIHR Portfolio studies. Of the 64 newly opening studies, 17 were clinical trials of investigation medicinal products (CTIMPs) and 17 were industry-funded/-sponsored studies.
3. The significant contributions of colleagues and teams working in EKHUFT R&I was recognised at the first annual CRN:KSS awards
4. Our strategy for 2016-2020 was presented to and approved by the Board of Directors in October 2016. Accompanying this we undertook a rebranding exercise, and hosted or participated in a number of events throughout the year intended to raise the profile of R&I amongst patients, public & staff.
5. Total income received on behalf of R&D during the year was £2.85m. Income related to commercial /industry study activities up 40% (£1.02m vs. £0.73m in 2015-16).
6. During 2016-17 financial year the Trust received £1.71m from NIHR/DH (via CRN: KSS, NIHR grant streams and directly). This included £69k from DH Research Capability Funding compared to £99k in 2015-2016.
7. R&D oversaw distribution of funds totalling £13,128 to Trust staff via Research Session Schemes.
8. During 2016-17 Trust researchers published 61 articles in peer-reviewed journals.
9. NHS R&D approval was granted within 30 days (from receipt of valid application) for 85% of NIHR Portfolio studies, meaning that the Trust achieved the target set down by the NIHR/DH. The median time to obtain NHS permission was 2 days.

2. Key Events during the 2016-17 Financial Year

Raising the profile for R&I: within the Trust, and in the local media

A number of events took place during the year which has raised our profile with patients, public and colleagues. These include 'Making a Difference with Research' (Harvey Hall, K&CH, 20th June 2016 – see Section 3 of this report), International Clinical Trials Day, the Trust Annual General Meeting, various events in the Quality & Innovation Hubs, and the Kent-wide Research Day.

The Kent-wide Research Day – themed “Celebrating Our Successes and Looking Forward” – was a joint venture delivered by all the research active delivery organisations in Kent & Medway (acute, mental health & community sectors), and sponsored by KentHealth – the University’s one-stop shop for health and social care research. Nearly 150 colleagues from NHS organisations and universities across K&M, as well as representatives from our patient population, Pfizer and NIHR Clinical Research Network: Kent, Surrey & Sussex (CRN: KSS) participated in the event on the University of Kent’s Canterbury snow-bound campus on 13th January 2017. EKHUFT’s Director of Research & Innovation Dr Tim Doulton led the team organising the event and provided the welcome and closing speeches at the event which celebrated achievements in research across the region. Attendees took part in a series of stimulating workshops intended to deliver even more and better research in the future.

Our research teams featured in the Kentish Gazette (Lavinia Davey and colleagues in the Haematological Oncology team) and on BBC News South East (Haemodialysis patients & PIVOTAL study participants Mr Derek King and Mr Carlton Cuff, Dr Tim Doulton & colleagues in the renal research team – see <https://twitter.com/bbcsoutheast/status/757640236113408001>).

Awards in Research & Innovation

The contribution of several individuals and teams within EKHUFT was recognised at the inaugural CRN: KSS awards held at the Copthorne Gatwick Hotel on 31st January 2017. The Trust was shortlisted for three of five categories for outstanding research and patient involvement work.

Outstanding contribution to commercial research in Kent, Surrey and Sussex

- Winners: EKHUFT Haematological Oncology (blood cancer) Team, K&C [photo, right]
- Highly commended: Mr Nishal Patel (Consultant Ophthalmologist, K&C and WHH)

Outstanding Patient and Public Involvement and Engagement (PPIE) activity

- Highly commended: EKHUFT's PPIE Steering Group, chaired by Ms Ruth Hulbert, Lead Research Nurse



Outstanding contribution to Research in Kent, Surrey and Sussex

- Winner: Dr Tim Doulton (Director of Research and Innovation and Consultant Nephrologist)
- Highly commended: Dr David Stephensen (Physiotherapist, Haemophilia Centre, K&C)
- Highly commended: Dr Ibrahim Balogun (Consultant Stroke Physician, WHH)

In addition, EKHUFTs R&I department decided to hold its' own awards this year to recognise and celebrate the hard work of research staff. The winners were as follows:

Team Award: Exceptional contribution to patient care through research: East Kent (Generic) Research Team

Individual Awards:

- Exceptional contribution to patient care through research: Lavinia Davey, Haematological Oncology Research Team Leader
- Rising Star: Tracy Hazelton, Clinical Studies Officer, Generic Research Team
- Unsung Hero: Sue Drakeley, Senior Research Nurse, Oncology Research Team [photo, above]
- Outstanding Team Member of the Year: Sarah Stirrup, Ophthalmology Research Nurse



Launch of our new strategy for 2016 to 2020

On 7th October 2016, we presented to the Trust's Board of Directors our Strategy for Research, Inquiry and Innovation for 2016-2020. This strategy, which arose from a rigorous consultation and authorship process involving many stakeholders from January 2016 onwards, describes how we will deliver our vision of 'Making a difference to the experience and outcomes of health care to the people of Kent, the NHS and internationally through Research, Inquiry and Innovation'.

Launch of a new title, visual identity and delivery staff uniform

Early in 2017 we underwent a name change from 'Research and Development' to 'Research and Innovation' to better describe what we do and better reflecting our vision and objectives as outlined in our newly launched strategy. Aligned to this we launched our new visual identity [below] that describes the very broad scope of the types of research that we do, and incorporates our strapline: "Good for you, good for the NHS."

Accompanying this, and following a period of consultation with R&I staff, we also launched a distinctive new uniform (see front cover of

this report) that not only gives greater prominence to the delivery teams, but for the first time provide consistent uniforms for both professionally registered (e.g. nursing) and non-registered staff.



Research and Innovation Catalyst

One of our new strategic objectives was to launch a new streamlined scheme for funding small research & innovation projects and collaborations that avoided the long lead times and perceived bureaucracy of our previous internal funding schemes. Named the 'Research & Innovation Catalyst' and modelled upon the BBC TV 'Dragon's Den' format, the first event took place in the Boardroom on 23rd March 2017 with a panel comprising Matthew Kershaw, CEO; Sally Smith, Chief Nurse; Chris Farmer, Clinical Professor of Medicine at University of Kent and Dr Tim Doulton, Director of Research & Innovation [photo, right, with winner Liz Van Rossen]. The panel were really excited by all the excellent ideas brought to the Boardroom, but we were particularly impressed by winner Liz Van Rossen's proposal which will generate important findings with real potential to improve quality of life for people with ankylosing spondylitis.



Research Session Scheme 2016-17

Using funding from NIHR Research Capability Funding (RCF) the Research Session Scheme (RSS) was able to support the following Trust staff:

- Jayanti Rai, Physiotherapist (0.2 WTE for one year, £8304)
- Dr Tom Webb, Consultant Stroke Physician, WHH (0.5 PA for one year, £4824)

Implementation of a new Research Database

Following the decision by CRN: KSS to adopt a new R&I database (EDGE) region-wide, the R&I department began the process of migrating data for 700 active studies from its existing database (ReDA) to EDGE. Once the migration process is complete, the new system will offer greater functionality, particularly to delivery staff. It will also enable more seamless upload of data – for example relating to study recruitment – directly to national systems, including the Central Portfolio Management System.

3. Patient & Public Involvement & Engagement

Patient & Public Involvement & Engagement (PPIE) activity within Research & Innovation has continued to grow and some significant progress has been made throughout the year. The PPIE Steering Group, formed in February 2016, continued to meet regularly to oversee and drive this important work stream. The PPIE related R&I strategic objectives are now reviewed at each meeting to report on progress and discuss ways of achieving our milestones.

Key achievements during 2016/17 include the following:

- A half-day event entitled 'Making a Difference with Research' took place at the Kent & Canterbury Hospital in June 2016 to which local patients, public & staff were invited. A range of speakers, including Simon Denegri, NIHR National Director for Patients and the Public and Chair of INVOLVE, presented on a variety of topics relating to research. Our own researchers and research participants also presented on research they have been involved in within EKHUFT. The event was hailed a great success and feedback was overwhelmingly positive. Approximately 80 people attended the event, one third of whom were patients or public.



Making A Difference with Research Participants (left to right): David Walsh (research participant & speaker), Tim Doulton, Ruth Hulbert, Brent Murray (research participant & speaker)

- 'Thank you' letters are now being sent to all participants who take part in research within the Trust which also incorporates a feedback survey, so that the experiences of our research participants can be monitored on a continuous basis. The participants are also offered the opportunity to get involved in our work by becoming an 'East Kent Research Friend' and are also asked to let us know if they are interested in finding out about the results of the study they took part in, once the results are available.

- Another event - 'Involving patients & the public in research: creating research conversation & building partnerships' - was hosted in February 2017 at William Harvey Hospital, in conjunction with CRN: KSS, to explore opportunities to get involved with health research. 33 people attended, over half of whom were patients or members of the public. The workshop was very positively received.
- Several examples of research taking place within EKHUFT have been featured on local television news, in the local press, the Trust's 'Your Hospitals' magazine, and on internal & external webpages.
- Internal promotional events were held internally to mark International Clinical Trials day in May 2016 and a stand was also hosted at the exhibition as part of the Trust AGM in October 2016.
- We have begun work on creating a video to promote Research & Innovation, featuring some of our researchers and participants, as well as working closely with our digital communications lead to refresh the R&I pages of the Trust website to make these more informative and 'patient-friendly'.

4. Key Metrics¹

Study activity

During 2016-17 the Trust had 367 active² research studies including 261 within the NIHR Portfolio and 106 non-Portfolio or “own account” studies. Included within these studies are 125 clinical trials of investigation medicinal products (CTIMPs) and 71 industry studies (64 Portfolio, 7 non-Portfolio). We recruited to 118 NIHR Portfolio studies, across 23 discrete disease areas.

The Trust R&I Department issued approval for 64 new studies between 1st April 2016 and 31st March 2017 (45 NIHR Portfolio and 19 non-Portfolio), of which 17 were CTIMPs and 17 were industry studies.

Participant Recruitment

Between 1st April 2016 and 31st March 2017 the Trust recruited 2128 participants to NIHR Portfolio studies compared to 1333 participants in 2015-16, an increase of 59.6%. We have continued to maintain a healthy balance with complex interventional (usually randomized controlled) and more straightforward observational and large-scale studies (Figure 1), across a very broad range of speciality areas.

NHS Permission

The NIHR has set NHS organisations an aspirational target of achieving NHS permission for a research study to open with 15 days of a valid application for 80% of studies. In 2016-17 we approved 45 new NIHR Portfolio studies, of which 45 (85%) were within 15 days. Our mean and median times to permission were 6 days and 2 days respectively.

Research Income

Research-related income to the Trust was similar to that seen last year (£2.85m vs. £2.79m in 2015-16) with income related to commercial/industry study activities up 40% (£1.02m vs. £0.73m in 2015-16). During the year the Trust was allocated £69k by the Department of Health via its Research Capability Funding stream, and this supported NIHR faculty members (present and future) directly and via the Trust’s Research Sessions Scheme (RSS).

GCP & R&I training for staff

Date	Title of Training	Venue	Attendees
18/04/2016	R&I HRA Workshop	KCH	16
26/04/2016	R&I HRA Workshop	WHH	9
05/05/2016	R&I HRA Workshop	QEQMH	10
08/07/2016	GCP Refresher	WHH	9
11/07/2016	GCP Intro	WHH	11
18/07/2016	R&I HRA Workshop	QEQMH	10

¹ Data relating to NIHR Portfolio studies obtained from NIHR Open Data Platform (KSS QlikView Pages) on 1st Sept 2017

² Active defined as open to recruitment or in follow-up phase.

03/10/2016	Valid Informed Consent Workshop	Pilgrims Hospice	6
28/10/2016	GCP Refresher	KCH	15
07/11/2016	Fundamentals of Clinical Research	WHH	14
14/11/2016	Fundamentals of Clinical Research	WHH	14
14/11/2016	Intro to GCP	KCH	15
23/01/2017	Intro to GCP	WHH	11
30/01/2017	PI Oversight Master Class	KCH	3
31/01/2017	PI Oversight Master Class	KCH	3
03/02/2017	GCP Refresher	WHH	12
23/02/2017	Building Research Partnerships	WHH	33

Statistical Advice

Statistical advice was provided by Paul Bassett (StatsConsultancy Ltd) to 14 Trust researchers by phone, e-mail and in face-to-face meetings.

Figures

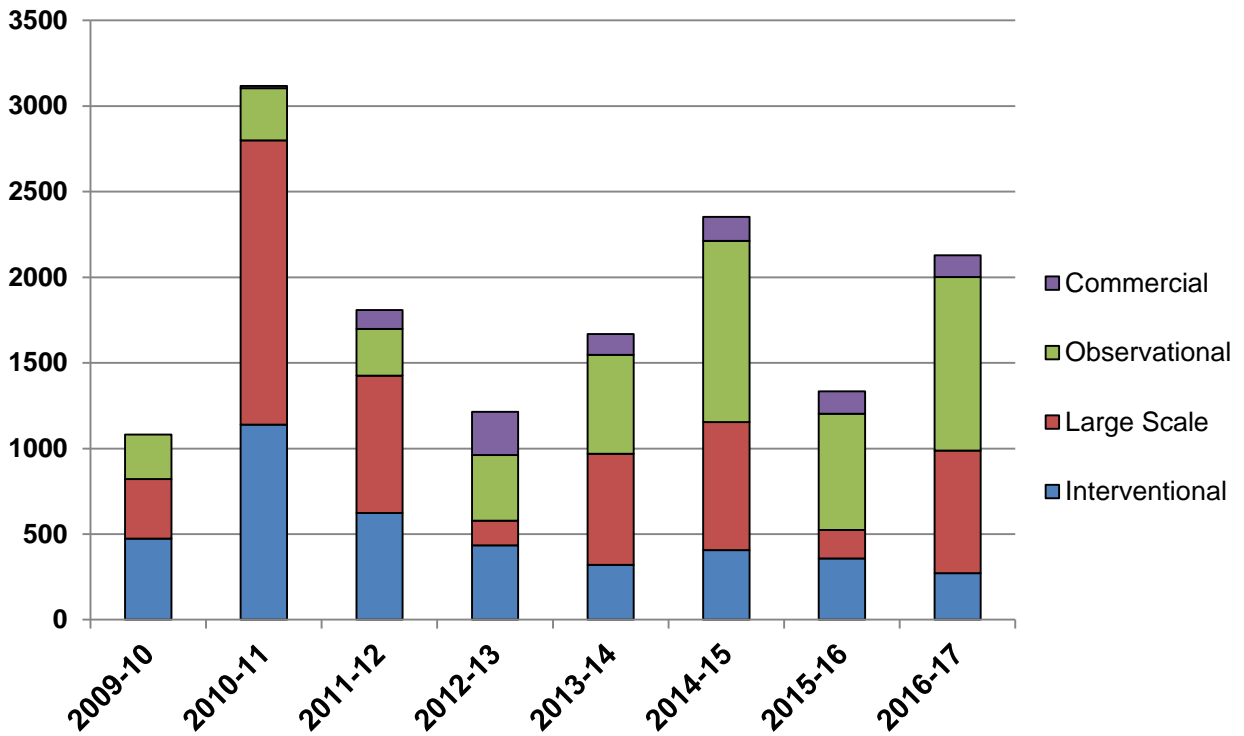


Figure 1. Recruitment to NIHR Portfolio studies by financial year and type of study

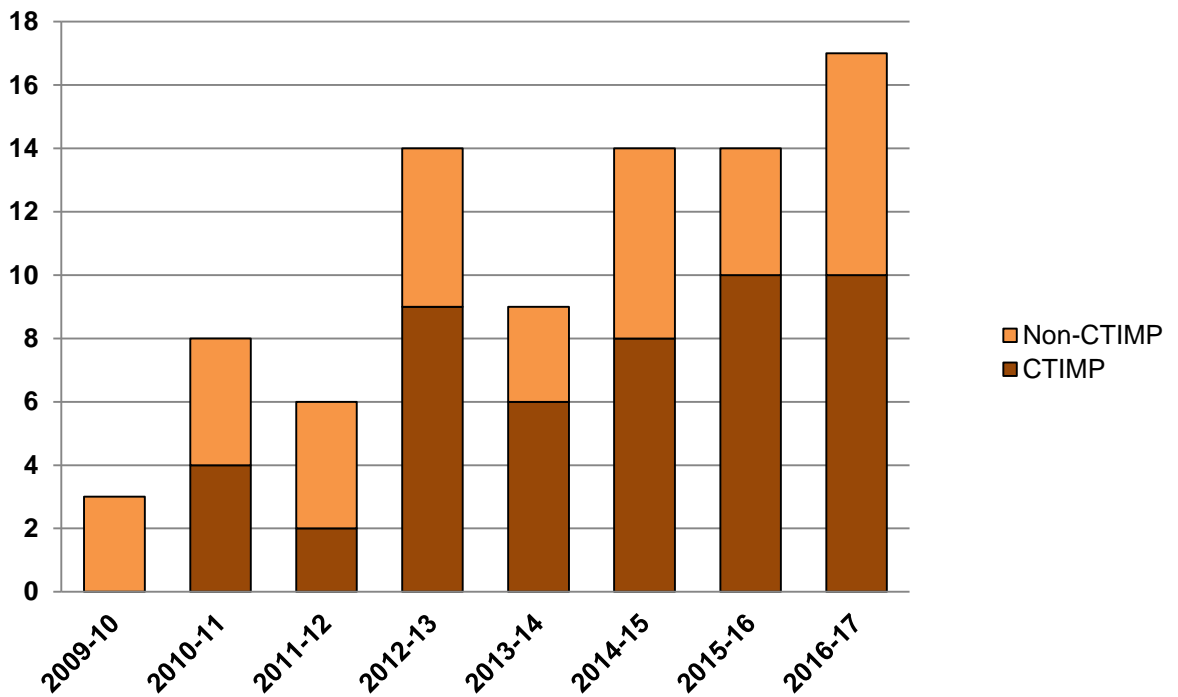


Figure 2. Industry studies opened by financial year

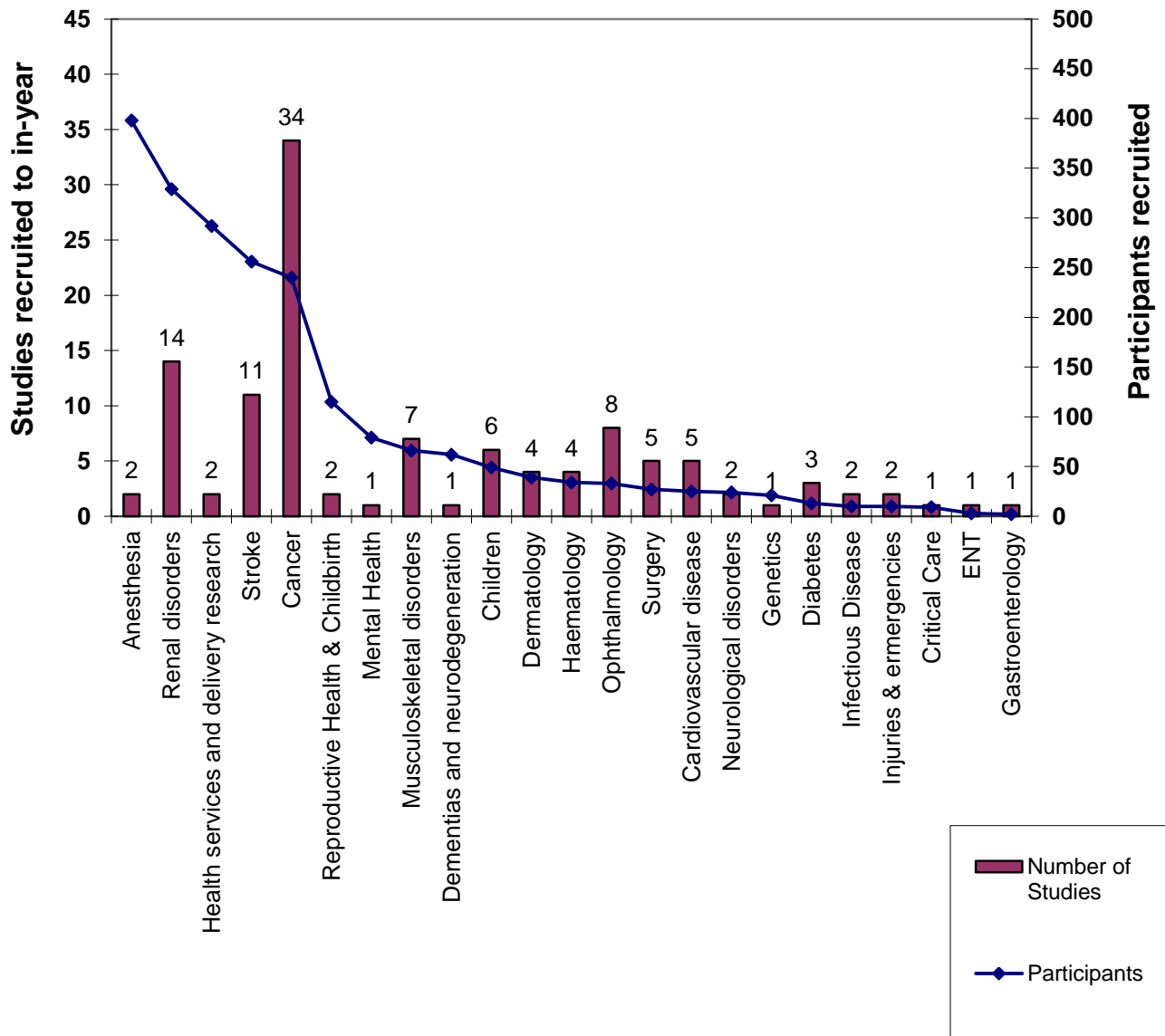


Figure 3. Recruitment and number of studies recruited to by NIHR specialty group (numbers above bars indicates number of studies recruited by each specialty group)

5. Overview of Research Activity during 2016-17 Financial Year

URGENT CARE & LONG TERM CONDITIONS DIVISION

Dr Nick Moran: Neurology research

Dr Moran is the King's principal investigator for the SYNAPS Trial, an MRD-funded multicentre study of rituximab as treatment for psychosis associated with anti-NMDAR antibodies. Dr Moran is the East Kent PI for the CODES Trial which is an NIH-funded multi-centre study the treatment of non-epileptic attack disorder. Dr Moran supervises a PhD student (Kent & Medway School of Pharmacy).

Dr Yvonne Morrissey: Healthcare of Older People research

Evaluation of methods to reduce adverse effects of polypharmacy in older people. Current project is Action Research to reduce admissions and readmissions from Care Homes due to the adverse effects of medication. A multi-disciplinary, multi-agency project with special reference to polypharmacy in Care Homes. Co-lead with Professor Kim Manley, Director of Transformation and Practice development, EKHUFT

Other research output

Y Morrissey, M Bedford, J Irving, C Farmer. How prevalent is hypotension due to medication in older people? Platform presentation at British Geriatrics Society Scientific Meeting, Liverpool May 2016

Dr Jeremy Bland: Clinical Neurophysiology research

Completed recruitment on trial of ultrasound therapy for carpal tunnel syndrome. Follow-up will complete late 2017. Completed recruitment for INDICATE-P trial comparing steroid injection and surgery for CTS with final results expected early 2018.

Other research output

Bland JDP. Focal Neuropathies. In: Mills KR, editor. Oxford Textbook of Clinical Neurophysiology. 1. Oxford: Oxford University Press; 2016.

SURGICAL SERVICES DIVISION

Mr Andrew Dibiase: Orthodontics Research

The focus of the research within the orthodontic department continues to investigate the effectiveness of new treatment techniques and the psycho-social impact of malocclusion. We have just completed a multicentre RCT in collaboration with Guys investigating the use of vibration force to speed up orthodontic tooth movement, the paper from the first part of which was awarded the Chapman Prize for research by the British Orthodontic Society in 2016. We have just submitted the final paper from this study for

publication. The final paper from a national multicentre RCT carried out in collaboration with the University of Manchester, looking at the use of protraction headgear for the treatment of class III malocclusion, was published. Our department was the largest recruiter to this study, which is changing current clinical practice in the UK. We are recruiting to a follow up study looking at the use of bone anchored maxillary protraction again in the treatment of class III malocclusion. Two MSc theses were successfully completed by our trainees, both of which have been published. Finally we are going through HRA approval for a large study looking at the psychological impact of malocclusion in school children which is being carried out in collaboration with the psychology department at Goldsmiths University, London. This has been funded by a grant from the British Orthodontic Society.

Other research output

- European Orthodontic Congress June 2016 Sweden
- British Orthodontic Society Chapman Prize presentation, Brighton Sept 2016

Book Chapters

The use of functional appliances in the correction of Class III malocclusion
In Orthodontic Functional Appliances Theory and Practice
Fleming PF, Lee R
Wiley-Blackwell 1st Edition 2016

Myths and Legends: Unravelling the complex associations between vibrational force, tooth movement and pain with fixed appliances.
Martyn T. Cobourne Andrew T. DiBiase, Neil Woodhouse, Spyridon N. Papageorgiou
In Anecdote, Expertise and Evidence: Applying new knowledge to everyday orthodontics
Kapila SD, Vig KWL, Huang GJ
The University of Michigan Center for Human Growth and Development and the Department of Orthodontics and Pediatric Dentistry 2017

Grant awards during 2016-17 FY

2016 Co-applicant British Orthodontic Society Foundation Grant £22,000 Bone Anchored Maxillary Protraction RCT

New high degree supervision during 2016-17 FY

MSc Kings College London. YouTube™ as an information resource for orthognathic surgery. E. Hegarty

MSc Kings College London A retrospective study comparing the loss of anchorage following the extraction of maxillary first or second premolars during orthodontic treatment with fixed appliances in adolescent patients. S.Hague

Ophthalmology Research



(Left to right: James Rand, Sarah Stirrup, Mr Afsar Jafree, Mr Nishal Patel)

Mr Afsar Jafree, Consultant Ophthalmologist

The STAR study (Kings) is a randomised control trial in Age Related Macular Degeneration (AMD), and looks at the use of stereotactic radiotherapy with patients requiring ranibizumab. We are the second highest recruiter in the country. ARIES (Bayer), a randomised study researching the different treatment patterns in AMD patients being treated with Aflibercept, is in follow-up. Investigating the use of light masks in early diabetic macular oedema (DMO), CLEOPATRA (Moorfields) has just closed at sixth highest recruiter in the country. LEAVO (Moorfields) is in follow-up, another randomised study comparing ranibizumab, aflibercept and avastin in patients with Central Retinal Vein Occlusion (CRVO).

Mr Nishal Patel, Consultant Ophthalmologist

iBOI (Roche), looking at burden of illness in patients with Geographical Atrophy (GA) has just recruited to target and was our fastest ever first patient recruitment, with 'green light' late afternoon and first participant at 10am the next morning! Another Roche sponsored study, PROXIMA, is in follow-up with patients visiting us every 6 months to gather epidemiological data on GA. BVMP (University of Oxford) is open and has Ophthalmology Matron Lynne Hadley as Co-Investigator. It is a randomised controlled trial to assess improved binocular visual function in young patients undergoing monocular cataract surgery with a bifocal intraocular lens. Also open is DRAKO (Bayer), looking at effectiveness of aflibercept in patients with DMO. IRISS (Almeira Sciences) looks at the safety of the Iluvien implant and is in follow-up, after recruiting over target. The Eylea Risk Register (Bayer) is closed above target with 15 participants.

Mr David Schultz, Consultant Ophthalmologist

ASCOT (Moorfields), a double masked randomised control trial studying the use of steroids in vitreoretinal surgery for open globe trauma, is open for participation.



Dr Rosina Zakri, Consultant Ophthalmologist

The SAFARI study (Novartis), looking at Ranibizumab for those patients who do not respond to Lucentis, has recently closed. It recruited over target and was the second highest recruiter in the UK.

Also in setup are two studies with new PIs:

Nick Kopsachilis – our first corneal study with new commercial partner Santen will look at Ikervis in a real world setting, for patients with severe keratitis in dry eye disease.

Hilary Webb – our first paediatric study and first study for Lead Orthoptist Hilary, EuPatch (Leeds Ophthalmology Unit) is studying at the role of glasses wearing in Amblyopia treatment.



Awards

Bayer Ophthalmology Honours 2016 - Sue Walker, Specialist Ophthalmic Science Practitioner and Photographer, Highly Commended, Outstanding Allied Health Professional

Bayer Ophthalmology Honours 2016 - Fran Smith – ECLO – Highly Commended, Best Patient Support Service

NIHR - Nishal Patel - Outstanding contribution to commercial research in Kent, Surrey and Sussex, 2016

EKHUFT R&I Team Awards – Sarah Stirrup – Outstanding Team Member of the Year, 2016

Poster presentations

Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, Baltimore:

- Lee HB, Zakri R and Patel N “Subretinal Hyperreflective Material seen on Optical Coherence Tomography as a Quantitative Biomarker in Retinal Angiomatous Proliferation treated with Intravitreal Ranibizumab”
- Ong BB, Katta M, Yvon C, Lu L and Patel N “SHRM as a biomarker of disease activity in classic and occult AMD subtypes”
- Patel, N on behalf of the Aflibercept Users Group, Medisoft UK “Intensification of Aflibercept monotherapy and outcomes at 24 months in patients with persistent wet AMD”
- Patel N, Sivaprasad S and Talks J “Vision improvement maintained at year 2 in patients with persistent neovascular AMD requiring intensive intravitreal aflibercept monotherapy through week 56”
- Zakri R, Patel N “Analysis of foveal angle after successful VMT detachment”

1st International Swept Source OCT & Angiography conference, Madrid:

- Ong BB, Robson C and Patel N “Correlation between angles in vitreo-macular traction (VMT) with visual acuity”

Invited Speaker

Mr Nishal Patel: “Clinical Trials”, The Macular Society Roadshow, Brighton

Mr Nishal Patel: Guest Speaker, HS-UK Retina Symposium 2017, Manchester

Mr Nitin Shrotri: Urology research

I was invited to moderate at the South African Endourological Society/World Congress of Endourology in Cape Town in November 2016. Having successfully co-hosted an event promoting NIHR Portfolio research in benign urology & uro-gynaecology in December 2016 with Tim Doulton and CRN:KSS, I was invited by the British Association of Urological Surgeons to lecture at their Annual Meeting on the Barriers to a Successful Research Set-Up (<https://youtu.be/ArrJRLQ-Xnw>) and also as an expert panelist on “Upper Urinary Tract Dilemmas: an MDM”. Our multi-centre UK snapshot of patients presenting with renal colic was also accepted at this meeting, where we submitted the second largest number of patient data. An audit of re-attendance following ureteroscopy showed good results and as Joint Lead for Benign Urological Disorders I have been top recruiter in KSS CRN for the multi-center TISU trial.

Presentations

Acute ureteric / renal colic - A UK snapshot June 2015-2016. Marsden T, Turney B, Shrotri N, Bultitude M, Rogers A, Gordon S, Keeley F, Wiseman O, Smith D. British Association of Urological Surgeons, Glasgow. June 2017.

Audit of Re-Attendance Following Ureteroscopy At A UK DGH. Catherine Elizabeth Lovegrove, Rhana Zakri, Ian Rudd, Nitin Shrotri. British Association of Urological Surgeons, Liverpool, UK. June 2016

Patient Satisfaction With Informed Consent On The Day Of Surgery - Catherine Elizabeth Lovegrove, Suna Mantori, Nitin Shrotri. Royal Society of Medicine, London. December 2016

Book Chapter

Shrotri, N. How I Do A TURP. In: Textbook Of Urology, Edited by Rane A et al; Springer Verlag: Published November 2016.

Invited Lectures

Establishing A Successful Research Portfolio In Your Unit - What Are The Barriers To Successful Set-Up? British Association of Urological Surgeons (BAUS) Glasgow – 26/6/17. Invitation received March 2017.

Panellist on Joint Session: Endourology And Oncology: Upper Urinary Tract Dilemmas: An MDM. British Association of Urological Surgeons (BAUS) – 28/6/17. Invitation received March 2017.

Ms Codruta Neumann: ENT Research

OTO-104 Meniere study, a randomised controlled study of transtympanic injection of dexamethasone in gel formulation vs placebo will run until the end of July 2017. Our target of 3 patients recruitment was exceeded (6 recruited). We are starting the follow-on study of open label transtympanic injection of OTO-104 dexamethasone for Meniere's patients from the initial double blind study. The preliminary results are very encouraging in terms of tolerability, safety profile and patient acceptance. Previous open label studies (non-placebo controlled) demonstrated that OTO-104 dexamethasone compares favourably with currently available treatments.

The patients suffering from dizziness in the context of Meniere's and recruited in the study were able to be fast-tracked and receive treatment in a swift manner in a one stop clinic. The transtympanic injections were performed in clinic, under local anaesthetic, and not theatres, freeing time in theatres to treat other patients.

We are embarking on a new NIHR portfolio study on the genetics of cholesteatoma, recruiting families with more than one member affected by cholesteatoma. We are hoping that the results will assist in a better understanding of chronic ear disease and possibly lead to individually tailored management. This will aim to mitigate the effect of a genetic predisposition or allow for a choice of a more aggressive or earlier treatment in predisposed individuals.

Other research output

Invited speaker at ENT Masterclass 3rd Audiology and Balance Masterclass 17th March 2017

ENT Masterclass entmasterclass.com is a group of international reputed ENT specialists from the UK and around the world delivering free of charge training for ENT residents, senior trainees, and specialist nurses. We teach on a variety of subjects including otology, rhinology, laryngology, head and neck surgery, paediatric ENT, balance and dizziness, audiology and medico-legal issues. I have been invited to teach in India, China, Hong Kong, South Africa and Europe as well as the UK. I have been invited to speak in their courses regularly since 2013.



SPECIALIST SERVICES DIVISION

Mr Andy Nordin & colleagues: gynaecological oncology research team

Our gynaecological oncology research team provides opportunities for women diagnosed with ovarian, cervical, endometrial and vulval malignancies to participate in clinical trials. Over the past year we have expanded our portfolio significantly. We have been successfully recruiting to **ICON 8B** which is a Phase II randomised trial for the first line treatment of women with newly diagnosed high risk stage 3-4 epithelial ovarian, fallopian tube or primary peritoneal comparing dose fractionated chemotherapy compared to standard three weekly chemotherapy. We are also running the **NiCCC** trial using Nintedanib vs. chemotherapy for women with clear cell carcinoma of ovary or endometrium. **OCTOPUS** is our newest study, and is a phase II second line trial of weekly paclitaxel +/- AZD2014 for platinum resistant ovarian cancer.

Apart from the ovarian cancer trials we are part of the **European Organisation for Research and Treatment of Cancer (EORTC) Quality of life Group** and have been involved in the development of specific modules relating to gynaecology patients and their wellbeing. For women diagnosed with endometrial cancer we have the **ENGOT 55102**, a randomised trial involving post-operative chemotherapy or no further treatment with node negative stage I-II intermediate or high risk cancer patients.

Our radiology **MrOC** study is looking at the impact of multiparametric MRI on the staging and management of patients with suspected or confirmed ovarian cancer. For those diagnosed with low risk early stage cervical cancer we have the **SHAPE** study which compares a radical hysterectomy and pelvic node dissection vs. simple hysterectomy and pelvic node dissection.

Very soon we hope to open our first ever commercial study **JAVELIN** (Pfizer) using a novel agent AVELUMAB for the treatment of ovarian cancer, which is expected to increase progression free survival by more than 7 to 8 months.

Dr Jindriska Lindsay & colleagues: haematological oncology (blood cancer) research team

During the FY 2016-2017 we had 10 clinical trials open to recruitment; 5 commercial and 5 investigator lead studies. We continued to be the leading recruiters to the **QUAZAR** (AML) and **OPTIMISMM** (Relapsed myeloma) studies in the UK and highest and fourth highest global recruiters respectively.

During the year the team recruited 16 patients into commercial myeloma studies, both frontline and in the relapsed / refractory setting; this has generated an enormous amount of work due to the complexity of the disease and its treatment, the frequency of patient visits and laboratory and radiological monitoring. All these studies enabled patients to gain early access to novel therapies otherwise unavailable.

We were selected and are progressing with the setup of 6 interventional studies which are planned to open Q2-Q3 2017.

We have been working in collaboration with solid tumour research team on the HORIZONS study facilitating the recruitment of patients with high grade lymphoma into this study which looks at the impact of cancer diagnosis and its treatment on quality of life.

EKHUFT haematology consultant Dr Chris Pocock was invited to become the UK Chief Investigator for a global study in frontline acute leukaemia that opened in January 2017.

Other research output

Abstracts presented at EHA Meeting in Copenhagen and ASH Meeting San Diego (including plenary session)

Solid Tumour oncology research team

This year has been challenging for the solid tumour research team but activity has continued to perform well in 2015-16. The total recruitment for oncology research studies within the Trust was 199. Oncology research activity in East Kent Hospitals continue for the majority of tumour types to maximise treatment opportunities for cancer patients.

ADD ASPIRIN: Phase III double-blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours.

Recruitment for ADD ASPIRIN is across 4 cohorts (Breast, Colorectal, Prostate and Upper GI).

In November 2016 East Kent was the top recruiter in Kent, Surrey Sussex with 28 patients over all 4 cohorts. Since then we have recruited a further 6 patients.

DETECT I: A prospective observational study to determine the negative predictive value of UroMark to rule out the presence of bladder cancer in patients with haematuria. Our first study to run with support from the Urology team. The study recruited well and enabled the team to participate in DETECT II.

OPTIMA: Optimal Personalised Treatment of early Breast cancer using Multi-Parameter Analysis

Adjuvant chemotherapy is currently standard practice for patients with node positive early Breast cancer. Current evidence suggests multi-parameter tests are able to predict which patients are likely to benefit from chemotherapy. OPTIMA aims to prove this and hence allow many patients to avoid chemotherapy safely.

SCOT: Short Course Oncology Therapy – A study of adjuvant chemotherapy in colorectal cancer

Six months of oxaliplatin based treatment has been the mainstay of adjuvant chemotherapy for colorectal cancer for the last 13 years. Neurotoxicity from oxaliplatin is cumulative, dose limiting and potentially irreversible. A shorter duration of treatment would save patients significant toxicity / time. The SCOT study has shown that 3 months adjuvant treatment is not inferior to 6 months treatment. Results and questions will be presented at ASCO 2017.

STAMPEDE: Systemic Therapy in Advancing or Metastatic Prostate cancer – Evaluation of Drug Efficacy

The STAMPEDE clinical trial has been recruiting in East Kent since 2009 and in May 2017 the abiraterone comparison results were presented at ASCO and published in the New England Journal of Medicine on 3rd June 2017.

Giving the drug abiraterone acetate and prednisolone alongside standard hormone therapy showed improved overall survival by 37%, failure free survival by 71% and symptomatic skeletal events by 55% with high risk or advanced prostate cancer according to results. This will mean a change in standard of care for men diagnosed with advanced or metastatic prostate cancer allowing them access to abiraterone earlier in their treatment pathway (currently awaiting NICE approval and funding).

Radiotherapy Studies The radiotherapy portfolio continues to grow with 4 studies opened over the past year and a further 2 due to open within the next 2 months.

Renal (kidney disease) research team

'Home grown' research in the NIHR Portfolio

We continue to investigate the value of a novel marker of renal function, serum cystatin C. In 2012 we responded to a Health Technology Assessment call (11/103/01) for funding for a project entitled "Accuracy of glomerular filtration rate (GFR) estimation using creatinine and cystatin C and albuminuria for monitoring disease progression in patients with stage 3 chronic kidney disease: an observational study in a multiethnic population". We were awarded £2m in March 2013 to undertake this work. Recruitment to this study closed in December 2016 with 1249 people having been recruited to six national centres. East Kent was the highest recruiting centre nationally with 298 patients entering the study here, thanks largely to the efforts of our research nursing team and the commitment of our consultants. The focus now shifts to the follow-up phase, with emphasis on keeping patients in the study over the next three years. During this time patients will attend for follow-up visits to record changes in their kidney function, including undertaking further reference kidney function tests (iohexol tests). The study is due to report in summer 2020. The study is complex and represents significant logistical challenges: to date 45,000 aliquots of serum and urine have been prepared from the patients recruited and 1,700 iohexol procedures have been undertaken.

Another high recruiting study, Alpha ("Defining normal bone turnover by mortality risk: a study of bone alkaline phosphatase in haemodialysis patients"), also closed to recruitment in December 2016, having recruited >3,000 haemodialysis patients nationally (>200 in East Kent) from 31 renal centres. This study also now enters a three year follow-up phase in which mortality and morbidity will be recorded and mapped to baseline measures of bone metabolism in the cohort.

Other NIHR Portfolio Studies

A number of our studies are now in follow-up, and include:

- PIVOTAL (non-Industry CTIMP) – Monthly follow-up visits continue for all patients. Baseline data completed, Kent and Canterbury ranked 1st out of all UK sites for completeness of data.
- BiCARB (non-Industry CTIMP) – Follow up due to finish Jan 2019
- RITAZAREM (non-Industry CTIMP) – Follow up due to finish in 2018
- PYRENEES (Industry CTIMP, 100% recruitment to time & target) – One remaining patient remains in follow-up until late 2017
- PEXIVAS (non-Industry CTIMP) – Follow up for the CTIMP closes in Autumn 2017

Studies that remain open to recruitment include:

- PAVE - Major success here! East Kent are currently 2nd highest recruiter to PAVE. To date we have randomised 18 participants and have an excellent system in place to enable us to regularly review new potentials for this important trial comparing drug-eluting vs. conventional angioplasty balloons when used in stenotic (narrowed) arterio-venous fistulae.
- aHUS – 5 recruited
- Calciphylaxis – 5 recruited
- PRED4 – 23 recruited
- Stop ACEi – 7 recruited
- RADAR – 211 recruited
- PDDOPDS – 30 recruited

Dr Tim Doulton (CRN:KSS Joint Specialty Group Lead for Renal Disorders) & Mr Nitin Shrotri co-hosted an event in West Kent in late 2016 to engage and encourage more urology colleagues – especially in West Kent – to become involved in NIHR Portfolio Studies. In addition, our colleagues from other Trusts and the Medway School of Pharmacy provided an overview of some very exciting home grown research that is under way.

Patient & Public Involvement Activities

We have enjoyed continuing to engage with patients, the public and staff to raise awareness of the renal research activities taking place and the opportunities for patients to get involved. We have a regular presence in all of the patient areas in the renal department, including our satellite sites in Medway and Maidstone as well as East Kent inpatient, outpatient and dialysis areas.

We have attended the renal patient support groups and the renal patient education mornings, where patients receive education about the services and treatment options for renal diseases. These events have enabled us to improve our visibility and introduce ourselves to new patients.

We have aimed to reach a wider group of people with our team Twitter account (@ResearchRenalEK) and have over 220 followers including patients and research colleagues. In one of the Trust QII Hubs at the Kent and Canterbury Hospital we promoted kidney health and World Kidney Day to visiting members of staff. We also supported International clinical trials day, talking to the general public in Ashford and Canterbury. Members of our team have also attended the University of Kent engagement day with the U3A. As well as attending the Involving patients & the public in research event, with one of our patients as an invited speaker, which was a great day to network with staff from other organisations and to hear the inspiring stories from patients involved in research.

Dr Vimal Vasu, Shermi George & Claire Moloney: Neonatal medicine research team

The Neonatal units within the Trust continue to be actively involved in clinical research.

NIHR Portfolio studies

ELFIN: This randomised controlled trial is evaluating whether giving very preterm infants supplemental lactoferrin (a natural antibiotic protein from cow's milk) reduces the number of serious infections.

Recruitment is on going and due to complete during 2017. To date, the neonatal unit has recruited 50 patients to this study and is in the top third of recruiting sites nationally.

PLANET2: The aim of this study is to understand better when to give transfusions of platelets to babies with low platelet counts. Recruitment is on going and also due to complete 2017. To date, the neonatal unit has recruited 6 patients to this study, exceeding the study recruitment target.

Future NIHR studies that we will be recruiting to include:

Baby-OSCAR: The aim of this study is to find out whether or not a confirmed large Patent Ductus Arteriosus (PDA) in very premature babies should be treated with ibuprofen within 72 hours of birth. (PI: Dr Amit Gupta)

SPRING study : A pilot study to understand whether preterm infants demonstrate enrichment for genes encoding neurodevelopmental disorders. (PI: Dr Vimal Vasu)

Non-NIHR portfolio studies

MINI study: The aim of this study is to assess the suitability of neonatal urine samples to measure global DNA methylation (completed)

CoNe study: The aim of this study is to better understand parental and professional views regarding consent in neonatal medicine (completed).

Oral presentations

Vimal Vasu. Parent and professional views regarding consent. RCPCH conference, Birmingham, May 2017

Magali Dubus, Vimal Vasu. The effect of prophylactic paracetamol upon post vaccination fever and related adverse events in preterm infants receiving the Bexero© Vaccine. Neonatal Society Summer Meeting, Brighton, 29 June 2017

Invited lectures

National Neonatal Audit Collaborator's Meeting, Birmingham, April 24 2017

Vimal Vasu. Documenting sepsis on the neonatal unit: a challenge for audit and research.

<https://youtu.be/qPfmGk7SmvQ>

Posters

Magali Dubus, Vimal Vasu. Is the Use of Prophylactic Paracetamol to Prevent Febrile Reactions Justified in Hospitalised Ex-Preterm Infants Receiving the New Meningitis B (Bexsero®) Vaccination? Neonatal Society Summer Meeting, Cambridge, July 2016

Hermione Race, Vimal Vasu. The impact of participation in a CQUIN on a term admissions in a term admissions in a tertiary centre. RCPCH conference, Birmingham, May 2017

CROSS-DIVISIONAL ACTIVITIES

East Kent Research team

Over the past year the East Kent Research Team has supported over 30 active studies across multi-speciality areas with at least 10 new studies in set up.

Growth areas for research within EKHUFT during the past year include Anaesthetics/ITU, Infection Control, Pain Management, Neurology & ENT. New studies have been opened in Diabetes, which is a major achievement for the Trust and testament to the persistence of Principal Investigator, Dr Stonny Joseph. He has been very active in seeking out these studies by completing numerous expressions of interest, ultimately on behalf of his patients to enable them to have the opportunity to take part in research. We are working in collaboration with other agencies & organisations including community Trusts and CRN: KSS to identify patients for studies.

In early 2017, the team delivered two very different studies over a three week period to achieve a high level of data collection and participant recruitment. Part of the data from one study will inform the Department of Health about what is required from early pregnancy units across the nation, to improve health care for this vulnerable group of patients. Delivery of both of these studies required a great deal of organisation and working together within the team to work to tight time frames across all three main trust sites. This also gave the opportunity to engage with other Health Care Professionals and spread the word about research is, and what we do within the trust. The end result demonstrated that it was possible to organise and deliver such studies at relatively short notice, and it meant that we exceeded our recruitment target very comfortably for the year end!

As a team, we are keen to engage with the public and Health Care Professionals alike. We have supported the events across the trust for the International Clinical Trials Day. We have dates booked to have sessions in the QII Hubs across the three sites, where we will promote a number of studies taking place across the trust, not only those within our team.

6. Peer-reviewed publications from April 2015 to March 2016

1. Balachandran AA, Wildman SS, Strutt M, Duckett J. Is chronic urinary infection a cause of overactive bladder? *Eur J Obstet Gynecol Reprod Biol.* 2016 Jun; 201:108-12. doi: 10.1016/j.ejogrb.2016.03.024. Epub 2016 Mar 24. Review. PubMed PMID: 27088624.
2. Balogun IO, Brown A, Bertoni M, Webb T, Hargroves D, Pullicino P. A Stroke Registry Data on the Use of Intravenous Recombinant Tissue Plasminogen Activator in Stroke of Unknown Time of Onset. *J Stroke Cerebrovasc Dis.* 2016 Aug; 25(8):1843-50. doi: 10.1016/j.jstrokecerebrovasdis.2016.03.039. Epub 2016 Apr 28. PubMed PMID: 27132489.
3. Balogun IO, Roberts LN, Arya R. Clinical and laboratory predictors of deep vein thrombosis after acute stroke: Does D-dimer really improve predictive power? *Thromb Res.* 2016 Oct; 146:133-134. doi: 10.1016/j.thromres.2016.08.010. Epub 2016 Aug 12. PubMed PMID: 27544034.
4. Balogun IO, Roberts LN, Patel R, Pathansali R, Kalra L, Arya R. Clinical and laboratory predictors of deep vein thrombosis after acute stroke. *Thromb Res.* 2016 Jun; 142:33-9. doi: 10.1016/j.thromres.2016.04.002. Epub 2016 Apr 9. PubMed PMID: 27115860.
5. Balogun IO, Roberts LN, Patel R, Pathansali R, Kalra L, Arya R. Thrombin Generation in Acute Ischaemic Stroke. *Stroke Res Treat.* 2016; 2016:7940680. doi:10.1155/2016/7940680. Epub 2016 Dec 25. PubMed PMID: 28116215; PubMed Central PMCID: PMC5220518.
6. Bland JDP, Ashworth NL. Does prior local corticosteroid injection prejudice the outcome of subsequent carpal tunnel decompression? *Journal of Hand Surgery Eur Vol.* 2016; 41(2):130-6.
7. Bogue P, Bolland M, How P, Benziger H. Pulmonary tuberculosis presenting as post-operative fever of unknown origin. *BMJ Case Rep.* 2017 Jan 6;2017. pii:bcr2016216329. doi: 10.1136/bcr-2016-216329. PubMed PMID: 28062417.
8. Brierley CA, DiBiase A, Sandler PJ. Early Class II treatment. *Aust Dent J.* 2017 Mar;62 Suppl 1:4-10.
9. Burnett AK, Russell NH, Hills RK, Kell J, Nielsen OJ, Dennis M, Cahalin P, Pocock C, Ali S, Burns S, Freeman S, Milligan D, Clark RE. A comparison of clofarabine with ara-C, each in combination with daunorubicin as induction treatment in older patients with acute myeloid leukaemia. *Leukemia.* 2017 Feb;31(2):310-317. doi: 10.1038/leu.2016.225. Epub 2016 Sep 2
10. Carter JL, Parker CT, Stevens PE, Eaglestone G, Knight S, Farmer CK, Lamb EJ. Biological Variation of Plasma and Urinary Markers of Acute Kidney Injury in Patients with Chronic Kidney Disease. *Clin Chem.* 2016 Jun; 62(6):876-83. doi: 10.1373/clinchem.2015.250993. Epub 2016 Mar 29. PubMed PMID: 27026288.
11. Chew FN, Patel N. Optical Coherence Tomography versus Fundus Fluorescein Angiography in Diagnosis of Type 2 CNV in Wet AMD. *Advances in Ophthalmology & Visual System* 2016; Volume 4, Issue 5
12. Cloherty G., Collier L P., Vasu V. Standardising neonatal respiratory support: a quality improvement initiative. *Infant* 2016; 12(6): 208-11.
13. DiBiase A. Orthognathic surgery: principles, planning and practice. *J Orthod.* 2017 Jun;44(2):145

14. DiBiase AT, Woodhouse NR, Papageorgiou SN, Johnson N, Slipper C, Grant J, Alsaleh M, Cobourne MT. Effect of supplemental vibrational force on orthodontically induced inflammatory root resorption: A multicenter randomized clinical trial. *Am J Orthod Dentofacial Orthop*. 2016 Dec; 150(6):918-927. doi: 10.1016/j.ajodo.2016.06.025. PubMed PMID: 27894540.
15. Duhovic C, Maguire B, Birnie A. A giant fungating tumour on the buttock. *BMJ*. 2017 Feb 2; 356:i6440. doi: 10.1136/bmj.i6440. PubMed PMID: 28153831.
16. Duhovic C, Mohsin M, Duarte-Williamson E, Baron S. Written treatment plans in atopic eczema management in children. *Br J Dermatol*. 2016 Dec;175(6):1361-1362. doi: 10.1111/bjd.14651. Epub 2016 Aug 11. PubMed PMID: 27061093.
17. Ferdi A, Kopsachilis N, Parmar D. Phlyctenulosis: a systemic diagnosis made or missed in the blink of an eye. *Clinical and Experimental Optometry* 2016; 100 (3): 285:287
18. George B, Nicholls K, Pompeus S, Vasu V. Providing effective evidence for the coroner. *Arch Dis Child Educ Pract Ed*. 2016 Apr;101(2):82-6. doi:10.1136/archdischild-2015-308584. Epub 2015 Sep 24. Review. PubMed PMID:26405225.
19. Gleeson M, Hawkes EA, Cunningham D, Chadwick N, Counsell N, Lawrie A, Jack A, Smith P, Mouncey P, Pocock C, Ardeshna KM, Radford J, McMillan A, Davies J, Turner D, Kruger A, Johnson PW, Gambell J, Linch D. Rituximab, cyclophosphamide, doxorubicin, vincristine and prednisolone (R-CHOP) in the management of primary mediastinal B-cell lymphoma: a subgroup analysis of the UK NCRI R-CHOP 14 versus 21 trial. *Br J Haematol*. 2016 Nov;175(4):668-672. doi: 10.1111/bjh.14287. Epub 2016 Aug 1.
20. Hadavi M, Hasannia S, Faghihi S, Mashayekhi F, Zadeh HH, Mostofi SB. Novel calcified gum Arabic porous nano-composite scaffold for bone tissue regeneration. *Biochem Biophys Res Commun*. 2017 Jul 8; 488(4):671-678. doi: 10.1016/j.bbrc.2017.03.046. Epub 2017 Mar 14. PubMed PMID: 28302485.
21. Hameso A, Bland JD. Prevalence of decompression surgery in patients with carpal tunnel syndrome 8 years after initial treatment with a local corticosteroid injection. *J Hand Surg Eur Vol*. 2017; 42(3):275-80.
22. Haque S, Sandler PJ, Cobourne MT, Bassett P, DiBiase AT. A retrospective study comparing the loss of anchorage following the extraction of maxillary first or second premolars during orthodontic treatment with fixed appliances in adolescent patients. *J Orthod*. 2017 Jun 8:1-9.
23. Hegarty E, Campbell C, Grammatopoulos E, DiBiase AT, Sherriff M, Cobourne MT. YouTube™ as an information resource for orthognathic surgery. *J Orthod* 2017 Jun;44(2):90-96.
24. Hendra L, Shrestha A, Joshi M, Basu S. Open intraperitoneal onlay mesh repair for medium-large lateral abdominal wall herniae. *Ann R Coll Surg Engl*. 2016 Nov; 98(8):595-596. Epub 2016 Jul 14. PubMed PMID: 27412806; PubMed Central PMCID:PMC5392869.
25. Hossain RR, Moosa AR and Patel N. Automatic versus Manual Segmentation of Choroidal Neovascularisation Lesions using Optical Coherence Tomography. *Advances in Ophthalmology & Visual System* 2017; Volume 6, Issue 1
26. Hussain W, Affleck A, Al-Niaimi F, Cooper A, Craythorne E, Fleming C, Ghura V, Langtry J, Lawrence C, Loghdey S, Naysmith L, Oliphant T, Rahim R, Rice S, Sivaramkrishan M, Stables G, Varma S, Mallipeddi R. Safety, complications and patients' acceptance of Mohs micrographic surgery under local anaesthesia:

results from the U.K. MAPS (Mohs Acceptance and Patient Safety) Collaboration Group. *Br J Dermatol*. 2017 Mar; 176(3):806-808. doi: 10.1111/bjd.14843. Epub 2017 Feb 22. PubMed PMID: 27377192.

27. Jayasundara J, Perera E, Chandu de Silva MV, Pathirana AA. Lymphangioma of the jejunal mesentery and jejunal polyps presenting as an acute abdomen in a teenager. *Ann R Coll Surg Engl*. 2017 Mar; 99(3):e108-e109. doi: 10.1308/rcsann.2017.0012. PubMed PMID: 28252346; PubMed Central PMCID: PMC5450291.
28. Jenkins LA, Mauger A, Fisher J, Hopker J. Reliability and Validity of a Self-paced Cardiopulmonary Exercise Test in Post-MI Patients. *Int J Sports Med*. 2017 Apr;38(4):300-306. doi: 10.1055/s-0042-122818. Epub 2017 Feb 20. PubMed PMID: 28219106.
29. Jones JR, Cairns DA, Gregory WM, Collett C, Pawlyn C, Sigsworth R, Striha A, Henderson R, Kaiser MF, Jenner M, Cook G, Russell NH, Williams C, Pratt G, Kishore B, Lindsay J, Drayson MT, Davies FE, Boyd KD, Owen RG, Jackson GH, Morgan GJ. Second malignancies in the context of lenalidomide treatment: an analysis of 2732 myeloma patients enrolled to the Myeloma XI trial. *Blood Cancer J*. 2016 Dec 9; 6(12):e506. doi: 10.1038/bcj.2016.114. PubMed PMID: 27935580; PubMed Central PMCID: PMC5223149.
30. Kapadia FN, Kapoor R, Trivedi M. Can Less be More in Intensive Care? *Indian J Crit Care Med*. 2017 Jan; 21(1):1-5. doi: 10.4103/0972-5229.198308. PubMed PMID: 28197043; PubMed Central PMCID: PMC5278583.
31. Kibuka M, Thornton JG. Position in the second stage of labour for women with epidural anaesthesia. *Cochrane Database Syst Rev*. 2017 Feb 24; 2:CD008070. doi: 10.1002/14651858.CD008070.pub3. Review. PubMed PMID: 28231607.
32. Lacey JC, Ghatora BK, Foot PJ, Barton SJ, De Cock R. Intraocular Lens Calcification After DSEK: A Mechanism and Preventive Technique. *Cornea*. 2016 Sep;35(9):e28-30. doi: 10.1097/ICO.0000000000000938. PubMed PMID: 27429090.
33. Mandall N, Cousley R, DiBiase A *et al*. Early class III protraction facemask treatment reduces the need for orthognathic surgery: a multi-centre, two-arm parallel randomized, controlled trial. *J Orthod*. 2016 Sep;43(3):164-75.
34. Marsden D, Giles R. The 4C framework for making reasonable adjustments for people with learning disabilities. *Nurs Stand*. 2017 Jan 18; 31(21):45-53. doi: 10.7748/ns.2017.e10152. PubMed PMID: 28097997.
35. Merali N, Yousuff M, Pronisceva V, Poddar A. Paraneoplastic polymyositis presenting as a clinically occult breast cancer. *Ann R Coll Surg Engl*. 2017 Feb; 99(2):e40-e43. doi: 10.1308/rcsann.2016.0301. Epub 2016 Sep 23. PubMed PMID: 27659377; PubMed Central PMCID: PMC5392829.
36. Morrissey Y, Bedford M, Irving J, Farmer CK. Older people remain on blood pressure agents despite being hypotensive resulting in increased mortality and hospital admission. *Age Ageing*. 2016 Nov; 45(6):783-788. Epub 2016 Jun 30. PubMed PMID: 27496937.
37. Oliver G, Jones M. ECG-based PICC tip verification system: an evaluation 5 years on. *Br J Nurs*. 2016 Oct 27; 25(19):S4-S10. PubMed PMID: 27792447.

38. Oliver G. Optimising patient safety when using elastomeric pumps to administer outpatient parenteral antibiotic therapy. *Br J Nurs.* 2016 Oct 27; 25(19):S22-S27. PubMed PMID: 27792443.
39. Oliver G. Transforming IV teams. *Br J Nurs.* 2017 Jan 26; 26(2):S3. doi: 10.12968/bjon.2017.26.2.S3. PubMed PMID: 28132554.
40. Patel P, Rebollo-Mesa I, Ryan E, Sinha MD, Marks SD, Banga N, Macdougall IC, Webb MC, Koffman G, Olsburgh J. Prophylactic Ureteric Stents in Renal Transplant Recipients: A Multicenter Randomized Controlled Trial of Early Versus Late Removal. *Am J Transplant.* 2017 Aug; 17(8):2129-2138. doi: 10.1111/ajt.14223. Epub 2017 Mar 17. PubMed PMID: 28188678.
41. Pohlers S, Martin R, Krüger T, Hellwig D, Hänel F, Kniemeyer O, Saluz HP, Van Dijck P, Ernst JF, Brakhage A, Mühlischlegel FA, Kurzai O. Lipid Signaling via Pkh1/2 Regulates Fungal CO₂ Sensing through the Kinase Sch9. *MBio.* 2017 Jan 31; 8(1). pii: e02211-16. doi: 10.1128/mBio.02211-16. PubMed PMID: 28143980; PubMed Central PMCID: PMC5263247.
42. Pollak TA, Moran N. Emergence of new-onset psychotic disorder following recovery from LGI1 antibody-associated limbic encephalitis. *BMJ Case Reports* 2017; doi:10.1136/bcr-2016-218328.
43. Pottel H, Delanaye P, Schaeffner E, Dubourg L, Eriksen BO, Melsom T, Lamb EJ, Rule AD, Turner ST, Glassock RJ, De Souza V, Selistre L, Goffin K, Pauwels S, Mariat C, Flamant M, Ebert N. Estimating glomerular filtration rate for the full age spectrum from serum creatinine and cystatin C. *Nephrol Dial Transplant.* 2017 Mar 1;32(3):497-507. doi: 10.1093/ndt/gfw425. PubMed PMID: 28089986.
44. Pottel H, Hoste L, Dubourg L, Ebert N, Schaeffner E, Eriksen BO, Melsom T, Lamb EJ, Rule AD, Turner ST, Glassock RJ, De Souza V, Selistre L, Mariat C, Martens F, Delanaye P. An estimated glomerular filtration rate equation for the full age spectrum. *Nephrol Dial Transplant.* 2016 May; 31(5):798-806. doi: 10.1093/ndt/gfv454. Epub 2016 Feb 29. PubMed PMID: 26932693; PubMed Central PMCID: PMC4848755.
45. Relph WL. Addressing the nutritional needs of older patients. *Nurs Older People.* 2016 Apr;28(3):16-9. doi: 10.7748/nop.28.3.16.s22. Review. PubMed PMID:27029988.
46. Relph WL. E-learning to meet a growing need for nutrition and hydration training. *Br J Nurs.* 2016 Oct 13; 25(18):1004. PubMed PMID: 27734736.
47. Singh S, Reddy S, Shrivastava R. Does laminar airflow make a difference to the infection rates for lower limb arthroplasty: a study using the National Joint Registry and local surgical site infection data for two hospitals with and without laminar airflow. *Eur J Orthop Surg Traumatol.* 2017 Feb; 27(2):261-265. doi: 10.1007/s00590-016-1852-1. Epub 2016 Sep 29.
48. Smith T, Streeter E, Choi W, Evans H, Eddy B, Krishnan R, Shrotri N. Are Specialist Nurse-Led Check Flexible Cystoscopy Services As Effective As Doctor-Led Sessions? *International Journal of Urological Nursing* 2016; Vol 10 No 2: 65-67.
49. Tekeli KM, McKenzie J, Goodger NM, Hendy CW. Transplant-related experience in pharyngo-oesophageal reconstruction: use of organ preservation techniques to improve ischaemic tolerance in free jejunal flaps. *Br J Oral Maxillofac Surg.* 2017 Apr;55(3):287-289. doi: 10.1016/j.bjoms.2016.07.023. Epub 2016 Aug 9. PubMed PMID: 27516161.

50. Thomas N, Jenkins K, McManus B, Gracey B. The Experience of Older People in the Shared Decision-Making Process in Advanced Kidney Care. *Biomed Res Int.* 2016;2016:7859725. Epub 2016 Nov 20. PubMed PMID: 27990438; PubMed Central PMCID: PMC5136397.
51. Tsakok T, Marrs T, Mohsin M, Baron S, du Toit G, Till S, Flohr C. Does atopic dermatitis cause food allergy? A systematic review. *J Allergy Clin Immunol.* 2016 Apr; 137(4):1071-8. doi: 10.1016/j.jaci.2015.10.049. Epub 2016 Feb 18. Review PubMed PMID: 26897122.
52. Tsaousis KT, Kopsachilis N, Tsinopoulos IT, Dimitrakos SA, Kruse FE, Welge-Luessen U. In Vitro Study of the Deturgescence Ability of Cultivated Human Corneal Endothelial Cells. *Cornea* 2016; 35 (5): 669-72
53. Tudose A, Hogg FRA, Bland JDP, Walsh DW Electrophysiological/sonographic mapping of the superficial peroneal nerve to facilitate biopsy under local anaesthesia *Br J Neurosurg* 2016; 31(2):264-5
54. Vanzan S, Wilkinson D, Ferguson H, Pullicino P, Sakel M. Behavioural improvement in a minimally conscious state after caloric vestibular stimulation: evidence from two single case studies. *Clin Rehabil.* 2017 Apr; 31(4):500-507. doi:10.1177/0269215516646167. Epub 2016 Jul 10. PubMed PMID: 27121862.
55. Varghese AM, Howard DR, Pocock C, Rawstron AC, Follows G, McCarthy H, Dearden C, Fegan C, Milligan D, Smith AF, Gregory W, Hillmen P; NCRI CLL Sub-Group. Eradication of minimal residual disease improves overall and progression-free survival in patients with chronic lymphocytic leukaemia, evidence from NCRN CLL207: a phase II trial assessing alemtuzumab consolidation. *Br J Haematol.* 2017 Feb;176(4):573-582. doi: 10.1111/bjh.14342. Epub 2016 Dec 29.
56. Vasu V, Turner KJ, George S, Greenall J, Slijepcevic P, Griffin DK (2017) Preterm infants have significantly longer telomeres than their term born counterparts. *PLoS ONE* 2017; 12(6): e0180082. <https://doi.org/10.1371/journal.pone.0180082>
57. Vatopoulou T, Lawson C, Pocock C. A case of Stage IA classical Hodgkin lymphoma with FDG-avid tonsils. *Br J Haematol.* 2016 Apr;173(2):178. doi: 10.1111/bjh.13953. Epub 2016 Feb 12. PubMed PMID: 26872151.
58. Westergreen-Thorne M, Lee SY, Babawale K, Lovegrove C, Brewer J, Shrotri N. Comparing The Diagnostic Accuracy Of Ultrasound In The Community And In The Hospital Setting For Urinary Calculi: A Retrospective Cohort Study. *Journal of Clinical Urology* 2017; Mar; Vol 10, Issue 2, 133-136.
59. Witham MD, Lamb EJ. Should chronic metabolic acidosis be treated in older people with chronic kidney disease? *Nephrol Dial Transplant.* 2016 Nov;31(11):1796-1802. Epub 2015 Sep 28. Review. PubMed PMID: 26420895.
60. Yang Y, Downey L, Mehta H, Mushtaq B, Narendran N, Patel N, Patel PJ, Ayan F, Gibson K, Igwe, F and Jeffery P Resource Use and Real-World Outcomes for Ranibizumab Treat and Extend for Neovascular Age-Related Macular Degeneration in the UK: Interim Results from TERRA Ophthalmology and Therapy 2017; 6:175–186
61. Youssef A, Hamade A. Pheochromocytoma: A Cause of Anemia. *Urol Case Rep.* 2017 Jan 28; 11:53-54. doi: 10.1016/j.eucr.2016.12.005. eCollection 2017 Feb. PubMed PMID: 28149750; PubMed Central PMCID: PMC5279738.

Appendix: Financial report - April 2016 to March 2017

CRN: KSS – 2016 -2017

The tabulation below reflects the notified baseline allocation for the CRN: KSS contract for the financial year 2016 – 2017

Annual Allocation £000's	Pay	Vacancy Factor	Total Pay	Non pay	Host Fees	Total	%
Nursing	655	(22)	633	10	33	677	56%
AC Support	255	(9)	246	4	13	263	22%
Pharmacy	216	(7)	209	3	11	223	19%
sub-total	1127	(38)	1089	18	57	1163	
Radiology				23		23	2%
Pathology				20		20	2%
Total Core Funding	1127	(38)	1089	62	57	1207	100%
Specialty Leads	18		18			18	
Research Capability Funding	30		30			30	
Contingency							
Strategic Investment	46		46			46	
Other Funding							
Total Additional Funding	94		94			94	
In-year adjustment							
Overall CRN:KSS Allocation	1221	(38)	1182	62	57	1300	

CRN: KSS Financial Position

The financial position to Month 12 reports an adverse variance @ £42k year to date

£000's	Annual Budget	Annual Actual	Annual Var
Nursing	655	673	(17)
AC Support	255	271	(16)
Pharmacy	216	208	8
Vacancy factor	(38)		(38)
sub-total Pay	1089	1152	(64)
Non Pay	18	18	
Host Fees	57	57	
sub-total Other	75	74	
Radiology	23	11	13
Pathology	20	25	(5)
sub-total SSDs	44	36	8
Total Core Funding	1207	1262	(56)
Specialty Leads	18	18	
Research Capability Funding	30	30	
Contingency			
Strategic Investment	46	32	13
Other Funding			
Total Additional Funding	94	80	13
In-year adjustment			
Overall CRN Allocation	1300	1343	(42)
Cumulative variance as a % of gross budget			(3.24%)

The over-spending on pay is mainly due to a combination of incremental drift and applied vacancy factor.

There is no negative impact on the Trust as Directorate reserves have been utilised to offset this overspend.

Other Income/Direct Receipts (Non-CRN)

A comparison between financial years for Q1 – Q4 is illustrated below:

£000's	Yr 2015 - 2016					Yr 2016 - 2017				
	Q1	Q2	Q3	Q4	Total	Q1	Q2	Q3	Q4	Total
Source										
Research Capability Funding	(25)	(25)	(25)	(25)	(99)	(17)	(17)	(17)	(17)	(69)
NIHR Projects	(203)	(9)	(65)	(39)	(316)	(130)	(81)	(64)	(64)	(338)
MRC/Other/Non-commercial	(36)	(38)	(16)	(88)	(178)	(26)	(49)	(22)	(22)	(120)
Commercial	(146)	(195)	(278)	(109)	(729)	(188)	(491)	(184)	(158)	(1022)
Total	(409)	(267)	(384)	(261)	(1321)	(362)	(639)	(287)	(261)	(1548)

Total Other Income receipts for Yr 2016 – 2017 increased by £227k (17%) compared to the previous Yr 2015 - 2016

Commercial income for Q1 – Q4 can be broken down as follows:

£000's	Yr 2016 - 2017				
	Patient Activity etc	Drugs Etc	Equipment	Total	%
Commercial Income					
Clinical Haematology	(475)	(231)		(706)	69%
Ophthalmology	(54)	(1)	(83)	(138)	13%
Stroke	(45)	(1)		(46)	4%
Clinical Oncology	(25)	(40)		(64)	6%
Other	(61)	(8)		(68)	7%
Total	(658)	(280)	(83)	(1022)	100%

CRN: KSS – 2017 – 2018 Contract Baseline

Annual Allocation
£000's

	Pay	Vacancy Factor	Total Pay	Non pay	Host Fees	Total	%
Nursing	586	(24)	562	10	33	605	54%
AC Support	249	(10)	239	4	13	256	23%
Pharmacy	212	(9)	203	4	11	218	19%
sub-total	1047	(42)	1004	18	57	1079	
Radiology				23		23	2%
Pathology				20		20	2%

Total Core Funding	1047	(42)	1004	61	57	1122	100%
--------------------	------	------	------	----	----	------	------

Overall CRN:KSS Allocation	1047	(42)	1004	61	57	1122	
----------------------------	------	------	------	----	----	------	--

The above allocation has been distributed to budget headings for the new financial year.

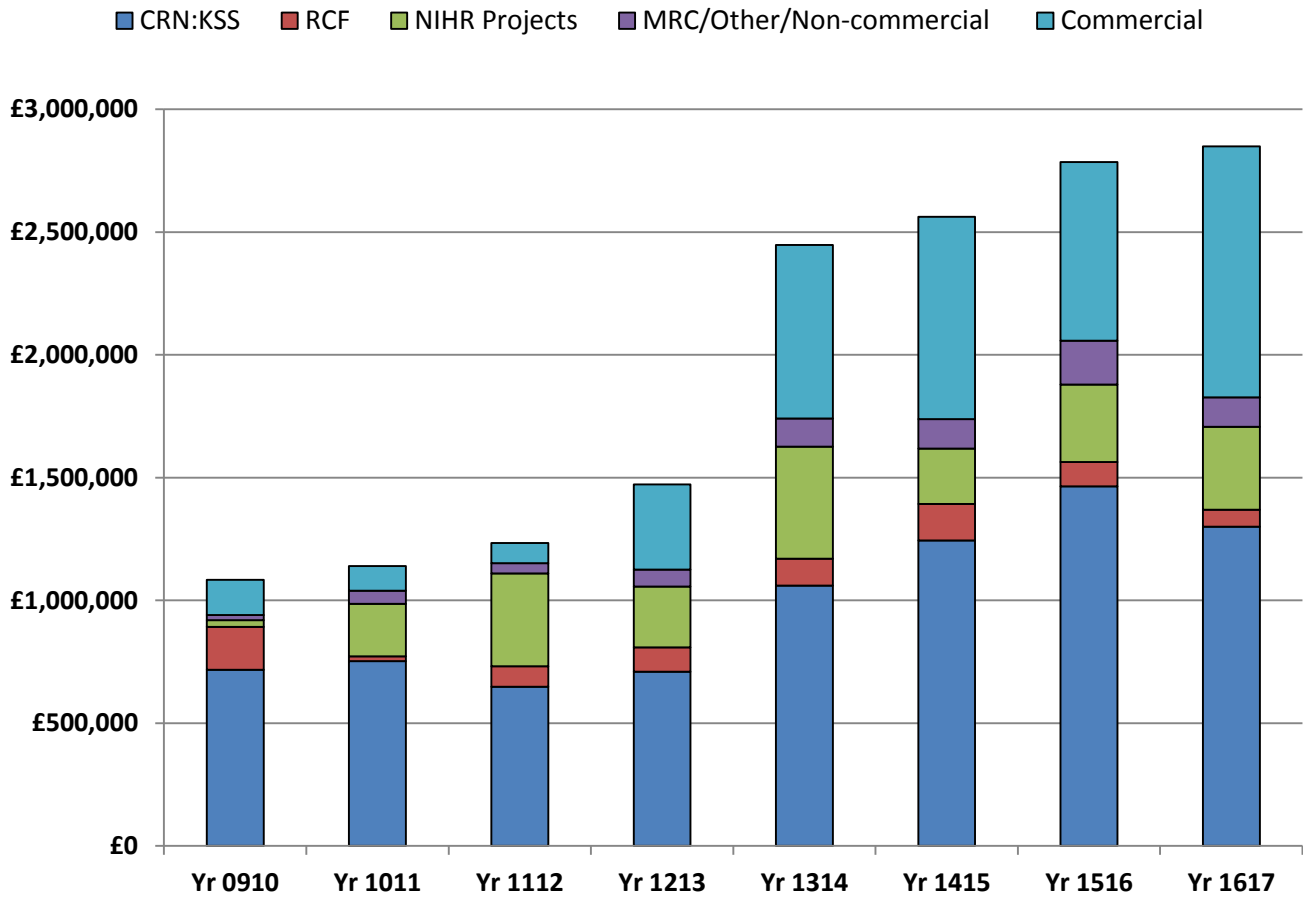


Figure. Breakdown of sources of R&I income by source and financial year

Jacky Douglas
 R&I Finance Manager
 27 September 2017