



## **Research & Development Department**

**Annual Report 2015-16**

## **Foreword**

The challenge we have faced this year is maintaining the momentum we achieved last year in recruitment to NIHR Portfolio studies. When taken at face value our overall recruitment in 2015-16 was somewhat disappointing. However, we have maintained recruitment to 112 studies across 18 different disease areas, our overall research related income has increased, we have maintained our industry study activity, and our researchers continue to win substantial grant awards and achieve national recognition for their work.

Enhanced engagement – with patients, public, colleagues and external stakeholders – is a national ‘must-do’ and is a major priority for us. To that end we were delighted to appoint two patient volunteers, Karen Barnes and Ian Danks, to advise and assist us with our work in many different areas. Moreover, in January 2016 we held a very well event at University of Kent where we came together with many of our stakeholders to begin development of our research and innovation (R&I) strategy for 2016-19. This work is now complete, and will be presented to the Board of Directors for approval in Autumn 2016.

Our vision for R&I will be “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”. We believe our strategy will provide renewed focus and enable us to build upon our many successes over the last three years, and will lay the ground for us delivering more home grown research to the benefit of our East Kent population.

**Dr Tim Doulton**  
**Director of Research & Development**  
**September 2016**

(Front cover picture: Dr David Stephensen, physiotherapist, with young research participant Charlie)

## Contents

Foreword	2
Contents & acknowledgments	3
Executive summary	4
Key events in R&D during 2015-16 financial year	5
Public & Patient Involvement & Engagement	8
R&D metrics	9
Overview of research activity during 2015-16 financial year	12
Neurophysiology: Dr Jeremy Bland	12
HCOOP: Dr Yvonne Morrissey	12
Stroke: Dr Tom Webb & colleagues	13
Orthodontics: Mr Andrew DiBiase	14
Ophthalmology: Mr Afsar Jafree and Mr Nishal Patel	14
Haematological oncology: De Chris Pocock & Dr Jindriska Lindsay	16
Oncology	16
Neonatology: Dr Vimal Vasu	16
Haemophilia: Dr David Stephensen & Dr Gillian Evans	17
Kidney (renal): Dr Edmund Lamb, Prof Chris Farmer, Dr Tim Doulton & colleagues	20
Ms Karen Jenkins	22
Paediatric OT: Dr Eve Hutton	23
Clinical Biochemistry: Dr Edmund Lamb	24
Clinical Quality: Prof Kim Manley	25
East Kent Research Delivery Team	27
Joint Community-EKHUFT Research Post	27
List of peer-reviewed publications from Trust researchers (April 2015 to March 2016)	29
Appendix: Finance Report	35

## Acknowledgements

I would like to express my thanks to all those PIs 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 1315 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 a 44% decrease on 2014-15.
2. During 2015-16 there were 86 studies given NHS R&D approval by the Trust of which 45 were NIHR Portfolio studies. Of the 86 newly opening studies, 20 were clinical trials of investigation medicinal products (CTIMPs) and 14 were industry-funded/-sponsored studies.
3. Notable successes by Trust staff included: Dr David Stephensen (RfPB grant, c. £250k), Dr Susannah Baron (British Association of Dermatology/NIHR Research Award); Dr Chris Farmer (appointed Clinical Professor of Medicine at University of Kent).
4. We appointed two patient volunteers, Karen Barnes and Ian Danks, to advise and assist us with our work in many different areas.
5. A number of events co-ordinated by the R&D Department took place during the year. These included: the R&D Annual Symposium, held at Harvey Hall, K&CH on 19<sup>th</sup> May 2015 and the EKHUFT R&D strategy workshop, held at University of Kent on 15<sup>th</sup> January 2016.
6. Total income received on behalf of R&D during the year was £2.78m. Industry-derived income decreased 11.5% to £729k.
7. During 2015-16 financial year the Trust received £1.88m from NIHR/DH (via Research Networks and directly). This included £98,935 from DH Research Capability Funding compared to £148,559 in 2014-2015.
8. R&D oversaw distribution of funds totalling £54,581 to Trust staff via the Internal Projects Grant and Research Session Schemes.
9. During 2015-16 Trust researchers published 68 articles in peer-reviewed journals.
10. 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 3 days.

## **2. Key Events in R&D during the 2015-16 Financial Year**

### **Strategy Workshop**

We held a very successful event at University of Kent on 15<sup>th</sup> January 2016, to which we invited stakeholder representatives from EKHUFT, local NHS organisations, local universities, Clinical Research Network: Kent Surrey Sussex, KSS Academic Health Sciences Network and Industry, as well as patient representatives. Sixty five attendees participated in plenary and small group sessions, the output from which has been extensively developed by our strategy working group to deliver an inclusive and comprehensive Research & Innovation strategy for 2016-19, which we plan to unveil in Autumn 2016.

### **Appointment of Chris Farmer as Clinical Professor at University of Kent**

We were delighted to hear of Chris Farmer's appointment as Clinical Professor at University of Kent. Chris has been a Consultant in renal medicine at East Kent Hospitals University NHS Foundation Trust for the past thirteen years. He has recently stepped down from the post of Associate Medical Director which he held for eight years, this is in order to take up a position as Clinical Professor at The Centre for Health Services Studies at The University of Kent. Throughout his medical career Chris has had a keen interest in clinical research including clinical trials, laboratory studies and large scale epidemiological research. Recently he has also been involved in studies examining the use of informatics in healthcare. He has fifty publications and has presented over one hundred times at national and international conferences, including plenary sessions and invited lectures. His work has informed national policy in the field of renal medicine.

Chris Bown, EKHUFT interim CEO said: "I am delighted by Chris's appointment as Clinical Professor in The Centre for Health Services Studies at The University of Kent. Chris is, and will continue to be, one of EKHUFT's most prodigious researchers. Chris has developed many fruitful collaborations with local Universities and other organisations and has an highly impressive track record in publication output, MD & PhD supervision and grant acquisition. He has achieved this alongside a busy clinical workload and highly demanding senior management position as Associate Medical Director for IT. I wish him all the very best in his new role, and look forward to his appointment bringing ever closer working between EKHUFT and University of Kent."

### **NIHR Research For Patient Benefit (RfPB) award to Dr David Stephensen**

Dr David Stephensen (Physiotherapist, Haemophilia Centre, K&CH – picture on front of this report) and co-researchers at the Royal London Hospital have been awarded £249,987 for Development Of a haemophilia Physiotherapy Intervention for optimum musculoskeletal health (DOLPHIN) – a feasibility study prior to conducting a randomized controlled trial.

Haemophilia is an inherited disorder affecting 1 in 10000 boys (only males are affected) where blood does not clot normally, leading to bleeding into muscles and joints. This results in muscular weakness and joints that are painful and difficult to move. David & colleagues recent work shows performance of everyday tasks such as walking, going up and down stairs and balancing on one leg are negatively affected and depend on muscle strength. David says "being able to participate in games and activities with their friends is one of the things that matters most to boys with haemophilia".

To evaluate the effectiveness of a muscle strengthening exercise intervention – for which there is currently a lack of evidence of benefit – with a randomised controlled trial (RCT) we estimate that 104 children would need to be recruited, requiring a multi-centre trial across many sites owing to the rarity of the condition. The aim of this project is to determine if it is feasible to conduct a full RCT. Firstly, we will develop an optimum exercise intervention by consulting experienced clinicians together with haemophiliac boys and

their families. Once developed, we will conduct a feasibility study of 20 boys at 2 sites to assess recruitment potential and retention, exercise adherence, safety and appropriateness of tests to measure outcomes. In addition, we will derive precise estimates of the sample size required and the relevant costs associated with delivering the intervention prior to conducting a clinical trial to test its effectiveness. Ultimately it is hoped this will result in EKHUFT leading a UK-wide trial.

**NIHR/British Association of Dermatology award to Dr Susannah Baron**

Dr Baron (right, pictured with colleague Dr Emilia Duarte-Williamson) was delighted to have been awarded the NIHR/British Association of Dermatologists 2015 award, which is given for an outstanding contribution to NIHR Dermatology studies.



Susannah said: “This has been a team effort and due to the hard work of the Research Nurses, Research team, the Dermatology team and our patients. I have been able to develop and expand our Dermatology research activities since being appointed Dermatology Research Lead for EKHUFT in November 2014. Our research portfolio is diverse and we are involved in industry and non-commercial studies in psoriasis, atopic eczema and food allergy, vitiligo, rosacea, chronic urticaria and new biologic medication for psoriasis. Despite having less than five full-time consultants, with 22,000 patient episodes per year, four consultants are now Principal Investigators (PI), I am PI for 5 studies, both of our Dermatology Speciality Registrars are co-investigators and all our clinical staff are research aware so enabling our patients to be fully involved in clinical research. Our department is now the lead recruiter for dermatology studies within the Clinical Research Network for Kent, Sussex and Surrey (CRN:KSS).”

**International Clinical Trials Day – 20<sup>th</sup> May 2015**

International Clinical Trials Day is celebrated around the world on or near the 20<sup>th</sup> May each year to commemorate the day that James Lind started his famous trial on the deadly disease scurvy. It provides a focal point to raise awareness of the importance of research to health care, and highlights how partnerships between patients and healthcare practitioners are vital to high quality, relevant research.

This year, we hosted a stand all day in the restaurant where we raised awareness of our fantastic achievements over the past year. We also used the opportunity to promote ‘Join Dementia Research’ ([www.joindementiaresearch.nihr.ac.uk](http://www.joindementiaresearch.nihr.ac.uk)) - a national service that offers people the chance to register their interest in taking part in dementia research, find suitable studies in the area, and let researchers know that they might be interested in taking part in their research.

Many of our research staff also took part in the #WhyWeDoResearch social media campaign during the day (right).



## Achievement of Global First Patient Recruitment by Haematological Oncology Team

Dr Chris Pocock and colleagues recruited the first patient globally to the Gilead 1580 study in follicular lymphoma – a fantastic achievement.

## REX Rapper Robot featured on ITV's Meridian News

Research work resulting from a collaboration between Dr Mohammed Sakel, Consultant in Neurorehabilitation, Dr Matthew Pepper & EKHUFT's medical physics department, industry partner REX Bionics and colleagues at University of Kent was featured on ITV's Meridian News early in 2016. The project – adopted into this NIHR Portfolio – is a 'Safety and Feasibility Evaluation of Robot Assisted Physiotherapy Exercises with REX'.

The innovative exoskeleton is designed to aid walking in people who usually rely on wheelchair due to injury to spinal cord from any cause. Any volunteers within UK are welcome to participate.



## Annual Symposium

The R&D Annual symposium took place on 19th May 2015 in the Harvey Hall, Postgraduate Centre, K&CH. There were 43 attendees. The winner of the prize for best oral presentation was Helen Hobbs (Renal, K&CH) and the best poster prize award went to Dr Yvonne Morrissey (Healthcare of Older People, K&CH).

## Internal Project Grant Scheme 2015-16

Using funding from NIHR Research Capability Funding (RCF) the Internal Project Grants Scheme (IPGS) and Research Session Scheme (RSS) were able to support the following Trust staff:

Applicant	Title of Study	Amount Awarded	Duration	Start Date	IPGS/RSS
Ms Emma Palmer Occupational Health Nurse	Singing for staff wellbeing	£12,743	1 year	04/01/2016	IPGS
Dr Jeremy Bland Consultant Neurophysiologist	A clinical and research database for carpal tunnel syndrome	£15,000 (part funding)	1 year	16/04/2015	IPGS
Mr Nishal Patel Consultant Ophthalmologist	Various NIHR Portfolio studies	1 PA	1 year	1/10/2015	RSS

### 3. Patient & Public Involvement & Engagement

The Trust committed to patient and public involvement & engagement (PPIE) in research. We seek to promote the research that we do, encourage greater recruitment of patients into our studies, to disseminate our findings and to promote evidence based clinical practice.



To facilitate this, in June 2015, we appointed our first two patient representatives, Karen Barnes & Ian Danks, on a voluntary basis to assist in the engagement, communications and public relations aspects of the R&D department. Both individuals brought with them extensive experience as patients within the NHS, as well as relevant knowledge & skills from various business areas within both the public and private domains, as well as third sector organisations.

Throughout the year, various initiatives have begun. A PPIE

Steering group has been formed which meets every 2 to 3 months and is chaired by the Lead Research Nurse. Membership includes the R&D Directors, as well as key individuals from the EKHUFT Communications team. The group is focusing on engagement and communication both internally and externally to raise the profile of the work we do. A half-day event entitled 'Making a Difference with Research' is planned for June 2016 to which local patients, public & staff will be invited. Work has also started on rebranding, refreshing the R&D pages of the website to make these more 'patient- friendly' and rolling out a thank you letter to all patients who take part in research within the Trust which will also incorporate a patient feedback survey.





## 4. R&D Metrics

### Study activity

During 2015-16 the Trust had 387 active research studies including 272 NIHR Portfolio studies that were open to new participants, with the remaining 115 studies being non-Portfolio studies or “own account” studies. Included within our active studies were 121 clinical trials of investigation medicinal products (CTIMPs). Currently, the Trust has 68 industry-funded and/or -sponsored studies active of which 57 are Portfolio and 11 non-Portfolio studies.

The Trust R&D Department issued approval for 86 new studies between 1st April 2015 and 31st March 2016 (45 NIHR Portfolio and 41 non-Portfolio), of which 23 were “Grey Area Projects”, 20 were CTIMPs and 14 were industry-funded/sponsored studies.

### Participant Accrual

The Trust recruited 1315 participants to NIHR Portfolio studies compared to 2353 participants in 2014-15, a reduction of 44%. However, we have continued to maintain a healthy balance with complex interventional (usually randomized controlled) and more straightforward observational and large-scale studies (Figure 1).

### 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 2015-16 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

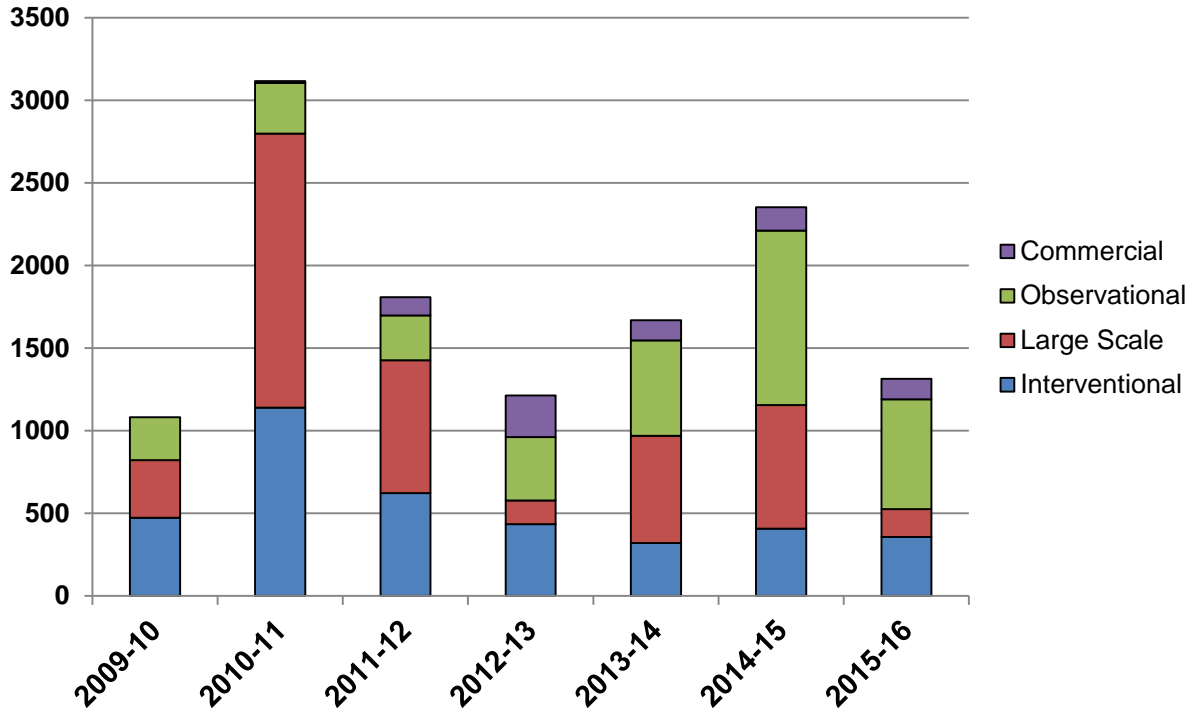
Research-related income to the Trust was similar to that seen last year (£2.78m vs. £2.56m in 2014-15) with Industry related income down 11.5% to £7293k. During the year the Trust was allocated £98,935 by the Department of Health for its Research Capability Funding, and this supported NIHR faculty members (present and future) directly and via the Trust’s Internal Project Grants Scheme (IPGS) and Research Sessions Scheme (RSS).

### GCP & R&D training for staff

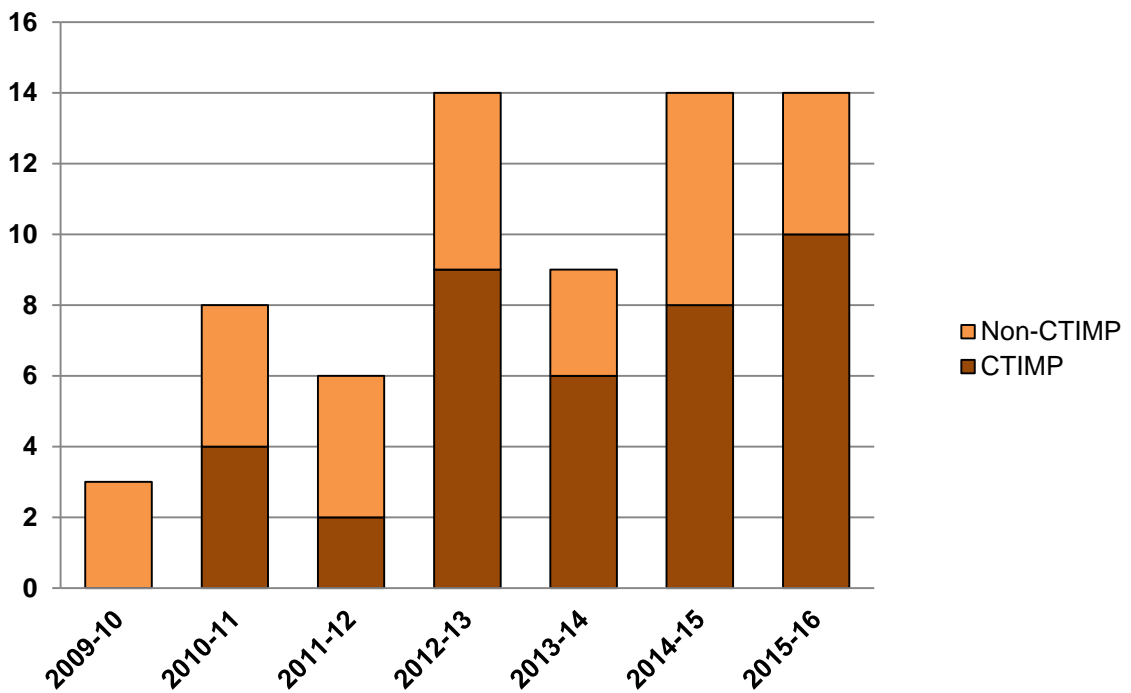
Training session	Date	Venue	Participants
R&D Workshop	27/04/2015	Post Grad QEQM	9
GCP Intro training	28/04/2015	Board room KCH	6
GCP Intro training	27/08/2015	KCH	
R&D Invoicing Workshop	28/05/2015	KCH	10
GCP Intro training	27/08/2015	KCH	16
GCP refresher training	06/10/2015	WHH	
GCP Intro training	09/11/2015	WHH	15
GCP Refresher training	06/10/2015	WHH	14
Introduction to the NIHR & CRNs	07/10/2015	WHH	17
GCP Refresher training	14/10/2015	Pilgrim’s Hospice, Canterbury	8
Fundamentals of Clinical Research (2 days)	14/12/2015 21/12/2015	WHH	13
Valid Informed Consent Workshop	22/01/2016	WHH	19
Dry Ice Training & Safety Workshop	18/02/2016	WHH	24
GCP Refresher training	26/02/2016	WHH	15

**Statistical Advice**

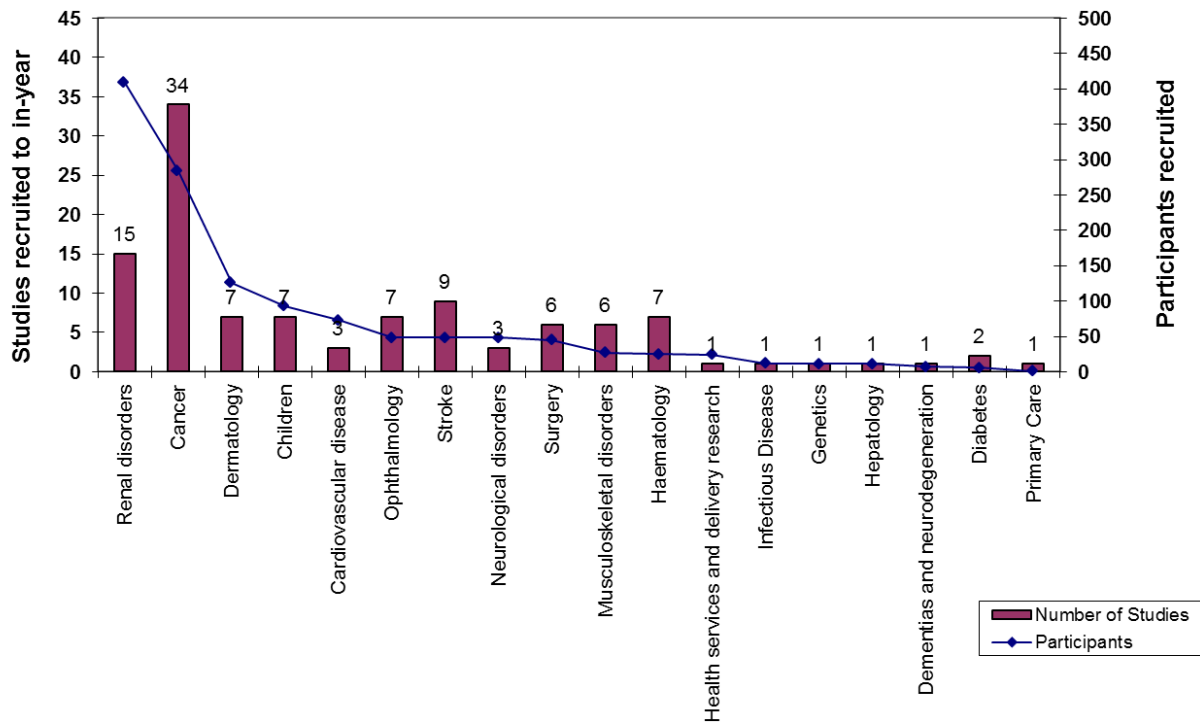
Statistical advice was provided by Paul Bassett (StatsConsultancy Ltd) to 9 Trust researchers by phone, e-mail and in face-to-face meetings.



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



**Figure 2.** Industry-funded and/or -sponsored studies opened in each financial year



**Figure 3.** Recruitment and number of studies recruited to by NIHR specialty group

## **5. Overview of Research Activity during 2015-16 Financial Year**

### **URGENT CARE & LONG TERM CONDITIONS DIVISION**

#### **Dr Jeremy Bland, Clinical Neurophysiology, Neurology**

Recruitment has continued to a study of ultrasound treatment for carpal tunnel syndrome (CTS) and has now reached 34 out of 40 participants. The department has joined a multicentre pilot study comparing injection to surgery in CTS (INDICATE-P) and has exceeded its recruitment target for this study (13 from 10 planned participants). The department gained an award from the Trust's Internal Project Grant Scheme to aid in conversion of the EEGSYS database, on which most of our research is based, and work on this project has commenced. Much of the work done this year has been preparatory – an application for generic ethics approval for the use of the EEGSYS database in research (still pending), an application to RFPB for a grant to fund a prospective study of serial injection as a treatment for CTS (decision due in June 2016) and a preliminary cohort study of patients beginning treatment with steroids for CTS in 2007 (submitted for publication). We are also in discussion with two NIHR portfolio studies which are already in funded/in progress which Canterbury would join as secondary centres – CAPS (Carpal tunnel syndrome, An investigation of the impact of neuropathic Pain and Somatosensory phenotype – Imperial College London) and REACTS (Return to Employment After Carpal Tunnel Surgery – Southampton University). Our website devoted to carpal tunnel syndrome at [www.carpal-tunnel.net](http://www.carpal-tunnel.net) remains a highly rated and popular public information source for all matters relating to carpal tunnel syndrome, attracting approximately 10,000 visitors per week worldwide.

#### **Other research output**

One presentation was given to the British Society for Clinical Neurophysiology of the preliminary results of the 2007 cohort study.

Invited lectures were given to the Association of Chartered Physiotherapists with an interest in orthopaedic medicine and injection therapy and to the British Association of Hand Therapists

#### **Grant awards during 2015-16**

EKHUFT Internal project grant scheme £15,000 – 1 year

#### **Dr Yvonne Morrissey, Consultant in Healthcare of Older People**

I have been working with Professor Chris Farmer and team to explore ways to tackle the problem of polypharmacy in older people which leads to hospital admissions and other adverse events. The work we have done to date has identified that a significant number of older people on blood pressure medication actually have low blood pressure. This is an important finding as it points to the importance of regular medication reviews in older people so as to prevent low blood pressure which can be associated with dizzy spells and falls especially in patients with comorbidities.

Our research has been presented at scientific meetings locally and nationally and we have been awarded two prizes (Best Poster and Best Platform presentation – see below). A resulting paper will be published in 2016.

I have also been working with Professor Kim Manley with whom I am co-leading an action research project to reduce adverse effects of polypharmacy in care homes. This is a multi-disciplinary project involving

cross-sector stakeholders and we have now been given ethical approval to commence a pilot study in a local care home.

### **Poster presentations**

Yvonne Morrissey, Michael Bedford, Jean Irving and Chris Farmer. Polypharmacy in the Elderly is Associated with Increased Mortality and Acute Kidney Injury. Presented at 52<sup>nd</sup> European Renal Association Congress May 30th 2015.

Yvonne Morrissey, Michael Bedford, Jean Irving and Chris Farmer. Polypharmacy in the Elderly is Associated with Increased Mortality and Acute Kidney Injury. Presented at EKHT Research and Development Symposium May 2015. Awarded “Best Poster” prize.

### **Oral Presentations at Scientific Meetings**

Y Morrissey, M Bedford, J Irving, C Farmer. How Prevalent is Hypotension due to Medication in Older People? Presented at British Geriatrics Society Falls Symposium September 2015. Awarded “Best platform presentation” prize.

### **Dr Tom Webb, Consultant Stroke Physician, William Harvey Hospital**

It has been another exciting year in stroke research with a number of new NIHR Portfolio stroke studies which we are actively recruiting into.

We are pleased to welcome and introduce two new Stroke Research Officers to the department, Eva Beranova and Anna Verrion (right). Eva and Anna joined us in September and have quickly got up to speed with the current portfolio stroke studies as well as those coming on-line in the near future.



The work Ibrahim Balogun has taken the lead on, looking at outcomes for patients with ischaemic stroke of unknown time of onset treated with intravenous thrombolysis, was published this year and makes an important contribution to our knowledge of stroke treatment.

We have also published a case report highlighting the challenges of stroke pathways and multimodal imaging in acute stroke.

We have continued to work on in-house stroke research as well as recruitment to national and international stroke research studies. Our work on Obstructive Sleep Apnoea in TIA and minor stroke is making progress and we hope to submit an application for funding from the NIHR in the next year. This was given a real boost by successful competitive application for the England-wide NIHR RDS Grant Writing Retreat which was submitted in January 2016, and which we will attend later in 2016.

Work is also progressing on the collaboration on cerebral microbleeds with Professor David Werring at the National Hospital for Neurology and Neurosurgery, Queen Square, London. Researchers from Professor

Werring's team have been assisting with analysis of routinely collected anonymised data from the TIA clinic and analysis of MRI brain scans. We hope to publish the results of this work in the coming year.

## **SURGICAL SERVICES DIVISION**

### **Mr Andrew Dibiase, Consultant Orthodontics**

Research in orthodontics has continued to focus on the efficiency of treatment and the psychosocial impact of orthodontics. Recruitment has been completed on a randomised controlled trial linked with Kings College London looking at the use of vibratory force to speed up tooth movement. The initial results of this trial have been presented internationally at both the European Orthodontic Congress and the International Orthodontic Congress as well as being published in the Journal of Dental Research, which has the second highest impact factor for a dental journal and Nature Scientific Reports again another high impact open access journal. One of these papers has also been awarded the British Orthodontic Society Chapman for research.

I have started recruiting to a national RCT on the use of bone anchored maxillary protraction to correct class III malocclusion, one of the few units in the country to carry out this cutting edge procedure. I have also been awarded a £89,000 grant from British Orthodontic Society to continue my research into bullying and malocclusion, and co-ran the pre-conference postgraduate course at the European Orthodontic Congress in Venice, 2015 on evidence-based practice. Finally I have just published the second edition of the Handbook of Orthodontics which I co-authored to excellent reviews

### **Other research output**

European Orthodontic Congress, Venice 2015  
International Orthodontic Congress, London 2015  
Angle Society of Europe, Austria 2016

### **Grant awards during 2015-16 FY**

2015 Lead-applicant BOSF Grant £86,892.55 Bullying study  
2016 Co-applicant BOSF Grant £22,000 BAMP study

### **New high degree supervision during 2015-16 FY**

S Haque MSc in Orthodontics Kings College London  
"Anchorage loss with either upper first or second premolar extractions"

## **OPHTHALMOLOGY**

### **Mr Afsar Jafree, Consultant Ophthalmologist**

Mr Jafree is Principal Investigator for two studies: stereotactic radiotherapy for wet age-related macular degeneration (STAR) – working with King's College, London, this is a randomised double-masked, sham-controlled, clinical trial comparing low-voltage X-ray irradiation plus 'as needed' ranibizumab vs. 'as needed' ranibizumab monotherapy. Patients attend King's College for stereotactic radiotherapy treatment (or sham) then are seen monthly at Kent & Canterbury Hospital. The team are lead national recruiters with 19 actively enrolled patients, recruited over a short period of time, and were recently invited to speak about their successful recruitment strategy at the national study meeting in London.

The other study is CLEOPATRA. Working with Moorfields, this multicentre phase III randomised controlled, single masked clinical trial will test the efficacy of light masks at preventing dark adaptation in the treatment of early diabetic macular oedema. It is now closed to recruitment but has 18 active patients using the light mask (or sham equivalent).

### **Mr Nishal Patel, Consultant Ophthalmologist**

Nishal Patel is Principal Investigator for seven open studies, and two now in follow-up:

The open studies are mainly commercial, including **PROXIMA-A (Roche)**, an epidemiological study looking at disease progression in patients with geographical atrophy secondary to dry age-related macular degeneration (AMD). This work supports the research into new drug therapy Lampalizumab, which will be the first treatment available for this condition. The other studies include **SAFARI (Novartis)**, for patients with wet AMD, treating those who did not respond to Aflibercept with Ranibizumab and **IRISS (Almeira Sciences)** a Phase IV observational study of patients who have received Iluvien implants for Diabetic Macular Oedema (DMO), which has exceeded target with 12 patients enrolled. **DRAKO (Bayer)** is a new study which has just opened, an observational study following patients who are having aflibercept treatment for DMO. The **Eylea Risk Register (also Bayer)** is recruiting well (11 patients), a questionnaire assessing physician and patient knowledge of safety and safe use of Aflibercept.

The non-commercial studies are **LEAVO (Moorfields Eye Hospital)**, currently 3 patients in a double-masked and randomised study comparing treatment with Aflibercept, Ranibizumab and Bevacizumab for Central Retinal Vein Occlusion (CRVO) and **BVMP (University of Oxford)**, a masked and randomised study trialling bifocal lenses in younger cataract patients.

There are a number of new studies in feasibility, and we are submitting a joint application with Moorfields and Belfast for a large multi-centre NIHR EME grant, for research into Retinal Oximetry as a biomarker in patients with Diabetic Retinopathy.

### **Other research output**

ARVO Annual Meeting Abstract June 2015

Incidence of exogenous endophthalmitis following intravitreal injections: Are we beating international standards? Kavita Aggarwal; James Nash; *Nishal Patel Invest. Ophthalmol. Vis. Sci.* 2015; 56(7):4183

Poster presented at ARVO 2015 and AAO 2015

A Novel Optical Coherence Tomography Biomarker for Anti-Vascular Endothelial Growth Factor Responses in Classic Choroidal Neovascularisation. Lin Lu, Elizabeth Hawkes, Susan Walker, Nishal Patel

### **New higher degree supervision during 2015-16**

Ophthalmology Research Nurse Sarah Stirrup was granted full scholarship by the CHSS at the University of Kent for the MSc in Applied Health Research in September 2015, and is researching the impact of AMD services on public health in Kent.

## **SPECIALIST SERVICES DIVISION**

### **Dr Chris Pocock & Dr Jindriska Lindsay, Consultant Haematologists & the haematological oncology research team, led by Sr Lavinia Davey**

This year has been relatively quiet for the Blood Cancer HCTU due to closure of high recruiting studies. However we have achieved a “global first” for the Gilead 1580 study in follicular lymphoma. We have established ourselves as the global leading recruiters for the QUAZAR Trial in AML and UK Leading recruiters for the OPTIMISSM Study in Myeloma.

Trials which have closed in the last year, with East Kent as the leading UK recruiters include the REMoDL-B study in high grade lymphoma, the PACIFICO study in follicular lymphoma and the GILEAD 123 study in CLL.

An East Kent consultant has been appointed UK chief investigator for three clinical trials.

#### **Other research output**

We have had representation on abstracts at the ASH Meeting in Orlando, the EHA meeting in Vienna and the BSH meeting in Edinburgh

#### **Oncology Research Team**

Prostate cancer claims approximately 10,000 lives per year in the UK. Most men, including those newly-diagnosed with metastatic cancer, were initially treated with hormone therapy. Docetaxel, a form of chemotherapy, was only offered once hormones stopped working.

In December 2015 *The Lancet* published interim results from the STAMPEDE trial. The data proved that combining Docetaxel with hormone therapy offered significant advantages. The research showed this approach could extend the lives of advanced prostate cancer patients by an average of 15 months. The publication of the results was a pivotal moment for patients. The *Lancet* article, alongside pressure from charities and clinicians, ensured NHS England reviewed the use of Docetaxel within the shortest possible timeframe. The benefit for patients and their families was clear. For those diagnosed with metastatic prostate cancer the possibility of lengthening their lifespan is enormously important. Speaking to the Prostate Cancer UK charity Toby from Devon said: “When, on average, people in my situation can expect to die from the cancer within a handful of years, being given the chance to extend our active lives by another 15 months or so is a really big deal. That’s an extra year to be with my family, enjoying my new grandchildren growing up and finishing off my life’s work.”

Prostate cancer accounts for one fifth of all male cancers. In 2013 there were 47,300 new cases in the UK. STAMPEDE secured early access to Docetaxel as standard care for all patients who might profit from it. The trial continues.

#### **Dr Vimal Vasu, Consultant Neonatologist**

Neonatal services within the Trust continue to be actively involved in clinical research:

#### **NIHR Portfolio studies**

1. Enteral Lactoferrin In Neonates (ELFIN Trial): This is a multi-centre randomised placebo-controlled trial of prophylactic enteral lactoferrin supplementation to prevent late-onset invasive infection in very



preterm infants aiming to recruit a total of 220 infants. The primary outcome is the incidence of microbiologically-confirmed or clinically suspected late-onset invasive infection (defined as more than 72 hours after birth) from trial entry until hospital discharge. To date, the neonatal unit has recruited 15 babies to this trial and the study has attracted funding for a 0.2 WTE research nurse.

2. Platelets for Neonatal Transfusion 2 (PLANET2 trial): This is a randomised controlled trial to compare two different platelet count thresholds for prophylactic platelet transfusion to preterm neonates. Recruitment commenced in April 2015 and to date, the neonatal unit has recruited 6 babies to this trial.

### **Non NIHR portfolio studies**

1. DNA Methylation In Newborn Infants (MINI study): This is a pilot study of methodology to establish whether DNA methylation status (a marker of epigenetic change) can be established from analysis of neonatal urine samples collected for clinical purposes. This trial has completed recruitment and is now closed. 28 babies were recruited to this trial.
2. An evaluation of the process of consent in neonatal intensive care medicine from an ethical and legal perspective (The CoNe Study). This is a study that is comparing professional and family view of consent for a number of commonly performed procedures on neonatal units. It will begin recruitment in the near future.

### **Other research output**

#### **Oral presentations**

Turner K, George S, Greenall J, Griffin D, Vasu V. (2015) Is Preterm Birth associated with Accelerated Telomere Shortening? Neonatal Society Spring Meeting 2015

#### **Poster presentations**

Dubus M, Vasu V. Is the use of prophylactic paracetamol to prevent febrile reactions justified in hospitalised ex-preterm infants receiving the new meningitis B (Bexero) vaccination? Neonatal Society Summer Meeting 2016 (Poster)

#### **Grant awards during 2015-16**

Kent, Surrey and Sussex Clinical Research Network - award of non-recurrent strategic funding (£22,748)

### **Dr David Stephensen, Physiotherapist and Dr Gillian Evans, Consultant Haematologist – Haemophilia Research**

The Haemophilia Centre has continued to initiate and lead UK wide multi-centre research as well as recruit to NIHR portfolio research. One of the key achievements this year was obtaining successful funding from the NIHR to lead a randomised clinical trial for physiotherapy intervention in children with haemophilia

#### **Investigator initiated research**

Stability Training And Balanced Locomotion Exercise intervention programme to reduce falls and balance dysfunction in people with haemophilia (STABLE): Dr David Stephensen in collaboration with colleagues from Canterbury Christ Church University is exploring if falls or the fear of falling is a problem for people with haemophilia and to see if this has any effect on mobility and balance. Findings of this work have been

presented at EAHAD and WFH. Building on this pilot study we are developing a bid for external funding with other leading Haemophilia Centres in the UK.

Haemophilia Arthropathy: Inter-rater Repeatability Of an Ultrasound Imaging Score (HORUS): The aim of this multicentre study lead by Dr David Stephensen aims to determine the inter-rater repeatability of the HEAD-US score performed by haemophilia physiotherapists who have undergone a short training programme and to evaluate the association of the HEAD-US with the clinical examination, Haemophilia Joint Health Score. (UKCRN ID 19944)

Development of a peri-operative isometric-resistance exercise intervention programme (Basic Exercise Training To Enhance Recovery - BETTER) for patients undergoing elective abdominal and thoracic surgery for cancer: In collaboration with colleagues at Maidstone & Tunbridge Wells NHS Trust and the University of Kent, Dr David Stephensen is aiming to improve functional outcomes for this patient group by exploring the feasibility of a RCT.

### **Participation in NIHR portfolio research**

ITP Registry: An observational investigation of disease progression, treatment effectiveness and co-morbid conditions of ITP. (UKCRN ID 14145)

GAPP: Study involving genotyping and platelet phenotyping in patients with mild bleeding disorders. (UKCRN ID 9858)

AHEAD: Non-interventional, multi-centre international study to describe the natural history of haemophilia A disease and long term outcomes in terms of effectiveness, safety and quality of life. (UKCRN ID 12416)

So-Fit: Multi-centre study comparing haemophiliac joint scores, prophylaxis treatment regimes and links to physical activity and quality of life in children and adolescents with haemophilia. In addition the monitoring of the methodology of the collection of data by these young patients is being studied. (UKCRN ID 16059)

Nurse facilitated adherence therapy for haemophilia (AnThem) Trial: Determine if nurse facilitated adherence therapy for haemophilia improves patient adherence to clotting factor replacement therapy, clinical appointments and health advice; and, affects the level of patient engagement and ownership of treatment. (UKCRN ID 12708)

National Study of a Pharmacokinetic-Focused Educational Package for Patients With Severe Haemophilia A: The study will capture severe haemophilia A patient reported outcome measures before and after PK-focused dosing discussions, including a standardised patient education package, that include personalised PK-guided dosing suggestions from a computational predictive device (myPKFIT®). The pragmatic study design recognises the CE marked myPKFIT® device is being implemented into routine care nationally and consequently only requires a single additional clinic visit for the purpose of consenting. (UKCRN ID 19315)

Rivaroxaban Observational Safety Evaluation Study (ROSE): Monitor the Safety and Utilization of Rivaroxaban (Xarelto®) for the Prevention of Stroke in Patients with AF, Treatment of DVT and PE, and the Prevention of Recurrent DVT and PE (UKCRN ID 13911). An observational study to monitor the safety and efficacy of rivaroxaban versus warfarin therapy for treatment of venous thromboembolism and stroke prevention in atrial fibrillation.

BRIDGE Study NIHR BioResource- Rare Diseases (NIHRBR-RD) study: Genetic analysis of inherited platelet conditions (UKCRN ID 11131). A thrombogenomics study to identify novel genes causing rare bleeding disorders and platelet function defects.

FIT-RIGEL 047: Phase 3, Multi-Centre, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic ITP (UKCRN ID 13685)

FIT-RIGEL 049: Follow on study from the FIT-RIGEL 047 (UKCRN ID 16835)

## **Other research output**

### **Poster Presentations**

Suckling, Stephensen, Cramp & Drechsler. Gait Deviations in Adolescent Boys With Haemophilia. World Federation of Haemophilia Musculoskeletal Congress, Belfast 2015; Haemophilia, 2015; 21: e552.

Stephensen, Taylor, Bladen & Drechsler. Relationship Between Physical Function and Joint Biomechanics in Boys With Haemophilia. World Federation of Haemophilia Musculoskeletal Congress, Belfast 2015; Haemophilia, 2015; 21: e542.

Suckling, Stephensen, Cramp & Drechsler. Gait Deviations in Adolescent Boys With Haemophilia. Physiotherapy UK Annual Conference, Birmingham, 2015. (Runner-up Best Poster)

Stephensen, Brown, Digby-Bowl, Swaine & Evans. Exploring the Significance of Falls in the Everyday Lives of the Older Person with Haemophilia. European Association of Haemophilia and Allied Disorders 9<sup>th</sup> Annual Congress, Malmo 2016; Haemophilia, 2016; 22(S2): PO42

Stephensen, Patel, Bowles, Elliot, Hart, Evans & Pasi. The Relationship Between Clinical Joint Health and Functional Ability in Adult Men with Haemophilia. European Association of Haemophilia and Allied Disorders 9<sup>th</sup> Annual Congress, Malmo 2016; Haemophilia, 2016; 22(S2): PO50

Roughley CA, Capomir M, Lindsay J, Pocock C, Ratnayake V, Saied K, Evans G. An update on prospective audit of Rivaroxaban as prophylaxis and treatment during myeloma therapy with immunomodulatory drugs (IMiDs) at East Kent Hospitals University NHS Foundation Trust. BSH 2016

Roughley CA, Capomir M, Lindsay J, Pocock C, Ratnayake V, Saied K, Evans G Prospective audit of rivaroxaban as prophylaxis and treatment during myeloma therapy with immunomodulatory drugs (imids) at East Kent Hospitals University Nhs Foundation Trust, Uk BSH 2015

UK-PK: A prospective national study to capture patient reported outcome measures following a pharmacokinetic focussed educational package in patients with severe haemophilia A. Badle S, van OS S, Batty P, Pink R, Mangles S, AustinS, Chowdray P, Curry N, Dolan G, Evans G. etal. EAHAD 2016 congress

### **Grant awards during 2015-16**

2016 – 2019     Research for Patient Benefit (RfPB) Programme: PB-PG-0215-36091; £247,816  
Stephensen, Evans, Drechsler, Bladen, Hashem, Yang, McKeown, Lowery, Higgins-Pellatt  
*Development of a haemophilia physiotherapy intervention (DOLPHIN)*

2015 – 2016     Pfizer Haemophilia Investigator-Initiated Research Program; £11,905  
Stephensen, Bowles, Classey, Taylor, Hooper, Wells, Patel  
*Haemophilia Arthropathy – Inter-rater Repeatability of an Ultrasound Imaging Score (HORUS) Study*

2014 – 2016     Kent University Hospitals NHS Foundation Trust Research Session Scheme; £25,636  
Stephensen & Swaine  
*STABLE (Stability Training And Balanced Locomotion Exercises) intervention programme to reduce falls and balance dysfunction in people with haemophilia*

- 2015 – 2018 NIHR Research for Patient Benefit (RfPB) Programme: PB-PG-0613-31107; £338,000  
Ali, Swaine, Stephensen, Hashem, Sherrington  
*Development of a peri-operative isometric-resistance exercise intervention programme (Basic Exercise Training To Enhance Recovery - BETTER) for patients undergoing elective abdominal and thoracic surgery for cancer*
- 2012 – 2015 William Scholl Podiatric Research & Development Endowment Fund; £132,403  
Izod, Drechsler, Stephensen, Bowen  
*What is the impact of early adult rheumatoid arthritis on the biomechanical and functional characteristics of the foot & leg?*
- 2012 – 2015 William Scholl Podiatric Research & Development Endowment Fund; £220,340  
Bowen, Arden, Dohoughty, Drechsler, Stephensen  
*Prevalence and risk factors for radiographic foot osteoarthritis in middle-aged women: the Chingford Study*

### **New higher degree supervision during 2015-16**

Stephensen, University of East London, Alterations in muscle and gait characteristics in young adults with haemophilia: Impact of continued prophylaxis (PhD, Chatzifragou, 2012-)

Stephensen, University of East London, What is the impact of early adult rheumatoid arthritis on the biomechanical and functional characteristics of the foot and lower limb? (PhD, Izod, 2013-)

### **Dr Edmund Lamb, Professor Chris Farmer, Dr Tim Doulton and colleagues, Kent Kidney Research Group**

The Kent Kidney Research Group has a research strategy linked to the understanding and prevention of chronic kidney disease (CKD) and acute kidney injury (AKI), resistant hypertension and the better management of established renal failure. The group contributes to many studies in the NIHR CRN Portfolio and is the lead centre for several UK-wide studies.

A key priority has been investigation of the value of a novel marker of renal function, serum cystatin C, as part of the HTA/NIHR funded eGFR-C study. We are the lead centre (and leading recruiter) for this multi-centre study which has recruited >1000 patients in the past year towards its target of 1320. Kent had contributed 228 of these patients by April 2016. Initial work related to the biological variability of measured and estimated GFR is being prepared for publication. We have completed an RfPB/NIHR-funded study investigating the biological variability of markers of acute kidney injury, including neutrophil gelatinase associated lipocalin (NGAL), kidney injury molecule-1 (KIM-1), cystatin C and others, and this work has been published in *Clinical Chemistry* (impact factor 7.5).

We are also lead centre for a British Renal Society funded study investigating the value of bone alkaline phosphatase as a predictor of outcome in haemodialysis patients. ALPHA opened to recruitment in March 2014 and has recruited >2500 haemodialysis patients across the UK to date (target 3000). A variety of other projects have been undertaken and published in collaboration with clinical biochemistry.

Studies investigating the utility of clinical decision support systems in the fields of both CKD and AKI are complete, funded by the NIHR (11/200428) and research investigating AKI risk modelling has been published by the NIHR. This work was carried out in collaboration with The University of Kent (Centre for Health Services Studies) and Canterbury Christchurch University. This work won a KSS AHSN award in 2015.

The group are actively collaborating with the University of Kent (Medway School of Pharmacy) using *in vitro* models to assess the mechanism of nephrotoxicity seen with some common drugs. This group is also investigating more accurate methods of identifying urinary tract infection in kidney transplant recipients. Dr Hannah Kilbride completed her MD thesis investigating the influence of AKI on progression of chronic kidney disease. In collaboration with Health Care of the Older Person Department (Dr Y Morrissey) the group have completed a study examining the risks of hypotension in the elderly.

The KKRK group is one of two renal research groups within CRN Kent, Surrey & Sussex. The Renal Research Nursing Team is supported by the NIHR (HTA grant, supporting Gillian Eaglestone – Team Leader), the BiCARB and PIVOTAL studies (supporting Elizabeth Clarke, Research Nurse) and CRN: KSS (2.8 WTE posts: Research Nurses Sarah Knight & Frances Morris and CTA Zara Garratt). A research scientist, Aisling Potter, also supports many of the studies and virtually every renal consultant is a named PI or co-investigator for one or more NIHR Portfolio studies.

In 2015-16, the team worked incredibly hard to recruit patients to 16 out of 18 open 'renal disorders' NIHR Portfolio studies across a wide range of conditions. At the start of the year we set ourselves an ambitious recruitment target of 395, and we achieved 96% of this figure with 380 patients joining our studies. Dr Tim Doulton is PI for a number of these – with outstanding support from Elizabeth, Frances and the rest of the team:

- PYRENEES – an Industry-funded study (Astellas) – is looking at the efficacy and safety of Roxadustat, a novel agent used to treat anaemia in people with CKD. We achieved 100% of our recruitment target for this study which is now closed.
- PIVOTAL – an RCT looking at high vs. low dose IV iron in people on haemodialysis. This is the largest RCT ever undertaken by the UK renal community and EKHUFT is the third highest recruiting centre (from over 50) in the UK. By the end of March we had recruited 86 patients since opening.
- PEXIVAS – a globally-recruiting RCT (2x2 factorial) comparing standard vs. lower dose glucocorticoids and plasma exchange (PLEX) vs. no PLEX in patients with life/organ-threatening systemic vasculitis. Since opening in early 2013 we've recruited 8 patients.
- RaDaR – a registry study in people with rare renal diseases
- PSV Genetics – a genome-wide association study in patients with vasculitis
- RITAZAREM – an RCT looking at maintenance therapy (monoclonal antibody rituximab [RTX] vs. azathioprine) in patients with relapsing vasculitis

Most other renal consultants are PIs for other Portfolio studies, many of which continue to recruit very well: UTIs in renal transplant patients (Prof Chris Farmer, 98% of target recruitment), EMPIRIKAL (Dr Hannah Kilbride), Calciphylaxis, ALPHA & PRED4 (Dr Mike Delaney), aHUS Registry (Dr Michelle Webb), PDDOPS (Dr Nilesh Shah), SPEAK (Dr Richard Kingston), STOP-ACE (Dr Nasir Abbas, 80% of target) and eGFR-C & BiCARB (Dr Paul Stevens, EKHUFT 1<sup>st</sup> and 2<sup>nd</sup> highest recruiter respectively in UK for these studies).

The BiCARB study looks at whether there are benefits to treating acidotic CKD stage 3 & 4 patients with sodium bicarbonate. STOP-ACE is looking at whether withdrawing ACE inhibitors or angiotensin receptor blockers helps preserve kidney function in more advanced CKD. In addition, the team are supporting PAVE, a study comparing paclitaxel coated vs. conventional balloon angioplasty in haemodialysis patients with narrowings of their fistulae. Dr Neelan Das (Interventional Radiology) is PI.

## **Other research output**

### **Book chapters & invited contributions**

Delaney MP, Price CP, Lamb EJ. Kidney Disease. In: Burtis CA, Brunz DE, Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, Elsevier, 7<sup>th</sup> edition, Chapter 35, pp 651-679, 2015

Lamb EJ, Price CP. Kidney Function Tests - Creatinine, Urea and Uric acid. In: Burtis CA, Bruns DE, Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, Elsevier, 7<sup>th</sup> edition, Chapter 21, pp 364-375, 2015

Lamb EJ. Assessment of Kidney Function in Adults. *Medicine* 2015;43 (July):368-373 DOI 10.1016/j.mpmed.2015.04.005

Lamb EJ, MacKenzie F. Analytical Aspects of Measurements and Laboratory Values in Chronic and Acute Kidney Disease. In: Turner N, Goldsmith D, Winearls C, Lamierre N, Himmelfarb J, Remuzzi G (eds), Oxford Textbook of Clinical Nephrology, Oxford University Press, 4<sup>th</sup> edition, Chapter 104, 2015

### **Oral presentations**

Morrissey Y, Bedford M, Irving J, Farmer C. How prevalent is hypotension due to medication in older people?

*Oral presentation at British Geriatrics Society Scientific Meeting, Liverpool May 2016*

Morrissey Y, Bedford M, Irving J, Farmer C. How prevalent is hypotension due to medication in older people? *Oral presentation at British Geriatrics Society Falls and Postural Stability Conference, Wembley, London September 2015. Awarded "Best platform presentation" prize*

Morrissey Y, Bedford M, Irving J, Farmer C. Polypharmacy in the elderly is associated with increased mortality and acute kidney injury. *Poster presentation at 52<sup>nd</sup> European Renal Association Congress May 30th 2015*

Parker C, Carter JL, Stevens PE, Knight S, Eaglestone G, Farmer CKT, Lamb EJ. The biological variation of novel urinary markers (IL-18 and TIMP2) of acute kidney injury in patients with chronic kidney disease. *Poster presentation at: Focus 2015, National Meeting of the Association for Clinical Biochemistry, Cardiff, UK, June 2015, shortlisted for the ACB Medal Award.*

### **New high degree supervision during 2015-16 FY**

Mr Christopher Parker, MSc Clinical Biochemistry, University of Manchester. (project title: The biological variation of novel urinary markers (IL-18 and TIMP2) of acute kidney injury in patients with chronic kidney disease). Passed with distinction 2015.

### **Karen Jenkins, Renal Nurse Consultant**

The aim of this qualitative study was a) to involve patients and carers in the research process and b) to understand the experiences of shared decision-making in older people (> 70 years) in two NHS Trusts in England. A core value of this research project was 'co-production' whereby patients and carers were involved in all aspects of the research process: writing the research proposal, developing interview questions, undertaking interviews and being involved in data analysis and dissemination of the findings.

The study team set up a Patient and Carer Group (PCG) with six participants who co-led the project with the three researchers. The PCG members undertook Trust volunteer training and research training which included development of interviewing skills. 29 people who had commenced dialysis, or had made a decision not to have dialysis, within the past six months were interviewed. Interview data was transcribed and analysed. There were challenges in recruiting people who were representative of the diverse patient population in one Trust.

Our study is innovative because patients and carers have been involved in every stage of the research process. Our findings have shown that older patients have generally been involved in the dialysis decision along with their families, but sometimes prefer the doctor to decide for them.

The implications for practice are that we need to consider delivering patient information in different ways for older people to enable this age group to better understand the concept of shared decision making.

## **Other research output**

### **Poster presentation**

UK Kidney Week University of Leeds 1<sup>st</sup> July 2015; Patient and carer involvement in Kidney Care research: Pearls and Pitfalls (abstract)

## **Eve Hutton, Paediatric Occupational Therapist**

The research collaboration between Canterbury Christ Church University, EKHUFT and the University of Kent, funded through Higher Education Innovation Funding and R&D funds has resulted in a business case that has resulted in the sustainable roll out of the Posted training programme across the UK. One day 'Train the Trainer' workshops have now been accredited by Canterbury Christ Church University and endorsed by the College of Occupational Therapists. The workshops are delivered through Canterbury Christ Church University, Centre for Work-based Learning. There is considerable interest from across the UK for this novel training programme designed to build the confidence of parents and carers of children with physical disabilities. The project has further strengthened research collaboration between the partners that will benefit the children and families we work with. I am currently working with EKHUFT CYP Therapy service to explore how we implement and evaluate this training in our localities.

With support from EKHUFT R&D and Canterbury Christ Church University I recently attended a NIHR Grant Writing Retreat organised by the NIHR RDS service. As one of only twelve projects selected from across the UK this was a unique opportunity to work with colleagues from Sussex Community Trust, co investigators and experts from the RDS on the development of a grant proposal '*Developing an intervention to promote the participation of children with physical disabilities in mainstream primary schools*' The research team intend to submit a proposal to the Research for Patient Benefit stream of the NIHR in December 2016.

In 2015 I was appointed Reader in Children's Health and Wellbeing at Canterbury Christ Church University. From June 2016 I will take up a half time post as Reader and maintain a clinical and research attachment to EKHUFT in an honorary capacity. The aim will be to strengthen the relationship between EKHUFT and The Faculty of Health and Wellbeing, Canterbury Christ Church University to support and promote research activity within CYP Therapy and Child Health. I was appointed as a member of the R&D Board at the College of Occupational Therapists in 2015 and I have recently been appointed to the NIHR Health Technology Assessment, Maternal and Child Health advisory group which will enable me to influence research priorities and benefit from research networks across the UK.

## Other research output

### Conference presentations

Hutton, E. (2015) POSTED increasing confidence in postural care. In: The OT Show, 25th-26th November, 2015, Birmingham NEC.

Soan, S., Hutton, E. and MacCobb, S. (2015) A kaleidoscope of enquiry - showcasing examples of collaborative practice to promote inclusive learning environments. In: BERA Conference 2015, 15th-17th September, 2015, Belfast.

Hutton, E. and Soan, S. (2015) Universal Strategies to support motor and functional skills in a sample of UK schools. In: European Academy of Childhood Disability Annual Congress 2015, 27th-30th May, 2015, Copenhagen. (Unpublished)

## CLINICAL SUPPORT SERVICES DIVISION

### Dr Edmund Lamb, Clinical Biochemistry

Clinical Biochemistry has an active research programme achieving significant grant outcome and high quality published output.

In collaboration with the Kent Kidney Care Centre there is a research strategy linked to the understanding and prevention of chronic kidney disease (CKD) and the better management of established renal failure. A key priority has been the evaluation of kidney function in older people.

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 successful in this grant bid and in March 2013 were awarded £2 million pounds to undertake this work. Currently 1000 people nationally have been recruited to this study (target 1320 people).

We received a further grant award of £145,000 in 2011 from the National Institute of Health Research (NIHR) Research for Patient Benefit scheme for a study investigating the biological variability of markers of acute kidney injury, including neutrophil gelatinase associated lipocalin (NGAL), kidney injury molecule-1 (KIM-1), cystatin C and others. Recruitment to this study is complete. This study has recently been accepted for publication in *Clinical Chemistry*, the leading journal worldwide in this field (impact factor 8).

Dr Edmund Lamb, Consultant Clinical Scientist, is a co-applicant on two further Health Technology Assessment (HTA) grant proposals. The first, in collaboration with a team in Dundee, is investigating the effects of bicarbonate replacement on progression of chronic kidney disease in older patients. The second project, led by a team from Newcastle, is assessing the relative merits of urinary albumin and protein in the assessment of pre-eclampsia. Both studies are actively recruiting.

We also have a research interest on the relationships between exercise, markers of atherogenesis and heart disease. We are currently collaborating with "Women's health and activity at middle-age (WHAM!)" with the University of East Anglia and the Institute of Food Research. Metabolomics has the potential to increase understanding, and thus the treatment of, obesity. In this study we are exploring the use of metabolomics to investigate the relationships between diet, exercise, body fat and metabolic status. A new study entitled the "comparison of metabolic equivalents between post heart attack and healthy males



during a standard exercise treadmill test” has just been funded by the EKHUFT research and development internal project grant scheme. This is a collaborative study involving Canterbury Christ Church University, University of Kent and EKHUFT.

Two members of staff hold Honorary/Visiting Senior Lectureships with the Department of Biosciences at the University of Kent: one member of staff has a Research Fellowship at Christ Church University College, Canterbury. There are active collaborations with several other institutions including Guys and St Thomas’ Hospitals and the Birmingham Clinical Trials Unit.

## **Other research output**

### **Oral presentations**

Parker C, Carter JL, Stevens PE, Knight S, Eaglestone G, Farmer CKT, Lamb EJ. The biological variation of novel urinary markers (IL-18 and TIMP2) of acute kidney injury in patients with chronic kidney disease. *Poster presentation at: Focus 2015, National Meeting of the Association for Clinical Biochemistry, Cardiff, UK, June 2015, shortlisted for the ACB Medal Award.*

### **Book chapters & invited contributions**

Lamb EJ, Price CP. Kidney Function Tests - Creatinine, Urea and Uric acid. In: Burtis CA, Bruns DE, Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, Elsevier, 7<sup>th</sup> edition, Chapter 21, pp 364-375, 2015

Delaney MP, Price CP, Lamb EJ. Kidney Disease. In: Burtis CA, Bruns DE, Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, Elsevier, 7<sup>th</sup> edition, Chapter 35, pp 651-679, 2015

Lamb EJ. Assessment of Kidney Function in Adults. *Medicine* 2015;43 (July):368-373 DOI 10.1016/j.mpmed.2015.04.005

Lamb EJ, MacKenzie F. Analytical Aspects of Measurements and Laboratory Values in Chronic and Acute Kidney Disease. In: Turner N, Goldsmith D, Winearls C, Lamierre N, Himmelfarb J, Remuzzi G (eds), Oxford Textbook of Clinical Nephrology, Oxford University Press, 4<sup>th</sup> edition, Chapter 104, 2015

### **New high degree supervision during 2015-16**

Mr Christopher Parker, MSc Clinical Biochemistry, University of Manchester. (project title: The biological variation of novel urinary markers (IL-18 and TIMP2) of acute kidney injury in patients with chronic kidney disease). Passed with distinction 2015.

## **CORPORATE DIVISION**

### **Professor Kim Manley, Clinical Quality**

My research continues to focus on the swampy lowlands of practice supporting practitioners and helping them with inquiring into and developing care that is person centred, safe and effective through using research approaches that are appreciative, collaborative, inclusive and participative. e.g. action research, appreciative inquiry, and realistic evaluation as well as phenomenology and critical ethnography. Realistic evaluation helps us to understand the relationships between context, mechanisms and outcomes and this is the focus of a current project across four acute NHS Trusts in the south-east which aims to identify the strategies that enable a safety culture, leadership and Quality improvement capability at the frontline.

Other projects, through using practice development as a complex intervention have led to insights into how the workforce can be developed across the health economy to support urgent and emergency care through systems leadership and a single competence framework.

Facilitation of transformation through taking an integrated approach to learning, development, improvement and inquiry is reflected in the development of international standards for facilitation through an e-Delphi study. Ongoing work continues in understanding how to develop effective workplace cultures and the role of clinical leadership through support of doctoral students and other collaborative projects.

### **Other research output**

#### **Current Visiting Professor/Recognitions**

University of Surrey  
Monash University Melbourne Australia  
2015 Nursing Times Top Nurse leaders Award

#### **Current Editorial Board Membership**

International Journal of Practice Development

#### **Grant Reviewer**

National Institute of Health Services Research  
Health Foundation

#### **Recent Conference papers**

May 2016 *Taking a Whole Systems Approach to Urgent & Emergency Care* YouGov. Transforming urgent and emergency care TUC Centre, London  
May 2016 *Clinical systems leadership* Society for Acute Medicine Titanic Centre, Belfast  
Oct 2015 *Effective workplace culture* Turn Up the Volume Conference University of Bristol  
Oct 2015 *Fusing Professional Horizons* Inaugural Professorial Lecture Canterbury Christ Church University, Canterbury  
Oct 2015 *Clinical Systems leadership – the qualities required for working across the health economy* Launch of EKHUFT Leadership Academy Ashford International Hotel, Ashford , Kent  
Mar 2015 *Transforming primary care: vision and reality: a whole systems approach to developing the workforce (with Carrie Jackson)* NHS England Central Southern Conference Norton Park Hotel, Winchester

#### **Recent Research Reports with ISBN numbers**

Jackson, C; Prof Manley K, CBE; Martin, A; Dr Wright T (2015) Continuing Professional Development (CPD) for quality care: context, mechanisms, outcome and impact Education Outcomes Framework Round 2 Funding Funded by NHS Employers, ECPD, Canterbury ISBN 978-1-909067-39-4

Manley K & Greaves J (2016) implementing & evaluating a community of practice for health visiting Final report Partnership involving Kent Community Health Foundation Trust and Medway Community Health  
Funded by Health Education Kent, Surrey, Sussex ECPD, Canterbury ISBN 978-1-909067-57-8

#### **Invited Chapter**

Manley K (2016) An overview of practice development. McCormack, B; McCance, T (eds) Person-centred Practice in Nursing and Healthcare: Theory and Practice (2<sup>nd</sup> ed) Wiley pp133-149  
EKHUFT Research & Development Annual Report 2015-16  
Authors: Dr Art Ationu & Dr Tim Doulton

## **PhD External Examiner**

### **University of Tampere, School of Health Sciences, Finland, 2016**

Nijolė Galdikienė

Nurses' occupational stress in primary health care: Evaluated in connection to organizational social context

### **De Montfort University, Leicester**

Ahmad Hamad Ma Ali

Case Study of the Evaluation of Ophthalmic Nurse Practitioner case on instance of advance practice nursing roles in Palestine

### **Sheffield Hallam University 2015, 2016**

Lisa Kerr Doctor of Education

Advanced Nurse Practitioners' (Emergency) perceptions of their role, positionality and professional identity.

### **University of West of England, 2015**

Jenny Child

Creating partnership by aligning the support needs of the neophyte registered nurse and the healthcare organisation: an appreciative inquiry

### **University of Wollongong, Sydney, Australia 2015**

Jenny Sim

Measuring the Quality and Safety outcomes of nursing practice

## **East Kent Research Delivery Team**

In 2014, the East Kent research team began working on the SIGNATURE CAIN trial. This study was designed to test the hypothesis that secukinumab was effective, safe and well tolerated in the treatment of moderate to severe chronic plaque-type psoriasis in patients who were inadequate responders (NICE definition) to anti-TNF $\alpha$  in a UK specific population. The PI Dr Duarte Williamson, and the East Kent research team, successfully recruited eight patients into this study, five went on to successfully complete the full treatment period. In 2015, our first patient completed and was delighted to be classified as psoriasis free! This patient suffered for the majority of his adult life with moderate/severe psoriasis, having a detrimental effect on both his physical and mental wellbeing. Upon completion of this clinical trial, the patient was happy to tell his story in CRN:KSS's Spring 2015 "Research and You" monthly newsletter, in which he described his journey, and explained how the results had had a hugely positive impact on his life stating "Having psoriasis has been soul destroying it's wonderful to have normal skin again". It was humbling and so extremely rewarding to know our team played a part in providing care which produced such amazingly successful results. As healthcare professionals, it is often too often too easy to become focussed on the obvious indicators of ill health. We can often overlook such small aspects of someone's life, and the impact on overall wellbeing. If clinical research has the ability to help even one person's quality of life, then it is so very worthwhile.

## **OTHER**

### **Janine Musselwhite, Community Acute Research Nurse**

EKHUFT and Kent Community Health Foundation Trust (KCHFT) were granted funding for a collaborative Research Nurse post, the first of its kind with the Kent Surrey and Sussex network. The position was filled in January 2016, by Janine Musselwhite. Since then Janine has been working with lots of different areas within EKHUFT, KCHFT and CRN:KSS. Her key goals have been to educate others within research about her

Community Acute Role. Meeting with individuals from Community and Acute to develop relationships and a better understanding of what support can be given.

Areas that Janine has had involvement in include:

- Assisting in the setup of a KCHFT sexual health study, which needed EKHUFT pathology support. Janine arranging training for KCHFT staff, secured access to EKHUFT labs and acted as the link between the two NHS providers.
- Assisting with set up of a study that involved EKHUFT, Pilgrims Hospice and KCHFT which had been struggling to move forward for almost two years due to organisation barriers
- Currently working on the capacity for an EKHUFT study that will include community physiotherapist involvement.

Janine has been personally invited to present at several meetings promoting her new Community Acute Research Nurse role. She has also been asked to be part of an East Kent project meeting that is looking at setting up a collaborative Research into COPD.

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

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## Appendix: Financial report - April 2015 to March 2016

### CRN: KSS – 2015 - 2016

The table below reflects the outturn baseline allocation for the CRN:KSS contract for the 2015-16 FY

Annual Allocation £000's	Pay	Vacancy Factor	Total Pay	Non pay	Host Fees	Total	%
Nursing	726	(42)	684	27	54	766	59%
AC Support	240	(14)	227	9	18	254	20%
Pharmacy	226	(13)	213	8	17	239	18%
Radiology				20		20	2%
Pathology				19		19	1%
<b>Total Core Funding</b>	<b>1192</b>	<b>(68)</b>	<b>1124</b>	<b>84</b>	<b>89</b>	<b>1297</b>	<b>100%</b>
Specialty Leads	23		23			23	
Research Capability Funding	44		44			44	
Contingency	98		98			98	
Strategic Investment	12		12			12	
Other Funding	1		1			1	
<b>Total Additional Funding</b>	<b>178</b>		<b>178</b>			<b>178</b>	
In-year adjustment		(11)	(11)			(11)	
<b>Overall CRN Allocation</b>	<b>1370</b>	<b>(79)</b>	<b>1291</b>	<b>84</b>	<b>89</b>	<b>1465</b>	

The in-year adjustment (reduction to allocation) was applied to the final Q4 payment of the 2015–16 allocation. This was in anticipation of a forecast breakeven position as year-end. This was achieved.

### CRN: KSS Financial Position

The cumulative variance as reported to the CRN: KSS to March 31<sup>st</sup> 2016 is indicated below:

£000's	Annual Budget	Budget YTD	Actual YTD	Var YTD
Nursing	680	680	680	( )
AC Support	225	225	228	(3)
Pharmacy	212	212	219	(7)
Pay balance	75	75		75
Vacancy factor	(68)	(68)		(68)
<b>sub-total Pay</b>	<b>1124</b>	<b>1124</b>	<b>1128</b>	<b>(4)</b>
Non Pay	45	45	32	13
Host Fees	89	89	89	
<b>sub-total Other</b>	<b>134</b>	<b>134</b>	<b>121</b>	<b>13</b>
Radiology	20	20	24	(4)
Pathology	19	19	20	(1)
<b>sub-total SSDs</b>	<b>39</b>	<b>39</b>	<b>44</b>	<b>(5)</b>
<b>Total Core Funding</b>	<b>1297</b>	<b>1297</b>	<b>1293</b>	<b>5</b>
Specialty Leads	23	23	23	
Contingency	98	98	93	6
Strategic Investment	12	12	9	3
Research Capability Funding	44	44	44	
Other Funding	1	1	1	
<b>Total Additional Funding</b>	<b>178</b>	<b>178</b>	<b>169</b>	<b>9</b>
In-year adjustment	(11)	(11)		(11)
<b>Overall CRN Allocation</b>	<b>1465</b>	<b>1465</b>	<b>1462</b>	<b>3</b>

Outturn variance as a % of gross budget 0.20%

The outturn position for CRN: KSS funded budget was break-even after accounting for the Q4 reduction in allocation

#### Other Income/Direct Receipts

Total income from other sources of direct receipts for the period to March 31<sup>st</sup> 2016 was £1,320,930 broken down as follows:

£000's Source	Yr 2014 - 2015		Yr 2015 - 2016		Inc/(dec)	
	£	%	£	%	£	%
Research Capability Funding	(149)	11%	(99)	7%	50	(33%)
NIHR Projects	(226)	17%	(316)	24%	(90)	40%
MRC/Other/Non-commercial	(121)	9%	(178)	13%	(57)	47%
Commercial	(823)	62%	(729)	55%	95	(12%)
<b>Total</b>	<b>(1318)</b>	<b>100%</b>	<b>(1321)</b>	<b>100%</b>	<b>(2)</b>	<b>0%</b>

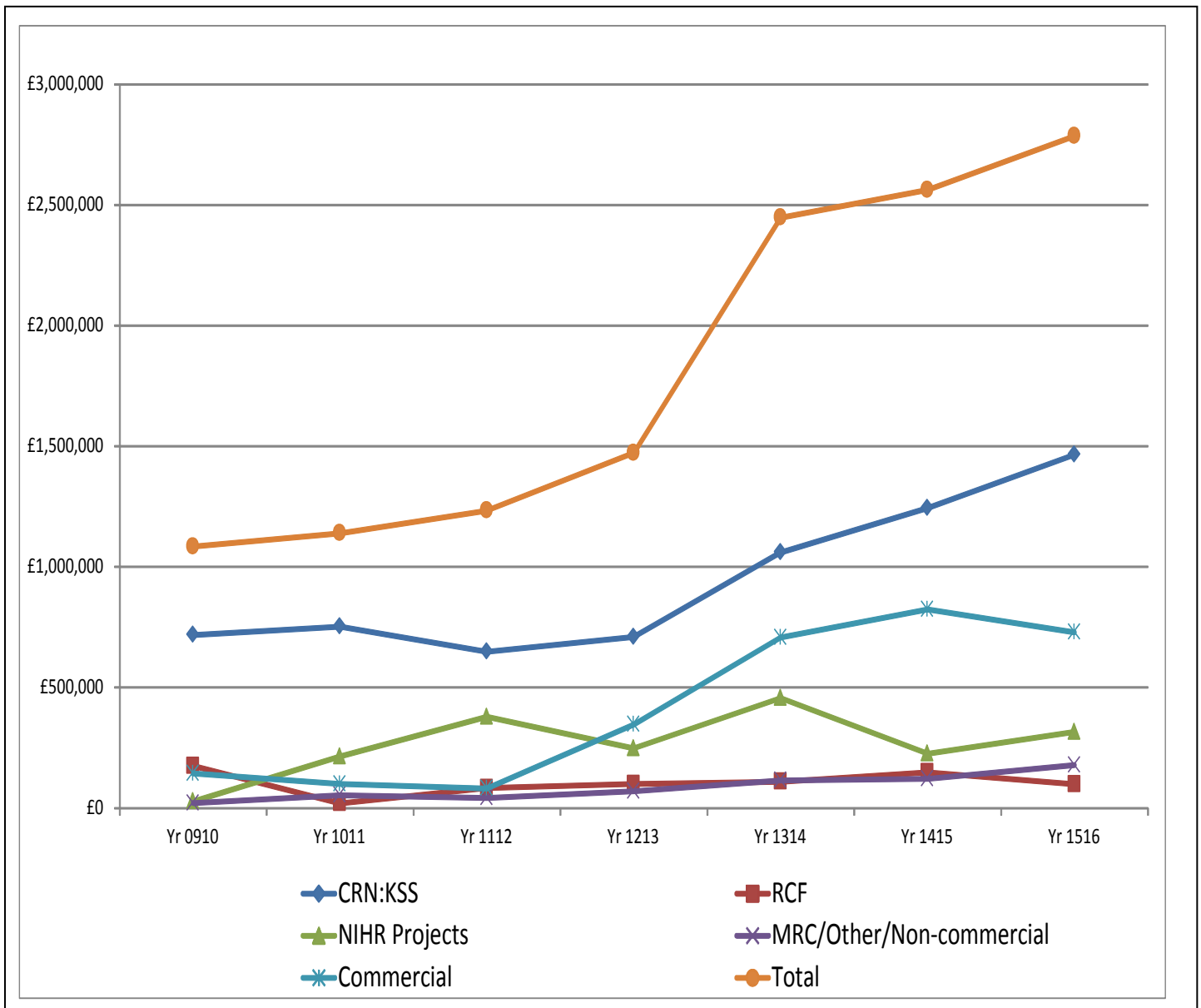
In overall terms income has remained on par compared to last year. Increases in NIHR/Non-commercial income has compensated for a reduction in industry related receipts.

Clinical Haematology generated 55% (£404k) of the overall total of industry receipts recorded during 2015-16. This includes invoices raised on behalf of Pharmacy.

A tabulation of total annual income receipts for the last several years is shown below.

£000's Source	Yr 1011	Yr 1112	Yr 1213	Yr 1314	Yr 1415	Yr 1516
CRN:KSS	(752)	(649)	(709)	(1060)	(1244)	(1465)
Research Capability Funding	(20)	(83)	(100)	(110)	(149)	(99)
NIHR Projects	(214)	(378)	(247)	(456)	(226)	(316)
MRC/Other/Non-commercial	(53)	(42)	(70)	(115)	(121)	(178)
Commercial	(100)	(81)	(346)	(707)	(823)	(729)
<b>Total</b>	<b>(1139)</b>	<b>(1233)</b>	<b>(1472)</b>	<b>(2447)</b>	<b>(2562)</b>	<b>(2785)</b>

The graphical analysis below depicts the general trend of income recovery over the main provider headings.



Jacky Douglas, R&D Finance Officer