



# Research & Innovation Department

## Annual Report 2018-19

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## Acknowledgements

I would like to express my thanks to all those PIs, delivery team staff, other researchers & Jo Isaacs who have contributed the content of this report, to Ruth Hulbert for the PPIE report and other contributions, Greta Novikova for the finance report and Jill Baker for assembling the first draft.

### **Dr Tim Doulton**

(Front cover picture: Some of our research staff with our new participant posters that you'll see around the Trust)

## 1. Executive Summary

1. During the year a total number of 2484 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 8.3% on 2017-18, and is our highest recruitment since 2010-11.
2. During 2018-19, 78 studies were given Capacity & Capability approval by the Trust of which 58 were NIHR Portfolio studies. Of the 78 newly opening studies, 19 were clinical trials of investigation medicinal products (CTIMPs) and 17 were industry-funded/-sponsored studies.
3. Research-related income to the Trust was down on last year (£2.35m vs. £2.7m in 2017-18) with income related to commercial-contract study activities also down on the previous year at £0.6m. This included £117k from DH Research Capability Funding.
4. The Trust has performed well in time taken to open and recruit to studies this year – for example, in Q4 our mean time from being selected as a participating site for any given study to recruiting our first participant was 50.9 days. This placed us 24<sup>th</sup> out of 206 provider organisations in England, and 1<sup>st</sup> in our league (league 2) of comparable organisations.
5. We have provided fifteen training sessions on various topics to 204 colleagues throughout the year.
6. We have restructured our non-cancer Research Delivery Teams to align to our three main sites (Margate, Canterbury & Ashford). In particular the size, presence and level of activity delivered by our WHH team have increased significantly enabling more patients receiving care on that site to participate in research.
7. We held a workshop on 4th March 2019 to update our strategy for the coming three years, taking into account changes to the local context in which research is happening (e.g. announcement of the new medical school for Kent & Medway). The output of workshop has contributed to a strategy update that we plan to present to Quality Committee and Board of Directors late in 2019.
8. EKHUFT staff – collectively or individually – were recipients of acclaims and/or prestigious awards during the course of the year. Ruth Hulbert, Lead Research Nurse, was accepted onto the 70@70 Programme and our Research Delivery Team were finalists at the Nursing Times Research Team of the Year awards.

## 2. Key Events during the 2018-19 Financial Year

### Strategy Refresh Workshop

We held a workshop on 4th March 2019 to update our strategy for the coming three years, taking into account changes to the local context in which research is happening (e.g. announcement of the new medical school for Kent & Medway). We had 25 delegates from within the Trust, local Universities, Clinical Research Network: Kent, Surrey, Sussex & pharmaceutical companies and the output of workshop has really helped us focus our strategic ambitions in R&I for the coming years. We plan to present this paper to Quality Committee and the Trust's Board of Directors in late 2019.

### Restructuring & development of research delivery teams

In October 2018, changes were made to the research delivery workforce within the Trust resulting in three main research delivery teams who support most specialties except Oncology (the existing cancer research teams continuing as they are). Each of these teams are now aligned to one of the three main sites and known as:

- Research Team: William Harvey Hospital (Team Leader: Tracey Cosier)
- Research Team: Kent & Canterbury Hospital (Team Leader: Angela Moon)
- Research Team: Queen Elizabeth the Queen Mother Hospital (Team Leader: Nikki Crisp)

The main aim of these changes is to improve efficiency, resulting in improved value for money. In addition, improving site-based presence will help to enable development of relationships with new PIs & specialties that have been less well supported in the past whilst, at the same time, continuing to deliver an excellent service to colleagues and patients in those specialties that have been highly active in the past.

The research team based at William Harvey Hospital has expanded significantly over the past year, both in terms of the size (3 staff have now increased to 7) and activity. Previously the team supported Stroke research almost exclusively, but are now supporting studies across a much broader range of specialties, including critical care, neurology and emergency care, whilst increasing recruitment within stroke. The team were also successful in securing suitable new office accommodation and laboratory facilities.



### Laboratory support for research

During 2018-19, laboratory support for research has increased significantly. In July 2018, Alicia Knight was appointed as Research Associate Practitioner. Based at QEQM hospital, this role involves supporting and coordinating the workload for research studies requiring pathology and laboratory support. In addition,

temporary space was identified so that lab support & sample processing facilities became available at all three of the main sites and space has also been identified at both QEQM and WHH for permanent dedicated research lab facilities.

## Student Nurse Placements

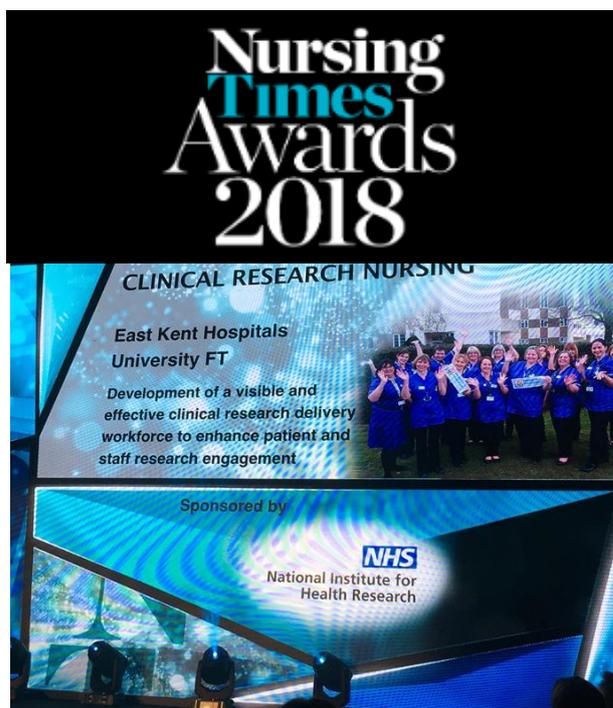
The first Student Nurse placements were successfully introduced and completed during 2018/19 in collaboration with CCCU. The students spent some time with each of the delivery teams during their placements, to ensure their experience was as interesting & varied as possible. Feedback has been very positive and we are hoping to continue with these going forward.

## Research Delivery team shortlisted for Nursing Times Award

The Research Delivery team were nominated for the prestigious Nursing Times Awards, Clinical Research Nursing category, and were delighted to be shortlisted. Led by research nurse Sarah Stirrup, the nomination focused on the work that the team had been doing to develop a visible and effective clinical research delivery workforce to enhance patient and staff research engagement in EKHUFT.

The award, sponsored by the National Institute of Health Research (NIHR), involved an in-depth judging process. Sarah was joined by Ruth Hulbert, Lead Research Nurse and Brent Murray, research patient and ambassador to deliver a presentation in London to a panel of nine judges.

This was followed in October by the award ceremony itself which was held at the Grosvenor House Hotel, London. Although the team did not go on to win the award, this was still a fantastic achievement and one that the team are justifiably proud of.



## NIHR 70@70 senior nurse & midwife leadership programme

Ruth Hulbert, Lead Research Nurse was accepted as a participant on the NIHR 70@70 senior nurse & midwife leadership programme commencing in May 2019. The programme is intended to 'form a new community of senior clinical nurses and midwives who will champion the promotion of an embedded research active culture, encourage and support innovation, and inform research priorities in their organisations'. Ruth will spend 2 days per week working on this for the next 3 years.

### Ruth's 70@70 success

Published 23 January 2019

Many congratulations to Ruth Hulbert who has successfully gained a place on the National Institute for Health Research (NIHR) 70@70 senior nurse and midwife leadership programme.

You may remember the scheme was set up as part of the NHS 70 celebrations last year and looked to 'form a new community of senior clinical nurses and midwives who will champion the promotion of an embedded research active culture, encourage and support innovation, and inform research priorities in their organisations'.

Although Ruth will stay within the Trust, from April onwards she will be spending two days a week on this role for the NIHR over the next three years to develop research capacity amongst our senior nurses and midwives. The other three days per week she will continue in her current role of leading our various research delivery teams across the Trust.

Tim Doulton, Director of Research and Innovation (R&I) said: "When Ruth first approached me about applying for this role, it was obvious to me that she would be a fantastic choice to engage senior nursing and midwifery colleagues across EKHUFT, and to drive forward our ambition to see research embedded at all levels within the Trust. I am, therefore, delighted to hear that the NIHR have appointed her to their 70@70 Programme, and I look forward to the undoubted impact it will have on our R&I capability and capacity over the next three years."

If you'd like to find out more about 70@70 please visit the [NIHR website](#).



Ruth Hulbert

## Annual R&I awards

As in previous years we made a number of awards at our end-of-year meeting. We are most grateful to CEO Susan Acott for attending our meeting and presenting awards, and to Non-Executive Director Jane Ollis and patient representative Ian Danks in choosing winners and runners-up. This year we had 47 nominations across our four categories and these were of an exceptionally high calibre. Not only are we proud of the extraordinary efforts of those nominated, but also most appreciative of the time taken by their colleagues making nomination. Recipients of awards were:

### 'Unsung Hero' category

Winner Andrew Gillian (Pharmacy KCH)  
Highly Commended Ophthalmic Imaging Team (KCH)

### 'Exceptional Contribution' category

Team Winner Multiple Sclerosis Team (KCH)  
Individual Winner Tracey Cosier (WHH Research Team)

### 'Rising Star' category

Winner Eleonore Gifford (KCH Research Team)  
Highly Commended Dr Salman Naeem (Emergency Department WHH)

### 'Most Engaging PI' category

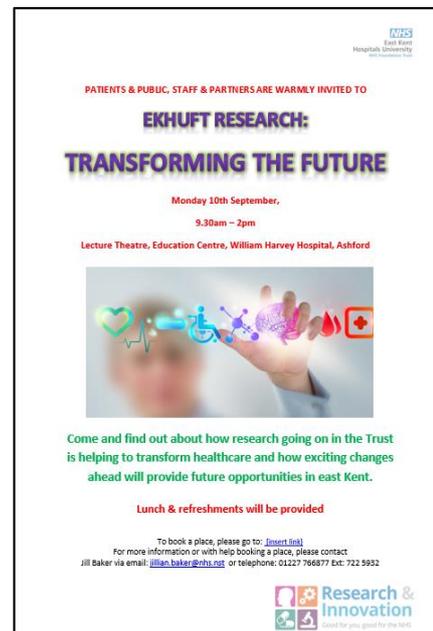
Winner Hilary Webb (Head Orthoptist)  
Highly Commended Dr Neil Richardson (Consultant Anaesthetist WHH)



Above: Some of our R&I Award winners with Susan Acott, EKHUFT CEO (far right)

### 3. People Involvement & Engagement

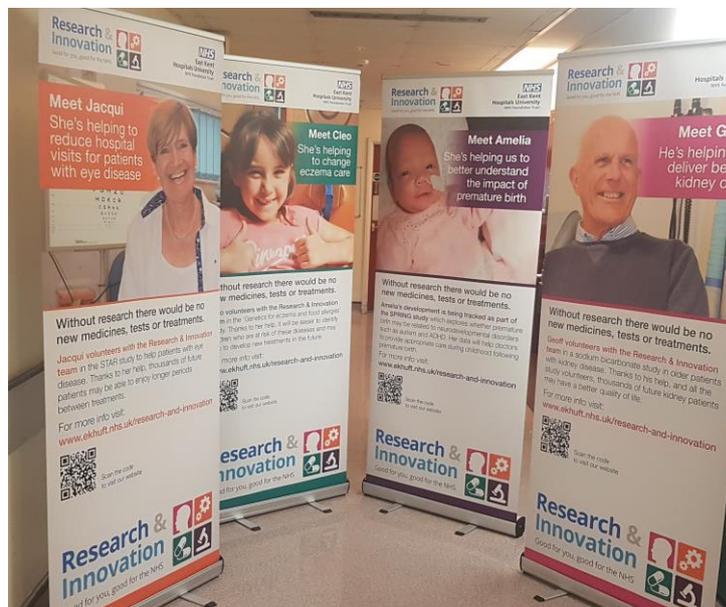
Our event: 'EKHUFT Research: Transforming the Future' Patients and public, staff and partners were all in took place at William Harvey Hospital on 10 September 2018. Trust Chairman, Professor Stephen Smith, opened the event and reminded the audience how vital research is to our organisation. A packed programme followed, which included talks by many of our active researchers, who all described the important research they have been involved in and how it has and will make a difference to the care and treatment of patients. The highlights of the event were the patients themselves, who told of their own involvement in research and how this had made a positive difference to them. The event was a great success with many of the attendees commenting on how interesting, positive and inspiring they found the day.



Work on our new R&I webpages continues although has not progressed as quickly as anticipated, mainly due to resource issues. However, the framework has been designed and a large amount of information written. The content now needs to be added and the new site can then be launched.

The number of research participants who have volunteered to become a 'Research Friend' now totals 295. This year our Research friends have helped with various activities including publicity events and meetings (attending and/or speaking), helped with our posters, provided input/ feedback for individual projects, volunteered to help with our webpages and share their story.

The research delivery teams continue to raise awareness and visibility across the Trust through wearing the R&I uniform, attending internal meetings and organising & attending publicity events. They also attend the lunchtime marketplace at the staff inductions days every fortnight to introduce the department and our work to new starters in the Trust.



## 4. Key Metrics<sup>1</sup>

### Study activity

During 2018-19 the Trust had 480 active research<sup>2</sup> studies including 323 within the NIHR Portfolio and 91 non-Portfolio or “own account” studies. Included within these studies are 113 clinical trials of investigation medicinal products (CTIMPs) and 70 industry studies (67 Portfolio, 3 non-Portfolio).

The Trust R&I Department issued confirmation of capability & capacity (C&C) for 78 new studies between 1st April 2018 and 31st March 2019 (58 NIHR Portfolio and 20 non-Portfolio), of which 19 were CTIMPs and 17 were industry studies.

We recruited to 117 NIHR Portfolio studies, across 24 discrete disease areas.

### Participant Recruitment

Between 1<sup>st</sup> April 2018 and 31<sup>st</sup> March 2019 the Trust recruited 2,484 participants to NIHR Portfolio studies compared to 2,293 participants in 2017-18, an increase of 8.3% 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.

### Performance in Initiation of Research<sup>3</sup>

Below we present comparative data, looking at time (mean number) days between ‘date site selected’ (DSS) and ‘first patient recruited’ (FPR) for 2018-19. Also presented is DSS to ‘date site confirmed’ which is an indication of efficiency initial study set up processes.

Time period	PII League <sup>4</sup>	DSS to FPR (mean, days)	Ranking in league	Ranking overall (England)	DSS to DSC (mean, days)	Ranking overall (England)
Q4 2018-19	2/6	50.9	1 <sup>st</sup> (/24)	24 <sup>th</sup>	2.9	7 <sup>th</sup> (/206)
Q3 2018-19	3/6	64.7	1 <sup>st</sup> (/22)	52 <sup>nd</sup>	3.2	7 <sup>th</sup> (/206)
Q2 2018-19	3/6	83.7	12 <sup>th</sup> (/17)	98 <sup>th</sup>	9.6	10 <sup>th</sup> (/204)
Q1 2018-19	3/6	76.7	6 <sup>th</sup> (/14)	72 <sup>nd</sup>	24.6	49 <sup>th</sup> (/203)

<sup>1</sup> Data relating to NIHR Portfolio studies obtained from NIHR Open Data Platform (KSS QlikView Pages)

<sup>2</sup> Active defined as open to recruitment or in follow-up phase.

<sup>3</sup> Data from Performance in Initiating and Delivering Clinical Research from NIHR Central Commissioning Facility

<sup>4</sup> ‘League’ is based on overall number of studies processed in each quarter, and ranks EKHUFT alongside sites of similar levels of research activity

## Research Income

Research-related income to the Trust was down on last year (£2.35m vs. £2.7m in 2017-18) with income related to commercial-contract study activities also down on the previous year at £0.6m. During the year the Trust was allocated £117k 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

In 2018-19 we provided 15 training sessions to 204 colleagues in a variety of locations as detailed below. In comparison, we provided training to 210 colleagues in 2017-18, 191 in 2016-17 and 166 in 2015-16.

Date	Title of Training	Venue	Attendees
21/05/2018	GCP Refresher	WHH	15
01/06/2018	GCP Intro	WHH	23
22/06/2018	PI Essentials Training	WHH	17
29/08/2018	GCP Intro	Trinity House	17
15/10/2018	Dry Ice Training & Safety Workshop	WHH	18
23/10/2018	GCP Refresher	KCH	9
23/11/2018	GCP Intro	WHH	15
04/12/2018	Valid Informed Consent Workshop	MTW	17
09/01/2019	GCP Intro	WHH	13
16/01/2019	GCP Refresher	MTW	11
15/02/2019	PI Essentials Training	KCH	17
18/02/2019	PI Essentials Training	QEQM	10
25/02/2019	PI Masterclass	WHH	6
01/03/2019	GCP Intro	WHH	8
18/03/2019	GCP Refresher	WHH	8

## Statistical Advice

Statistical advice was provided by Paul Bassett (StatsConsultancy Ltd) to 18 Trust researchers by phone, e-mail and in face-to-face meetings.

Figures

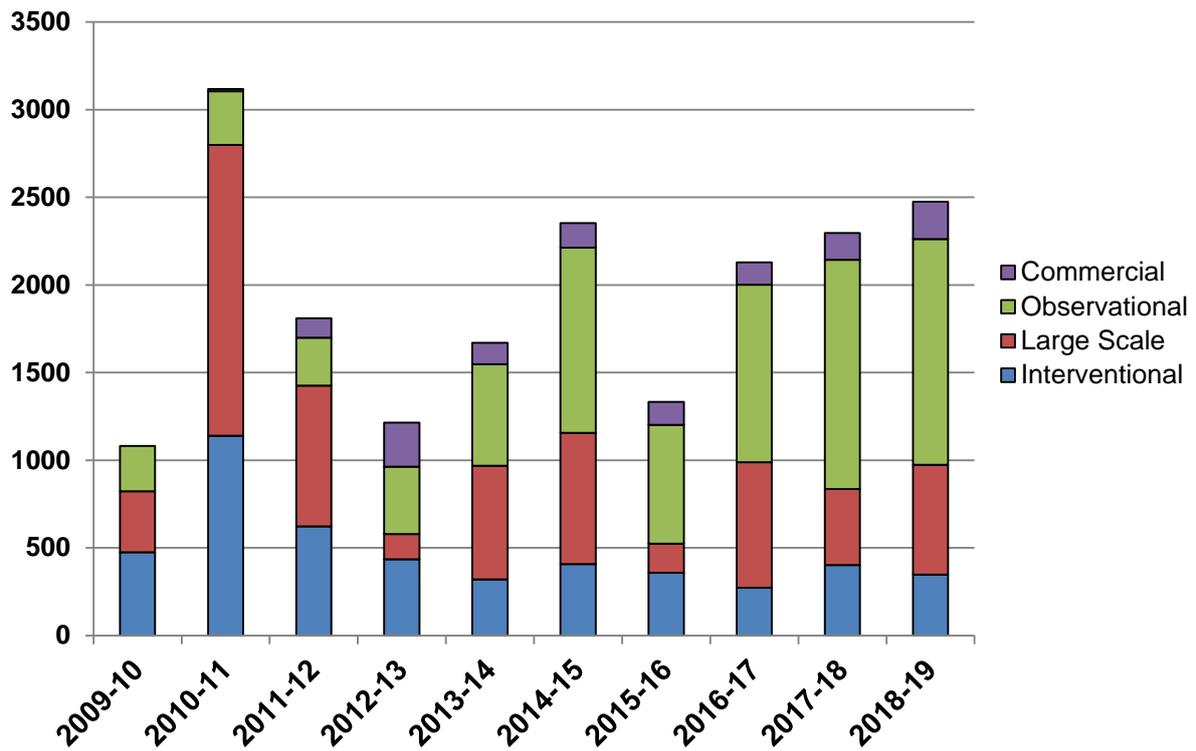


Figure 1. Recruitment to NIHR Portfolio studies by financial year and type of study

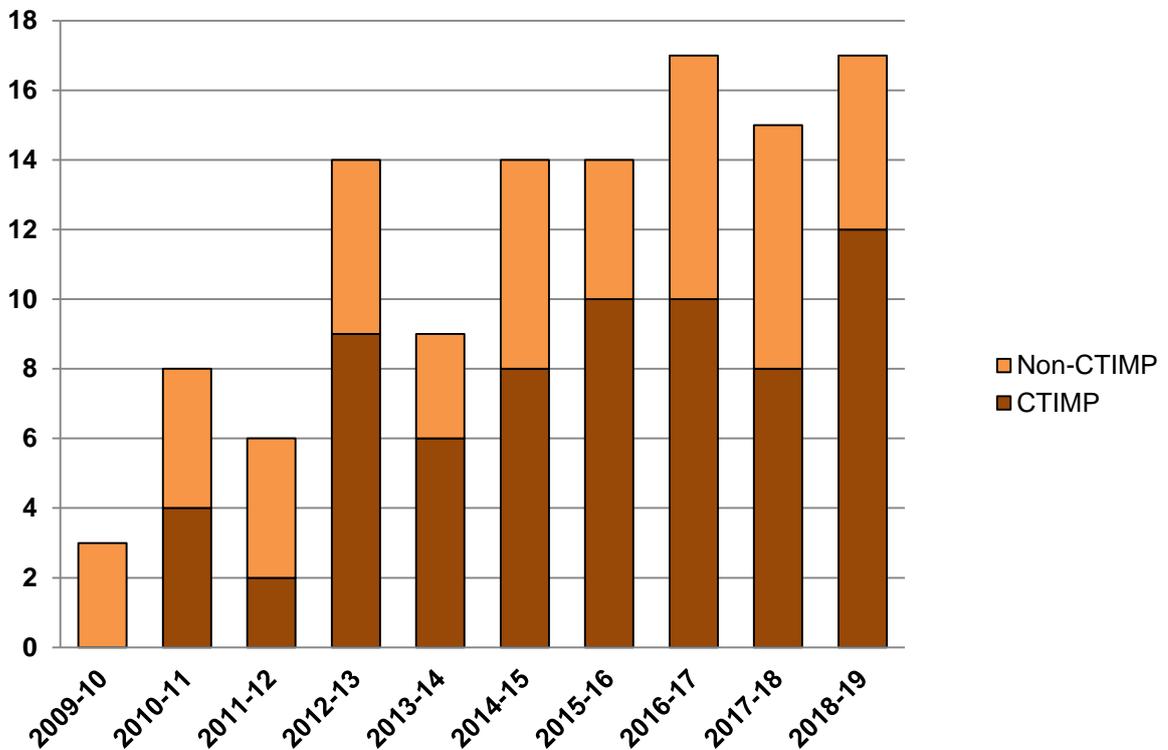
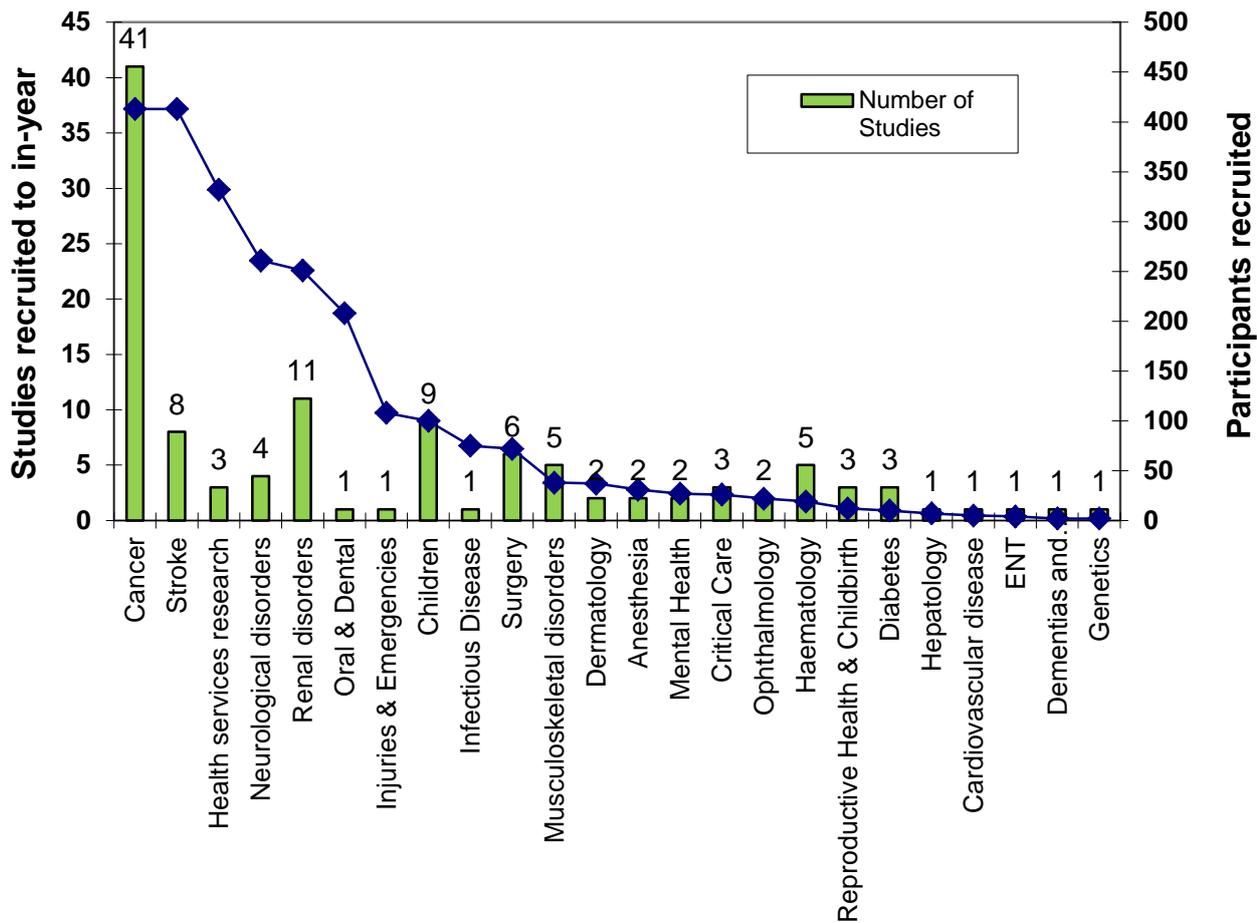


Figure 2. Industry studies opened by financial year



**Figure 3.** Recruitment to NIHR CRN Portfolio studies during 2018-19 FY. Green bars & numbers indicate discrete studies recruited to; blue diamonds indicate total participant recruitment - both by CRN Specialty Group

## 5. Overview of Research Activity during 2018-19 Financial Year

### Solid Tumour Oncology Research Team: Sue Drakeley & colleagues

The Solid Tumour Oncology Research Team provides opportunities for cancer patients to improve treatment outcomes. These alternative treatments include CTIMPs and radiotherapy, along with quality of life assessments to improve future pathways.

[ESTHER - A disease registry study to prospectively observe treatment patterns and outcomes in patients with HER2-positive unresectable locally advanced or metastatic breast cancer](#)

ESTHER closed to recruitment in April 2018. EKHUFT recruited 16 patients which was over our initial target of 15 patients. We were 6<sup>th</sup> out of 26 sites nationally. Patients will be followed up for at least 5 years after the last patient enrolled (approx. 2023).

[GO2 - Optimizing Chemotherapy for Frail and Elderly Patients with Advanced Gastroesophageal Cancer](#)

At the ASCO 2019 Annual Meeting the results presented for the GO2 phase III trial. Please open the below PDF to read this presentation.



GO2 ASCO slides  
02-06-2019.pdf

[ENZARAD - Study Title: Randomised phase 3 study of enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised, prostate cancer.](#)

Enzalutamide is a new hormone treatment taken as tablets. Previous trials have proven that enzalutamide improves survival and quality of life in men with prostate cancer that has stopped responding to standard hormone treatments and chemotherapy. This large, international randomised trial will determine if treatment with enzalutamide can improve survival and quality of life in men starting radiation and hormone therapy for prostate cancer that does not seem to have spread beyond the prostate. Here at EKHUFT we recruited 18 patients and were 10<sup>th</sup> in the top recruiters worldwide.

[STAMPEDE – Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy](#)

The STAMPEDE trial was set up to see if we could improve prostate cancer treatment by adding things to standard hormone therapy. The results for the radiotherapy comparison were reported in October 2018. These results suggest that people whose prostate cancer has a low metastatic burden and who are starting long-term hormone therapy for the first time are likely to benefit from radiotherapy in addition to the current standard treatment. STAMPEDE think these results will help improve how future patients with prostate cancer are treated.

<http://www.stampedetrial.org/media/1995/radiotherapy-to-the-primary-tumour-for-newly-diagnosed-metastatic-prostate-cancer.pdf>

The STAMPEDE trial is still carrying on, and is looking at a number of other approaches that might help improve treatment of men with prostate cancer.

HORIZONS study: Understanding the impact of cancer diagnosis and treatment on everyday life

This observational study closed to recruitment on 31<sup>st</sup> March 2019. We recruited a total of 41 patients over 3 cohorts (Gynae – 14, Breast – 17, NHL – 10).

PERSEPHONE - Duration of Trastuzumab / Herceptin® with Chemotherapy in Patients with Early Breast Cancer: six months versus twelve

EKHUFT recruited a total of 74 patients into PERSEPHONE with the trial closing July 2015. Four years on and the results of the study have been published online in The Lancet. These results show that women who took Herceptin for six months fared no worse than patients who had standard 12 months treatment in terms of breast cancer returning.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)30650-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30650-6/fulltext)

## **QEQM Research Team: Nikki Crisp & colleagues**



Our team has undergone a number of changes over the past year and is now working towards a more efficient site-based model. We have welcomed the integration of delivery staff previously supporting stroke studies. This has allowed the whole team to support new areas and for PIs to consider other research areas within their speciality. We are also supporting the delivery and set-up of studies in new areas of obstetrics, respiratory and pre-term birth.

We are keen to engage with new PIs. In the past year we have supported new PIs in Cardiology, Respiratory, Dermatology and Obstetrics. We wish to further the development of non-medical PIs and are currently supporting Nurses and Therapists new to this role.

Our surgical team involvement continues to grow with the development of strong working relationships with surgeons, theatres and ward staff. We are also growing research activity in Anaesthetics, MS, Cardiology and Gastroenterology.

One of our biggest achievements has been the growth of commercial-contract studies. We have had particular success in medical device commercial studies, gaining recognition for being top international recruiters which has led to being approached to participate in our first Clinical Trial of a Medical Device involving a non-CE marked device.

Our team continues to develop. We have a Research Associate Practitioner to co-ordinate pathology research activities. Two members of our team have completed their care certificates and one member of the team is a GCP Facilitator who supports the delivery of GCP and PI training across the Trust. The team have also welcomed the introduction of student nurse placements and are committed to supporting this initiative. We continue to promote research through hospital events, research notice boards and social media.

**Other research output (conference proceedings, abstracts, poster & oral presentations; invited lectures; invited contributions to books etc.):**

Liz Van Rossen – abstract accepted for a poster presentation at the Annual European Congress of Rheumatology EULAR 2019

## **Ophthalmology: Nishal Patel**

**Precis of research:** Retinal Research with interest in Artificial Intelligence

**Other research output (conference proceedings, abstracts, poster & oral presentations; invited lectures; invited contributions to books etc.):**

Invited speaker Feb 2019 College of Optometry: OCT Angiography: Going with the flow

Invited speaker Oct 2018 National OCT meeting: OCT Back to the future

ARVO poster abstracts

Reverse polarity OCT Angiography as a biomarker of neovascular and ischaemic retinal diseases

### **Role of OCTA Flow Indices in Neovascular ARMD**

Clinical outcomes of anti-VEGF naïve and non-naïve Ozurdex treated eyes in Diabetic Macular Oedema (DMO).

Clinical outcomes of naïve and non-naïve Ozurdex treated eyes in Retinal Vein Occlusion



### **New high degree supervision during 2018-19:**

PhD University of Kent, Artificial intelligence in Diabetic macular oedema using OCT imaging  
MSc Ophthalmology University of Edinburgh  
MSc Christchurch University

### **Peer-reviewed publications during 2018-19 FY:**

- 1) Safety and Efficacy of Switching from Aflibercept to Ranibizumab in Patients with Neovascular Age-Related Macular Degeneration in Europe: SAFARI Study
- 2) Ocriplasmin for vitreomacular traction in clinical practice: the INJECT study
- 3) Subretinal Hyper-Reflective Material Seen on Optical Coherence Tomography as a Biomarker for Disease Monitoring in Age-Related Macular Degeneration
- 4) Resource Use and Real-World Outcomes for Ranibizumab Treat and Extend for Neovascular Age-Related Macular Degeneration in the UK: Interim Results from TERRA

**Neuro-rehabilitation: Dr Mohamed Sakel** (FRCP) Consultant Physician in Neuro-rehabilitation & Director of Neuro-rehabilitation Service

**Karen Saunders** Consultant Research Fellow, Neuro-physiotherapist

It has been an exciting year for the neuro-rehab clinical research team. Dr Mohamed Sakel has continued to develop and lead a diverse portfolio of innovative clinical research activity. The outstanding calibre of his research activity was recognised on June 14<sup>th</sup> 2018, when he was presented with an Award of Honour as an Outstanding NHS Star Leader. The Award was made in recognition of achievements above and beyond traditional clinical practice, with Dr Sakel's identified track record of high quality clinical research focused on improving patients' lives being of an outstanding calibre. Research partnerships have been strengthened with local, regional and international charities leading to high research impact. In April 2018, Dr Sakel and Karen were invited and presented lectures as part of "MS Awareness Week" at the local Kent MS Therapy Charity Centre, which has subsequently resulted in numerous individuals, who attend the Centre, taking part in the current Rapper 4 robotic balance trial. There has been widespread interest across the South East with MS Therapy Charity centres in Surrey, Brighton and Reading supporting and disseminating information to their members.



Over the year, Dr Sakel has been invited and presented clinical research updates to numerous local, regional and international Brain Injury Charity Meetings, including Headway, Epilepsy Now, and SWBF Foundation. In addition he is Chair of Kent Brain Injury Forum Charity, so contributes regular research updates to AGM meetings.



In October, Dr Sakel chaired a highly successful 9th Brain Injury Multi-disciplinary Conference, sharing news on cutting edge research on neuro-modulation for the treatment and relief of symptoms of Parkinson’s Disease (Professor David Wilkinson & Dr Sakel) and balance research using robotics in MS (Karen & Dr Sakel). The conference was fully booked (100 people) and feedback evaluation identified a large positive research impact with respondents identifying that the learning gained would enhance and improve their clinical practice.

In November, Karen was awarded postgraduate qualification in Qualitative Research Methods from Oxford University with completion of their Masters module. This qualification along with attending a Professional Course on research approaches for evaluation of professional practice, including realist evaluation and implementation science, has endowed the neuro-rehabilitation

research team with enhanced research expertise and skills to investigate and explore attitudes, beliefs and behaviours and how these factors impact on clinical practice and healthcare delivery.

In March 2019, Dr Sakel launched and chaired an International Research Conference in Bangladesh to mark the initiation of collaborative research on Hearing rehabilitation in Dementia (SENSECOG Asia). His research activity now spans several continents (UK, Europe, US, Canada and Bangladesh) and he is Principal Investigator for the only robotic exoskeleton trials in the UK. Dr Sakel has specialist expertise and research interests in robotic exoskeleton research; assistive technologies; brain-computer interface for neuro-rehabilitation; spasticity management using Botulinum Toxin; neuro-modulation and rehabilitation for stroke survivors; vestibular stimulation for treatment of Parkinsons Disease and Brain Injury; Minimally Conscious States; Motor Neurone Disease and patient experience research.



Professor Stephen Smith (Trust Chair) invited Dr Sakel to present a lecture with interactive discussion to the first Trust Governors and members meeting at the William Harvey Hospital on March 5<sup>th</sup>. Dr Sakel gave a presentation on “Innovative clinical research into balance rehabilitation using the Rex robotic device”, which was described by one of the attending Governors as “inspirational”, reflecting a very positive impact made at an open public meeting attended by Trust Governors and members of the general public.

**Other research output (conference proceedings, abstracts, poster & oral presentations; invited lectures; invited contributions to books etc.):**

Oral presentations on EU research projects to members of Kent Brain Injury Forum charitable organisation in annual general meeting (19/04/2018) KS & Dr Sakel

Presentation of EU projects at NAIDEX 2018 (25-26/04/2018) KS

Joint invited lecture presentations at Kent MS Therapy Centre on “Mobility enhancement through robotic bionic clinical research” (Dr Sakel) and “Review of the benefits of Neuro-physiotherapy in MS” (KS) 27/04/2018

Invited poster presentation of patient clinical case report “Neuro-physiotherapy focused on sensory stimulation into the cortico-spinal system for motor recovery post basal ganglia stroke” at 12<sup>th</sup> International Society of Physical and Rehabilitation Medicine (ISPRM) in Paris, France (08-12/07/2018)  
K Saunders

Invited lecture on neuro-rehabilitation research by Dr Sakel given at Epilepsy Here now charity AGM meeting and oral presentation on EDUCAT project given by KS (03/09/2018)

3 poster presentations at “Transforming the future Research & Innovation” conference (EKHUFT) on 10/09/18 (KS & Dr Sakel) : Rapper 3 clinical research into balance program using robotic exoskeleton for people living with MS; Educat & Adapt EU projects.

“International collaborations - Research without Borders” International Symposium presented by Dr Sakel (02/10/18). Oral presentation at American Congress of Rehabilitation Medicine (ACRM) in Dallas, US.

Dr Sakel organised and chaired the 9th East Kent Brain Injury Multi-disciplinary Conference (12/10/18) with 13 guest speakers of both UK and international repute presenting research and clinical updates on a diverse range of innovative topics. The event was fully booked with approximately 100 people in attendance. Audience feedback identified topic content and organisation as excellent and that information and updates provided would be taken away and shared with their colleagues in other organisations, so clinical practice and learning was positively influenced by the event.

Invited presentation of Robotic clinical research trials at Selkams Regional MS meeting by Dr Sakel (25/01/2019).

Presentation of Rapper 4 clinical research trial to Kent Brain Injury AGM members attending meeting (28/02/2019) KS.

Presentation of Educat & Adapt EU projects at NAIDEX 2019 (26-27/03/2019) KS

## **Corporate Clinical Quality: Professor Kim Manley**

### **Precis of research: 'Guiding Lights for leadership in all contexts'**

This UK wide research team led by Professors Kim Manley (CCCU&EKHUFT) & Belinda Dewar of University of West of Scotland with Professors Assumpta Ryan (University of Ulster) and Debbie Roberts (University of Bangor) used a realist and appreciative framing approach to answer the question, How to strengthen Nursing, Midwifery and Allied Health Professional Leadership in all contexts? The study developed a synthesis based on the context, mechanism and output (CMO) configuration of realist evaluation. 132 papers were reviewed in regards to what works well and why and in what contexts leading to the development of cross cutting themes. Stakeholders contributed to ongoing interrogation, analysis and synthesis of the literature and cross cutting themes. Knowledge generated from the integrative literature review, a social media strategy and sense making workshops across the UK led to further development and co-creation of five "simple rules".

Development of 'simple rules', led to concept of 'guiding lights' which acts as a set of principles to enable and strengthen leadership within a range of contexts. These principles include 'The Light Between Us as interactions in our relationships', 'Seeing People's Inner Light', 'Kindling the Spark of light and keeping it glowing', 'Lighting up the known and the yet to be known' and 'Constellations of connected stars'

The realist methodology with additional synthesis from key stakeholders has provided new knowledge about the principles of effective leadership in health care. This new knowledge has been presented in such a way that facilitates use of 5 principles to inform further research, practice and policy development.

### **Other research output (conference proceedings, abstracts, poster & oral presentations; invited lectures; invited contributions to books etc.):**

#### **International Conference Symposia**

Manley, K., Jackson, C., McKenzie, C., Martin, A., Wright, T. (2018) Using participatory, practice development, delphi and realist research approaches to understand how frontline teams can use the workplace to integrate learning, development, improvement and innovation. Symposium. Royal College of Nursing International Research Conference, 17-19 April, Birmingham.

Manley, K., Jackson, C., McKenzie, C., Martin, A., Wright, T. (2018) Using participatory, practice development, delphi and realist research approaches to understand how frontline teams can use the workplace to integrate learning, development, improvement and innovation. Symposium. STTI 4th Biennial European Conference, 4-6 June, Cambridge.

#### **International Conference Presentations and Workshops**

Manley K, Jackson C (2019) *The Venus model for person centred transformation- supporting frontline teams to use the workplace to integrate learning, development, improvement and innovation* International RCN Education Conference 12-13<sup>th</sup> March Bristol

Manley, K; Jackson C; (2019) *The Venus Model: Inter-professional Learning for sustainable person-centred transformation* International Network for Health Workforce, Education Royal College of Surgeons, Dublin 2019

Manley, K., Jackson, C., McKenzie, C., Martin, A., Wright, T. (2018) *Transformational theories for continuous professional development (CPD): the workplace as a resource for learning and improving. Enhancing Practice* Leading and Facilitating within Practice Development 22-24 August, Basel, Switzerland.

Manley, K., Jackson, C., McKenzie, C., Martin, A., Wright, T. (2018) *Quality clinical leadership for improving patient safety with patients, carers and staff centre stage.* Enhancing Practice 2018 Leading and Facilitating within Practice Development 22-24 August, Basel, Switzerland.

Cardiff, S., Manley, K., Sanders, K., Webster, J. (2018) *Recognising and developing person centred, safe and effective workplace cultures that are also good places to work.* Enhancing Practice 2018 Leading and Facilitating within Practice Development 22-24 August, Basel, Switzerland

### **Keynote Addresses**

Manley K; Jackson C (2019) *The Venus Model for Person-Centered Sustainable Transformation – I. Leadership and Facilitation & The Venus Model for Person-Centered Sustainable Transformation – II. Practice Development, Improvement and Culture Change* Shared Decision-Making: Person-Centred Care, and the Values Agenda (SDM-I Conference). Monday 25<sup>th</sup> and Tuesday 26<sup>th</sup> March 2019. The Weston Hall, Ealing Campus, University of West London, UK. European Society for Person Centred Healthcare

Manley K (2018) *Developing Nurse, Midwife and AHP Leaders to provide person-centred, safe and effective care.* Manchester University NHS Foundation Trust Research Conference 'Sowing the seeds for research excellence.' Manchester 11th May

### **Grant awards during 2018-19:**

£48k Health Education England based on a capability and impact framework aligned to systems leadership linked to 25 years of research into consultant practice, to develop a self assessment tool and educational framework for multi-professional consultant practitioners

£30k Marie Curie UK To develop an integrated competence and career framework based around the person rather than the profession for providing person centred, safe and effective care

### **New high degree supervision during 2018-19 FY:**

Dr Ciaran Crowe (PhD by publication/portfolio): Transforming maternity services Action research study - linked to CCCU

Deidre Munro (Full time PhD): Realist synthesis and action research study to develop strategies that enable civility in the workplace CCCU & Republic of Ireland

Sharon Lee (PhD by publication/portfolio): Realist synthesis to answer what works and why for the new primary care networks locally.

#### **Peer-reviewed publications during 2018-19 FY:**

Manley K; Martin, A; Jackson C; Wright T A realist synthesis of effective continuing professional development (CPD): a case study of healthcare practitioners' CPD *Nurse Education Today* 2018; October. Volume 69: 134–141. <https://doi.org/10.1016/j.nedt.2018.07.010>

## **Neurology: Dr Sreed Harikrishnan**

### **Publications**

1. Cousins O, Girelli E, Harikrishnan S Neuromyelitis optica: an elusive cause of dysphagia BMJ Case Reports CP 2019;12:bcr-2018-227041
2. Zarkali A, Cousins O, Athauda D, et al Glial fibrillary acidic protein antibody-positive meningoencephalomyelitis Practical Neurology 2018;18:315-319

### **Poster**

1. Oliver C, Hina K, Sreedharan H WED 143 Chronic relapsing inflammatory optic neuritis (CRION) in the neuroinflammatory clinic Journal of Neurology, Neurosurgery & Psychiatry 2018;89:A16-A17

### **Research (details available via R&D)**

- Teriquol
- MS Registry
- TOPS study

## **Medicine: Dr Frank Muller**

**Precis of research:** Bowel cancer screening and Patient Care with Gastroenterological problems

**Other research output (conference proceedings, abstracts, poster & oral presentations; invited lectures; invited contributions to books etc.):**

Fegredo J; Patani B, Muller AF; Outcomes in patients who decline bowel cancer screening colonoscopy after positive faecal occult blood testing. *Gut* 2018 (abstract)

Preziosi G, Ha SM, Al-Hasani H, Fegredo J, Bagla N, Muller AF, Sebastian J, Tsiamoulos ZM

Complex Colorectal Polyp service in Southeast region: first annual results of a new service Gut 2018 (abstract)

Rashid Chawdhary F J, Muller, A F. A missed opportunity ? Colonoscopy withdrawal times in a large DGH Gut 2018 (abstract)

Peer-reviewed publications during 2018-19 FY:

Mallet M; Vincent N; Muller AF : Patient Management : Gastroparesis. The Foundation Year Journal 2018; 3 : 72-75.

## **Haemophilia Centre (Cancer Services): Dr Gillian Evans**

### **Precis of research:**

Our research programme is multidisciplinary and includes commercial studies, investigator initiated and portfolio research. The department has a successful NIHR and commercial funding and publication record. The breadth of our research programme is outlined at the end of this report. Eight out of nine studies have recruited to time and target. We continue to horizon scan for future potential studies. The breadth of research studies offered allows the team to offer new therapies and interventions to a significant proportion of our patients. We have opened a gene therapy trial in haemophilia B which offers the opportunity for cure of haemophilia.

### **Other research output (conference proceedings, abstracts, poster & oral presentations; invited lectures; invited contributions to books etc.):**

DOLPHIN Study: During the last year we completed recruitment to our NIHR RfPB funded study which aimed to evaluate the feasibility of conducting a randomised controlled trial of an age-appropriate physiotherapy intervention designed to improve muscle strength, physical function and the way boys use their joints during walking and everyday activities. In partnership with children with haemophilia, their families and clinicians we have co-produced an intervention. In terms of dissemination to patients and the public, we have published study newsletters on the Haemophilia Society website, published a summary of the study in the quarterly member's magazine of the Haemophilia Society as well as presenting the study at the annual patient conference of the Haemophilia Society in November 2018. Furthermore, the study was featured on the BBC SouthEast Today news programme on 3rd January, 2019 on the lunchtime and evening editions including interviews with the chief investigator as well as a parent of one of the boys participating in the study were featured providing a personal experience on why they were participating and what the study meant to them. Dissemination to healthcare professionals and researchers has included sharing newsletters and study updates on the ResearchGate platform <https://www.researchgate.net/>, open access publication of the protocol to BMJ Open, poster presentations at the Annual Congress of the European Association for Haemophilia and Allied Disorders in Prague in February 2019 and the World Confederation of Physical Therapy Congress in Geneva in May 2019.

Point-of-care-ultrasound: We have established point-of-care ultrasound clinics to evaluate early signs of arthropathy in people with haemophilia and have received a research grant to explore the feasibility of teaching patients to perform self-assessment of bleeding episodes at home to reduce the need to attend hospital - “the ultimate selfie”, just like they are taught to perform venepuncture to administer their treatment.

Combined Physiotherapy-Podiatry Clinic: We have established a combined physiotherapy-podiatry clinic for people with haemophilia to improve foot and ankle health. Patient satisfaction with the clinic is very high and 90% received an intervention they would not previously received. Clinically, patients have reported less pain and fewer bleeds following this intervention.

Gene Therapy Trial Opened: This year we opened and recruited our first patient to a A Phase I/II, Open Label, Multicentre, Ascending Single Dose, Safety Study of a Novel Adeno- Associated Viral Vector (FLT180a) in Patients With Haemophilia B.

#### International Conference Poster Presentations

##### *European Association of Haemophilia and Allied Disorders, Prague, 2019*

- Stephensen D, Camp C, Carroll L, Collins P, Elston D, Gallagher P, Khair K, McKeown W, O’Hara J, Shapiro S, Stanworth S, Waterman A, Woollard L, Upadhyaya S Laffan M. The top 10 research priorities in bleeding disorders: A James Lind Alliance Priority Setting Partnership.
- Stephensen D, Bladen M, Carroll L, Drechsler WI, Lowery D, Pellatt-Higgins T, Saloniki E, Hashem F. Development Of A Haemophilia Physiotherapy Intervention For Optimum Musculoskeletal Health (Dolphin Trial)

##### *World Federation of Haemophilia Musculoskeletal Congress, Madrid, 2019*

- Dodd C, Travelli A. Combined Physiotherapy and Podiatry Haemophilia Clinic: Establishing a New Service

##### *World Federation of Haemophilia World Congress, Glasgow, 2018*

- Harbidge H, Stephensen D, Wells A. Inter-rater variability of global gait score assessment using the HJHS criteria.
- Pasi J, Hart DP, Stephensen D, Patel V. A novel physiotherapy-led musculoskeletal clinic – the perceptions of persons with haemophilia.
- Laffan M Camp C, Carroll L, et al., Research priorities in bleeding disorders: A James Lind Alliance Priority Setting Partnership
- T. Roberts, M. Mathias, N. Curry, S. Mangles, M. Makris, P. Collins, C. Tait, S. Austin, M. Laffan, **G. Evans**, J. Hanley, M. Phillips, Charlie Hay, P. Chowdary UK EHL Outcomes Registry – 18 month update

##### *British Society for Haematology Meeting, Glasgow 2019*

- Nichola Cooper, Drew Provan, Marie Scully, Phillip L.R. Nicolson, Charles Percy, Catherine Bagot, Jecko Thachil, Quentin A. Hill, Tim Nokes, Henri Grech, Charlotte Bradbury, Tina Dutt, Kate Talks, Gillian Evans, Sue Pavord, Sarah Wexler, Nicholas Ramscar, Andrew Ervin, Luke Saunders. Real world effectiveness of thrombopoietin receptor agonists (TRAs) in the management of immune thrombocytopenia (ITP) in the UK: results from a post-hoc analysis of the TRAIT study.

### **Grant awards during 2018-19 FY:**

1. Sobi Investigator Initiated Research Grant; £21,418, Stephensen. *Identifying Performance-based Outcome measures of Physical function in people with haemophilia.*
2. Health Education Kent, Surrey and Sussex (HEKSS)/NIHR Integrated Clinical Academic Programme. Research Internships for Nurses, Midwives and Allied Health Professionals (Collaboration with University of Kent)
3. Novo Nordisk Access to Insight Clinical Research Grant; £169,500, Stephensen, Hart, Pasi. *Home ultrasound – empowering the haemophilia patient to distinguish between bleeding and non-bleeding episodes*
4. NIHR Research for Patient Benefit (RfPB) Programme: PB-PG-0215-36091; £247,816, Stephensen, Evans, Drechsler, Hahsem, Yang, Bladen, McKeown. *Development Of a haemophiLia PHysiotherapy INtervention for optimum musculoskeletal health (DOLPHIN) - feasibility of a randomised controlled trial*
5. EKHUFT Research and Innovation Catalyst Funding, £7,500: Dodd. *Development of a Pilates-based Haemophilia InTervention (PHIT study)*

### **New high degree supervision during 2018-19 FY:**

Dr David Stephensen is currently supervising 3 PhDs, one of which is a HEE/NIHR doctoral fellowship, 2 HEE/NIHR Pre-doctoral fellowships and 2 MSc research dissertations in collaboration with University of Kent, Canterbury Christ Church University, St Georges' University, University of West England and Kings College London

#### Doctoral and pre-doctoral research programmes;

- HEE/NIHR Clinical Doctoral Research Fellowship, Developing a rehabilitation intervention for the management of chronic arthritic joint pain in people with haemophilia. St Georges' University,
- HEE/NIHR Clinical Doctoral Research Fellowship application, Effect of portable pulsed short wave therapy on pain and bleed resolution in people with haemophilia. University of South West England
- HEE/NHIR Pre-doctoral Clinical Academic Fellowship (PCAF), Effects of Galvanic Vestibular Stimulation (GVS) on postural instability in patients with Parkinson's disease – a dose comparison study
- Development of ultrasound self-assessment to enable for patients with haemophilia to detect and manage acute musculoskeletal bleeding events. Doctoral Programme, Canterbury Christ Church University, Novo Nordisk Access to Insight Clinical Research Grant
- Effects of swimming rehabilitation on pain, function and quality of life for patients with persistent low back pain. Doctoral Programme, Canterbury Christ Church University

#### Masters research supervision

- Effect of a 12-week muscle strengthening programme on strength, gait and function in children with haemophilia, Kings College London
- Comparison of biomechanical gait parameters of young children with haemophilia to adolescents with haemophilia, Kings College London

## Peer-reviewed publications during 2018-19 FY:

1. Hashem F, Bladen M, Carroll L, Dodd C, Drechsler WI, Lowery D, Patel V, Pellatt-Higgins T, Saloniki E-C, Stephensen D. Protocol for a feasibility randomised controlled trial of a musculoskeletal exercise intervention versus usual care for children with haemophilia. *BMJ Open* (In Press)
2. Shapiro S, Stephensen D, Camp C, Carroll L, Collins P, Elston D, Gallagher P, Khair K, McKeown W, O'Hara J, Stanworth S, Waterman A, Woollard L, Upadhyaya S, Laffan M. The top 10 research priorities in bleeding disorders: a James Lind Alliance Priority Setting Partnership. *British Journal of Haematology*. 2019 (In Press) doi:10.1111/bjh.15928.
3. Stephensen D, de Kleijn P, Matlary RE, Katzerova M, McLaughlin P, Ryan A, Lobet S. Scope of practice of haemophilia physiotherapists: a European survey. *Haemophilia*, 2019; 25(3):514-520. doi:10.1111/hae.13727.
4. Stephensen D, Bladen M, Carroll L, Drechsler WI, Lowery D, Pellatt-Higgins T, Saloniki E, Hashem F. Development of a haemophilia physiotherapy intervention for optimum musculoskeletal health (Dolphin trial). *Haemophilia* 2019; 25(S1): PO76
5. Stephensen D, Camp C, Carroll L, Collins P, Elston D, Gallagher P, Khair K, McKeown W, O'Hara J, Shapiro S, Stanworth S, Waterman A, Woollard L, Upadhyaya S Laffan M. The top 10 research priorities in bleeding disorders: A James Lind Alliance Priority Setting Partnership. *Haemophilia*, 2019, 25(S1) PO75
6. Scott MJ, Xiang H, Hart DP, Palmer B, Collins PW, Stephensen D, Sima CS, Hay CRM. Treatment regimens and outcomes in severe and moderate haemophilia A in the UK: The Thunder Study. *Haemophilia*, 2018; 25(2):205-212. doi:10.1111/hae.13616
7. Stephensen D, Bladen M, McLaughlin P. Recent advances in musculoskeletal physiotherapy for haemophilia. *Therapeutic Advances in Hematology*. 2018; 9(8) 227-237
8. Stephensen D, Hashem F, Corbett K, et al., Effects of preoperative and postoperative resistance exercise interventions on recovery of physical function in patients undergoing abdominal surgery for cancer: a systematic review of randomised controlled trials. *BMJ Open Sport Exerc Med*. 2018; 25:4(1):e000331. doi: 10.1136/bmjsem-2017-000331.
9. Stephensen D, Classey S, Harbidge H, Patel V, Taylor S, Wells A. Physiotherapist inter-rater reliability of the Haemophilia Early Arthropathy Detection with Ultrasound protocol. *Haemophilia*. 2018; 24(3):471-476 2018.
10. Harbidge H, Stephensen D, Wells A. Inter-rater variability of global gait score assessment using the HJHS criteria. *Haemophilia*, 2018; 24 (S5): 165, W-FPMSK-002(366).
11. Pasi J, Hart DP, Stephensen D, Patel V. A novel physiotherapy-led musculoskeletal clinic – the perceptions of persons with haemophilia. *Haemophilia*, 2018; 24 (S5): 166, W-FPMSK-007(252).
12. Laffan M Camp C, Carroll L, et al., Research priorities in bleeding disorders: A James Lind Alliance Priority Setting Partnership. *Haemophilia*, 2018; 24 (S5): 655.
13. Stephensen D, Classey S, Hopper D. Exploring patient perceptions of ultrasound “selfies” to engage patient confidence in recognizing and managing musculoskeletal bleeding episodes. *Haemophilia*, 2018; 24(S1): 13.
14. Patel V, Stephensen D, Jawad A. The clinical effectiveness of intra-articular injections (IAI) in patients with haemophilia. *Haemophilia*, 2018: 24 (S1); 27
15. Ben Johnson, Rachel Doak, David Allsup, Emma Astwood, Gillian Evans, Charlotte Grimley, Beki James, Bethan Myers, Simone Stokley, Jecko Thachi, Jonathan Wilde, Mike Williams, Mike Makris, Gillian C. Lowe, Yvonne Wallis, Martina E. Daly, Neil V. Morgan on behalf of the UK GAPP Study Group. A

comprehensive targeted next-generation sequencing panel for genetic diagnosis of patients with suspected inherited thrombocytopenia *Res Pract Thromb Haemost.* 2018;2:640–652.

16. Quentin A. Hill, John D. Grainger, Jecko Thachil, Drew Provan, Gillian Evans, Mamta Garg, Charlotte Bradbury, Catherine Bagot, John A. Kanis, Juliet E. Compston, and on behalf of the British Society of Haematology in conjunction with the UK ITP forum. The prevention of glucocorticoid-induced osteoporosis in patients with immune thrombocytopenia receiving steroids: a British Society for Haematology Good Practice Paper *British Journal of Haematology*, 2019, 185, 410–417

## Studies Open to Recruitment

<b>UKAITPR</b>		
United Kingdom Adult Idiopathic Thrombocytopenic Purpura (ITP) Registry: An Investigation of Disease Progression, Treatment Effectiveness, and Co-morbid Conditions		
<b>P.I. Dr G Evans</b>		
<u>EDGE ID:</u> 27693 <u>R&amp;I:</u> 2008/HAEMA/01 <u>Protocol ID:</u> 4961 <u>NIHR Portfolio Study ID:</u> 4961	<b>Royal London Hospital</b> <u>C.I. Dr V McDonald</u> (amendment 5) 0207 377 7000 Ext. 61114 <u>Data Manager:</u> Haroon Miah uk-ityp.registryteam@nhs.net	<u>Study opened:</u> 30.07.08 <u>Recruited:</u> 102
<b>A:Sure Elocta</b> (Observational) 24 month non interventional study to evaluate the effectiveness of Elocta compared to conventional factor products in the prophylactic treatment of patients with Haemophilia A		
<b>P.I. Dr K Elliott</b>		
<u>EDGE ID:</u> 72298 <u>R&amp;I:</u> 2016/KCC/14 <u>NIHR Portfolio Study ID:</u> 30352	<b>Funder &amp; Sponsor: SOBI</b> Andrea Goodyer CRA <u>Tel:</u> 01480403696 <u>Cell:</u> 07930277125 <u>Email:</u> AGoodyer@mapigroup.com or CRA_ASURE@mapigroup.com www.mapigroup.com	<u>Study Opened:</u> 02/03/2017 <u>Recruitment extended to:</u> 30/04/2019  <u>Recruitment Target:</u> 8  <u>Recruited:</u> 10 5 Elocta and 5 Control patients
<b>Haemophilia Centre Project</b> NIHR BioResource – Rare Diseases		
<b>P.I. Dr C Roughley</b>		
<u>EDGE ID:</u> 21874 <u>R&amp;I:</u> 2014/KCC/12 <u>NIHR Portfolio Study ID:</u> 15941	<u>Senior Research Study Coordinator:</u> Lindsey Berends <u>Email:</u> lindsey.berends@bioresource.nihr.ac.uk	<u>Study Opened:</u> 22/12/2014  <u>Recruited:</u> 39
<b>Bayer 19580</b> Multiple escalating dose study of BAY 1093884 in adults with Haemophilia A or B with or without inhibitors		
<b>P.I. Dr C Roughley</b>		
<u>EDGE ID:</u> 105727 <u>R&amp;I:</u> 2018/KCC/06 <u>NIHR Portfolio Study ID:</u> 37338	<b>Sponsor: Bayer AG, D-51368 Leverkusen, Germany</b> <u>CRA:</u> Jason Kane	<u>Study Opened:</u> 25/09/2018  <u>Recruitment Target:</u> 1

<b>EHL – Extended half-life – observational study</b>		
Evaluation of Real World Outcomes with Extended half-life concentrates for routine clinical use in Haemophilia A & B		
<b>P.I. Dr G Evans</b>		
<u>EDGE ID:</u> 85013	<b>Royal London Hospital</b>	<u>Study Opened:</u> 28/02/2017
<u>R&amp;I:</u> 2016/HAEM/02	<u>Trial Manager:</u> Mark Phillips	<u>Recruitment Target:</u> 6
<u>NIHR Portfolio Study ID:</u> 32890	<u>Address:</u> Trial Manager, Gene Therapy Trials Katherine Dormandy Haemophilia and Thrombosis Centre Royal Free Hospital Pond Street London, NW3 2QG <u>Email:</u> mark.phillips@ucl.ac.uk <u>Tel:</u> 02077 940500 ext 38784 <u>Patient registration email form to:</u> rf.ehlregistry@nhs.net	<u>Recruited:</u> 8

<b>FIX-GT</b>		
Factor IX gene therapy trial – A Phase I/II, Open label, Multicentre, Ascending Single Dose, Safety Study of a Novel Adeno-associated Viral Vector (FLT180a) in Patients With Haemophilia B		
<b>P.I. Dr G Evans</b>		
<u>EDGE ID:</u> 100077	<u>CRA for Syneos:</u> Mike Dymond	<u>Study Opened:</u> 04/02/2019
<u>R&amp;I:</u> 2018/HAEM/03	<u>Email:</u> mike.dymond@syneoshealth.com	<u>Recruitment Target:</u> 1
<u>NIHR Portfolio Study ID:</u> 34906		

## Studies Closed to Recruitment

<b>AHEAD</b>		
<b>ADVATE HAEMOPHILIA OUTCOME DATABASE</b>		
<b>P.I. Dr G Evans</b>		
<u>EDGE ID:</u> 13152	Baxalta	<u>Study Opened:</u> 12/11/2012
<u>R&amp;I:</u> 2012/HAEMO/02	<u>Senior Clinical Research Associate:</u> Renee Babayemi	<u>Study Closed to Recruitment:</u> 20/11/2014
<u>NIHR Portfolio Study ID:</u> 12416	<u>Email:</u> Renee.Babayemi@synteract.com	<u>Recruitment Target:</u> 5
		<u>Recruited:</u> 6

<b>FLIGHT</b>		
<b>A multicentre randomised trial of first line treatment pathways for newly diagnosed immune thrombocytopenia: Standard steroid treatment versus combined steroid and mycophenolate</b>		
<b>P.I. Dr G Evans</b>		
<u>EDGE ID:</u> 66564	<u>C.I.:</u> Charlotte Bradbury	<u>Study Opened:</u> 03/10/2017
<u>R&amp;I:</u> 2017/KCC/07	<u>Email:</u> c.bradbury@bristol.ac.uk	<u>Study Closed to Recruitment:</u> 08/02/2019
<u>NIHR Portfolio Study ID:</u> 34919	<u>Research Manager:</u> Julie Pell	<u>Recruitment Target:</u> 4
	<u>Data Manager:</u> Paula Foscarini-Craggs	<u>Recruited:</u> 8
	<u>Email:</u> flight@cardiff.ac.uk	

<b>DOLPHIN</b>		
<b>Development of a haemophilia physiotherapy intervention for optimum musculoskeletal health.</b>		
<b>C.I. Dr D Stephensen, P.I. C Dodd</b>		
<u>EDGE ID:</u> 97442	Feasibility Of RCT and exercise intervention. Three years feasibility study before study is rolled out to other sites.	<u>Study Opened:</u> 31/05/2018
<u>R&amp;I:</u> 2016/HAEM/01		<u>Study Closed to Recruitment:</u> ?
		<u>Site Recruitment Target:</u> 5
		<u>Recruited:</u> 5

## 6. Peer-reviewed publications from April 2018 to March 2019<sup>5</sup>

1. Abohelaika S, Wynne H, Avery P, Robinson B, Jones L, Tait C, Dickinson B, Salisbury J, Nightingale J, Green L, Kamali F. Individual and monitoring centre influences upon anticoagulation control of AF patients on warfarin: A longitudinal multi-centre UK-based study. *Eur J Haematol*. 2018 Oct;101(4):486-495. doi: 10.1111/ejh.13130. Epub 2018 Aug 3.
2. Ahmad E, Hafeez K, Arshad MF, Isuga J, Vrettos A. Hypothyroidism conversion to hyperthyroidism: it's never too late. *Endocrinol Diabetes Metab Case Rep*. 2018 Aug 3;2018. pii: 18-0047. doi: 10.1530/EDM-18-0047. eCollection 2018.
3. Akhtar M, Boshnaq M, Nagendram S. Quality improvement measures: effects on rectal cancer tissue biopsy process. *Int J Health Care Qual Assur*. 2018 Aug 13;31(7):775-783. doi: 10.1108/IJHCQA-06-2017-0097.
4. Alexander V, Rudd J, Walker D, Wong G, Lunt A, Hamakarim Z, Bell S, Balfour A, Davis J, Pitkin L, Pelser A. Thy 3F and 3a malignancy rate, a multisite regional retrospective case series. *Ann R Coll Surg Engl*. 2018 Sep;100(7):545-550. doi: 10.1308/rcsann.2018.0103. Epub 2018 Jul 3.
5. Aquilina A, Pirotta T, Aquilina A. Acute liver failure and hepatic encephalopathy in exertional heat stroke. *BMJ Case Rep*. 2018 Jul 30;2018. pii: bcr-2018-224808. doi: 10.1136/bcr-2018-224808.
6. Arshad MF, Ahmad E, Biddanda AN, Sharif M. Status dystonicus: a diagnosis delayed. *BMJ Case Rep*. 2018 Sep 12;2018. pii: bcr-2018-226531. doi: 10.1136/bcr-2018-226531.
7. Barrientos JC, O'Brien S, Brown JR, Kay NE, Reddy NM, Coutre S, Tam C, Mulligan S, Jaeger U, Devereux S, Pocock C, Robak T, Schuster SJ, Schuh A, Gill D, Bloor A, Dearden C, Moreno C, Cull G, Hamblin M, Jones JA, Eckert K, et al. Improvement in Parameters of Hematologic and Immunologic Function and Patient Well-being in the Phase III RESONATE Study of Ibrutinib Versus Ofatumumab in Patients With Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. *Clin Lymphoma Myeloma Leuk*. 2018 Dec;18(12):803-813.e7. doi: 10.1016/j.clml.2018.08.007. Epub 2018 Aug 18.
8. Belcher HJCR, Smith H. Extended dynamometry: reference values. *J Hand Surg Eur Vol*. 2019 Feb;44(2):196-202. doi: 10.1177/1753193418805959. Epub 2018 Nov 8.
9. Boshnak N, Boshnaq M, Elgohary H. Evaluation of Platelet Indices and Red Cell Distribution Width as New Biomarkers for the Diagnosis of Acute Appendicitis. *J Invest Surg*. 2018 Apr;31(2):121-129. doi: 10.1080/08941939.2017.1284964. Epub 2017 Feb 16.

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<sup>5</sup> Articles appearing in peer-reviewed publications are identified through two sources: firstly, by PubMed search using search term ((((((((((Queen Elizabeth the Queen Mother Hospital[Affiliation]) OR William Harvey Hospital[Affiliation]) OR Kent and Canterbury Hospital[Affiliation]) OR East Kent University[Affiliation]) OR East Kent University NHS[Affiliation]) OR East Kent University Hospital[Affiliation]) OR East Kent University Hospitals[Affiliation]) OR East Kent Hospital) OR East Kent Hospitals)) AND ("2017/04/01"[Date - Publication] : "2018/03/31"[Date - Publication])), following which each abstract is manually checked for at least one EKHUFT author affiliation; **this list may duplicate or be in addition to publications cited elsewhere in this report.**

10. Boshnaq M, Phan YC, Martini I, Harilingam M, Akhtar M, Tsavellas G. Limberg flap in management of pilonidal sinus disease: systematic review and a local experience. *Acta Chir Belg.* 2018 Apr;118(2):78-84. doi: 10.1080/00015458.2018.1430218. Epub 2018 Feb 1. Review.
11. Bowman A, Rudolfer S, Weller P, Bland JDP. A prognostic model for the patient-reported outcome of surgical treatment of carpal tunnel syndrome. *Muscle Nerve.* 2018 Dec;58(6):784-789. doi: 10.1002/mus.26297. Epub 2018 Oct 15.
12. Brimiouille M, Al-Lami A, Marzouk S, Emerson H, Balfour A, Dhar V, Nixon IJ. Ensuring patient safety when implementing a new diagnostic pathway for thyroid nodules. *Ann R Coll Surg Engl.* 2018 May;100(5):366-370. doi: 10.1308/rcsann.2018.0031. Epub 2018 Mar 15.
13. Chitambira B, McConaghy C. Use of optokinetic chart stimulation to restore mobility and reduce ataxia in a patient with pseudo-Cushing ataxia. *BMJ Case Rep.* 2018 Aug 23;2018. pii: bcr-2018-225346. doi: 10.1136/bcr-2018-225346.
14. Christakoudi S, Runglall M, Mobillo P, Tsui TL, Duff C, Domingo-Vila C, Kamra Y, Delaney F, Montero R, Spiridou A, Kassimatis T, Phin-Kon S, Tucker B, Farmer C, Strom TB, Lord GM, Rebollo-Mesa I, Stahl D, Sacks S, Hernandez-Fuentes MP, Chowdhury P. Development of a multivariable gene-expression signature targeting T-cell-mediated rejection in peripheral blood of kidney transplant recipients validated in cross-sectional and longitudinal samples. *EBioMedicine.* 2019 Mar;41:571-583. doi: 10.1016/j.ebiom.2019.01.060. Epub 2019 Mar 2.
15. Coltart GS, Irvine C. Skin Failure. *Skinmed.* 2018 Jun 1;16(3):155-158. eCollection 2018. No abstract available.
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## Appendix: Financial report - April 2018 to March 2019

### CRN: KSS Financial Position 2018-19

The financial position for the period ending the 31st March 2019 (Month 12) reports a break even position. The SSD's spend is £12k YTD for Pathology and £2.7k YTD Radiology. This is included in the Host Fees.

#### Annual Allocation

£000's

	Annual Budget	Budget YTD	Actual YTD	Variance YTD
<b>Pay</b>				
Nursing	735	735	690	45
A&C Support	204	204	222	(18)
Pharmacy	66	66	68	(2)
Vacancy factor	(42)	(42)	(17)	(25)
<b>Sub-total Pay</b>	<b>963</b>	<b>963</b>	<b>963</b>	<b>0</b>
<b>Non-Pay</b>				
Host fees	56	56	56	0
<b>Sub-total Other</b>	<b>56</b>	<b>56</b>	<b>56</b>	<b>0</b>
<b>Total Core Funding</b>	<b>1,019</b>	<b>1,019</b>	<b>1,019</b>	<b>0</b>
<b>Specialty Leads</b>	<b>16</b>	<b>16</b>	<b>16</b>	<b>0</b>
<b>Total Additional Funding</b>	<b>16</b>	<b>14</b>	<b>14</b>	<b>0</b>
<b>Overall CRN Allocation</b>	<b>1,035</b>	<b>1,033</b>	<b>1,033</b>	<b>0</b>
<b>Cumulative variance as a % of gross budget</b>				<b>0.00%</b>

#### Other Income/Direct Receipts (Non-CRN:KSS)

A comparison between financial years for Months 1 to 12 2018-19 is illustrated below:

£000's	Year 2016 - 2017	Year 2017 - 2018	Year 2018 - 2019	% Change 17/18 vs 18/19
Research Capability Funding	(69)	(96)	(117)	21%
NIHR Projects	(338)	(476)	(443)	(7%)
MRC/Non-Industry/Other	(120)	(241)	(152)	(37%)
Industry	(1,022)	(737)	(604)	(18%)
<b>Total</b>	<b>(1,548)</b>	<b>(1,550)</b>	<b>(1,315)</b>	<b>(15%)</b>

Total Other Income receipts for Yr 2018 - 2019 have reduced by 37% and Industry Income has reduced by 18% compared to the previous financial year. However, the RCF income has increased by 21% compared to that of the previous financial year.

Income trends for industry can be influenced by various factors such as back-log invoicing, seasonality of patient treatments etc.

Income derived from Industry sources for Yr 2018 - 2019 can be broken down as follows:

<b>£000's</b>	<b>Year 2018 - 2019</b>			
<b>Source</b>	<b>Patient Activity</b>	<b>Drugs</b>	<b>Total</b>	<b>%</b>
<b>Clinical Haematology</b>	(337)	(58)	(395)	<b>66%</b>
<b>Cardiology</b>	(31)	(2)	(32)	<b>5%</b>
<b>Renal</b>	(23)	(9)	(32)	<b>5%</b>
<b>Neuro Rehab</b>	(25)		(25)	<b>4%</b>
<b>Physiotherapy</b>	(22)		(22)	<b>4%</b>
<b>Stroke</b>	(19)		(19)	<b>3%</b>
<b>Gynae/Oncology</b>	(17)	(1)	(18)	<b>3%</b>
<b>Surgery</b>	(13)	(1)	(14)	<b>2%</b>
<b>Clinical Oncology</b>	(11)		(11)	<b>2%</b>
<b>Ophthalmology</b>	(9)	(2)	(11)	<b>2%</b>
<b>Gastroenterology</b>	(10)		(10)	<b>2%</b>
<b>Other</b>	(13)	(1)	(14)	<b>2%</b>
<b>Total</b>	<b>(529)</b>	<b>(74)</b>	<b>(604)</b>	<b>100%</b>

The majority of industry derived income is accumulated from Clinical Haematology with a 66% share of the overall total.

#### **CRN: KSS – 2019 - 2020**

The 2019-20 financial year allocation for core service provision is @ £1.028m. A small increase of 0.88% compared to that of 2018-19.

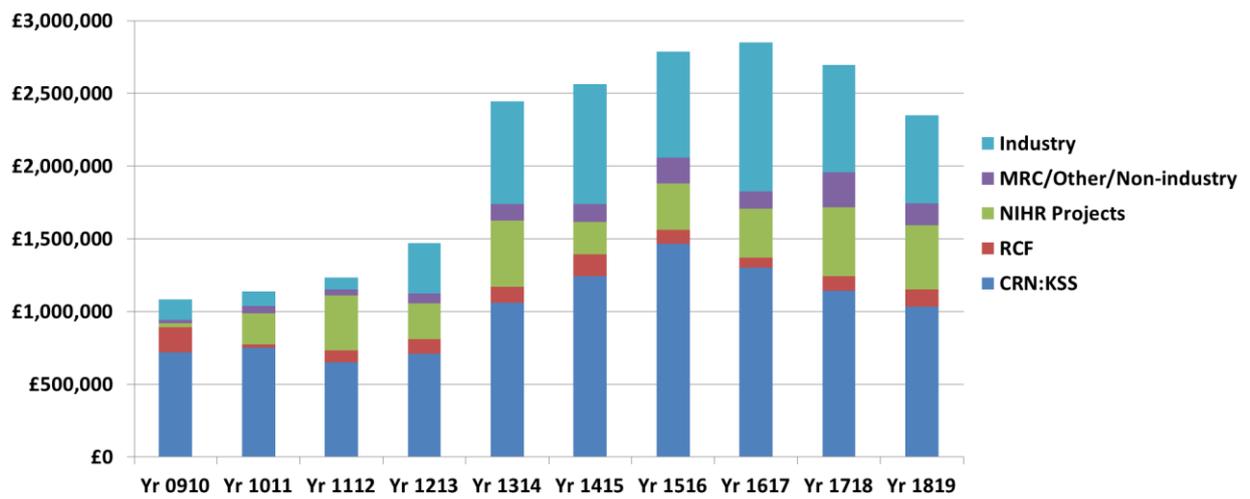


Figure: Overview of income by financial year & source

**Greta Novikova**  
**Acting R&I Finance Officer**