



Research & Innovation Department

Annual Report

2019 - 2020

&

2020 - 2021

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Ms Jessica Evans

1. Executive Summary

- 1. During the previous two years, a total of 2793, patients (2019-20), and 5,002 (2020-21) 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 annual increase of 12% and 79% respectively.
- 2. In 2019/20, we actively recruited to 110 studies of which 10 were commercial/Industry studies and 26 were clinical trials of investigation medicinal products (CTIMPS). All except 2 of the studies were on the NIHR Portfolio. R&I assessed and issued Capacity and Capability (C&C) confirmation for 60 studies to begin at East Kent sites during the period.
- 3. The Covid-19 pandemic impacted research activity in the Trust with the suspension of setup arrangements for new studies and recruitment paused for all non-urgent projects. The result was a 47% reduction in studies actively recruiting and 50% fewer projects receiving C&C confirmation. Recruitment numbers however, increased significantly on the previous year - boosted by the work done to set-up and drive forward Covid-19 related studies.
- Research related income to the Trust was £2,699k for 2019-20, and £2,957k for 2020-21. This has increased, although income related to commercial-contract study activities has fallen to £593k from the previous year of £704k. There was £128k and £109k from DH Research Capability Funding for the respective years. The Covid-19 claim for loss of income was £332k.
- 5. During 2019-20, 55 projects were recorded as Site Selected. Our mean time from being selected as a participating site to site confirmation was 92 days.15 projects were Site Selected in Quarter 4 of the period - the start of the pandemic. 2 of these projects were Covid-19 related and were set-up in 27 days. The other 13 were suspended or delayed by Covid-19 and had an average set-up time of 115 days. 6 projects with 2019/20 Site Selection dates are still in set-up. These have been delayed due to Covid-19. All non-urgent recruitment was suspended, with many projects remaining dormant for the whole period and into 2020/21.

During 2020/2, 42 projects were recorded as Site Selected. Average was 40 days from Site Selection to Site Confirmation. 12 projects with 2019/20 Site Selection dates are still in setup. These have been delayed due to Covid-19. 17 Covid-19 studies were opened, with an average set-up time of 14 days. The delivery teams have successfully recruited over 3800 participants to Covid-19 related projects.

- 6. We have provided 10 training sessions on various topics to 79 colleagues throughout the period 2019-21. Unfortunately, face to face training had to be suspended or moved online due to restrictions during 2020-21.
- 7. Our strategy is due to be updated shortly, to reflect the changes in focus for R&I, and also to incorporate the advent of the Clinical Trials Unit.

2. Key Events during the 2019-20 and 2020-21 Financial Years

CTU

Business case submitted end of 2020 outlining the proposal for EKHUFT to establish an acute-based Clinical Trials Unit (CTU). The capital cost is £1.62m and the recurrent cost is £422k therefore the breakeven income would need to be £450k. CTUs following the grant model are designed to breakeven. The median income for CTUs is £750k. EKHUFT would be taking this forward on behalf of the Kent & Medway system.

Building on the current momentum created by the COVID-19 pandemic, the first intake of Kent and Medway Medical School (KMMS) in September and funding to Discovery Park, EKHUFT has a unique opportunity to develop and support clinical staff and specialties by creating a robust Clinical Trials Unit (CTU) within EKHUFT. CTUs are specialist units which are set up to design, conduct, analyse and publish clinical trials and other well-designed studies as well as coordinating the delivery of trials involving investigational medicinal products which must be conducted in compliance with the UK Regulations. These specialist units consist of a clinical delivery area and an administrative function with the aim of having high quality and cuttingedge clinical trials that affect outcomes for patients. The CTU will accelerate the necessary research and innovation pipelines and architecture to deliver the Research Strategy, deliver significant cost savings to the whole health system, strengthen EKHUFT's position and collaborations with KMMS and Discovery Park while providing research benefits to Kent & Medway's stakeholders. EKHUFT's aim is to use its position as an acute Trust to develop higher quality research and leverage this advantage for commercial research gain with organisations locally, nationally and internationally. EKHUFT has established an informal relationship with the Imperial College Healthcare CTU to develop a formal mentorship. In 2020, The Haemophilia Centre was awarded a £0.5M grant from the NIHR to sponsor and lead a UK multi-centre clinical trial of an exercise programme for children with haemophilia. Additionally, EKHUFT has been building on previous successes with the British multi-national Smith & Nephew to develop future commercial research studies. Finally, initial conversations have taken place with Pfizer to initiate a commercial relationship to conduct studies in the future at EKHUFT. Overall, EKHUFT is one of the largest acute Trust's in the country which serves between 700,000 and 1,000,000 people across various local and regional services. All this, coupled with EKHUFT's strong research pedigree, provides a strong foundation for a successful CTU at EKHUFT.

Recent developments and EKHUFT successes in the research landscape which support EKHUFT's need for a CTU:

- Establishment of the new KMMS with the first intake of students in September 2020.
- £2.5m Government funding awarded to Discovery Park in Sandwich to accelerate delivery
 of incubator space for drug discovery, cell and gene therapy, digital health, manufacturing
 and medtech firms.
- During the recent COVID-19 pandemic, EKHUFT opened and recruited 2,627 patients into 10 research studies, including RECOVERY, the largest randomised clinical trial in the world.
- One of only two sites in Kent, Surrey and Sussex selected to trial convalescent plasma for COVID-19.

- Significant increase in research interest amongst staff to deliver high quality home-grown clinical trials for patients in East Kent as a result of participation in COVID-19 trials.
- The research team have successfully designed, achieved national research ethical approval and NIHR portfolio adoption of BERRY. This is a novel interventional study looking at early treatment of COVID-19. This is a home-grown study which is now open and successfully recruiting. The study will aid CTU accreditation and has allowed EKHUFT to successfully demonstrate we can undertake home grown research and undertake CTU work. This treatment is only available to EKHUFT patients at present. Apart from oxygen and steroids all other COVID-19 treatments at this time are only available through research studies.

The proposal is for investment to recruit to key roles to meet the required UK CTU regulations and capital investment for conversion of designated space for CTU delivery suites and equipment at QEQM.

Early 2021 – successful application for funding of CTU.



Laboratory support for research

During 2019/20 an area of the main laboratory on the WHH site was refurbished so that there is now a dedicated research laboratory area at all 3 of the main sites.

R&I laboratory link, Aisling Potter, is now IOSH trained, so is able to provide Health & Safety as well as laboratory training for all research staff who require this, which will help to speed up training turn-around times in the future.

An electronic folder has now been created on the shared drive, which is accessible for all R&I staff and which contains all laboratory-related documentation, including temperature logs, equipment service records & certificates, written instructions on how to find Lab UKCAS accreditation certificates and how to find lab reference ranges.

A 'sample processing' facility for the community and mental health research teams has now been set up for their studies in Maidstone. Also, the Haemophilia studies are now processed in the Haemophilia lab which should help alleviate pressure at KCH which is the busiest site in terms of research laboratory activity.

Student Nurse Placements

In association with Canterbury Christ Church University, several further student nurse placements successfully took place within R&I during 2019/20. Students rotated between each of the research delivery teams to provide a broad and varied experience for the students and

feedback continued to be very positive. R&I were not able to accommodate student throughout 2020/21 due to the Covid-19 pandemic but it is hoped these can be restarted again in September 2021.

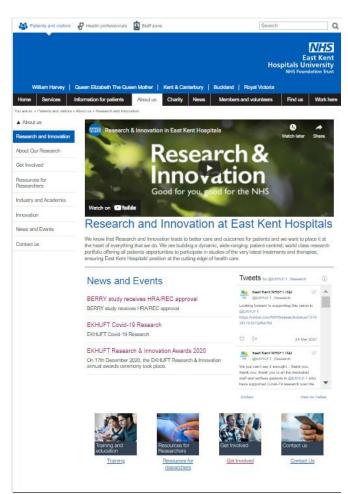
Launch of the Research & Innovation Website

Our new web pages have now been launched and are regularly updated with useful information, including advice and resources for researchers, news & events and ways to get involved.

There are also links to training resources, and ways to get in touch with the team.

The website is accessible to all, from both within and outside of EKHUFT and can be accessed via the following link:

https://www.ekhuft.nhs.uk/patients-and-visitors/about-us/research-and-innovation/



Annual R&I Awards

As in previous years, we made a number of awards at our meeting in December via Webex, in lieu of being able to hold a face to face End of Year Meeting in April 2020. We are very grateful to Brent Murray, our patient representative, and Helen Graham, Research Delivery Manager (Cancer) Lead for Workforce & Wellbeing, from the NIHR Clinical Research Network for choosing the winners and runners up in each category. We had a record 84 nominations, including to our latest category of Outstanding Contribution during Covid-19. Not only are we proud of the extraordinary efforts of those nominated, but also most appreciative of the time taken by their colleagues making the nominations. Recipients of the awards were:

Exceptional Contribution

Winner Individual Natasha Schumacher **Highly Commended** Individual Dr Jindriska Lindsay Winner Team General Surgery - QEQM

Highly Commended Team Neuro Rehab Clinical Research Team

Rising Star

Winner Individual Carly Price **Highly Commended** Individual Moya Young

Winner Team Main Theatres QEQM **Highly Commended** Team Cardiology Team QEQM

Unsung Hero

Winner Individual **Sharon Turney Highly Commended** Individual Lavinia Davey Winner Team **Urology EPR**

Highly Commended Team Surgical Admissions Lounge (QE)

Most Engaging PI

Winner Individual Dr Neil Richardson Individual **Highly Commended** Dr Guna Gunathilagan

COVID-19

Winner Individual Dr Gabriele Boehmer **Highly Commended** Individual **Heather Weston** Team Winner WHH Research Team **Highly Commended** Team KCH ITU Team

3. People Involvement & Engagement

In May 2019, we hosted an event at WHH, in conjunction with KSS CRN for all the Kent-based patient research ambassadors. Our R&I patient representative helped to organise and facilitate the meeting which included information updates, training and a guest speaker. The event was very well attended and received.

During 2020/21 it has not been possible to hold any face-to-face meetings or events for our Research Friends, patients or members of the public, but we will resume these later in 2021, when restrictions allow.

The number of research participants in EKHUFT who have volunteered to become a 'Research Friend' now totals 365. These individuals are contacted whenever input or involvement is required from patients or members of the public for research or related activity. Regular news bulletins are sent out to keep our Research Friends informed of our work and ways they can get involved. Several research participants have shared their experience of research on the new R&I webpages.

Patient Research Experience Surveys

During 2019-20, we received feedback from 225 participants, from a total of 3,370 in KSS overall (6.7%). The total for 2020-21 was 52, out of a total of 784 in KSS (6.6%), as the decision was taken early during the pandemic not to include Covid-19 patients in the research experience survey.

The feedback from participants remained very positive for both years. The vast majority of respondents reported that they felt valued and would take part in research again. The most commonly cited area for improvement was the desire to be kept more informed about the progress and findings of the research. This, along with all other relevant feedback, has been communicated to all patient-facing research staff.

4. Key Metrics

Study Activity

In 2019/20, we actively recruited to 130 studies - of which 10 were commercial/Industry studies and 26 were clinical trials of investigation medicinal products (CTIMPS). All except 2 of the studies were on the NIHR Portfolio. R&I assessed and issued Capacity and Capability (C&C) confirmation for 60 studies to begin at East Kent sites during the period.

During 2020/21 the COVID-19 pandemic impacted on research activity in the Trust, with the suspension of set-up arrangements for new studies and recruitment paused for all non-urgent projects. The result was a 47% reduction in studies actively recruiting and 50% fewer projects receiving C&C confirmation.

Participant Recruitment

Between 01/04/19 and 31/03/20, the Trust recruited 2,793 participants to NIHR Portfolio studies compared to 2,494 participants in 2018-19, an increase of 12%. In 2020-21, this figure increased further to 5,002, a further increase of 79%. There were 17 Covid-19 studies, which recruited a total of 3,816 patients. In total we supported 91 studies across 22 discrete disease areas. We have also continued to maintain a healthy balance with complex interventional (usually randomised controlled) and more straightforward observational and large-scale studies (Figure 1),

Performance in Initiation of Research

Project set-up timescales

2019/20:

55 projects were recorded as Site Selected from 01/04/19 - 31/03/20.

Average **92** days from Site Selection (start of site C&C arrangements) to Site Confirmation (signing contracts).

15 projects were Site Selected in Quarter 4 of the period - the start of the pandemic. 2 of these projects were Covid-19 related and were set-up in 27 days. The other 13 were suspended or delayed by Covid-19 and had an average set-up time of 115 days.

6 projects with 2019/20 Site Selection dates are still in set-up. These have been delayed due to Covid-19.

All non-urgent recruitment was suspended, meaning that the Date Site Confirmed to First Patient Recruited timescale was an average of **266** days, with many projects remaining dormant for the whole period and into 2020/21.

2020/21:

42 projects were recorded as Site Selected from 01/04/20-31/03/21.

Average **40** days from Site Selection to Site Confirmation.

12 projects with 2019/20 Site Selection dates are still in set-up. These have been delayed due to COVID-19.

17 COVID-19 studies were opened, with an average set-up time of 14 days. The delivery teams have successfully recruited over **3800** participants to Covid-19-related projects.

A data validation project began in February 2021, aiming to improve the quality of East Kent data held on the EDGE database. This process identified errors in the dates recorded for site initiation and delivery targets. The errors have been corrected through the validation process and a minimum dataset applied to ensure the integrity of future data inputting. However, before the errors were corrected, that data was used to inform performance reporting to both East Kent teams and Department of Health (through the Quarterly Performance in Initiating and Delivery process).

Amendment turnaround

120 Amendments received since 7th December 2020.

65% - less than 10 days.

16% - between 10 & 20 days.

19% over 20 days (usually due to Sponsor awaiting approvals

Research Income

Research related income to the Trust was up on last year (£3.0m vs £2.7m in 2019-20). Income related to commercial contract study activities was down on the previous year at under £0.6m.

During the year the Trust was allocated £109k by the Department of Health via its Research Capability Funding stream, and this supported NIHR faculty members (present and future) directly.

Project Short title	Project site date Selected to date Confirmed clock	Project site date site selected	Project site date site confirmed	First site patient recruited (org)	Recruited (total)
RECOVERY trial	14	17/03/2020	31/03/2020	31/03/2020	304
PanSurg PREDICT study	5	09/04/2020	14/04/2020		0
UKOSS: Pandemic Influenza in Pregnancy	12	08/04/2020	20/04/2020		0
GenOMICC	1	21/04/2020	22/04/2020	02/05/2020	112
Pregnancy and Neonatal Outcomes in COVID-19	0	27/05/2020	27/05/2020	04/06/2020	5
REMAP-CAP	0	30/06/2020	30/06/2020	06/10/2020	2
Psychological impact of COVID-19 - 19	2	12/05/2020	14/05/2020	15/05/2020	443
TACTIC-R (COVID-19)	60	08/06/2020	07/08/2020	08/11/2020	8
BERRY	0	04/01/2021	04/01/2021	05/01/2021	33
Using medical-detection dogs to identify people with SARS-CoV-2.	11	06/07/2020	17/07/2020	21/07/2020	377
FALCON C-19	34	10/11/2020	14/12/2020	05/01/2021	112
Clinical Characterisation Protocol for Severe Emerging Infection	27	28/01/2020	02/03/2020	19/03/2021	1774

SUMMARY

Set up complete	17
Still in set-up	1
Studies recruited to	10
Average set-up time (days)	14
Total Recruited	3170

R&I training

In 2019/20 we provided 9 training sessions to 70 colleagues at a variety of locations as detailed below. During 2020/21, due to the Covid-19 pandemic, face to face training had to be suspended, however some training was provided online via NIHR Learn including GCP training, and online Dry Ice training was provided by an external provider for R&I staff who required this.

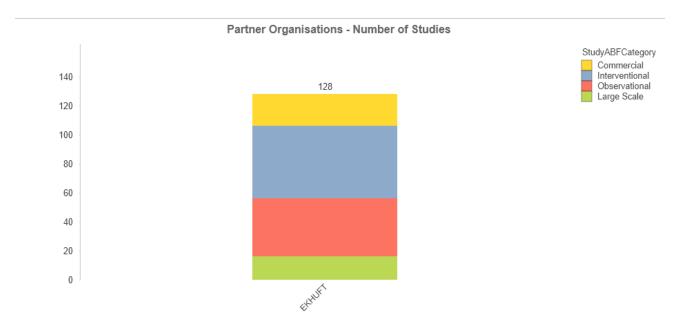
Date	Title of Training	Venue	Attendees
01/10/2019	Research Champions Development Day	WHH	4
30/09/2019	GCP Refresher	WHH	16
10/10/2019	Staff Workshop - Quality, Safety & Transformation Research	QEQM	3
14/10/2019	Staff Workshop - Quality, Safety & Transformation Research	КСН	4
04/11/2019	GCP Intro	WHH	14
25/11/2019	Research Champions Development Day	KCH	4
26/11/2019	Staff Workshop - Quality, Safety & Transformation Research	WHH	7
21/01/2020	Research in Practice	WHH	14
19/03/2020	Research Champions Development Day	WHH	4
October 2020	Safety Training Workshop: Using, Storing and Transporting Dry Ice (e-learning)	Online	9

Statistical Advice

Statistical advice was provided by Paul Bassett (StatsConsultancy Ltd) to 10 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.

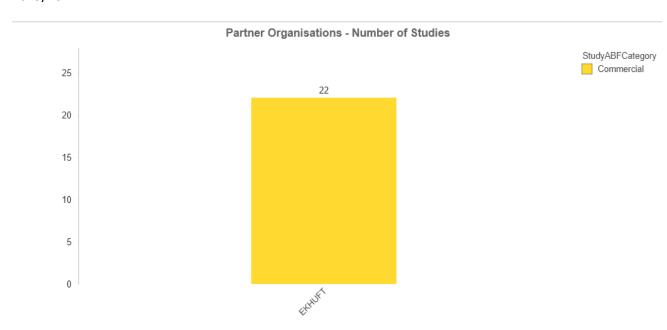
2019/20:



2020/21:

Figure 2. Industry studies opened by financial year.

2019/20:



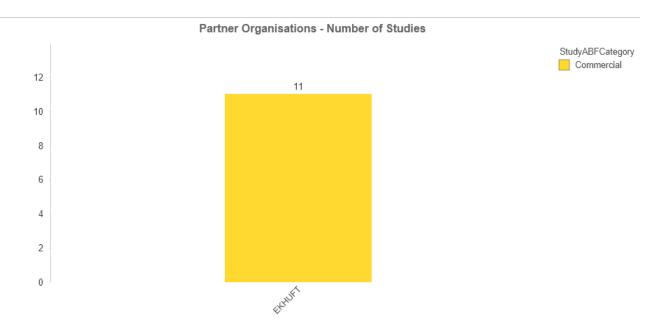


Figure 3. Recruitment to NIHR CRN Portfolio studies during 2019-20 FY. Green bars & numbers indicate discrete studies recruited to; blue diamonds indicate total participant recruitment - both by CRN Specialty Group.

5. Overview of Research Activity during 2019-20 and 2020-21 Financial Year

Solid Tumour Oncology Research Team: Sue Drakeley & colleagues

Highlights & Achievements

- Diversification Redeployment
- Supportive- offering help
- Safety maintaining patient safety and GCP
- Data –time management of scheduled data points.

Challenges & Changes

- Communication
- Follow ups
- Working Patterns
- Team

Priorities & Ambitions

- Opening all hibernated studies
- Complete set up of hibernated studies
- Working towards how we used to work by seeing patients face to face, along with the consultants
- Getting back to normal

WHH Research Team: Tracey Cosier & colleagues



Highlights & Achievements

- 2369 Participants enrolled
- 538 Non-COVID-19 participants
- Collaborated across various teams to deliver COVID-19 studies
- Opened new studies in new study areas
- Welcomed new team baby





Challenges

- The ever-changing team
- Working from home
- Initial training and involvement staff on the Recovery trial
 - Pausing and restarting studies x2

Priorities / Ambitions for the Year Ahead

- Continue to develop new areas
- Engage new PI's
- Continue the growth of our commercial portfolio
- Support development of CTU



KCH Research Team: Gemma Hector & colleagues

Highlights & Achievements

- Team Development
- Recruitment to both Non-UPH and UPH studies
- Supporting vaccine delivery and other departments

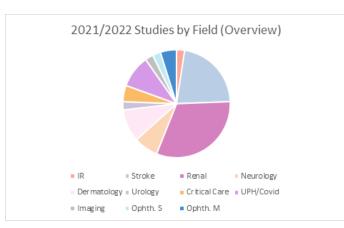
Challenges & Learning

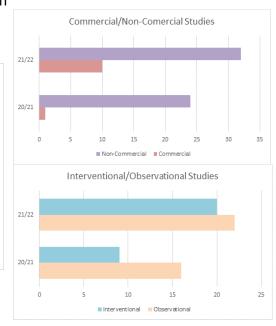
Challenges Study delivery against the background of a pandemic

The restart process

Learning Change of approach

Teamwork and communication





Haemato-Oncology – Lavinia Davey & colleagues

Despite a Challenging year with Covid-19 19 we have successfully:

- Managed to keep all patients on CTIMP studies, safely delivering all clinic-based visits procedures & assessments
- Worked collaboratively with pharmacy to implement sponsors' urgent safety measures to allow for home delivery of oral CTIMPS thereby reducing risks to high risk patients from attending the hospital to collect treatment
- Set up systems and processes for the provision of pharma remote source document verification in order to meet critical timepoints such as clinical cut offs & data locks - now r-SDV routine but a time-consuming practice – contracts renegotiated

We were invited to provide Nurse Consultancy representation at the Janssen EMEA Daralex working group meeting in Brussels to share insights and experiences of using Daratumumab subcutaneous injection within our recent myeloma trials which resulted in Christine spending a day in London filming!!!

2 Publications (and 2 manuscripts pending) with EK Haem-onc PIs included in authorship:

- Maintenance Therapy with oral 5 Azacytidine for Patients with Acute Myeloid Leukemia in First Remission after Chemotherapy **NEJM**
 - We were the only UK Haematology department cited on paper
- Prognostic indices in diffuse large B-cell lymphoma in the rituximab era: an analysis of the UK National Cancer Research Institute R-CHOP 14 versus 21 phase 3 trial - British Journal of Haematology

Haemophilia & Thrombosis Centre: Dr Gillian Evans

Multi-Disciplinary Team: 3 Haematologists, 2 Physiotherapists and 1 Research Nurse 8 Commercial and Non-Commercial studies open to recruitment

A-More Study:

Observational Study to Evaluate Long-Term Effectiveness of Elocta on Joint Health

• Site enrolled the 1st and 2nd UK participants into the study.

Dolphin-II Study:

RCT of a physiotherapy intervention for children with haemophilia

- Home-grown NIHR grant funded multi-centre UK study
- EKHUFT to be Sponsor of Study
- First recruitment planned for May 2021.

FIX Gene Therapy – Long Term Follow-Up:

- Follow up Gene Therapy study for Haemophilia B, International Phase I/II trial
- Saving of £10,000 per month for dept

Other news:

FLIGHT:

Flight-A multicentre randomised trial of First Line treatment pathways for newly diagnosed Immune

Thrombocytopenia: Standard steroid treatment versus combined steroid and mycophenolate

• Results accepted for publication in the New England Journal of Medicine.

Neonatal Research: Dr Vimal Vasu, Shermi George & Clare Moloney

0.4 WTE neonatal research nurse time

For the past 12 years, consistently recruited to NIHR portfolio studies (RCTs, observational, commercial, non-commercial)

Currently 3/6 NNU consultants act as PI/Co-I for studies (max. 4) Collaborative research with School of Biosciences, University of Kent Support perinatal trials (PreCEPT, GBS3)

Open NIHR portfolio studies

Optisurf (reopening soon): 101

Observational study looking at surfactant dosing/method and neonatal respiratory outcomes

FEED1: 10

RCT of gradual (standard) enteral feeding versus full enteral feeds in preterm infants

SurfON: 1

RCT of early surfactant v expectant management in late preterm/term infants with RDS

Potential new NIHR studies

AZTEC: RCT of Azithromycin v placebo and neonatal respiratory health (progress on hold subject to ensuring ongoing funding for neonatal research services)

Early v late neonatal PN (Funding application stage)

GBS3 (Perinatal trial): (progress on hold subject to ensuring ongoing funding for neonatal research services)

Palliative Care Research supported by EKHUFT

Methylphenidate versus placebo for fatigue in advanced cancer – MePFAC – re-opened last week, after being amended for delivery in the community, across all sites.

MABEL (morphine for breathlessness) probably not going ahead, BETTER-B (mirtazapine for breathlessness) in early discussion.

Initial approach about a peer to peer support study for families/carers of patients with MND.

A number of studies independent of EKHUFT – around hospice at home, palliative diagnosis, what is a 'good death', how non-clinical staff support patients, the language used around death, supporting GPs in recognising palliative needs, new development in bereavement services.

Pilgrims Hospices Organisational Strategy 2021 -2026

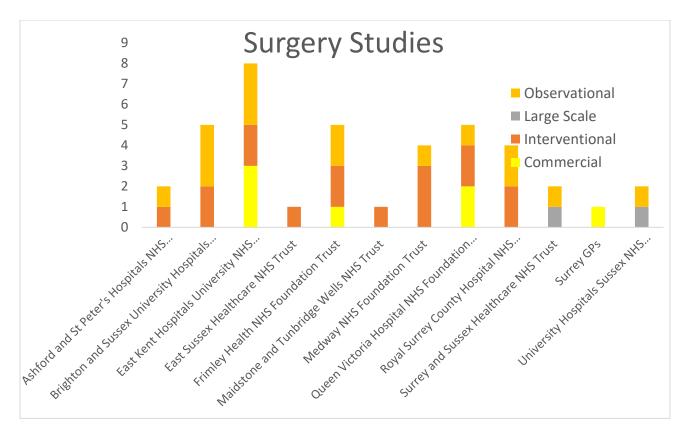
Further training and development will ensure a suitably skilled workforce, rooted in evidenced-based practice. Participation in research will enable Pilgrims to remain influential leaders at the forefront of developing practice, ensuring our care remains of the highest standard; empowering other professionals to improve end-of-life care through our education and research programmes.

QEQM Research Team: Jo Deery & colleagues

Over the years 2019-2021 much triumph and tribulation has occurred both in UK Research as a whole and locally at our site.

We enjoyed triumph in surgical commercial research during 2019 and in to 2020, with surgical medical device trials. These trials require collaborative research across departments such as the surgical admissions lounge, wards, orthopaedics, general surgery and theatres. KSS awarded Partner Awards to both our team lead and research director/PI for their contributions to commercial research within KSS. This collaborative working shone through again late in 2020 when the site was the first open and first to recruit in another international commercial surgical medical device trial. The engagement of theatres has been paramount in this and their eagerness and willingness to assist, shines through!





As Covid-19 began to peak in both the first and second waves across 2020 and 2021, we had to adapt and completely change the way we worked. Prioritising urgent public health research over all other research studies we had open or in set up.

Under the pressure, our team thrived and opened 8 COVID-19 studies across 4 departments. Wards, ITU, obstetrics and the outpatients Covid-19 swabbing station. We also helped to develop and open, a homegrown Covid-19 study looking at the use of elderberry extract in treating the progression of Covid-19 illness. Our site has gained interested from zealous junior doctors across the hospital championed by the Respiratory Consultant team. We are the only site in KSS to open Tactic — a CTIMP randomised control trial looking at inpatient treatments for Covid-19. Now that the curve is reducing, the importance is shifting back to reopening our none Covid-19 studies but also to the impact of long Covid-19. We will now be focusing on supporting one of our own Clinical Research Practitioners to be a PI on a long Covid-19 study on site.

Over this period, we have waved goodbye to some amazing team staff and welcomed some keen and enthusiastic new ones. Two further staff members have also gained their care certificates over this period, giving them more opportunities for the future.

After a successful request to the Trust for the funding for a clinical trials unit, the QEQM will be the first site to open a clinical hub unit and our team are eagerly awaiting the opportunities this will bring to research at our site. Whatever the future brings in relation to Covid-19 – we know that we will adapt and overcome any challenges we are faced with for the good of our patients and research as a whole.



Care Certificates

6. Peer-reviewed publications from April 2018 to March 2019¹

1. Managing CVADs in 2020.

Oliver G. Br J Nurs. 2020 Oct 22;29(19):S3. doi: 10.12968/bjon.2020.29.19.S3.PMID: 33104425

2. Rituximab as therapy to induce remission after relapse in ANCA-associated vasculitis.

Smith RM, Jones RB, Specks U, Bond S, Nodale M, Aljayyousi R, Andrews J, Bruchfeld A, Camilleri B, Carette S, Cheung CK, Derebail V, Doulton T, Forbess L, Fujimoto S, Furuta S, Gewurz-Singer O, Harper L, Ito-Ihara T, Khalidi N, Klocke R, Koening C, Komagata Y, Langford C, Lanyon P, Luqmani RA, Makino H, McAlear CA, Monach P, Moreland LW, Mynard K, Nachman P, Pagnoux C, Pearce F, Peh CA, Pusey C, Ranganathan D, Rhee RL, Spiera R, Sreih AG, Tesar V, Walters G, Weisman MH, Wroe C, Merkel PA, Jayne D; RITAZAREM coinvestigators; RITAZAREM co-investigators. Ann Rheum Dis. 2020 Sep;79(9):1243-1249. doi: 10.1136/annrheumdis-2019-216863. Epub 2020 Jun 24.PMID: 32581088

- 3. Timing of radiotherapy after radical prostatectomy (RADICALS-RT): a randomised, controlled phase 3 trial. Parker CC, Clarke NW, Cook AD, Kynaston HG, Petersen PM, Catton C, Cross W, Logue J, Parulekar W, Payne H, Persad R, Pickering H, Saad F, Anderson J, Bahl A, Bottomley D, Brasso K, Chahal R, Cooke PW, Eddy B, Gibbs S, Goh C, Gujral S, Heath C, Henderson A, Jaganathan R, Jakobsen H, James ND, Kanaga Sundaram S, Lees K, Lester J, Lindberg H, Money-Kyrle J, Morris S, O'Sullivan J, Ostler P, Owen L, Patel P, Pope A, Popert R, Raman R, Røder MA, Sayers I, Simms M, Wilson J, Zarkar A, Parmar MKB, Sydes MR. Lancet. 2020 Oct 31;396(10260):1413-1421. doi: 10.1016/S0140-6736(20)31553-1. Epub 2020 Sep 28.PMID: 33002429
- Lisfranc injury: A review and simplified treatment algorithm.
 Grewal US, Onubogu K, Southgate C, Dhinsa BS. Foot (Edinb). 2020 Dec;45:101719. doi: 10.1016/j.foot.2020.101719. Epub 2020 Jul 6.PMID: 33038662 Review
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Appendix: Financial Headlines for Research & Innovation for the Financial Year 2020-21

CRN: KSS - 2020-21

The 2020-21 financial year allocation for core service provision is £1.11m. A small increase of 3% compared to that of 2019-20.

CRN: KSS Financial Position 2020-21

The financial position for the year 2020-21 reports a breakeven position. The SSD's spend is £14k YTD for Pathology. There was no expenditure for other SSD's reported in 2020-21. This is included in the Host Fees.

Additional funding was received to date is shown separately in the table below.

Annual Allocation				
	Annual Budget	Budget YTD	Actual YTD	Variance YTD
	£000's	£000's	£000's	£000's
<u>Pay</u>				
Nursing	646	646	613	34
A&C Support	353	353	359	-6
Pharmacy	71	71	71	-0
Vacancy Factor	-42	-42	0	-42
Sub-total Pay	1,029	1,029	1,043	0 -15
Non-Pay				
Host fees	40	40	25	15
Sub-total Other	40	40	25	15
Total Core Funding	1,069	1,069	1,069	0
ADDITIONAL FUNDING				
Specialty Leads x3	12	12	12	0
CCG Excess Treatment Costs Funding (RETAKE)	9	9	9	0
Add: CANCER	5	5	5	0
Add: REMAP/CCP	8	8	8	0
Add: staffing costs within financial year 20/21	5	5	5	0
Total Additional	39	39	39	0
Total CRN Funding 2020-21	1,108	1,108	1,108	0

Total R&I Income Receipts by Type

A comparison between financial years 2019-20 and 2020-21 is illustrated below:

Overall, R&I income increased by 10%. The largest increase between the two years is seen on the Covid-19 income claim and NIHR projects.

The RCF funding decreased by 15% compared to last year, the funding value varies from year to year.

The NIHR funding increased by 35% compared to that of the previous financial year due to ISOFIT study funding receipt of £194k in the financial year 2020-21.

Industry income decreased by 16% compared to the previous financial year. However, this is being offset by the Covid-19 claims for the loss of income for closed/paused studies.

£332k Covid-19 funding relates to the period from March 2020 to March 2021. The potential income loss review is ongoing.

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

	Year 2019 - 2020 £000's	Year 2020 - 2021 £000's	% Change 19/20 vs 20/21
Research Capability Funding	(128)	(109)	(15%)
NIHR Projects	(398)	(539)	35%
Non-Industry & Other	(389)	(276)	(29%)
Industry	(704)	(593)	(16%)
Covid-19 claim (loss of income)	0	(332)	100%
CRN	(1,080)	(1,108)	3%
Total	(2,699)	(2,957)	10%

Income derived from Industry sources for the Financial Year 2020-21 can be broken down as follows:

£000's	Year 2020 - 2021			
Specialty	Patient Activity	Drugs	Total	%
Clinical Haematology	(317)	(29)	(347)	58%
Ophthalmology	(50)	(2)	(52)	9%
Physiotherapy	(42)	0	(42)	7%
Cardiology	(26)	(0)	(26)	4%
Renal	(22)	(1)	(23)	4%
Haemophilia	(20)	(1)	(21)	3%
Clinical Oncology	(18)	(6)	(24)	4%
Gynae/Oncology	(18)	(4)	(22)	4%
Dermatology	(14)	(1)	(15)	2%
Surgery	(6)	0	(6)	1%
Other	(15)	(0)	(15)	3%
Total	(548)	(45)	(593)	100%

The majority of industry derived income is accumulated from Clinical Haematology with a 58% share of the overall total.

