

Research and Innovation Quarterly Update – Q3, February 14th 2018

Performance

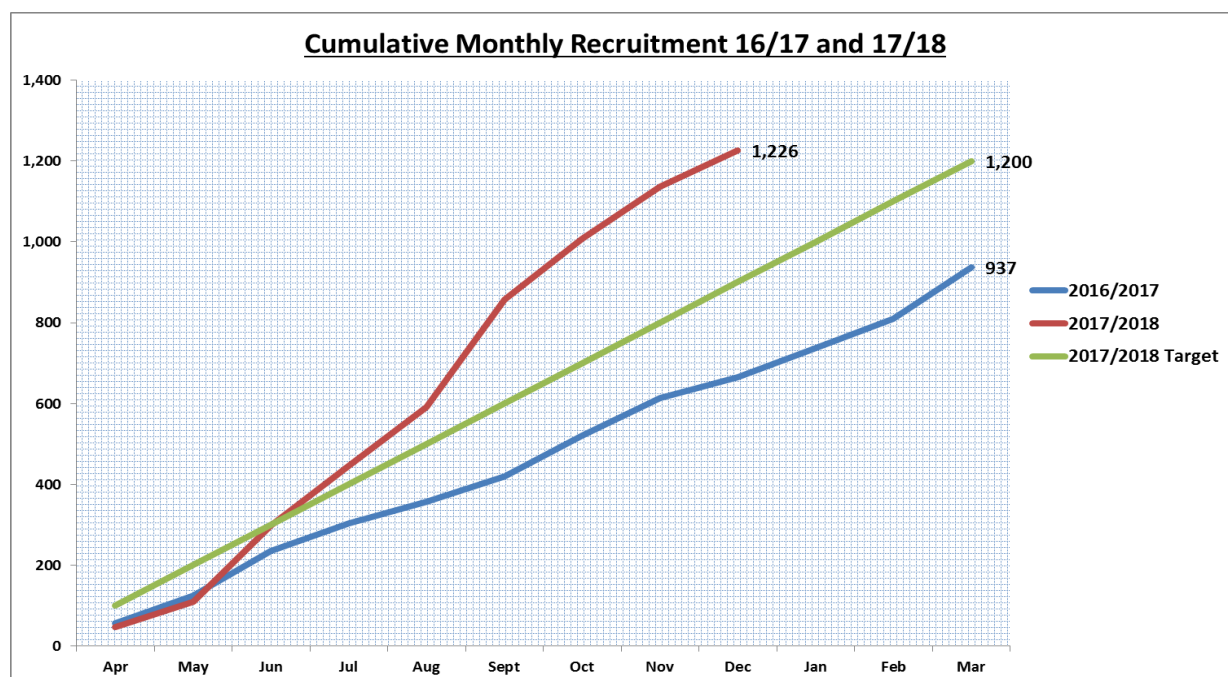
The Research and Innovation team continue to drive improvements in recruitment performance in National Institute of Health Research studies. Recruitment Q3 17/18 (data cut 28th December) is above that in Q2 2016/17; 1226 participants recruited, compared to 665 this time last year (46% increase). The 17/18 recruitment target of 1200 was met by mid-December and has now been exceeded (Graphs 1 and 2)

A stretched target of 1500 recruits by year end is now in place. As of 14th February recruitment is at 1402.

Numbers of open studies remains reasonably static at 82 for this point in the year. Of these 77 are now actively recruiting compared to 58 at Q2 17/18. With respect to “recruitment to time and target” (the main KPI to impact future CRN East Midlands budget allocation); 72% of non-commercial (increased by 6% from Q2) and 100% of commercial studies are currently recruiting to 100% time and target against a target of 80%. Trials are spread across most specialities in the organisation with more clinical research activity being conducted in the areas of Cancer, Cardiovascular disease, Gastroenterology, Reproductive Health and Childbirth and Stroke.

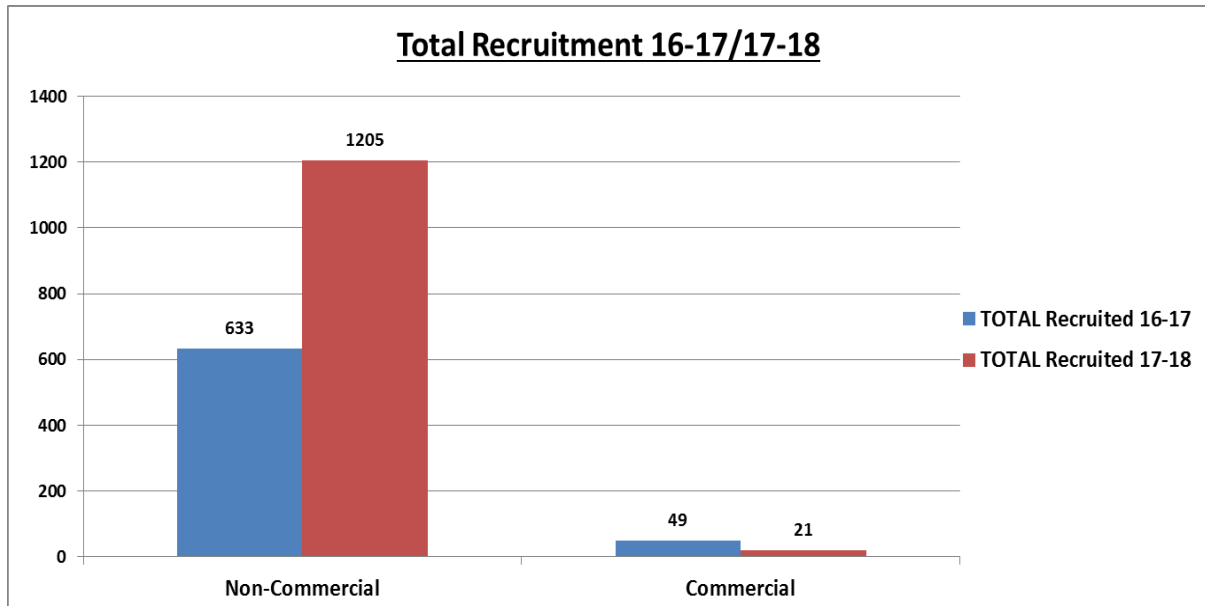
Graphs 1-4 identify performance in recruitment against 17/18 target, commercial and non-commercial recruitment benchmarked against 16/17, study activity and performance of research active areas across the Divisions. The data cut for all graphs is 28th December 2017.

Graph 1: Cumulative Monthly Recruitment 16/17 and 17/18

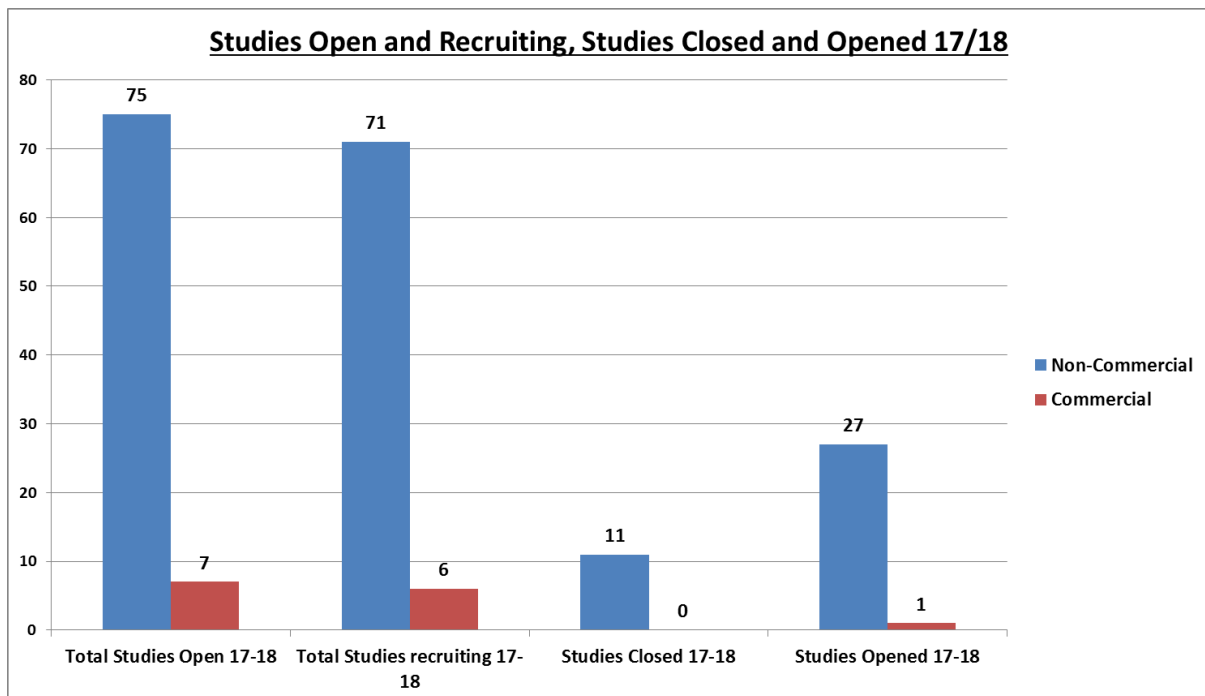


	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
2016/2017	57	124	235	304	357	419	520	614	665	737	810	937
2017/2018	47	109	297	446	590	858	1,008	1,137	1,226			
2017/2018 Target	100	200	300	400	500	600	700	800	900	1,000	1,100	1,200

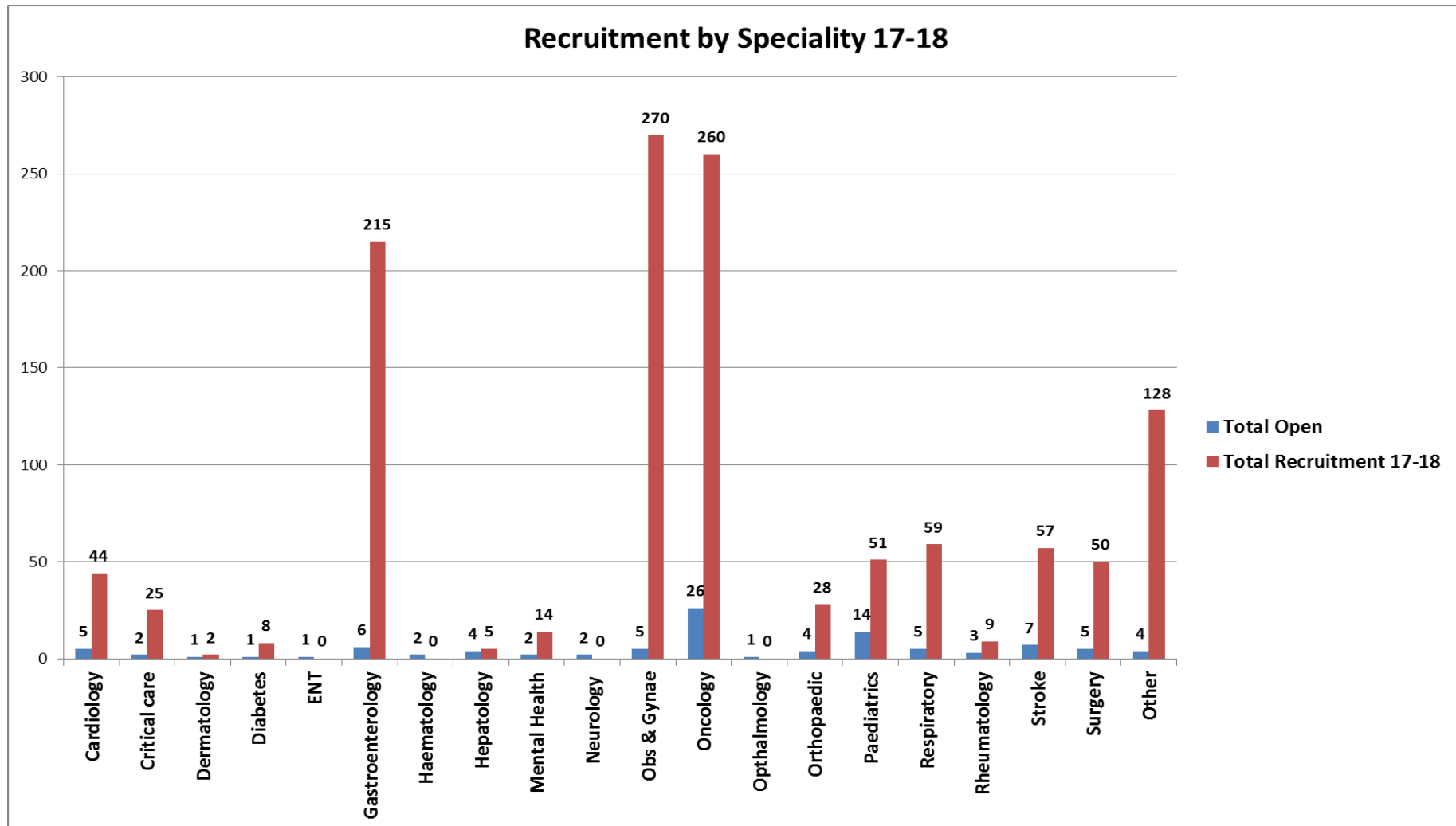
Graph 2: Total Recruitment 16/17 vs 17/18 (Commercial and Non-commercial)



Graph 3: Studies Open and Recruiting, Studies Opened and Closed 17/18



Graph 4: Recruitment by Speciality 17/18



Research as and Quality Improvement

One of our main areas of focus is to directly improve the lives of our patients and their families through the research we conduct at SFH. Recent work presented by NHSi establishes a direct link in CQC reports between research and quality improvement; in fact Trusts that achieve an *Outstanding* rating there is often focus in the report on research done by frontline staff. Research will now become a formal part of CQC inspections providing us with the opportunity as an organisation to promote local organisational behaviours that offer the best possible research choices and benefits to patients. NHS organisations like SFH have more opportunity to make a difference through research with a wider portfolio, and success in this approach has been demonstrated through performance in this year.

As a committed research active organisation we aspire to ensure research and patient care are a continuum and not 2 separate worlds. We have started working with the senior nursing team to fund, train and support clinical frontline staff to experience research and become involved in setting up and recruiting to trials within their areas and would like to roll this out further with support from the Trust.

Growth and Development

We continue to work hard to attract studies to the organisation and are currently in the process of setting up the OPTIMAL study looking at the reduction of re-admission rates within 30 days of being discharged from hospital by using Patient Discharge Advocates. In other centres the re-admission rate has been reduced by 20%. There is the opportunity to include 100 participants per month in to this trial and demonstrate a real impact on our service. There is a potential for this to lead to a significant increase in NIHR funding in subsequent years.

An example of a particularly successful study at SFH in the last quarter is *SPIRE - Saving Babies' Lives Project Impact and Results Evaluation*. The UK has one of the highest stillbirth rates in high-income countries with more than 3,600 every year, many of those born at term potentially avoidable. The study aim was to analyse and evaluate the "Saving Babies' Lives" care bundle introduced in to maternity care in April 2015. Evidence shows that benefits are achieved at a faster pace through implementing the care bundle as a package rather than individually. SFH contributed to this study thanks to the flexible and integrated approach from R&I, Maternity and Information teams. SFH was the highest recruiting site in the study with 11% of the total national recruitment (213 patients and staff) recruited in just 3 weeks.

Our relationship with commercial research sponsors continues to strengthen as we attract a variety of trials from the pharmaceutical industry and commercial sponsors. Many of these companies are returning to our organisation as SFH remain successful in delivering to these studies.

Risks to research portfolio growth

We have seen an increase in commercial activity over the past several years and but this is now beginning to plateau with numbers of studies and recruitment remaining reasonably static. We hope to reverse this and regain an upward trend by developing a dedicated research unit on the Kingsmill

site. This will allow us to take on more complex trials, requiring multiple study visits and ensure our patients can be cared for and treated in a suitable environment, with appropriate staffing and equipment.

Clinical Research Facility

Currently our research team only have access to one room in King's Treatment Centre Clinic 1, which is not suitably equipped for most of the trial activity, or logistically suitable for staff or patients involved in the trials. The proposed research unit would ideally comprise of the conversion of an existing ward area, having the advantage of already being set up for clinical activity with easy access to support services. Based on the space requirements identified provision of a 4 bedded research area, along with consultation rooms, a procedure room, a patient waiting area and lab/storage facilities would be suitable. This option would ensure costs to purchase equipment and make sure suitable adjustments are kept low, avoiding the need for capital spend. This has been factored in to the 17/18 R&I revenue spend. A CRF floor plan and details were submitted to the space committee for review in December 17 and discussions with Estates and Facilities ongoing since September 2017.

Risks from not being able to develop a CRF include:

- Inability to expand portfolio of research opportunities for patients at their local hospital
- Reduced access for patients to new novel treatments
- Less attractive to commercial sponsors to open studies at SFH
- Lost opportunity to increased commercial income – Sites with a dedicated research facility attract an additional £1400 per study opened, in addition to reimbursement of study costs plus 70% overhead.
- Inability to improve the environment and experience for patients taking part in research trials
- No option to improve research facilities for conducting trials that are already active
- Inability to expand research activity into Phase II or Phase III studies
- Impact on retention of staff and opportunity for further expansion of an integrated R&I function across the organisation

Portfolio Balance

Funding for NHS research activity from the DoH is managed through local Clinical Research Networks (East Midlands CRN) and is activity based. Yearly funding allocations take in to account not just performance in terms of overall recruitment and recruitment to time and target, but the types of studies an organisation is running. This is termed Activity Based Funding (ABF) and comprises 3 categories; Large scale studies >10k Sample size, Observational and Interventional. Each attract a specific weighting based on complexity which in turn translates to the value in funding attributed see Table A).

Table A: ABF Complexity weightings 17/18

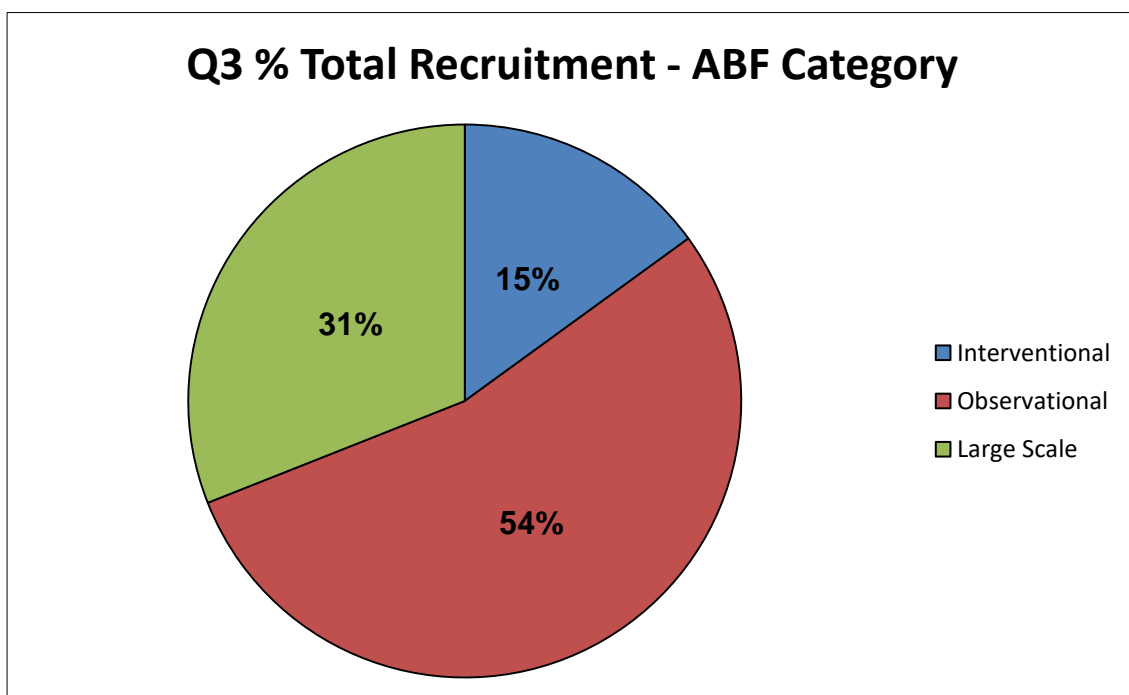
	Complexity weighting 2017/18
Band 1 – Large Scale UK total sample size 2 >10,000	1
Band 2 - Observational	3.5
Band 3 - Interventional	11

Table B - Demonstrates the current portfolio at SFH. The majority of studies fall in to Band 2. In order to maximise funding opportunities we need to shift this picture to one where there is a closer balance between Band 2 and Band 3 studies. Generally speaking studies in Band 3 are often commercial studies or those requiring multiple visits and complex interventions or investigations as part of those visits. Without the dedicated research space that will allow us to conduct studies to readdress this balance the organisation risks missing out on available funding.

Table B: Q3 Total Recruitment - ABF Category

Category	% of total recruitment
Interventional	15%
Observational	54%
Large Scale	31%

Graph 5: Open Studies in ABF Category



Technologies in Research

The use of advanced technologies in collecting, analysing and evaluating data in research is now widely used, as in any other discipline. There is often incompatibility between different institutions and organisations in terms of access to specific programmes, software and information technology. This can create barriers for NHS organisations wishing to participate in a particular research study; for example the OPTIMAL study as referenced above requires the sharing of data electronically via a server, rather than input into a database which requires specialist equipment, operating systems and software. In this instance a detailed description of what is required has been provided to NHIS and a scoping approval document has been completed for them to present to the Digital Strategy Implementation Board. It is likely these types of issues will occur more frequently in the future if NHS organisations do not have the ability to emulate technologies being used to respond to such requests.

Contractual obligations

SFH has an external reporting responsibility to the Department of Health via the Clinical Trials Platform. This national KPI for NHS Trusts; "Performance and Initiation in Clinical Research" Q2 report has been submitted at the end of October 2017. We are currently awaiting the outcome report. All previous submissions can be viewed on the Trust's internet site.

Finance

The budget forecast for 2017/18 from the East Midlands CRN provided us with a 0.3% increase (£731,162.40) on 2016/17 funding. This was due to high performance, specifically in relation to studies recruiting to time and target. This is despite the CRN East Midlands predicting a 3% reduction in funding across our region. Budget planning was completed and accepted without revision by the CRN and the month 8 return demonstrates spend in line with predictions.

Commercial activity is invoiced quarter on quarter with a predicted income at this point in the year of £71k by end of Q4 17-18. This should increase as we deliver more commercial trials throughout the financial year.

The organisation has also met the qualifying criteria to receive Research Capability Funding (RCF) from the Department of Health of £20,000 in 2017/18. This funding will enable SFH as a research active organisation to maintain research capacity and capability by contributing towards sponsorship, governance costs, financial management and staff support for researchers working on NIHR supported studies, where applicable. We also continue to support Divisional research activity by funding research PAs on an annual basis.

2018/19 Indicative budgets have now been released by East Midlands CRN with a budget for SFH of £714,137.55 which is a 2.38% reduction. Funding is based on a 2 year period on overall recruitment and performance therefore 17/18 increased activity and performance will influence 2019/2020 budget.

A Band 6 Research Practitioner joined the team in late September 2017. Scoping was carried out regards replacing a vacant Band 4 post with a role more responsive to the developing research portfolio. We have now appointed a Band 5 Trainee Research Midwife who is due to start at the end of February 2018. We also worked closely with Senior Nurse Leads to develop our Research Champion scheme further, and have provided the opportunity for 2 frontline nurses the opportunity to work with the R&I team 1 day a week for 12 months. This will be supported by a structured programme of learning to equip the individuals with the appropriate knowledge and skills to support and foster a research culture in their clinical specialities on their return. Following evaluation of the programme and funding we aim to roll this out further over the next 2 financial years.

Planned Developments 2017/18

1. Once appropriate space is identified commence the process of developing the Clinical Research Facility, staffing this and considering associated change management.
2. Forecast planning – considering study closures in 2017-18 and the potential for new studies to be opened, including reviewing the balance of a portfolio in terms of study complexity, commercial vs non-commercial activity
3. Continue the development and implementation of an R&I communication and engagement strategy in conjunction with the communications team, to promote engagement and awareness with staff and patient's across the organisation. Include a dedicated R&I web page/site
4. Large scale process mapping and review of R&I set up processes to optimise lean working and maximise use of current Research Management System EDGE.
5. Develop and deliver a Research Champion educational training programme and fund a programme for frontline staff to experience research and become involved in setting up and recruiting to trials
6. Scoping the feasibility of commencing an out of hours/on call research nurse service that would allow us to open more studies and increase recruitment in areas such as ITU and ED
7. Conducting the first patient experience survey through the Meridian system; specifically aimed at patients taking part in research at the organisation. The research arena, as other areas of the NHS, can be quite metric driven and it is important to provide assurances that the care we provide as part of a trial, be it a simple qualitative study or a complex drug trial is outstanding. We are currently discussing with the senior nursing team the most effective forum to feed back this data
8. Investigate the benefits of forming strategic research partnerships with NUH and other regional healthcare providers
9. Planning an event evening focused on research at SFH, and how this can benefit our community. To include talks from Research Investigators and the R&I Director and a showcase of current research.

Summary

The service we provide continues to deliver better outcomes for our patients at SFH, allowing them access to new and different treatments. The reputation of the Research and Innovation department and SFH as a research active organisation continues to grow. We have strong associations with other NHS Trusts and Universities and are committed to expanding the research activity, breadth of our portfolio and facilities at SFH through development and delivery of our Research strategy.

Without commitment to and development of a research facility at SFH we will be missing a significant opportunity to grow our research portfolio and provide equitable access to new interventions and treatments to our patient population. We will still deliver and perform well with the portfolio of studies we have, but we will not be able to grow. The portfolio will remain static and the portion of NIHR funding the organisation receives is likely to decrease year on year de-stabilising the R&I function and trial activity at SFH. There may also be an impact on retention of skilled research nursing staff and negative impact on the strong relationships built with the clinical areas to integrate and deliver research.

At a national level an Impact and Value assessment produced by KPMG on behalf of the NIHR estimated that commercial research activity contributed £192 million to NHS trusts in 2015/16, a combination of £176 million in estimated income from sponsor companies and £16 million in estimated pharmaceutical cost savings.

At a local level research can have positive outcomes in terms of increased quality of care, patient satisfaction and financial benefits to the organisation. It is well known that organisations that are research active provide better care to their patients and have better outcomes. A study looking at data from 209,968 patients diagnosed with bowel cancer in England between 2001 and 2008 found that bowel cancer patients are more likely to survive in research active hospitals (GUT, 2017). Another study in 2015 demonstrated a direct association between higher levels of research activity and lower levels of patient mortality following emergency admissions, and this trend continued even after taking staffing and structural factors into account (PLOS 2015). It is important as a research active organisation that wherever possible we continue to make the changes and meet the requirements needed to advance our research activity and build research capacity for the future.