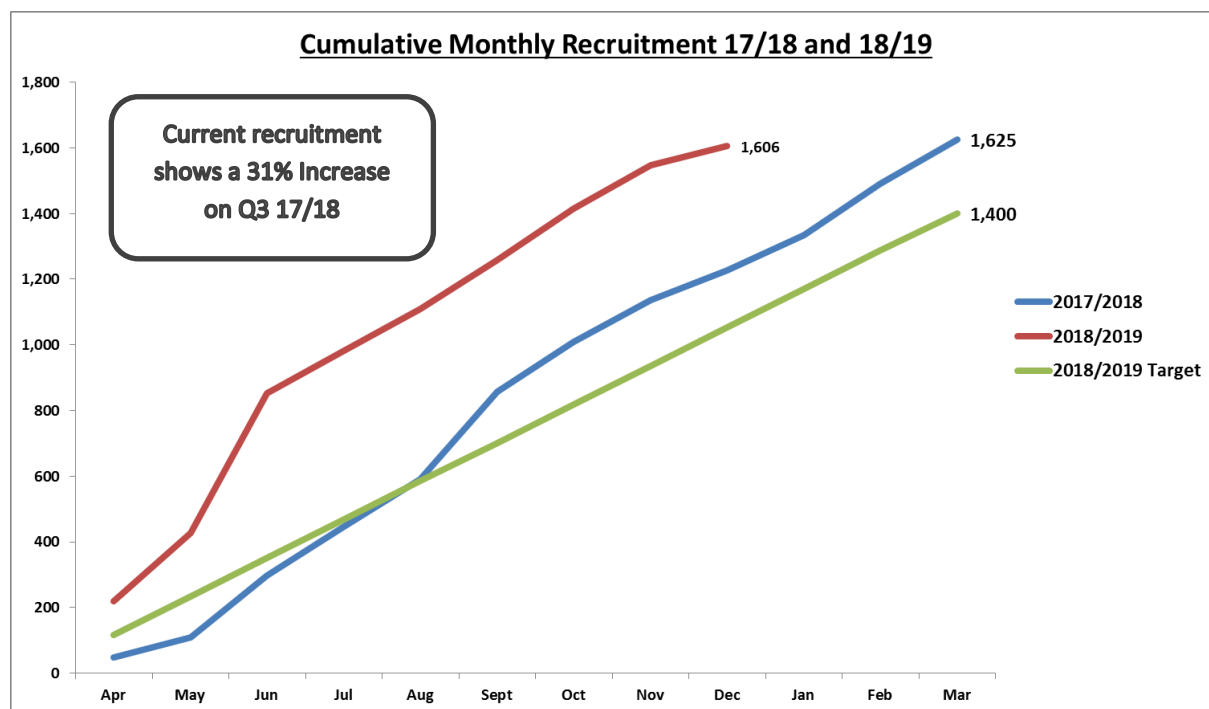


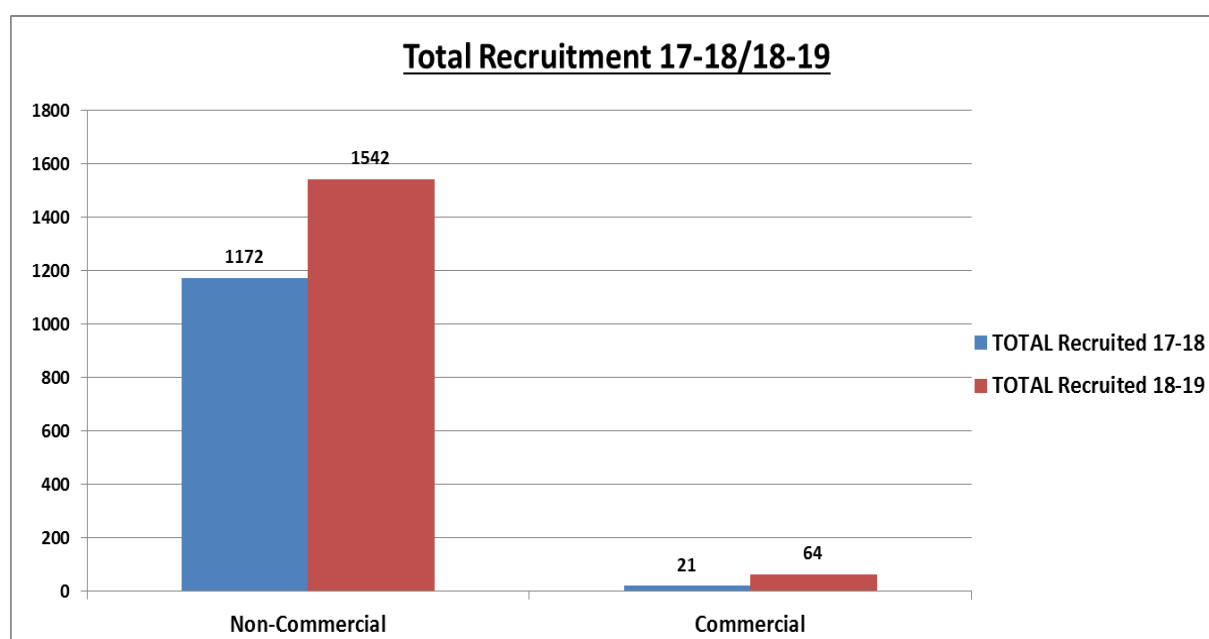
Research and Innovation Annual Update – Q3, February 13th 2019

Performance

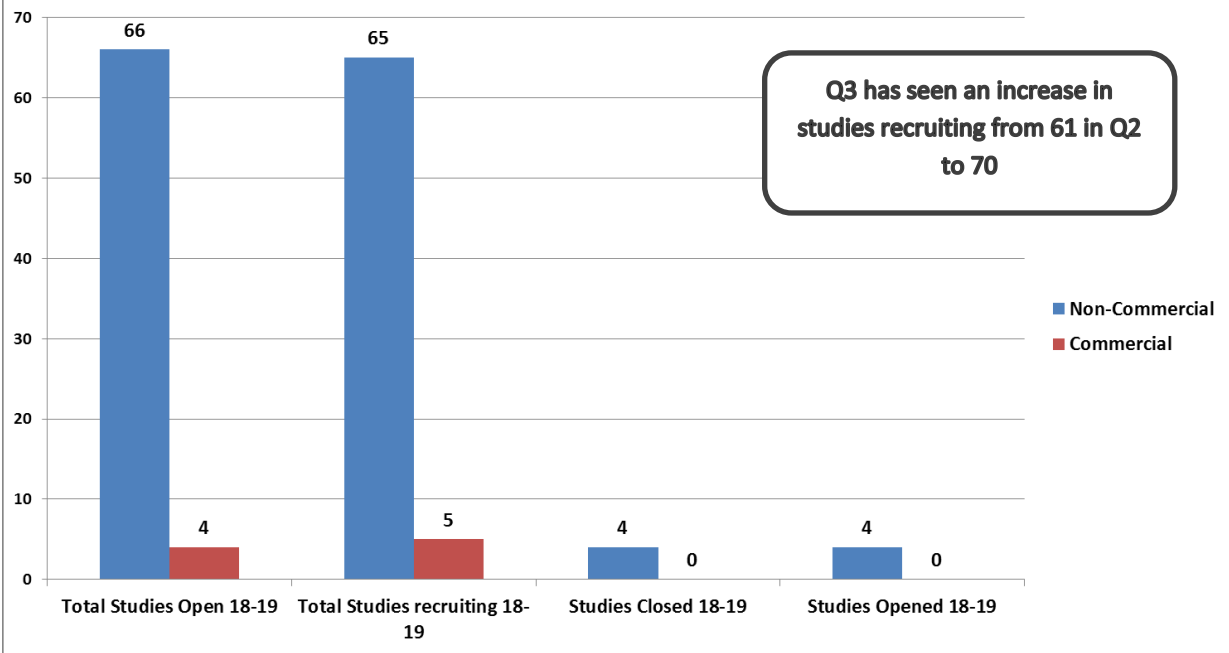
At Q3 the 18/19 recruitment target has been met with current recruitment at 115% of planned annual total.



	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
2017/2018	47	109	297	446	590	858	1,008	1,137	1,226	1,335	1,492	1,625
2018/2019	218	427	852	983	1,110	1,259	1,414	1,547	1,606			
2018/2019 Target	117	234	351	468	585	702	819	936	1,053	1,170	1,287	1,400

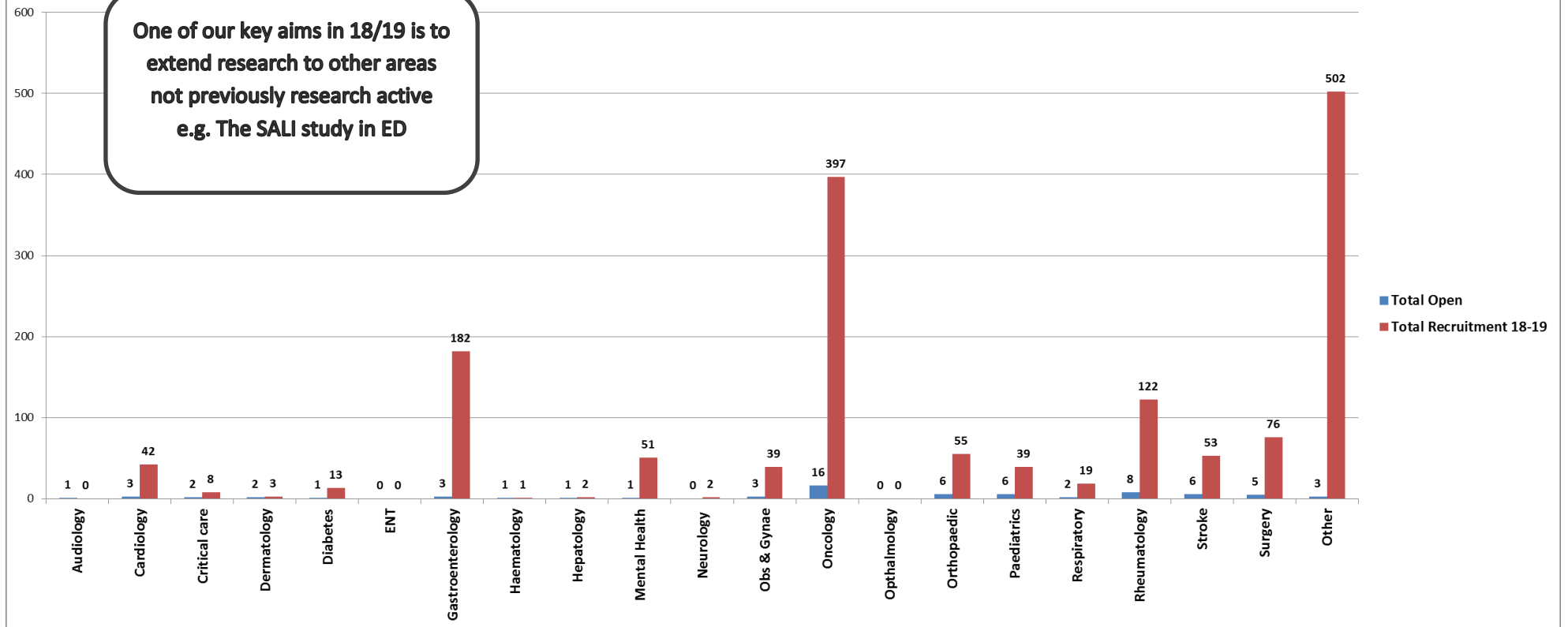


Studies Open and Recruiting, Studies Closed and Opened 18/19



Recruitment by Speciality 18-19

One of our key aims in 18/19 is to extend research to other areas not previously research active e.g. The SALI study in ED



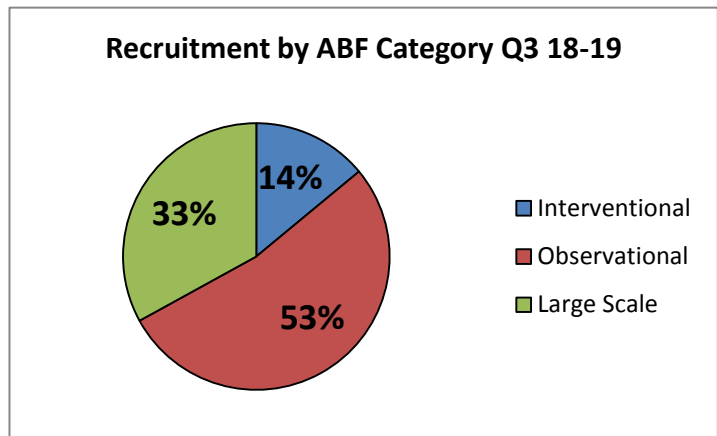
The data cut for all graphs is 31st December 2018

Portfolio Balance

Funding for NHS research activity from the DHSC is managed through local Clinical Research Networks (East Midlands CRN) and is activity based. This is termed Activity Based Funding (ABF) and comprises 3 categories; Large scale studies >10k Sample size, Observational and Interventional. Each attracts a specific weighting based on complexity which in turn translates to the value of funding attributed.

ABF Complexity weightings 18/19

	Complexity weighting 2018/19
Band 1 – Large Scale UK total sample size 2 >10,000	1
Band 2 - Observational	3.5
Band 3 - Interventional	11



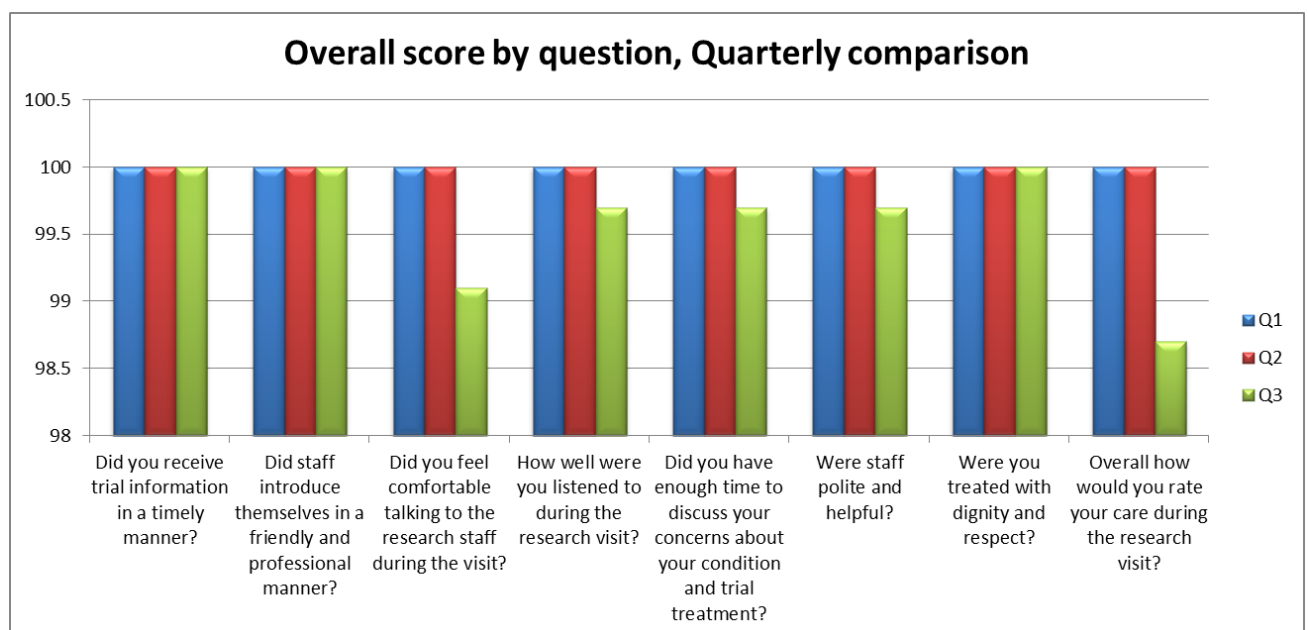
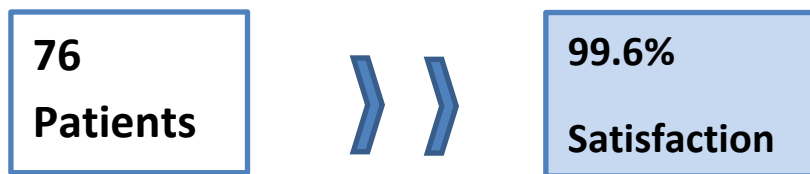
Finance

<p><i>18/19 CRN East Midlands Income £714,137.55</i></p> <p><i>Indicative budget envelope 2019/20 is based on a 4.05% decrease</i></p>	<p><i>Commercial income at Q3</i></p> <p><i>£37,155.04</i></p> <p><i>For re-investment back into future research capability and capacity</i></p>
<p><i>Support for clinical nursing in Critical Care and Emergency Department for Q4 to support new studies</i></p> <p><i>£15,500.00</i></p>	<p><i>New funding model for Consultant Research PA support – ensures allocation is performance based and access is equitable</i></p>

Patient Experience

R&I re-launched the patient experience survey for research participants in mid-October 2018

At Q3 76 patients had completed surveys with an average satisfaction score of 99.6%



Industry Research Portfolio

A key objective for 18/19 is to regain traction on increasing commercial research activity. EMCRN selected SFH as a key area for growth in their Annual Delivery Plan 2018-19. Exceeded planned targets at Q3:

SFH recruitment in to a commercial trial c.f to London Trusts

9 trials opened and recruited/ing
 75% trials interventional
 2 commercial trials in set up
 Commercial RTT – 75% C.F target
 80%

Pre-surgical, Study to Compare the Biological Effects of AZD9496 versus Fulvestrant in Women with Breast Cancer

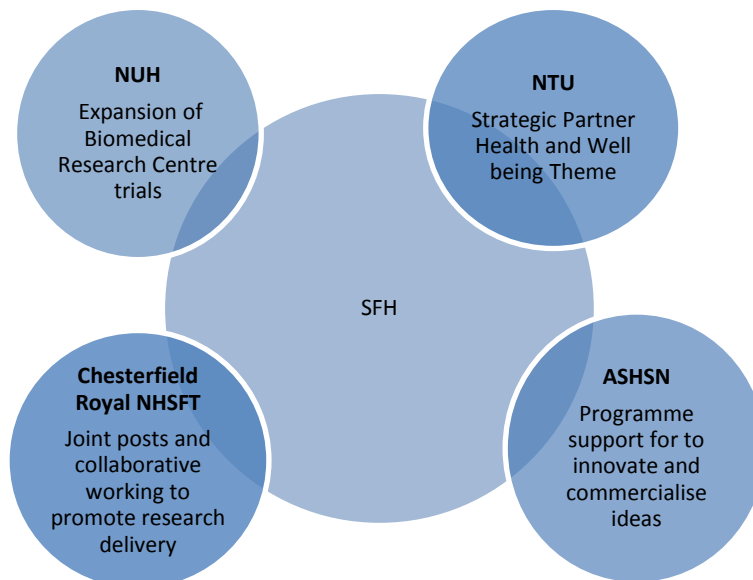
Trust Name	Trust Type	Participants
Sherwood Forest Hospitals NHS Foundation Trust	Acute	5
Barts Health NHS Trust	Acute	2
Imperial College Healthcare NHS Trust	Acute	2
NHS Lothian	Scottish Health Board	2
Guy's and St Thomas' NHS Foundation Trust	Acute	1

Discussions continue surrounding identification and agreement for a suitable space for the dedicated Clinical Research Facility. Expected update for available space due in April 2019.

Workforce

- SFH is supporting a Research Academy to embed research in to clinical care and support staff recruitment – Band 5 posts across Medicine, Surgery and Urgent/Emergency care have been advertised as part of a targeted launch with video and press release.
- Joint Research Midwife Band 6 post with Chesterfield Royal working across both organisations place to support maternity studies. Funded from bid to CRN Innovation fund due to finish March 2019. A further joint organisational post has been agreed for 19/20 covering the specialities of Respiratory and Cardiology.
- SFH has successfully secured a trial with University of Oxford including funding for a Band 6 Research Nurse and Band 2 Administrator to run the study for 12 months.

Collaborations



Highlighted Risks

R&I Finance model - The annual income achieved from the conduct of trials (mainly commercial trials) over the period 2016/17 was circa £135k, and in 2017/18 £82k. Currently, this income is split between R&I and the Divisions, based on a national income distribution model. The Divisions also received an additional £125k in 2018/19 to directly support trial activity, in the form of research PA's and staff costs in support departments, e.g pharmacy. R&I annual income share has ranged between £30-45k over the past 3 years. There is currently potential to request this income remains in R&I as deferred income in order to be used to further develop the service and build capacity and capability.

However, this is not guaranteed and the outcome can be dependent on wider organisational pressures leading to a negative impact on business planning for the year ahead.

The Department of Health considers the support and delivery of commercial industry-funded research to be a priority. It acknowledges the money generated from this research is a valuable source of income for NHS organisations to develop capacity for new research, and maintain this funding flow (NIHR Commercial Income Distribution Model, 2015). As NIHR budgets are decreased year on year (7.6% cut over 2 years, excl pay award costs) there is a stronger emphasis on the need for a more flexible funding model to support activity using commercial funds.

If the model remains the same there is significant risk that by 2020/21 we will be unable to continue funding the same level of Research Nurse/AHP's, PA support and support departments to deliver trials. The likelihood is this will lead to a downward spiral in research activity, further reducing funding and decreasing the deserved opportunity of our patients to access novel treatments and interventions through research at their local hospitals. In the past few years the R&I department has increased research performance year on year whilst significantly raising the profile of SFH research, both internally and across the region. It is a key part of the Trust strategy and we would like to secure the ability to drive this forward in the future.

Excess Treatment Costs - from 1st October 2018 there have been a number of changes in the way NHS providers are expected to manage excess treatment costs (ETCs) related to non-commercial research. Providers are now expected to absorb ETC's to the level of 0.01% of their total operating income (£29,544 for full year). These thresholds have been set in partnership with NHS Improvement, and any agreed ETCs beyond these will be reimbursed. There is a potential risk to trial activity if this cost is not supported as we would be unable to open certain studies at this site. The risk of this occurring is considered low based on previous data; only 1 study in 18 months having ETC's totalling £800.

Brexit – R&I is leading on the Research and Clinical Trials section of the local EU Exit Readiness preparations that feed in to the Risk Committee. As an organisation SFH acts as a participating site and do not sponsor any clinical trials of investigational medicinal products (CTIMP's). Sponsors of CTIMP trials currently active at the Trust have been contacted and requested to provide assurance regarding their contingency plans for IMP supply in the case of a "no deal" Brexit. This will be documented and reviewed at regular intervals to ensure responses are received. The risk to patients in trials is currently considered low.

Summary

Our Research and Innovation department is now well established and includes a multidisciplinary infrastructure supporting a broad range of research activity across many clinical areas of the Trust. 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.

At a local level research can have positive outcomes in terms of increased quality of care, patient satisfaction and financial benefits to the organisation. A Retrospective cross-sectional study looking at data For 129 English National Health Service hospital Trusts, from National Institute for Health Research study activity data, Summary Hospital-level Mortality Indicator (SHMI) scores and Care Quality Commission (CQC) ratings demonstrates a positive link between better CQC outcomes and the intensity of interventional research trials at NHS Trusts (Jonker and Fischer 2018). Previously the papers and evidence have only focused on mortality rates. 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.

Appendix 1

Our Vision

To make research part of our daily business

Our Mission

At SFH, research is about improving the care we give to our patients to make sure it is outstanding. Embed research excellence as part of our culture, and deliver this with a highly skilled knowledgeable workforce as part of everyday care.

Our Aims:

1. Strong research activity in more clinical specialities, define and secure our areas of strength and establish high class research facilities

- Focus on priority areas where we have existing strengths
- Embed research in as part of clinical service
- Increase partnership working to make the most of our potential

2. Work with more industry organisations to deliver clinical trials that change people's lives for the better

- Develop relationships with leading commercial sponsors and CRO's
- Broaden our commercial research portfolio
- Work in collaboration with EMCRN Industry team as a priority site for increasing commercial activity

3. Involve more of our patients and staff in high quality research

- Make research more visible and provide more research opportunities for our patients
- Enable patients to engage in PPI activities across our organisation and our region
- Deliver research that is important to our patients
- Improve the quality and standard of our care through participation in research

4. Develop and support a workforce with the skills to deliver world class research

- Develop a sustainable research academy to build the skills of our staff
- Develop career pathways for research staff and encourage collaborations with academic institutions
- Engage and support our research investigators
- Invest commercial research income in to building future capacity and capability