

Recommendation <input checked="" type="checkbox"/> DECISION <input type="checkbox"/> NOTE	<div style="border: 1px solid black; padding: 2px;">The Trust Board</div> <p>is asked to Receive and Approve the Research & Innovation (R&I) Annual Report 2016/17</p>
Reporting to:	Trust Board
Date	27 July 2017
Paper Title	Research & Innovation (R&I) Annual Report 2016/17
Brief Description	<p>Research activity continues to flourish in the Trust with 2030 patients entered into National Research Ethics Committee approved studies. Additionally R&I provided practical support, advice and training to staff for 15 own account or further education research projects.</p> <p>National High Level Objectives (HLOs) were met for recruitment, number of commercial studies opened and time to target recruitment for non-commercial studies. We continue to work towards HLOs related to overall time and recruitment target achieved and our priority for the coming year will be to increase our commercial activity, in particular in cancer studies.</p> <p>We will continue to work with partner organisations to increase the opportunities for our patients to enter clinical trials to improve patient outcomes and provide access to novel and innovative treatments.</p>
Sponsoring Director	Medical Director
Author(s)	Dr Nigel Capps, R&I Director, Angela Loughlin, R&I Manager & Sister Helen Moore, Clinical Trials Manager
Recommended / escalated by	
Previously considered by	
Link to strategic objectives	
Link to Board Assurance Framework	
Equality Impact Assessment	<ul style="list-style-type: none"> ● Stage 1 only (no negative impacts identified) ● Stage 2 recommended (negative impacts identified) <ul style="list-style-type: none"> ● negative impacts have been mitigated ● negative impacts balanced against overall positive impacts

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- This document is for full publication
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- This whole document is exempt under the FOIA

Research & Innovation Annual Report 2016/17

June 2017

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1. INTRODUCTION

The NHS Constitution, published in January 2009, commits to innovation and to the promotion and conduct of research to improve the current and future health and care of the population. The commitment features in one of seven key principles - the principle that the NHS aspires to high standards of excellence and professionalism. Essentially research is a core part of the NHS.

Research ultimately is about developing and delivering more effective and more efficient care to patients. There is good evidence that organisations that are research active routinely have improved patient outcomes, with benefits not restricted to just those who participate in research activities.

NHS patients therefore can expect to be informed of approved research that is relevant to their health and care. Our Research and Innovation (R&I) team provide the essential infrastructure for all specialties to have the opportunity to offer their patients appropriate participation.

With funding from the National Institute for Health Research (NIHR) since 2008/09, to develop our research infrastructure, activity has grown significantly and has increased year on year. We are part of the West Midlands Clinical Research Network (CRN), the largest CRN in the country.

2. PURPOSE

This report provides an overview of the Research and Innovation (R&I) activity from April 2016 to March 2017. It presents the activity in terms of measured progress towards mandated targets and performance metrics.

3. AIMS

- To improve outcomes in healthcare through research within a high quality caring environment.
- To promote high quality research across the Trust within a framework of effective, efficient research governance and Good Clinical Practice (GCP) and develop the infrastructure to support this core NHS work.
- To meet national requirements for recruitment into portfolio trials to time and target.
- To maintain good financial governance.

4. NATIONAL METRICS

The NIHR CRN High Level Objectives are the agreed performance metrics for CRN activity. They include targets to increase the proportion of studies in the NIHR CRN Portfolio that deliver to their planned recruitment time and target, to reduce the time taken to achieve confirmation that Trusts have the Capacity & Capability to deliver a study and to reduce the time taken to recruit first participants into NIHR CRN Portfolio studies. They were introduced in April 2010.

8.1 THE OBJECTIVES

HLO 1: Increase the number of participants recruited into NIHR CRN Portfolio studies.

Measure: Number of recruits to NIHR Portfolio Studies in 2016-17, as a percentage of agreed target.

HLO 2: Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time.

Measure: Percentage of studies that recruited to time and target. Closed studies only.

HLO 3: Increase the number of commercial contract studies delivered through the NIHR CRN.

Measure: Number of Commercial studies initialised (given NHS Permission) to date this year, compared with last year.

HLO 4: Reduce the time taken between 'Date Site Selected' to 'Date Site Confirmed'

Measure: Proportion of studies achieving Capacity & Capability within the 40 day target.

HLO 5: Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies

Measure: Percentage of studies achieving first recruit within 30 days of 'Date Site Confirmed'

8.2 PERFORMANCE AGAINST THE METRICS

HLO 1: Increase the number of participants recruited into NIHR CRN Portfolio studies

- The Trust achieved excellent recruitment again this year with 2030 patients entering Research Ethics Committee approved research – against a CRN target of 1800
- **GREEN** RAG rating.
- SaTH contributed 3.5% of the West Midlands CRN recruitment, an increase from 3.2% last year.

HLO 2: Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment target and time for studies which closed in 2016-2017.

- For commercial studies 2 out of 6 studies i.e. 33%
- **RED** RAG rating

Of the remaining four studies 2 closed early due to reaching their national or global recruitment target, the other two were closed early at our site due to changes in the protocol which made them undeliverable locally.

- For non-commercial studies 8 out of 13 i.e. 62%
- **GREEN** RAG rating

has improved significantly by 22% on last year's figures.

HLO 3: Increase the number of commercial contract studies delivered through the NIHR CRN

- Number of commercial studies initialised 2015-16 = 7
- Number of commercial studies initialised 2016-17 = 9
GREEN RAG rating

This has been achieved despite our challenges regarding Pharmacy (see below), by focusing more on studies which do not require their support.

HLO 4 & HLO 5

Due to the change in the National approval process (see challenges below), Trust level data is not reportable for HLO4 and HLO5 for 2016-17.

5. RESEARCH ENGAGEMENT

An important aspect of the development of R&I within the Trust is engagement, both internally with staff, service users and carers, and externally with partnership organisations, including the NIHR CRN, other NHS Trusts and academic institutions.

Ultimately our ambition is to ensure that service users have equity of access to research opportunities in all areas of the trust and to link in with primary care and community colleagues to maximise recruitment potential.

The Research & Innovation Committee provides strategic oversight of the implementation of the National Research Governance Framework and supporting the implementation of the NIHR and CRN objectives to:

- Increase the number of patients participating in clinical trials
- Improve the speed, quality and integration of research
- Provide equity of access to high quality research

The membership of the Committee comprises the R&I Director, R&I Manager, Clinical Trials Manager, Clinicians, Pharmacists, Finance link, Librarian, Allied Health professionals and two patient representatives. The Committee meets once a month.

The R&I department has an internal clinical trial audit and monitoring programme which reviews projects at the recommendation of the Committee, or if an issue is identified during the running of a study either by the study sponsor, by the Principal Investigator or the R&I team. Findings are fed back to the relevant parties and the R&I Committee.

6. SUCCESSES

- In the NIHR league table in terms of number of patients recruited SaTH was 74th out of 459 Trusts and in terms of the total number of studies open SaTH was 60th out of 459 Trusts.
- The R&I department has supported the recruitment of the first families into the Rare Diseases Cohort of the 100,000 Genomes Project with 21 participants (probands and relatives) in the project thus far. We have now established monthly clinics, so are able to offer this opportunity to all potentially eligible patients with rare diseases. We are currently rolling out the project to cancer patients.
- The Trust acts as a subsidiary site for the South Staffordshire and Shropshire Healthcare NHS Foundation Trust, with Pathology and Radiology performing investigations for their commercial studies, hence generating extra income.
- SaTH currently serves as a continuing care site for Birmingham Children's Hospital (BCH) Oncology trials – where patients are recruited at BCH and receive their treatment nearer their homes. This can be challenging as we receive no funding in R&I for this activity.
- SaTH has a research training programme facilitated in-house. The mandatory Good Clinical Practice Training (GCP) is facilitated by the Clinical Trials Manager and 124 SaTH staff were trained during 2016-17.

- We have 3 trained facilitators for the NIHR CRN Principal Investigators Master Class Training including the Trust Lead Research Nurse and Senior Research Sisters. 17 Principal Investigators, 6 Co-Investigators and 2 research healthcare professionals employed by SaTH were trained during 2016-17.
- SaTH has 4 Nurse Principal Investigators in currently recruiting non-interventional trials. One of these was our leading recruiter into cancer studies in 2016/17, recruiting 23% of all the cancer patients who entered a clinical trial.
- R&I gave advice on developing research ideas, protocol writing and submission for regulatory approval on 15 own account research projects during 2016-2017.
- SaTH employees produced a total of 58 publications during 2016-2017. A list of which can be found on the library internet site <http://www.library.sath.nhs.uk/research/>
- SaTH held promotional events once again on International Clinical Trials. Information stands were present on both hospital sites and the clinical teams visited wards to talk to patients and staff about participating in clinical trials. The OK to ASK campaign was incorporated into the day.
- SaTH R&I were the recipients of two recent national awards for their involvement and recruitment into the National MS Registry study. The first award was for the quality of the data submitted by the research team, the second for the quality of the linked participant consent, done by online secure linkage.
- The Oncology R&I Team were nominated at the annual WMCRN awards by the Sponsor of the Breast trial MAMMO-50, for being the top recruiter from over 50 sites in the country at the time.
- SaTH recruited the first patient in the UK to the DARS Head & Neck radiotherapy study.
- SaTH was the 3rd highest recruiter in the UK into the ACCEPT Paediatric study which was an evaluation of the methodology used in the assessment of acceptability of paediatric medicines.

7. CHALLENGES

- Capacity issues continue in Pharmacy and we are currently in a position where we have no interventional commercial studies open in Cancer, and few non-commercial. This is a major ongoing risk. The issue lies with the capacity of the aseptic unit in Pharmacy to make up the products involved. To address this we are working with pharmacy to explore outsourcing the products and exploring funding opportunities for pharmacy staff.

- Clinician engagement remains challenging as many Principal Investigators will not participate or increase their research commitments due to competing job plan activities. We are actively encouraging non-medic Principal Investigators to run studies at SaTH.
- Funding allocation from the NIHR has meant another 5% cut. This has been challenging and we have used much of our reserve monies to plug this gap. We hope to address the Pharmacy issues and increase our commercial activity to increase income, we will also explore funding initiatives released via the Clinical Research Network throughout the year.

8. FINANCIAL

The Research & Innovation Department continues to be fully self-funded from external income, mainly from the NIHR CRN. This income is ring-fenced and can only be used for staff and service support costs resulting from involvement in portfolio research. In addition to this funding stream we compete to conduct commercial trials to generate additional income.

- A quarterly breakdown of named research staff costs including pay point and whole time equivalent is required by the CRN for reporting back to the Department of Health.
- Some of the CRN funding is used for additional work from support services and monthly amounts are given to Pharmacy, Radiology, Radiotherapy Physics and Pathology to support their involvement in research activity in the Trust.
- Commercial studies are costed using the national costing template. A Standard Operating Procedure is in place for apportioning research income based on national guidelines. The income is shared between the service where the study is taking place, the support services involved and the R&I department who provide the clinical and administrative staff to support the PI in the running of the study.
- Research income is held for services in an account within R&I, to be used by them for own account research, education or other appropriate and agreed activity.
- The R&I portion of commercial income is used for non CRN-supported staff costs and all non-pay costs.
- During 2016-17 R&I operated within budget
 - The Income was:

DH/NIHR income	£956,837
Commercial income to R&I	£143,940
Total R&I income	£1,100,777
Commercial income for research active services	£68,498
Total Income to the Trust	£1,169,275

9. PERFORMANCE AGAINST OBJECTIVES & PRIORITIES SET FOR 2016-17

- **Grow commercial activity in the Trust and, in particular, in areas where we have not conducted any commercial research.**

This year we have increased the number of commercial studies opened, and we are currently negotiating a commercial study which will also recruit our first paediatric patients into commercial trials. Commercial activity has increased by 28% on last year.

- **Increase the NIHR CRN income by optimising breadth and balance of non-commercial research and improving our CRN time and target metrics.**

We are actively seeking clinicians in new specialties. We hold quarterly portfolio review meetings with team leads to monitor the recruitment of participants into each study. We actively look for gaps in the portfolio and seek out potential studies, and are continually developing our internal feasibility pathways to ensure a realistic and achievable target is set with our Principal Investigators

- **Increase the profile of R&I within the Trust and in the community**

We celebrated international clinical trials day once again, with a visit from the Chief Operating Officer of the West Midlands Clinical Network. In conjunction with our Communications Dept. the Shropshire Star interviewed a clinical trial patient, her Research Nurse and the Clinical Trials Manager. A newsletter was produced by the department and disseminated via our communications team. We present at most Clinical Governance Specialty meetings to raise the profile of Clinical Research and its benefits to our patients at SaTH on an annual basis. We also present at AGMs and MDT events. We present externally at national and international meetings. The Clinical Trials Manager presented “Bite-Sized Best Practice: Creative Research” at the West Midlands Clinical Research Network Annual Event, and at the SaTH Nursing & Midwifery Forum.

- **Increase the number of Principal Investigators within the Trust**

The number of Principal Investigators has increased by 13% on last year. SaTH has 4 Nurse Principal Investigators in currently recruiting non-interventional trials.

- **Have a clinician act as research link in all departments at the Trust.**

This will be set as a priority for next year

- **Establish a link with the primary care network to enable appropriate colleagues to act as a patient identification centres for our studies.**

The Research & Innovation Manager has been attending the Cross Staffordshire and Shropshire Research group, which includes membership from GP practices and CCG's and has linked with the WMCRN portfolio Manager for commercial studies in primary care. We are hoping to include GP practices as Patient Identification Centres in the coming year.

- **Involve the Patient Representatives more in the wider work of R&I**

We currently have two patient representatives who are core members on our R&I Committee. As we develop our in-house projects further the Patient Representatives will become key in providing the patient perspective on research design and implementation.

- **Assist Pharmacy in the appointment of a designated trials pharmacist to improve capacity and give R&I one point of contact.**

There has been an issue regarding the funding for this post which was to be part-funded by the CCG. The post has not yet been advertised.

- **To encourage and facilitate participation into the national 100,000 Genomes Project.**

Recruitment has begun at SaTH - see "Successes".

10. OBJECTIVES & PRIORITIES 2017-18

- To encourage and facilitate participation into the Cancer cohort of the 100,000 genomes project.
- Facilitate the adoption of our first research project on the NIHR Clinical Research Network Portfolio.

- Solve the issues with pharmacy and re-commence interventional trials in Oncology and Haematology.
- Have a clinician act as research link in all departments at the Trust.

11. LONG TERM OBJECTIVES

- Work with the STP Programme to ensure fit-for-purpose facilities for the R&I team and trial participants.
- Increase engagement with all professional groups to encourage more researchers to develop their own research and have their study adopted onto the CRN portfolio.
- Have SaTH sponsored Clinical Trials of Investigational Medicinal Products.
- Develop our own Chief Investigators to conduct multi-centre portfolio research.
- Contribute to SaTH achieving University Hospital Status