

<b>Reporting to:</b>	<b>Trust Board - 24 September 2015</b>
<b>Title</b>	Research & Innovation Annual Report 2014/15
<b>Sponsoring Director</b>	Dr Edwin Borman, Medical Director
<b>Author(s)</b>	Dr Nigel Capps, R&I Director, & Marion Adams, R&I Manager.
<b>Previously considered by</b>	
<b>Executive Summary</b>	<p>Research activity continues to flourish across the Trust with 1,555 patients entered into National Research Ethics approved studies. Additionally R&amp;I provided practical support, advice and training to staff for 18 own account or further education research projects.</p> <p>National High Level Objectives (HLOs) were met for recruitment, time to approve new studies and increasing commercially funded research. We continue to work towards HLOs related to time to recruit first patient and overall time and recruitment target achieved. We were the leading Trust in the West Midlands Clinical Research Network for increasing participation in industry funded research and our conversion rate for expressions of interest to lead to being accepted as a site, in competition with the rest of the UK, has reached 50%. Our involvement in such research has given patients the opportunity to access new treatments otherwise unavailable through the NHS whilst saving on drug costs and reducing in-patient events.</p> <p>The Trust profile continues to be raised in the research world. We will remain, for the second year, in the national top 100 recruiters on the NIHR/Guardian website. We achieved top recruitment in the UK for 4 global studies and entered the first patient in the UK for 1 other.</p> <p>R&amp;I continues to maintain good financial governance and is funded from external source. The ability to continue to develop and grow both research and innovation is hampered by severely inadequate accommodation both at RSH &amp; PRH.</p>
<b>Strategic Priorities</b>	
1. Quality and Safety	<input checked="" type="checkbox"/> Reduce harm, deliver best clinical outcomes and improve patient experience. <input type="checkbox"/> Address the existing capacity shortfall and process issues to consistently deliver national healthcare standards <input type="checkbox"/> Develop a clinical strategy that ensures the safety and short term sustainability of our clinical services pending the outcome of the Future Fit Programme <input type="checkbox"/> To undertake a review of all current services at specialty level to inform future service and business decisions <input type="checkbox"/> Develop a sustainable long term clinical services strategy for the Trust to deliver our vision of future healthcare services through our Future Fit Programme
2. People	<input checked="" type="checkbox"/> Through our People Strategy develop, support and engage with our workforce to make our organisation a great place to work
3. Innovation	<input checked="" type="checkbox"/> Support service transformation and increased productivity through technology and continuous improvement strategies
4. Community and Partnership	<input type="checkbox"/> Develop the principle of 'agency' in our community to support a prevention agenda and improve the health and well-being of the population <input checked="" type="checkbox"/> Embed a customer focussed approach and improve relationships through our stakeholder engagement strategies
5. Financial Strength: Sustainable Future	<input type="checkbox"/> Develop a transition plan that ensures financial sustainability and addresses liquidity issues pending the outcome of the Future Fit Programme
<b>Board Assurance Framework (BAF) Risks</b>	<input checked="" type="checkbox"/> If we do not deliver <b>safe care</b> then patients may suffer avoidable harm and poor clinical outcomes and experience <input type="checkbox"/> If the local health and social care economy does not reduce the <b>Fit To Transfer (FTT)</b> waiting list from its current unacceptable levels then patients

	<p>may suffer serious harm</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Risk to <b>sustainability</b> of clinical services due to potential shortages of key clinical staff</li> <li><input type="checkbox"/> If we do not achieve safe and efficient <b>patient flow</b> and improve our processes and capacity and demand planning then we will fail the national quality and performance standards</li> <li><input checked="" type="checkbox"/> If we do not get good levels of <b>staff engagement</b> to get a culture of continuous improvement then staff morale and patient outcomes may not improve</li> <li><input checked="" type="checkbox"/> If we do not have a clear <b>clinical service vision</b> then we may not deliver the best services to patients</li> <li><input checked="" type="checkbox"/> If we are unable to resolve our structural imbalance in the Trust's <b>Income &amp; Expenditure</b> position then we will not be able to fulfil our financial duties and address the modernisation of our ageing estate and equipment</li> </ul>
<p><b>Care Quality Commission (CQC) Domains</b></p>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Safe</li> <li><input checked="" type="checkbox"/> Effective</li> <li><input checked="" type="checkbox"/> Caring</li> <li><input checked="" type="checkbox"/> Responsive</li> <li><input checked="" type="checkbox"/> Well led</li> </ul>
<p> <input checked="" type="checkbox"/> Receive    <input checked="" type="checkbox"/> Review  <input type="checkbox"/> Note        <input type="checkbox"/> Approve </p>	<p><b>Recommendation</b></p>

## Research & Innovation (R&I) Annual Report 2014 – 2015

### Aims

- Improve outcomes in health care 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.
- Meet national requirement for recruitment into portfolio trials to time and target.
- Maintain good financial governance.
- Supporting Trust values.

### Background

With the provision of funding from the National Institute for Health Research (NIHR) since 2008/09 to develop the research infrastructure within the Trust activity has grown significantly. The Trust is part of the West Midlands Clinical Research Network (CRN), the largest in the country.

The Trust is measured against time to approval, time to recruit first patient, recruitment per trial to time and target and overall recruitment within the Trust.

2014/15 saw the introduction of much change from the merging of the 5 networks into 1. The full impact of this is still emerging as the difficulty of change management for such a large CRN has delayed the process.

Research is one of the tripartite agenda items for the NHS and continues to be essential for the Health and Wealth of the Nation. It provides the evidence base for improving care and health outcomes. It crosses all the clinical services, with the R&I Clinical Trials team providing the essential infrastructure for all specialities to have the opportunity to offer their patients participation in clinical trials.

It has been recognised for some time that participation in clinical trials benefits individual patients in terms of outcome, even if they are in the standard care arm of a study. Recent evidence has now shown that research active Trusts have better mortality rates than non-research active Trusts, taking into account all other variables

The Research & Innovation Committee provides a strategic vision in 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

During 2014 the Chairman of the Trust Board asked the department to support innovation and we have embraced this – as Research and Innovation rather than Research & Development.

## **Research Objectives**

To ensure all research taking place within the Trust is run in accordance with current legislation and Clinical Trials Good Clinical Practice (GCP).

- To encourage current Investigators and potential new Principal Investigators (PIs) to develop their research activity with a focus on UKCRN portfolio studies and Industry funded commercial studies.
- To identify barriers to research and work towards overcoming these.
- Make available to patients as wide a variety of high quality clinical studies as resources will support.
- To provide the infrastructure, support and advice required by potential and active researchers.
- To support and guide local research with a view to developing high quality local research leading to the adoption of local research onto the National Portfolio in the future
- To maintain an overview of current research with respect to governance, GCP and recruitment and take appropriate action where inadequacies are identified.
- To ensure adequate funding from the Research Network and commercial activity to support the service.

## **Performance against National Metrics**

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

Measure: Number of recruits to NIHR Portfolio Studies in 2014-15, as a percentage of agreed target

Specialty	Total no of recruiting studies 2013/14	Recruitment 2013/14	Total no of recruiting studies 2014/15	Recruitment 2014/15
Cancer	25	399	28	404
Cardiovascular	9	600	7	485
Gastro-Intestinal	15	292	10	58
Stroke	3	4	3	18
Respiratory	1	1	5	27
Reproductive Health	5	36	4	45
Medicines for Children (inc non drug studies)	7	98	7	52
Renal	5	38	7	132
Dementia/neurology	2	46	4	300
Dermatology	1	1	1	3
Critical care	1	6	3	6
Ophthalmology	1	22	1	16
Audiology	1	13	0	0
Haematology	1	3	1	5
Other	1	1	1(MSK)	5
Local		26	1	1
Totals	81	1586	83	1555

- Recruitment against our target for national portfolio trials was 101%. Green RAG rated.
- The Trust has maintained the high level of recruitment achieved last year with 1555 patients entering Research Ethics Committee approved studies.
- SaTH contributed 2.9% of the West Midlands network recruitment, 9<sup>th</sup> out of 31 organisations. The combined Primary Care organisations in this report contributed the most patients - 21%.
- It is expected that we will remain in the NIHR list of 100 top recruiting hospitals but national data has not yet been published. .
- There has been a large increase in the number of actively recruiting Principle Investigators jumping from 36 to 55
- The Trust acts as a Continuing Care site for local children recruited into cancer studies at Birmingham, delivering all relevant treatment and follow up care.
- The Trust supports research in the wider community. In 2014/15 radiology and pathology support was provided for 3 ongoing commercial trials in primary care and mental health.
- Total number of national portfolio studies recruiting during the year was 82 plus 1 Research Ethics Committee approved local study

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.

- Overall 50%, RED rag rated,
- Ranked 9<sup>th</sup> out of 41 across the WMCRN.
- Commercial 3/4 succeeded - 75%, non-commercial 5/12 succeeded - 42%
- Many factors affecting this are outside our control such as the rate of recruitment globally. However, we need to continue to work closely with Principal Investigators to ensure they have considered their patient population and all exclusion criteria carefully when estimating potential recruitment numbers.

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.

- The number of commercial studies open to recruitment at some point during 2014/15 has increased to 13 from 11 in 2013/14. Overall in the WMCRN the number of commercial trials has reduced.
- We have increased our conversion rate of submission of expressions into acceptance as a research site from 40% in 2013/14 to 50%. These are all in our established research areas. Areas still developing their expertise and confidence in research rarely submit EOIs for commercial trials which are much more demanding than academic studies. It is also much harder for new researchers to be chosen.  
27 expressions of interest submitted, 2 studies were withdrawn from the UK,  
10 studies have selected us as a site, 10 rejections and 5 outcomes still awaited.

HLO 4: Reduce the time taken for NIHR studies to achieve NHS permission

Measure: Proportion of studies achieving the 15-day CSP Process Improvement target

- **98%** of new studies were approved within this target. Green RAG rated.
- 44 new portfolio studies were approved during the year plus 3 non-portfolio studies and 3 shared/continuing care studies approvals.
- R&D also advised on and the R&D Committee reviewed 4 projects requiring Trust approval but now outside the remit of Research Ethics Committees.

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 permission

- Achieved overall 50%, Red Rag rated. 67% in commercial trials, Amber RAG rated and 45% in non-commercial trials, Red RAG rated
- Nationally the target is for first recruitment anywhere in the country within 30 days of Trust approval and 70 days of Ethics approval and excludes studies with recruitment targets under 12.
- We are unlikely to meet this WMCRN target since many of our studies are in specialized areas with low recruitment targets. Discussions between Principle Investigators and the R&D Committee have resulted in agreement that low number studies usually address important questions in rare conditions that will not be answered unless all centres contribute a small number of patients and should be supported regardless of this target.

## **How we did against Other Research Objectives and Priorities for 2014 – 2015**

### **1. Improve R&I accommodation at RSH so staff and equipment essential to achieving targets can be put in place:**

- Equipment was purchased and staff have recently been appointed based on agreement to alter the current accommodation at RSH. However this is still awaited and the service is at crisis point.

### **2. Continue to promote awareness of research to staff, patients and public:**

- 2 promotional events held at both hospital sites for staff and public, with local radio and newspaper coverage of the main public event.
- Communications bulletins sent out trust wide.
- Talks to staff groups and public groups given by R&I staff.

### **3. Provide educational sessions for all research interested staff:**

- Clinical Trial Good Clinical Practice training, which is a legal requirement for all staff working on research involving patients, provided locally with 95 staff newly trained or updated during 2014/15.
- 2 staff talks organised - from the Research Design Service and the Academic Health Science Network.
- Access to Health Research Authority update sessions made available to relevant services.
- Repeat Understanding Statistics day held, again over subscribed.
- Hosted 2 local events run by WMCRN.
- 1 to 1 training provided for researchers where in-house monitoring has identified problems

## **How we did against Additional Long Term Objectives**

1. **Increase engagement with all professional groups to encourage new researchers to develop own account research:**
  - Senior R&I staff attend various clinical governance meetings and MDTs
  - Advice on developing research ideas, protocol writing and submission for regulatory approval given on 18 projects
  - R&I presence at new doctors induction day.
  - R&I clinical staff providing practical support for the running of some local research to ensure the research does not fail and conforms to research governance.
2. **Develop the infrastructure within R&I to drive and support high quality local research including protocol writing, grant application, Research Ethics Committee submissions and national portfolio adoption applications:**
  - With the remit to also support Innovation this is increasingly important but we have been unable to move forward with this in any significant manner because of severe space constraints
  - 2 Trust staff are developing research protocols with the potential for attracting grant funding and adoption onto the National Portfolio.
3. **Increase commercial trial activity to provide capacity build funds for the above and on-going research nurse/allied health professional and administrative support to see local studies through to conclusion:**
  - a. Commercial activity has been increased; additional income should arise from this in 2015/16 since payment is in retrospect.
  - b. 2014/15 additional commercial income and that projected for 2015/15 studies has been allocated to cover the reduced WMCRN funding for 2015/16 and permit growth in all research. The growth in non-commercial studies is essential to attract the necessary WMCRN funding in future years.
  - c. Commercial income supported all the non-clinical activity that R&I deliver.
4. **Develop academic links with local universities and access to statistical support for local researchers.**
  - a. Clinical statistician sourced who is able to provide ad hoc support to researchers at an hourly rate.
  - b. Undertaking a European Union funded study in reproductive health in collaboration with Cork and Keele Universities.
  - c. Supporting NIHR PhD application for a pathology clinical scientist
  - d. Unable to support fertility PhD project as requires commitment to 5 years of funding

## **Additional Benefits from Research Participation**

- 71 known publications by SaTH staff during 2014, including conference reports, journal articles, published RCTs, and case reports.  
The full report can be found at:  
<http://library.sath.nhs.uk/wp-content/uploads/2015/06/SaTH-Staff-Publication-Report-2014.pdf>
- Patients who are not eligible for a clinical trial have benefitted from the growth of research within the Trust:
  - Participation in UKCRN 4078 showed that the closer cardiac monitoring within the trial was beneficial and was adopted as Standard of Care for all patients.
  - A trial of a new drug delivery method provided training and support for the research nurses treating the patients, which was rolled out to the clinical teams when the delivery system became standard of care for all patients.
- Individual patient satisfaction is very high. Written and verbal communications from those participating in clinical trials have expressed gratitude both for the improved outcomes experienced as a result of the trial intervention and the level of care provided by the research team.
- Financial savings:
  - 2 oncology clinical trials investigating reducing treatment length recruited 18 patients between them which reduced the number of chemotherapy cycles by 99, giving significant savings in drug costs and day centre chair time.
  - Drugs are provided free within commercial studies and some academic studies
  - Additional treatment options with potential of reducing in-patient stays and surgical interventions in some gastro-enterology studies
- Raising Trust profile:
  - Listed in the top 100 recruiters on the NIHR/Guardian website.
  - Achieved highest recruitment in the UK in 4 studies
  - Highest recruiter into urological studies in the West Midlands.
  - Recruited first patient in the UK for an international pharmaceutical study.

## **Innovation**

Developmental work commenced during 2014/15 with approaches made by the R&I Manager to the Heads of Scheduled and Unscheduled Care and a brief talk at a Clinical Directors meeting. The promotion work undertaken with the name change brought forward staff requiring help but we have only been able to promise to provide this once our pressing space needs have been resolved.

For significant success to be achieved, some Trust funding will be required.

## **Financial**

- The research and development department continues to be fully self-funded from external income. This income is ring fenced and can only be used for the additional staff costs and service support costs resulting from involvement in national portfolio research. This funds research nurses/allied health professionals, trials data co-ordinators and facilitators, some middle grade clinical time and covers additional work for support services i.e. Pharmacy, Pathology, Radiology and Radiotherapy physics.
- A quarterly breakdown of named research staff costs including pay point and whole time equivalent is required by the Network for reporting back to the DH.
- Commercial studies are costed using National Costings. Trial income is shared between the service delivery unit in which the research takes place, the support services involved and the R&I department who provide the trials staff to support the PI.
- A Standard Operating Procedure is in place for apportioning research income based on national guidelines. Research income is held for services in an account within R&I to be used by them for own account research, staff training and purchase of equipment.
- R&I portion of commercial income is used for staff costs and all non-pay costs.

- R&I operated within budget

DH/NIHR income	£802,768
Commercial/Trial generated income to R&I	£137,547
<b>Total R&amp;I income</b>	<b>£940315</b>
Commercial/Trial generated income for research active services	£137,144
<b>Total Income to the Trust</b>	<b>£1,077459</b>

## **Challenges**

- A new model of funding allocation was agreed by the WMCRN partnership group in 2015. From 1<sup>st</sup> April 2015 funding changes from a population and target driven allocation to one related to activity based funding units based on the median activity of the previous 3 years.
  - Category 1 non-interventional trials recruiting 10,000+ patients = 1 ABFU
  - Category 2 non-interventional trials recruiting < 10,000 patients =3 ABFU
  - Category 3 interventional trials = 14 ABFU

There is some expectation that another level of interventional trials will be introduced to differentiate between the workload of the simple and complex trials.

- SaTH core funding was reduced by 17% for 2015/16 but we have successfully bid for enough additional strategic funding to replace this. There may be the opportunity to bid for slippage money later in the year.
- To safeguard future income we need to increase our activity based funding units. Since staff are working to capacity to achieve the high recruitment level of the past 2 years, finance has agreed the spend of accrued commercial income on additional staff using short term contracts. This is expected to secure the extra income in the future to turn some of these into permanent posts and thus continue to increase research activity into the future.
- Until the space needs of the service are addressed what we can achieve is limited. The service at RSH is in crisis with growth having started based on the expectation that at least short term changes would have been made, if not longer term ones. It was expected that R&I would either be moving into the Copthorne building or into an area vacated by the move of another service into that building. This has not so far been agreed.
- With the move of Womens and Childrens services to PRH and thus the increase of activity on that site, the space needs for the Trials team at PRH have also becoming pressing.
- Some services continue to have minimal or no participation in research as they are struggling to meet the clinical demands on their doctors' time. However new consultants coming into the Trust in the past year have expressed interest in becoming research active and we need to be able to support them appropriately.
- Services that are highly research active are keen to do more but have reached capacity. The possibility of research fellow posts to support these areas has been explored but has not been supported by the network.
- National changes to the way research is approved within the NHS presents many unanswered questions related to how the Trust will maintain its legal obligations related to research.
- Driving and supporting innovation is an additional challenge with no funding provided.

## **Opportunities**

- We have become an attractive site for commercial research giving us the opportunity to grow in this area further. These studies generate income and often provide access for patients to new or unfunded treatments. However these studies are more time consuming for both the PI and trials staff than non-commercial studies as they need to conform to FDA requirements.
- We are investing in the future with the appointment of several new staff on fixed term contracts. If we can increase research activity significantly this will attract additional funding, which will allow us to make these permanent posts. In particular Womens and Childrens is an area with great potential to increase activity.
- There are a growing number of both doctors and non-medical staff interested in developing their own research, which we are keen to nurture and support.
- National changes to the way research is approved within the NHS may free resources to support increased activity.

## **Staff Metrics**

<b>Number of staff</b>	<b>31</b>
<b>Staff wte</b>	<b>23.12</b>
<b>Information governance</b>	<b>87%</b>
<b>Appraisals</b>	<b>100%</b>
<b>Fire safety awareness</b>	<b>94%</b>
<b>Load moving and handling</b>	<b>100%</b>
<b>Infection prevention and control</b>	<b>96%</b>
<b>Hand hygiene competence</b>	<b>88%</b>
<b>PM&amp;H</b>	<b>92%</b>
<b>Adult basic life support</b>	<b>92%</b>
<b>Safe guarding adults</b>	<b>96%</b>
<b>Safe guarding children</b>	<b>100%</b>
<b>Conflict resolution</b>	<b>83%</b>
<b>equality &amp; diversity</b>	<b>83%</b>
<b>harassment &amp; bullying</b>	<b>97%</b>
<b>Making every contact count</b>	<b>100%</b>
<b>Sickness</b>	<b>2.34%</b>

**Authors:** Dr Nigel Capps, Director of R&I and Marion Adams, R&I Manager  
**Director responsible:** Dr Edwin Borman, Medical Director