

Research and Development – 6 monthly update 1 April 2019

Three wavy lines in blue, green, and pink/magenta colors that sweep across the bottom of the page.

Agenda Item No: 10.1

Trust Board Report

Meeting Date:	1 st April 2019
Title:	Research & Development – 6 monthly update.
Executive Summary:	<p>This report reflects R&D performance since April 2018.</p> <p><u>Key achievements:</u></p> <ul style="list-style-type: none"> • A total of 3361 participants have been recruited into research studies across the Trust to date in 18/19. • As at 27/03/019, 3260 participants have been recruited into Portfolio studies*. This is 102% against the annual target set by the CRNWM (3202). • This is the highest ever number of patients recruited into Portfolio research at the Trust. • The R&D Directorate continues to provide alternatives to existing patient care, treatment and choice. • Research activity across a broad range of clinical specialties – not reliant on one study for recruitment. • Feedback from research participants confirms that they value the opportunity to take part in research and that they feel supported and cared for when doing so. • Continued high ratings from external study monitors. • CRN: West Midlands core funding of £1,034,070 allocated – no underspend reported. • The Directorate continues to manage delivery of research in spite of a large reduction in core funding, necessitating ongoing skill mix review and a restructuring of the department. <p>*Based on data uploaded to EDGE as at 27/03/19</p>
Action Requested:	Receive and note performance report.
For the attention of the Board	
Assure	<ul style="list-style-type: none"> • This report summarises the performance of the Trust against the NIHR High Level Indicators for research delivery for Quarters 1-3 2018/19. • The report also includes updates with regards to Finance, Governance and Patient and Public Involvement activity within R&D.
Author + Contact Details:	Tel 01902 307999 extn.4218 Email jamescotton@nhs.net Prof. James Cotton, R&D Director.
Links to Trust Strategic Objectives	<ol style="list-style-type: none"> 1. Create a culture of compassion, safety and quality 2. Proactively seek opportunities to develop our services 3. To have an effective and well integrated local health and care system that operates efficiently 4. Attract, retain and develop our staff, and improve employee engagement 5. Maintain financial health – Appropriate investment to patient services

	6. Be in the top 25% of all key performance indicators
Resource Implications:	None

CQC Domains	<p>Safe: patients, staff and the public are protected from abuse and avoidable harm.</p> <p>Effective: care, treatment and support achieves good outcomes, helping people maintain quality of life and is based on the best available evidence.</p> <p>Caring: staff involve and treat everyone with compassion, kindness, dignity and respect.</p> <p>Responsive: services are organised so that they meet people's needs.</p> <p>Well-led: the leadership, management and governance of the organisation make sure it's providing high-quality care that's based around individual needs, that it encourages learning and innovation, and that it promotes an open and fair culture.</p>
Equality and Diversity Impact	None
Risks: BAF/ TRR	n/a
Public or Private:	Public
Other formal bodies involved:	Trust Management Committee
NHS Constitution:	<p>In determining this matter, the Board should have regard to the Core principles contained in the Constitution of:</p> <ul style="list-style-type: none"> • Equality of treatment and access to services • High standards of excellence and professionalism • Service user preferences • Cross community working • Best Value • Accountability through local influence and scrutiny

Report Details																	
1	<p>NIHR CRN WM Performance Targets (RWT)</p> <p>1.1 <u>NIHR High Level Objective (HLO) 1 – Increase the number of participants recruited into NIHR CRN Portfolio studies.</u></p> <p>Table (a) provides study recruitment for the Trust into NIHR Portfolio studies during 18/19.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: center;">No. of participants recruited to date 2018-19</th> <th style="text-align: center;">% Recruitment against Trust target (3202)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">3260</td> <td style="text-align: center;">102%</td> </tr> </tbody> </table> <p>This is the best year for recruitment of patients into NIHR adopted studies.</p> <p>RWT currently also has 7 recruiting studies, led by Trust researchers, adopted onto the NIHR Portfolio. The details of these studies and the patients recruited to date in 18/19 are given below:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Study Name</th> <th style="text-align: center;">CI</th> <th style="text-align: center;">Specialty</th> <th style="text-align: center;">RWT recruits</th> </tr> </thead> <tbody> <tr> <td>Faecal bile acid study</td> <td>Prof M Brookes</td> <td>Gastroenterology</td> <td style="text-align: center;">21</td> </tr> <tr> <td>Kidney protection using</td> <td>Mr Luckraz</td> <td>Cardiovascular</td> <td style="text-align: center;">71</td> </tr> </tbody> </table>	No. of participants recruited to date 2018-19	% Recruitment against Trust target (3202)	3260	102%	Study Name	CI	Specialty	RWT recruits	Faecal bile acid study	Prof M Brookes	Gastroenterology	21	Kidney protection using	Mr Luckraz	Cardiovascular	71
No. of participants recruited to date 2018-19	% Recruitment against Trust target (3202)																
3260	102%																
Study Name	CI	Specialty	RWT recruits														
Faecal bile acid study	Prof M Brookes	Gastroenterology	21														
Kidney protection using	Mr Luckraz	Cardiovascular	71														

the RenalGuard© system in cardiac surgery			
Assessment of plasma and urine NGAL for the early prediction if acute kidney injury after cardiac surgery in adults	Prof Gama	Clinical Chemistry / Cardiovascular	154
Optimising neonatal service provision for preterm babies (27-31 weeks)	Dr T Pillay	Neonatal	33
Biomarkers in pregnant inflammatory bowel disease patients	Dr H Steed	Gastroenterology	8
Family planning in inflammatory bowel disease	Dr H Steed	Gastroenterology	6
Sentimag along with routine evaluation of sentinel node biopsy.	Miss R Vidya	Surgery/Oncology	4
Total			297

1.2 NIHR HLO 2 – Increase the proportion of studies recruiting to time and target.

Of the 59 studies that closed during the first 9 months of 2018/19:

- (a) 46.4% of commercial studies and
- (b) 45.2% of non-commercial studies recruited to time and target.

The target for this indicator is 80%. The factors which have affected achievement of this target have been lack of eligible patients in rare disease and/or difficult to recruit to studies. This a particular issue for commercial studies where 12 out of the 15 studies closed had overall recruitment targets of 5 patients or less.

1.3 NIHR HLO 3 – Increase the number of commercial contract studies

16 new commercial portfolio studies opened at RWT during the first 9 months of 2018/19.

1.4 NIHR HLO 4 – Proportion of studies achieving set up at site within 40 calendar days

29% of the 48 new studies set-up at RWT during Qtrs 1-3 2018/19 were within 40 days.

The target for this indicator is 80%. Study set-up times have been adversely affected by significant reductions in capacity within the R&D project management team during 18/19 arising from financial constraints and vacancies. It is expected that recent new appointments and ensuring time efficient processes are in place will improve performance.

1.5 NIHR HLO 5 – Proportion of studies achieving first participant recruited within 30 days of date site confirmed

Of the 30 new studies opened and recruited into this year to date,
 (a) 67% of commercial studies and
 (b) 78% of non-commercial studies recruited first participant within 30 days.

The target for this indicator is 80%. Factors affecting achievement of this target include lack of eligible patients that meet the study criteria and delays in the study sponsor giving the 'green light' to start recruitment e.g. awaiting study drug delivery / additional training.

2 Overall Research Performance

2.1 Overall research recruitment and activity across the Trust for Qtrs 1-3 2018/19 is given in table (b) below and further detailed in Appendix 1.

Table (b) – All Study Recruitment

Study Category	Recruitment 18/19
Portfolio – non-commercial	2941
Portfolio – commercial	319
Non-commercial (other)	101
Commercial (direct)	0
Total	3361

3 Finance

3.1 2018/19 Research Funding

The R&D Directorate has received the following funding to support Trust research activity during 18/19:

- *CRN: West Midlands Allocation*
 - Core Funding £1,034,070
 - Strategic Funding £64,496

This represents a £54,425 decrease in core funding from 17/18.

All funding has been allocated, with a breakeven position reported at Qtr 3.

- *Commercial Research Income – Quarters 1-3*
 - Invoices based on contracted research activity £927,883

At month 10 there were approx. £310k in bad debts (outstanding invoices over 60 days) for completed research activity. One Haematology study (MAIA) accounts for £190k of this debt and is being considered by the Trusts legal team. The high value of these debts is a result of increased invoicing activity and are resulting in significant cost pressures within the R&D accounts.

3.2 2019/20 Research Funding

The R&D Directorate has been notified of the following funding from the CRN WM for 2019/20

- Core Funding £982,367
- Strategic Funding £81,726

This represents a reduction of £51k in core allocation to support Trust Portfolio research activity.

<p>4</p>	<p>Patient & Public Involvement</p> <p>4.1 <u>Publicity and Communication</u></p> <ul style="list-style-type: none"> • A dedicated twitter account, managed by the Trust communications team, for research at RWT went live in early 2018: @RWTResearch • A growing number of individuals, research organisations and sponsors are following this account to hear about innovative research taking place at RWT. A cross-section of studies active this year include: <p><u>Cardiovascular</u></p> <p>VISION: The study aims to look at the role of blood tests for damaged heart muscle after heart surgery and to see if levels of troponin (heart protein) are related to recovery.</p> <p>NGAL: Assessment of plasma and urine NGAL for the early prediction of acute kidney injury (AKI) after cardiac surgery in adults. This is an own account study.</p> <p><u>Stroke</u></p> <p>RIGHT 2: The aim of this study is to decide if blood pressure lowering treatments like GTN should be given to patients soon after they've had a stroke, to give them a better chance of recovery.</p> <p><u>Obstetrics</u></p> <p>BUMP: Blood pressure monitoring in higher risk pregnancy to improve the detection and monitoring of hypertension.</p> <p>STOPIT 2: An open randomised trial of the Arabin pessary to prevent preterm birth in twin pregnancy.</p> <p><u>Children/Neonatal</u></p> <p>RAACENO: Reducing Asthma Attacks in Children using Exhaled Nitric Oxide as a biomarker to inform treatment strategy.</p> <p>REACT: Evaluation of real time continuous glucose monitoring in the very preterm infant, using glucose sensors with paper based algorithm.</p> <p><u>Rheumatology</u></p> <p>EXCEED: Research study to compare drug treatments in active psoriatic arthritis.</p> <p><u>Oncology</u></p> <p>DETECT II: An observational study to determine the sensitivity of the UroMark assay to detect new and recurrent low, intermediate and high grade bladder cancer.</p> <p><u>Haematology</u></p> <p>COLUMBA: A study of subcutaneous vs intravenous administration of Daratumumab in patient with relapsed or refractory multiple myeloma.</p> <p><u>Sexual Health</u></p> <p>Safetxt: A randomised controlled trial of a safer sex intervention delivered through mobile phone messaging. The study is testing whether text messages providing information and tips to increase safer sex helps young people adopt safe sex behaviours.</p>
<p>5</p>	<p>Governance</p>

As part of our on-going commitment to quality and performance, the R&D Directorate continues to review and support quality assurance in line with European and UK regulator standards.

5.1 External Inspections.

- For the period of 1st April 2018 to 28th February 2019, 323 monitoring site visits have been conducted by study sponsors.
- 2 external audits for regulatory purposes relating to research activities were undertaken during Qtr 3 2018/19. These were commercial sponsor audits for studies being undertaken at Cannock Hospital. Reports are awaited.

5.2 Annual Audit Programme

15 audits have been completed up to end February 19, as per audit plan.

	Total
Delegation Log Audit	1
Consent Audit	0
External Access to Clinical Portal	11
Study Site File Audits	1
Out of Hours Process	1
Monitor Reports Audit	1
	15

Audit results are reported to the R&D Directorate Governance meeting and action plans agreed as necessary.

6 Awards and Commendations

The Trust has also been recognised by commercial and non-commercial research sponsors during 18/19 for ranking highest in the UK for recruitment into studies in the following specialties:

- Oncology
- Cardiology
- Rheumatology
- Paediatrics

Appendices

1	Trust Research Activity 2018/19
---	---------------------------------

Appendix 1 – Trust Research Activity 2018/19

April 18 – February 19	KPI's									
	Research Active	No. of NIHR Portfolio Trials	Accruals (NIHR Portfolio)	No. of open Non-Portfolio trials	Accruals (Non Portfolio)	No. of own account trials	Active PI's	Active CI's in dept	Linked Research Nurses	Linked CTAs/ AHP's
Emergency & Medical Division										
Rehabilitation & Ambulatory Medical Group	Y	13	44	3	0	0	5	0	3	1
Medical Group										
Respiratory	Y	8	8	3	0	1	2	1	1	1
Gastroenterology & Hepatology	Y	23	382	5	7	4	4	3	2	1
Diabetes	Y	6	23	0	0	1	4	1	1	1
Renal	Y	14	27	6	0	1	3	1	1	1
Emergency Services Group	Y	3	109	0	0	0	2	0	0	0
Oncology & Haematology Group	Y	35	77	10	0	2	15	2	10	4
Total		102	670	27	7	9	35	8	18	9
Surgical Division										
Pathology/Clinical Chemistry	Y	2	157*	2	0	2	2	2	0	0
Critical Care Services Group	Y	3	0	4	0	0	2	0	1	1
Cardiology/Cardiothoracic Service Group	Y	16	466	5	6	7	9	4	5	2
Surgical Services Group										
General Surgery	Y	1	3	0	0	1	1	1	2	0
Orthopaedics	N									
Urology	Y	2	4	0	0	0	2	0	3	1
Ophthalmology/Head and Neck Services Group	Y	7	12	3	88	2	3	2	3	1
Obs & Gynae	Y	13	640	6	0	1	1	1	2	1
Total		44	1282	20	94	13	20	10	16	6
Community, Childrens & Support Services Division										
Adult Community Services	N									
Sexual Health	Y	2	6	0	0	0	1	0	1	1
Radiology	Y									
Therapies & Pharmacies Group	Y	0	0	1	0	0	0	0	0	0
Nutrition & Dietetics	N									
Rheumatology	Y	20	257	1	0	0	5	1	7	2
Dermatology	Y	3	52	1	0	0	2	0	3	1
Children's Services	Y	26	134	5	0	1	8	1	3	1
Total		51	447	8	0	1	16	2	15	6
Corporate / Health Service Delivery	Y	4	171	11	0	2	2	2	0	0
Genetics	Y	2	151	0	0	0	0	0	0	0
Total		6	322	11	0	2	2	2	0	0
Total		203	2723**	66	101	25	73	22	52	21

*Trust sponsored Portfolio study involving Cardiovascular and Clinical Chemistry – Chief Investigator Prof R. Gama

**Based on figures from CPMS up to end Feb 19.