








The Royal Wolverhampton NHS Trust		
Trust Board Report		
Meeting Date:	29 th June 2015	
Title:	Research and Development Annual Report 2014/15	
Executive Summary:	This performance report provides a summary of research and development operational activity during the time period April 2014 to the end of December 2014.	
Action Requested:	To receive the report for assurance	
Report of:	Research & Development Director	
Author:	Dr J Cotton, R&D Director	
Contact Details:	Tel 01902 694200 Email jamescotton@nhs.net	
Resource Implications:	Finance, workforce, time, facilities	
Public or Private: (with reasons if private)	Public Session	
References: (eg from/to other committees)	Nil	
Appendices/ References/ Background Reading	Divisional Research Activity 2014/15.	
NHS Constitution: (How it impacts on any decision-making)	<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 	
Background Details		
1	<p>Overview</p> <p>This report reflects R&D performance from April 2014 up to end March 2015. This has been a challenging year for both the Directorate and research teams across the Trust. The Directorate has continued to perform well against performance targets relating to the time taken to complete local review and approve studies. However, the rate of recruitment of patients into studies has been disappointing and the senior R&D management team will continue to seek ways to address this during 2015/16.</p>	

The R&D Directorate provides a number of complementary additions to existing patient care, treatment and choice. 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.

Achievements for period April 14 – March 15

- Sustained approval of trials within 30 days.
- 89% of studies approved within 15 days.
- Patient feedback and engagement processes in place.
- Continued high ratings from external study monitors.
- CRN: West Midlands funding of £1,633,399 received and utilised.

The Directorate is fully aware that during 2015/16 the following challenges will need to be addressed:-

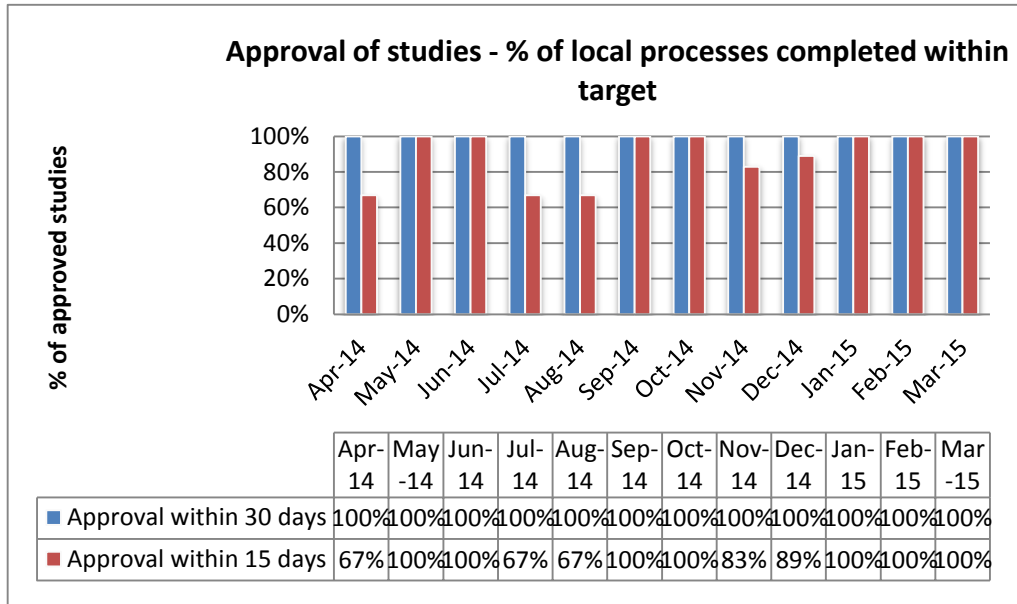
- Increasing recruitment into all research studies
- Increasing medical research capacity
- Increase nursing/AHP research opportunities (Acute/Community care)
- Increasing own account portfolio research
- Motivating inactive clinical services
- Improving recruitment times
- Maintain high levels of patient and monitor satisfaction
- Addressing R and D accommodation shortcomings

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NIHR WMN CLRN Performance Targets (RWT)

(a) Trust Approval Times

NIHR High Level Objective (HLO) 4 – To reduce the time taken for eligible studies to receive permission through CSP.



The Trust consistently issues local R&D approval within 30 calendar days of receipt of a valid application. The R&D Directorate is also actively working towards meeting the challenging indicator, introduced from April 2014, for completing local review within 15 calendar days. 89% of studies were approved during 2014/15 within this target.

(b) Trust Approval / SIV to First Patient First Visit (30 days)

NIHR High level Objective (HLO) 5 – NHS Trust Permission to First Patient Visit

This HLO is probably the most difficult to achieve, RWT trials are in the main interventional and/or randomised clinical trials (RCT's). Table (b) provides the position of RWT against HLO5 for 2014/15.

Common variables which impact on this HLO target include complexity of the trial, SIV requirement for non-commercial studies, patient availability and awaiting 'green light' / supplies from study sponsor.

Table (b) Permission to First Patient Visit

For commercial studies, the calculation starts from the later of the SIV or the Trust R&D Approval date.

Study Type	<=30 days	>30 days	% Achieved
Commercial	9	15	38%

Non-Commercial	9	33	21%
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(c) Trust Annual Recruitment

The Trust 14/15 annual recruitment target set locally by the CRN West Midlands is 3925. This includes an additional target for Cannock services transferred from MSFT. Table (c) provides the annual recruitment for the Trust into NIHR Portfolio studies, whilst all Trust research activity as at 31/03/15 is presented in Table (d).

Table (c) – Portfolio study Recruitment Report Update

Target 2014-15	Number of Participants Recruited 2014-15	% Recruitment against Target
3925	1294	33%

Table (d) – Study Participation 2014/15

Study Category	No. of Active Studies (Recruiting/Follow-up)	Recruitment 14/15
Portfolio - non-commercial	101	1000
Portfolio - commercial	49	294
Non-commercial (other)	22	66
Commercial (direct)	11	55
Own account	7	18
PIC	4	11
Total	194	1441

* An additional 296 participants were involved in a non-consenting study not requiring any direct patient contact (UKCRN 8899 - Prevalence of abnormal PrP using appendix tissue).

Research performance across the Trust is illustrated within the Divisional Report, attached as Appendix 1.

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Patient & Public Involvement

3.1

Engagement in Research

In addition to the 1,441 patients recruited into research trials to date during 2014/15, over 30,000 have been screened for eligibility against the 194 active trials.

3.2

Research Participant Survey

The R&D Directorate continue to proactively seek the views of research

participants through a questionnaire distributed to all participants once they have completed active treatment as part of that study.

During 2014/15, 97 completed questionnaires were received. These included studies undertaken within Oncology, Diabetes, Gastroenterology, Haematology, Ophthalmology, Respiratory, Renal and Stroke services. The results continued to show that participants felt research was important to improve health care (99%), they felt supported during their involvement in the study (97%), 79% would take part in a further study and 87% would recommend involvement to a family member or friend.

Four patients have recorded videos for the R&D Directorate team which have been shown at meetings attended by senior Trust staff and also within the R&D Directorate to provide feedback to research staff.

3.3

Publishing Performance in Initiating and Delivering Clinical Research

In accordance with NIHR requirements, RWT provided and published data on performance in initiating and delivering clinical research at the end of January 2015. The Trust is required to publish this data on a quarterly basis, including making it available on the Trust internet site. The R&D Directorate are exploring ways in which this data can be made more understandable and accessible to patients and the public in the future.

4

Governance

An increase in trial activity inevitably leads to an increase in external sponsor monitoring visits. The monitoring visits are undertaken by Pharmaceutical Companies, Charitable Organisations and University sponsors. During 2014/15, 415 monitoring visits were conducted. Monitors continued to welcome the monitoring feedback forms which provide the R&D management team with an independent level of quality assurance and for these visits 90% were rated as good or excellent.

External Inspection.

The Trust received an MHRA GCP Compliance Inspection on the 11th and 12th February 2015. This was an un-triggered inspection on a completed Gastroenterology study sponsored by Swansea University. Initial feedback confirmed that there were no major or critical findings. Examples of good practice at the Trust were recognised by the MHRA. A draft report was received in March 2015 and an action plan submitted to the MHRA and study sponsor to address the items identified. A final report is awaited.

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HR & Workforce

Overall research workforce capacity spread across the Trust is provided within the Division report attached as Appendix 1.

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Claims/Complaints

There are currently two complaints registered against the R&D Directorate. No patient safety complaints/claims registered. All documentation and additional supportive evidence has been provided to the Trust Legal Services for external review.

<u>Nature of Complaints registered</u>	<u>Complainant</u>	<u>Parties involved</u>
• Alleged breach of contract	Company	RWT/UW
• Possible breach of PID data	Patient	RWT/Sponsor

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Wolverhampton University/RWT Update

During 2014-2015 the Professor for Clinical Practice and Innovation, Magi Sque, working in partnership with the Royal Wolverhampton NHS Trust and University of Wolverhampton researchers has been involved in the following:

Research

- (i) **Local:** Prof. Sque (PI), in partnership with co-investigators at the Royal Wolverhampton NHS Trust (RWT) and the University of Wolverhampton (WLV), was successful in securing funding from Health Education England - North West (£71,372) for the project: *Home from home?: A case study of the first year settlement experiences of EU migrant nurses working in one NHS Trust*. If we are to find effective responses to health professional mobility in a changing Europe, we need to better understand these individuals regarding their motivations and experiences. The arrival of a cohort of 35 EU nurses in January 2015 provided RWT with an unprecedented opportunity to add to the much needed national body of knowledge concerning the motivations and settlement experiences of an EU nursing cohort. The overall aim of this 18-month study is to gain insight and understanding of EU migrant nurses' experiences of employment in the NHS and settlement into the community during their first year in Wolverhampton. Key motivators to the retention of EU nurses and any life enhancing factors that may add quality to the lives of migrant nurses will be identified. The study opened in March 2015 and will complete in August 2016. Twenty EU nurses will be interviewed on four occasions over 13 months using an acculturation questionnaire and qualitative interview.
- (ii) **Regional/National:** Final stage RfPB proposal, '*An evaluation of the perceived impact of potential donor and family care on consent to donation after circulatory death*'. This bid was unsuccessful, rejected at final Board.

Implementation Organ Donor Memorial Study

Nine artworks for the memorial were chosen for development following the exhibition held at Wolverhampton University in December. A final five artworks were pitched, by their student designers, from the School of Creative Art and Design, to an Awarding Panel at RWT on the 19 February. A winning artwork was agreed by the Panel. An award ceremony to recognise the

students' works was held on the 27 February. Cheryl Etches OBE presented the first and joint second awards. Technical specifications for the memorial are underway.

Trust Swan Model of End of Life and Bereavement Care

Prof. Sque is a member of the Creating Best Practice Team working on the above service development. Her main role has been to generate an enduring philosophy for RWT that underpins the operation of the Swan model; and to introduce a methodology for change that promoted building on the best. A paper in support of these issues is available.

Mentorship

The National Junior Leadership Academy (NJLA) aims to support high performing nursing students to construct a leadership identity early in their career journey, equipping them to target the challenges they are likely to face due to the healthcare reforms. Prof. Sque facilitated a two-week internship in January 2015 for the above programme. The intern was able to shadow her activities and those of nurses leading in a variety of roles at RWT. The intern also attended WLV's Faculty of Education, Health and Wellbeing Staff Research Conference, PhD supervision, and a guided data analysis session with Prof. Sque and a researcher at RWT.

Prof. Sque was also mentor to the West Midlands Clinical Academic Graduate Internship Programme (CAIP) October 2014-March 2015. Her intern is a Research Nurse at Birmingham Children's Hospital. The intern successfully completed her internship with an excellent literature review on massage as therapy for children having chemotherapy for cancer treatment. Prof. Sque also taught on CAIP the programme, '*Ethical issues in research design and project management*', 11 March 2015.

Internal Quality Review

Prof. Sque was part of the team at RWT that piloted the new peer ward governance quality review on 27 January 2015.

Memorandum of Understanding between MOHAN Foundation in India and NHS Blood and Transplant

Prof. Sque was part of the Steering Group that developed a Memorandum of Understanding (MoU) between the MOHAN Foundation in India and NHS Blood and Transplant to share best practice to promote the importance of organ donation and transplantation to improve donation rates in both countries. She attended the signing and launch event of the MoU in the House of Lords on the 26 February 2015 and has joined the MoU Implementation Group.

RCN Congress Bournemouth 21-25 June 2015

In March, working with the RCN and Nursing Professoriate West Midlands, Prof. Sque was able to secure a seminar at the RCN Congress on '*Caring for the dying and their relatives in acute settings: could we be doing more?*'. The seminar will bring together experts in the field, with the following objectives:

- (i) To reinforce a national dialogue about how to facilitate the best care

	<p>for the dying and those important to them in acute care settings.</p> <p>(ii) To raise awareness about person-centred care that underpins the delivery of the priorities of the Leadership Alliance for Care of Dying People, allowing for a robust system of assessment, care planning and construct evaluation.</p> <p>(iii) To understand communication as a key determinant of information exchange, shared power, responsibility and therapeutic alliance.</p> <p>(iv) To understand that any initiatives considered should first be vetted in the context of the patient's perspective. What is right for our patients is right for us.</p>
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Appendix 1 - Divisional Research Activity 2014/15

April 14 - March 15	KPI's														
	Research Active	No. of NIHR Portfolio Trials	Accruals (NIHR Portfolio)	No. of open Commercial trials	Accruals (Commercial)	No. of Non-Commercial trials	Accruals (Non-commercial)	No. of own account trials	Accruals (own account)	No. of open trials (PIC site)	Accruals (PIC site)	Active PI's	Active CI's in dept	Linked Research Nurses	Linked CTAs/AHP's
Division 1															
Diagnostic Services Group															
Radiology	Y														
Pathology/Clinical Chemistry	Y							1	0				1		
Theatres/ICCU Service Group	Y	3	71	0	0	0	0	0	0	2	0	2	0	1	1
Cardiology/Cardiothoracic Service Group	Y	11	127	1	26	0	0	3	17	0	0	9	3	5	0
Surgical Services Group															
General Surgery	Y	2	65	0	0	1	0	0	0	0	0	4	0	4	0
Orthopaedics	N														
Urology	Y			1	4	0	0	0	0	0	0	3	0	3	1
Obs & Gynae	Y	3	17	0	0	2	6	0	0	0	0	6	0	2	1
Ophthalmology/Head and Neck Services Group	Y	6	70	0	0	1	0	2	0	0	0	4	2	5	1
Total		25	350	2	30	4	6	6	17	2	0	28	5	20	4
Division 2															
Nursing	Y	0	0	0	0	2	18	0	0	0	0	5	0	0	0
Children's Services Group	Y	10	60	1	11	4	12	0	0	0	0	11	0	3	1
Adult Community Services	N														
Rehabilitation & Ambulatory Medical Group	Y	10	100	0	0	2	1	0	0	1	0	6	0	3	1
Medical Group															
Respiratory	Y	9	57	0	0	1	1	0	0	0	0	4	0	2	1
Gastroenterology	Y	12	55	0	0	3	26	1	1	0	0	4	2	2	1
Diabetes	Y	7	54	0	0	0	0	0	0	0	0	3	0	2	1
Renal	Y	9	57	0	0	2	0	0	0	0	0	4	0	2	1
Rheumatology**	Y	15	117	13	9	1	1	0	0	1	11	3	1	8	2
Dermatology**	Y	10	96	2	3	1	0	0	0	0	0	4	0	4	2
Sexual Health	Y	1	201	0	0	0	0	0	0	0	0	1	0	1	1
Nutrition & Dietetics	N														
Emergency Services Group															
Therapies & Pharmacies Group	Y	0	0	0	0	1	0	0	0	0	0	1	0	0	0
Oncology & Haematology Group	Y	42	147	4	2	1	1	0	0	0	0	16	0	11	6
Total		125	944	20	25	18	60	1	1	2	11	62	3	36	16
Medical Physics	Y														
Infection Control	N														

** Including Cannock research activity

*PIC – Patient Identification Centre