








The Royal Wolverhampton NHS Trust		
Trust Board Report		
Meeting Date:	30 th March 2015	
Title:	R&D Directorate Report	
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 – Quarter 3 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 This report reflects R&D performance and activity from 1st April 2014 up to 31st December 2014. This has been a challenging period for both the Directorate and the 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 are seeking ways to address this.</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 – December 14

- Sustained approval of trials within 30 days.
- 84% of studies approved within 15 days.
- Patient feedback and engagement processes in place.
- Continued high ratings from external study monitors.
- CRN: West Midlands contingency funding of £21,861 received.

The Directorate is fully aware that the following challenges 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
- Support the Cannock Chase Hospital R&D Team

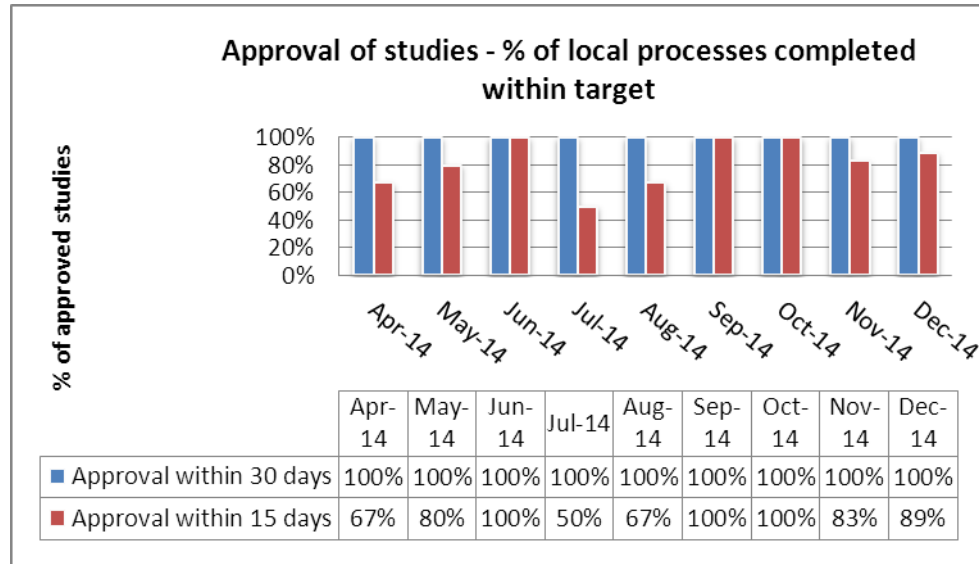
On 1st November 2014, research activities being undertaken at Cannock Chase Hospital were transferred to RWT. The R&D Directorate at RWT is providing support to Clinical Trials Unit colleagues and research active clinicians at Cannock Hospital. This presents an excellent opportunity to develop and strengthen research across both sites. The Cannock Rheumatology Clinical Trials Unit have been recognised as being at the forefront of clinical innovation and translational research and NIHR data in 2013 identified it as the largest commercial rheumatology trials unit in the UK. The Cannock Dermatology service have made great progress over the past 15 months in developing their portfolio of research studies, involving both commercial and non-commercial sponsors.

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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. The Trust is currently achieving 84% against this target for studies approved during 2014/15.

(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). The number of Trials opened at RWT since April 2014 achieving the target of First Patient First Visit within 30 days of R&D permission is shown in table (a):

Table (a) Permission to First Patient Visit

Study Type	<=30 days	>30 days	% Achieved
Commercial	4	6	40%
Non-Commercial	7	19	27%

Common variables which impact on this HLO target:-

- Timing of Site initiation visit (SIV) required post approval
- Complexity of trial
- Patient recruitment period
- Patient availability
- Providing a more realistic 'expected start date'
- Awaiting sponsor supplies

(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 (b) provides the latest recruitment for the Trust into NIHR Portfolio studies, whilst the RWT recruitment into all Trust research activity as at 31/12/14 is presented in Table (c).

Table (b) – Portfolio study Recruitment Report Update

Target 2014-15	Number of Participants Recruited 2014-15	% Recruitment against Target
3925	888	23%

Table (c) – RWT Actual Recruitment 31/12/14

Study Category	No. of Active Studies (Recruiting/Follow-up)	Recruitment to date 14/15
Portfolio - non-commercial	113	743
Portfolio - commercial	35	145
Non-commercial (other)	25	80
Commercial (direct)	7	39
Own account	7	15
Total	187	1022

Research performance across the Trust is illustrated within the Divisional quarterly update, the report for Quarter 3 2014/15 is attached as Appendix 1.

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3.1 Patient & Public Involvement

Engagement in Research

In addition to the 1022 patients recruited into research trials to date during 2014/15, over 18000 have been screened for eligibility against the 187 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 the third quarter of 2014/15, 31 completed questionnaires were received. These included studies undertaken within Gastroenterology, Ophthalmology, Respiratory and Stroke services. The results continued to show that participants felt research was important to improve health care (97%), they felt supported during their involvement in the study (97%), 77% would take part in a further study and 87% would recommend involvement to a family member or friend.

3.3	<p>Publishing Performance in Initiating and Delivering Clinical Research</p> <p>In accordance with NIHR requirements, RWT provided and published data on performance in initiating and delivering clinical research at the end of October 2014. 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.</p>									
4	<p>Governance</p> <p>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 April – December 2014, 312 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.</p>									
5	<p>HR & Workforce</p> <p>Overall research workforce capacity spread across the Trust is provided within the Division report attached as Appendix 1.</p>									
6	<p>Claims/Complaints</p> <p>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.</p> <table border="1" data-bbox="375 1400 1364 1556"> <thead> <tr> <th><u>Nature of Complaints registered</u></th> <th><u>Complainant</u></th> <th><u>Parties involved</u></th> </tr> </thead> <tbody> <tr> <td>• Alleged breach of contract</td> <td>Company</td> <td>RWT/UW</td> </tr> <tr> <td>• Possible breach of PID data</td> <td>Patient</td> <td>RWT/Sponsor</td> </tr> </tbody> </table>	<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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7	<p>CRN West Midlands/RWT Update</p> <p>The RWT Board Meeting in October 2014 approved Dr Cotton's position on the CRN: West Midlands partnership group and for him to act with delegated responsibility for the Trust Board. Dr Cotton has since attended monthly meetings on behalf of RWT.</p>									
8	<p>Wolverhampton University/RWT Update</p> <p>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:</p>									

(a) Nursing Professoriate for the West Midlands

A follow up meeting of the above group took place on the 6th December at the University of Wolverhampton Science Park. The aim of the meeting was to plan a way forward and agree terms of reference. The day was supported by RWT and the University of Wolverhampton, and funded by the RCN. The outcomes of the day were that there would be a representation of the Group at the RCN Congress in June to carry out an agreed activity. The group also look to run a symposium in the autumn about '*What's happening with bereavement care in the West Midlands?*' This event fits well with the ambitions of the Trust to uplift to 'the level of the best' end of life and bereavement care agendas.

(b) Research

Prof. Sque is leading three caring sciences research bids submitted in partnership with the Trust and the University of Wolverhampton.

(i) **Local:** 'Home from home?: A case study of the first year settlement experiences of EU migrant nurses working in one NHS Trust'. The

overall aim is to gain insight and understanding of EU migrant nurses' experiences of settlement into the community, and employment in the NHS during their first year in RWT. 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. Funding £68,469 is being considered by Health Education England.

(ii) **Regional/National:** Second stage proposal, 'An evaluation of the perceived impact of potential donor and family care on consent to donation after circulatory death'. The research aims to evaluate the

perceived impact of potential donor family care (PDF) on the donation decision in the event of Donation after Circulatory Death (DCD). Instrumental case study was selected for its focus on investigating a particular case (DCD) to provide evidence concerning an identified issue of critical importance (family experiences of, and satisfaction with PDF care). Study sites will be 15 NHS Trusts, five which will be regional. Funding sought - £441,579.20, NIHR Health Services and Delivery Research Programme.

(iii) **European Commission:** 'Deceased organ and tissue donation: Advancing European systems policy and practice (TODDAS)'. TODDAS will be a highly innovative European Training Network (ETN), in the newly emerging, supra-disciplinary field of deceased

organ and tissue donation research, finding solutions, through integrated PhD studies, to address the shortage of organs for transplantation in Member States (MS) and producing a new generation of practitioners to lead organ donation initiatives in the European Union (EU). Funding sought €3,018,699.72, European Commission.

(c) West Midlands Clinical Academic Internship Programme

Prof. Sque will be supporting the next round of the above programme starting in March 2015. The taught element of the programme is structured to enable interns to develop skills in the design and delivery of clinical research. Interns are expected to carry out a small project or desk research as part of their programme.

(d) Implementation Organ Donor Memorial Study

Following a student competition to inform the above artwork an exhibition was held over three days at the beginning of December 2014 in the School of Art and Creative Design at the University of Wolverhampton. The exhibition was an opportunity to choose nine projects to take forward for development. Over 70 people; a wide cross section of RWT staff, university personnel and the public were invited to judge. The nine projects chosen are now under development and will be pitched to the Awarding Panel in February 2015, who will choose the final winning artwork. Students are being mentored by staff within the School.

(e) Conference presentations

Prof. Sque gave an invited plenary, '*Current challenges in approaching relatives of potential organ donors following brain death,*' at the EDTCO Congress, 3-5 October 2014, Budapest: and presentation, '*The influence of temporality on donation decision-making,*' on 15 December 2014, at the Deconstructing Donation Conference, Lancaster University.

(f) Organ Donation Community Campaigning

Prof. Sque was instrumental in helping to organise a pre-Christmas organ donation campaign with the Wolverhampton Wanderers Football Club. For the match on the 6th December donation information was given in the match programme, and an announcement urging folk to discuss their decisions with their family and join the NHS Donor Register was given out at half time. Twenty-five volunteers drawn from the Trust, the University of Wolverhampton and the public handed out over 3,500 organ donation leaflets to people attending the match.

Appendix 1 - Divisional Research Activity

April – December 2014	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	Potential PI's	Active CI's in dept	Linked Research Nurses	Linked CTAs/AHP's
Division 1																
Diagnostic Services Group																
Radiology	N															
Pathology	N															
Theatres/ICCU Service Group	Y	1	89	0	0	0	0	0	0	2	0	2		0	1	1
Cardiology/Cardiothoracic Service Group	Y	14	68	1	26	1	0	2	0	0	0	8		1	4	0
Surgical Services Group																
General Surgery	Y	4	64	0	0	1	0	0	0	0	0	4		0	4	0
Orthopaedics	N											0				
Urology	Y	3	1	1	2	0	0	0	0	0	0	3		0	2	1
Obs & Gynae	Y	8	31	0	0	3	6	0	0	0	0	8		0	3	1
Ophthalmology/Head and Neck Services Group	Y	8	19	0	0	3	0	3	0	0	0	4		3	4	1
Total		38	272	2	28	8	6	5	0	2	0	29		4	18	4
Children's Services Group																
Children's Services Group	Y	11	15	1	9	4	0	0	0	0	0	11		0	3	1
Adult Community Services																
Adult Community Services	N															
Rehabilitation & Ambulatory Medical Group																
Rehabilitation & Ambulatory Medical Group	Y	10	43	0	0	1	1	0	0	0	0	4		0	3	1
Medical Group																
Respiratory	Y	9	66	0	0	0	0	0	0	0	0	4		0	3	1
Gastroenterology	Y	14	343	0	0	3	24	1	2	0	0	5		1	2	0
Diabetes	Y	5	28	0	0	0	0	0	0	0	0	3		0	4	1
Renal	Y	6	41	0	0	3	0	0	0	0	0	4		0	3	0
Rheumatology	Y	7	26	0	0	0	0	0	0	1	11	2		0	3	0
Dermatology	Y	4	21	0	0	0	0	0	0	0	0	4		0	3	0
Sexual Health	Y	1	0	0	0	0	0	0	0	0	0	1		0	1	1
Nutrition & Dietetics	N															
Emergency Services Group																
Emergency Services Group	N															
Therapies & Pharmacies Group																
Therapies & Pharmacies Group	Y	0	0	0	0	1	0	0	0	0	0	1		1	0	0
Oncology & Haematology Group																
Oncology & Haematology Group	Y	46	176	4	1	3	49	0	0	0	0	10		0	12	4
Total		113	759	5	10	15	74	1	2	1	11	49		2	37	9
Medical Physics																
Medical Physics	N															
Infection Control																
Infection Control	N															

*PIC – Patient Identification Centre