








The Royal Wolverhampton NHS Trust		
Trust Board Report		
Meeting Date:	25 th July 2016	
Title:	Research & Development Directorate Report	
Executive Summary:	This performance report provides a summary of research and development operational activity during the time period April 2016 to the end of June 2016.	
Action Requested:	To receive the report for assurance	
Report of:	Research & Development Director	
Author:	Dr J Cotton, R&D Director	
Contact Details:	Tel 01902 694218 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 Qtr 1 2016/17.	
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 2016 up to the end of June 2016. The R&D Directorate and research teams across the Trust have continued to perform well against a number of key indicators and NIHR High Level Objectives. At the end of Qtr 1, the Trust was marginally under its pro-rata recruitment target for Portfolio research studies (90%). The Directorate</p>	

has also continued to perform well against performance targets relating to the time taken to complete local review and approve studies.

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 – June 16

- Patient feedback and engagement processes in place.
- Continued high ratings from external study monitors.
- CRN: West Midlands core funding for 16/17 of £1,175,937 confirmed.

The Directorate continues to address the following challenges during 2016/17:-

- 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

2

NIHR WMN CLRN Performance Targets (RWT)

2.1

R&D Performance

Since April 2016, a new process of issuing approval for NHS research has been in place. Research approval is now given at national level by the Health Research Authority (HRA), alongside REC and MHRA approvals where required. This removes the duty on individual organisations to give permission for research, instead, Trusts are required to review and confirm local capacity and capability to deliver the approved research.

This change in process has been accompanied by a change in national performance targets.

(a) NIHR High Level Objective (HLO) 1 – Increase the number of participants recruited into NIHR CRN Portfolio studies.

The Trust 16/17 target for recruitment into NIHR Portfolio adopted studies is 2000. Table (a) provides the recruitment as at end Q1 2016/17 for the Trust into NIHR Portfolio studies, whilst all Trust research activity as at 30/06/16 is presented in Table (b).

Table (a) – Portfolio study Recruitment Report Update

Target 2015-16	Pro rata target Q1 2015-16	No. of participants recruited 2015-16	% Recruitment against pro rata target	% Recruitment against annual target
2000	500	452	90%	23%

Table (b) – Study Participation 2016/17

Study Category	No. of Active Studies (Recruiting/Follow-up)	Recruitment to date 16/17
Portfolio - non-commercial	154	352
Portfolio - commercial	69	100
Portfolio own account	0	0
Non-commercial (other)	10	111
Commercial (direct)	5	1
PIC	9	0
Total	247	564

(b) NIHR HLO 3 – Increase the number of commercial contract studies

15 commercial portfolio studies were opened at RWT during Q1 16/17. This equates to 39% of the total number opened during 15/16, indicating a good

level of performance against this indicator.

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

3 studies were submitted to the Trust for set up under the new HRA process during Q1 16/17. Of these, 2 were set up within 40 calendar days and 1 is being assessed (still within 40 day timescale).

(d) NIHR HLO 5 – Proportion of studies achieving first participant recruited within 30 days of date site confirmed / 30 days of permission if Trust approved study

This HLO is probably the most difficult to achieve, RWT trials are in the main interventional and/or randomised clinical trials (RCT's). Table (c) provides the position of RWT against HLO5 for Q1 2016/17.

Common variables which impact on this HLO target:-

- Timing of Site initiation visit (SIV) required post confirmation/approval
- Complexity of trial
- Patient recruitment period
- Patient availability
- Awaiting sponsor supplies

Table (c) Confirmation/Approval to First Patient Visit

Study Type	<=30 days	>30 days	% Achieved
Commercial	1	4	20%
Non-Commercial	4	1	80%

3 Overall Research Performance

The overall research performance across the Trust for Q1 2016/17 is illustrated in Appendix 1.

The Trust has received notable success and national recognition for recruitment in a number of areas, including:

Dermatology:

- Best recruiting site into Hi-light Vitiligo study.

Rheumatology:

- Highest recruiting site into British Society for Rheumatology Biologics Register - Ankylosing Spondylitis (BSRBR-AS) study.

Haematology

- Received '5 subjects randomised' badge for MAIAA study comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Subjects with Previously

<p>4</p> <p>4.1</p> <p>4.2</p> <p>4.3</p>	<p>Untreated Multiple Myeloma who are Ineligible for High Dose Therapy <u>Oncology</u></p> <p>- Top recruiting site into Caliber study - A randomised feasibility study of chemoresection and surgical management in low risk non muscle invasive bladder cancer</p> <p>Patient & Public Involvement</p> <p><u>Engagement in Research</u></p> <p>In addition to the 564 patients recruited into research trials to date during Q1 2016/17, over 1200 have been screened for eligibility against the 247 active trials.</p> <p><u>Patient Survey</u></p> <p>The R&D Directorate continue to proactively seek the views of research participants through a questionnaire distributed to all participants recruited into a study more than 6 months but less than 12 month previously.</p> <p>In April 2016, 744 research participants received questionnaires asking about their experiences of taking part in research. 324 were returned (44% response rate).</p> <p>Overall results show that 98% of respondents felt that research is important to improve health services. 92% felt the care and communication provided to them by the research team was excellent and 89% said that they felt supported throughout their study.</p> <p>74% would take part in further research, 90% would recommend it to a friend or family member.</p> <p>The full results of this survey are available from the R&D Department. Specialty results will also be provided to enable research teams and Directorates to receive feedback regarding their studies.</p> <p><u>Publicity and Communication</u></p> <ul style="list-style-type: none"> • A dedicated email address for patient research enquiries is available: randdpatientenquiries@nhs.net • On 19th May 2016, the R&D Directorate took part in the re-launch of the Trust Charity event at The Molyneux. This was a fantastic opportunity to showcase the research activities undertaken at RWT and to publicise the new Research Charity Fund. • International Clinical Trials day took place on 20th May 2016. Trust staff, patients and visitors alike were invited to stop at stalls in the WMI, UECC entrance and CCH to find out about research taking place at the Trust and to register interest in receiving further information.
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5	<p>Governance</p> <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.</p>									
5.1	<p><u>Monitor Feedback</u></p> <p>An increase in trial activity inevitably leads to an increase in external sponsor monitoring visits. During Q1, 109 visits have been conducted by study sponsor companies. Monitoring visits are undertaken by Pharmaceutical Companies, Charitable Organisations and University sponsors.</p> <p>The completion of monitor feedback forms after each visit provides the R&D management team with an independent level of quality assurance. Feedback received during Qtr1 rated 86% as good or excellent.</p>									
5.2	<p><u>External Inspections.</u></p> <p>The Trust did not receive any external inspections relating to research activities during Q1.</p>									
6	<p>HR & Workforce</p> <p>Overall research workforce capacity spread across the Trust is provided within the Division report attached as Appendix 2.</p>									
7	<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="0" style="width: 100%;"> <thead> <tr> <th style="text-align: left;"><u>Nature of Complaints registered</u></th> <th style="text-align: left;"><u>Complainant</u></th> <th style="text-align: left;"><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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8	<p>Wolverhampton University/RWT Update</p> <p>During Q1 2016/17 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> <p><u>Research projects submitted awaiting outcomes</u></p> <p>Walker W. (PI) Sque M. Denison S. Blower T. Fisher J. Willis D. and Kirlew G. <i>General nurses' training needs, and their acceptance and satisfaction with the use of video-based instructional materials for developing palliative care</i></p>									

skills. Marie Curie Research Grants Scheme, funding requested **£117,659**
[NB First stage proposal was successful and second stage submitted 24 June]

Righetti A (PI), **Sque M.** Copeman A. Davies K. *Transitioning into an adult healthcare system for adolescents and young adults living with a chronic disease: parents' perspectives*. Submitted to General Nursing Council for England and Wales Trust (GNCT), funding requested **£9,590**.

Publications

POLICY IMPACT

Morgan M. Kenten C. Deedat S. Farsides B. Newton T. Randhawa G. Sims J. and **Sque M.** (2016) Increasing the acceptability and rates of organ donation among minority ethnic groups: a programme of observational and evaluative research on Donation, Transplantation and Ethnicity (DonaTE) NIHR Programme Grants for Applied Research 4:4
<http://dx.doi.org/10.3310/pgfar04040>

Conference attendance/dissemination

Member of the Scientific Committee and Session Chair 4th ELPAT Congress, Organ Transplantation: Ethical, Legal and Psychosocial Aspects: Global Challenges, 22-25 April 2016, Angelicum Congress Centre, Rome; Italy. Four Abstracts accepted:

- **Sque M.** *Life Lines: A father's personal account of organ donation* - Oral Presentation
- **Sque M** and Walker W. *'A little dollop of good in a very dark time': What organ donation meant to donor families* - Poster Presentation
- Galasinski D. and **Sque M.** *Organ donation agency: A discourse analysis of correspondence between donor and organ recipient families* - Oral Presentation
- Walker W. and **Sque M.** *Recognising the gift of organ and tissue donation: an evidence-based approach* - Poster Presentation.

Project development

Prof Sque has been involved in the development of the evaluation questionnaire for Swan End of life and Bereavement Care Service.

A discussion paper was prepared for Cheryl Etches by Prof Sque with regard to further embedding/uplifting the research culture at RWT, particularly within the caring sciences.

Appendix 1 - Divisional Research Activity Q1 2016/17

April – June 16	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)	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				1		
Theatres/ICCU Service Group	Y	1	0	0	0	0	0	0	0	1	1	0	1	1
Cardiology/Cardiothoracic Service Group	Y	14	90	0	0	0	0	0	0	0	7	3	5	0
Surgical Services Group														
General Surgery	Y	1	0	0	0	1	0	1	0	0	3	1	4	0
Orthopaedics	N													
Urology	Y	1	0	0	0	0	0	0	0	0	3	0	3	1
Obs & Gynae	Y	9	8	0	0	0	0	0	0	2	5	0	2	1
Ophthalmology/Head and Neck Services Group	Y	10	71	0	0	1	0	1	0	0	4	2	5	1
Children's Services Group	Y	18	17	0	0	3	0	0	0	3	11	0	3	1
Total		54	186	0	0	5	0	3	0	6	34	7	20	4
Division 2														
Adult Community Services	N													
Rehabilitation & Ambulatory Medical Group	Y	16	33	0	0	0	0	0	0	1	7	0	3	1
Medical Group														
Respiratory	Y	13	20	0	0	0	0	0	0	1	2	0	2	1
Gastroenterology	Y	20	77	0	0	0	0	0	0	0	3	2	2	1
Diabetes	Y	6	1	0	0	1	0	0	0	1	2	0	2	1
Renal	Y	12	34	0	0	2	109	0	0	0	2	0	2	1
Rheumatology	Y	21	36	0	0	0	0	0	0	0	2	2	8	2
Dermatology	Y	7	21	1	0	0	0	0	0	0	3	0	4	2
Sexual Health	Y	1	0	0	0	0	0	0	0	0	1	0	1	1
Nutrition & Dietetics	N													
Emergency Services Group	N													
Therapies & Pharmacies Group	Y			0	0	0	0	1	0	0	12	1	0	0
Oncology & Haematology Group	Y	73	44	4	1	2	2	0	0	0	18	0	11	5
Total		169	266	5	1	5	111	1	0	3	52	3	36	16
Medical Physics	Y													
Infection Control	N													

*PIC – Patient Identification Centre