

Trust Board

**Date of Meeting** 24 March 2014

**Title of Report:** **Research and Development**  
Clinical Director Trust Management Report

**Author** R&D Directorate Manager

**Summary:** Monthly Performance Update

**Action Required by the receiving committee:**

<input type="checkbox"/> Decision <input type="checkbox"/> Approval <input type="checkbox"/> Receive for Information <input checked="" type="checkbox"/> Receive for Assurance	Decision of Committee (to be entered after the meeting)
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**Implications**

<b>Clinical</b>	Without R&D patient choice will be directly affected, clinicians will be less engaged in the advancement and delivery of innovative healthcare.
<b>Patients, carers or the public</b>	Patients and Carers opt to participate in research to help them and to help others. Gaining access to new uses of drugs, pre licenced drugs and products gives them the opportunity of choice when standard treatment is no longer an option.
<b>Resources</b>	Finance, workforce, time, facilities
<b>References</b>	Health and Social Care bill, NIHR
<b>Assurances linked to report subject</b>	System Plan, Patient Safety, CQC Registration, NHSLA, Information Governance, Health & Safety, MHRA, NIHR.
<b>Assurance framework number</b>	(if on the Board Assurance Framework)
<b>Risks Identified:</b>	If support is not agreed and R&D is unable to move forward with its development and vision the R&D culture in the Trust will be restricted to few and limited number of patients will be able to participate in research. In the long term the funding and facilities need to be considered by the board as to gain more income, ALL clinical areas need to be active but this increases the need for specialist staff to cover areas no already covered.
<b>Include Risk Grade (categorisation matrix/Datix number/Risk Register Number)</b>	HIGH AMBER – C4

## BACKGROUND DETAILS

### 1. Executive Summary

This monthly report reflects the performance up to 28<sup>th</sup> February 2014. To date, this has been an exceptional period for both the Directorate and the research teams across the Trust. Nationally, R&D activity is measured by a range of high level objectives alongside locally set key performance targets.

The R&D Directorate provides a number of complementary additions to existing patient care, treatment and choice. Our developing research culture is now clearly evidenced through the data gathered within our local project management system (LPMS) and is endorsed further by feedback from patients and external monitor surveys.

Achievements for period April 13 – February 14

- Sustained approval of trials within 30 days.
- Increased own account research adopted onto the NIHR portfolio
- Recruitment into portfolio trials 10% above annual performance of 12/13
- Overall substantial increase in patient trial participation
- RWT secured WMLCRN Host contract
- Research teams identified as top recruiters for national/International trials
- Increased adoption of research across many Trust clinical areas.
- Patient feedback and engagement processes in place
- Reduction of studies approved but not recruited reduced to 14%
- Additional CLRN contingency funding of £95,763 awarded
- CLRN budget for 14/15 submitted
- First research District Nurse identified for new trial
- Partnership with AHSN developing
- Industry collaboration expanding

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

- 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

As the current geographical research infrastructure and leadership within the West Midlands remains in a transitional phase, it is business as normal for the Directorate. The new hosting arrangements will support further collaborative/inter-Trust research opportunities through shared resources, activity and development. Increasing engagement of clinical and non-clinical colleague networks regionally is starting to evolve. A recent request from Mid Staffordshire NHS Trust to provide funded workforce capacity at Cannock will be supported by

the RWT R&D Directorate. The part time R&D Manager at Mid Staffs leaves her post on the 31<sup>st</sup> March 2014 and interim arrangements are being led by RWT R&D who will complete a transition plan for the virtual splitting of R&D activity as per the clinical arrangements outlined recently. This will take into account resources, KPI targets and governance arrangements until formal organisational changes have been completed. Funding from Midstaffs for a period of 3 months has been approved to cover the interim management support required from RWT/UHNS.

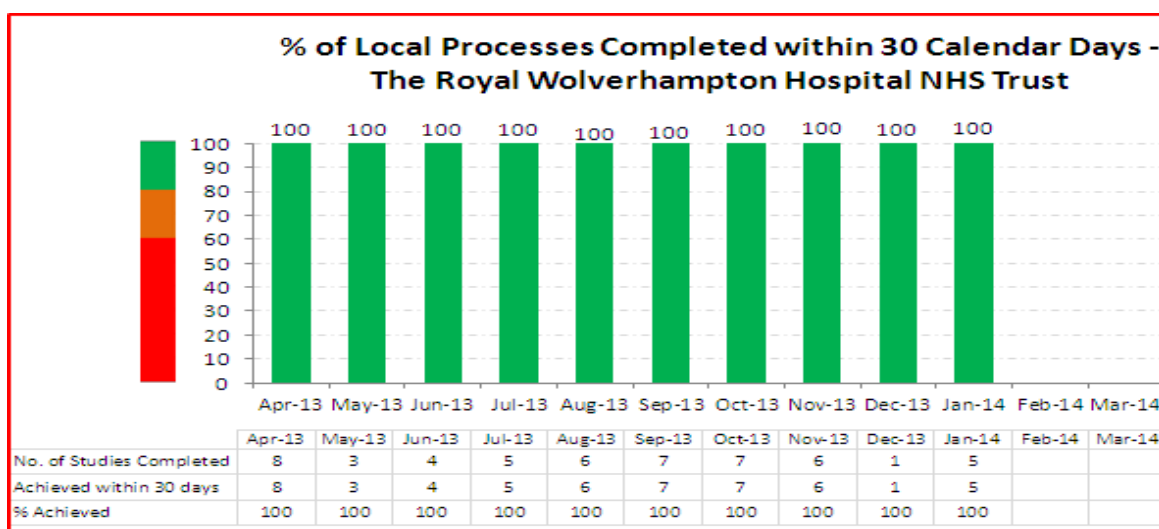
## 2. NIHR WMN CLRN Performance Targets (RWT)

### 2.1 R&D Performance

#### (a) Trust Approval Times (30 days)

##### NIHR High level Objectives 1 & 2 - Percentage of Local Processes Completed within 30 Calendar Days.

RWT continues to meet this target consistently and given the volume of studies presented to RWT, this is a good achievement. Table (a) provides a monthly break down of studies submitted and approved.



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

##### NIHR High level Objective (HLO) 3 – 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). Nationally, feedback on the difficulty of meeting this HLO target has been communicated through the CLRN RM&G networks leads.

Table (b) provides the current position of RWT against HLO3.

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

Table (b) Permission to First Patient Visit

Month	No. of open studies with 1 <sup>st</sup> recruit this month	No. of studies achieving FPFV < 30 days	% of studies achieving FPFV <30 days
April-13	3	1	33%
May-13	1	0	0%
June-13	2	0	0%
July-13	5	0	0%
August-13	2	0	0%
September-13	3	0	0%
October-13	4	1	25%
November-13	1	0	0%
December-13	1	0	0%
January-13	2	0	0%
February-13			
March-13			
<b>Total</b>	<b>24</b>	<b>2</b>	<b>8%</b>

**(c) High Level Objective 4 - Recruitment Performance against Target**

The Trust 13/14 annual recruitment target set locally by the WMNCLRN was 3777, equating to be 17.96% of the WMNCLRN 21,029 target. Table (c) provides the latest WMNCLRN recorded recruitment for the Trust, whilst the actual RWT recruitment at 28/02/14 is presented in Table (d).

**Table (c) – RWT WMCLRN Recruitment Report Update**

Target 2013-14	Number of Participants Recruited 2013-14	% Recruitment against Target
3777	3050	81%

The report from the WMNCLRN is reporting slightly under the actual performance for the period as external sponsors have not uploaded all information prior to the reporting date. The actual recruitment of participants recruited into portfolio trials is 3200, 84.7% of annual target and so far 10% above previous year annual achievement.

**Table (d) – RWT Actual Recruitment 28/02/14**

<b>Study Category</b>	<b>No. of Active Studies (Recruiting/Follow-up)</b>	<b>Recruitment to date 13/14</b>
Portfolio - non-commercial	127	1382
Portfolio - commercial	35	122
Portfolio – own account	2	1692*
Non-commercial (other)	20	438
Commercial (direct)	13	30
Own account	7	65
<b>Total</b>	<b>204</b>	<b>3729</b>

\* This table does not include portfolio study DRN which recorded 17,002 patients into the Diabetes (randomised interventional) study.

#### **(d) Trials Approved but no Recruitment Recorded**

There are currently 17 studies (14% of active trials) that have not recruited any patients. Of these, patients have been screened for eligibility in 6 studies and 8 studies (rare patients) have small targets over substantially longer recruitment timeframes. An additional 2 studies have been suspended by the sponsor.

### **3. Overall Research Performance**

The overall research performance across the Trust is illustrated in the Divisional quarterly update report; this is attached as Appendix 1.

### **4. Finance**

The R&D Directorate has successfully applied for, and received, additional contingency funding of £95,763 to increase workforce capacity on new studies. CLRN Budgets are not expected to be underspent.

### **5. Patient & Public Involvement**

#### **5.1 Engagement in Research**

In addition to the 20,741 patients recruited overall into research trials, 16,187 were screened for eligibility against >208 trials. To date, 36,928 RWT patients have actively been considered for or recruited into clinical trials.

#### **5.2 Patient Survey**

Following on from the successful introduction of an R&D patient survey, an updated version was introduced in November. The patient survey is designed for patients that have completed treatment to provide feedback on their research experience anonymously.

The survey provides a good opportunity to capture and review a participant's research

journey and is an invaluable source of information to ensure that R&D is delivered to the high standards required.

To date, 29 completed surveys have been received. Initial feedback is extremely positive, with 100% of the patients reporting that they felt supported throughout their research experience. The role of research in improving health services was supported by all patients.

A sample of comments received so far:-

*"I was treated with the utmost care and respect by all of the team. I was told on the first meeting I would be looked after and they certainly did that"* - **Cancer Research Patient.**

*"I enjoyed the experience, the company, the professionalism and felt valued, there are really no adverse comments at all"* – **Respiratory Research Patient.**

*"Taking part in this research was a little way to pay back all the wonderful support and consideration shown to me at all times during my treatment for bowel cancer. Having received first class treatment, your research may help another person in the future"* – **Gastroenterology Research Patient.**

### 5.3 Posters / Website

- Research Posters are now displayed in clinical areas.
- Pop up display boards are prominent in key areas across the Trust
- Patient information service, is now displaying the 'OK to ASK' poster
- The Trust Web site has been updated and will be updated periodically
- A dedicated email address for patient research enquiries has been activated: [randdpatientenquires@nhs.net](mailto:randdpatientenquires@nhs.net)

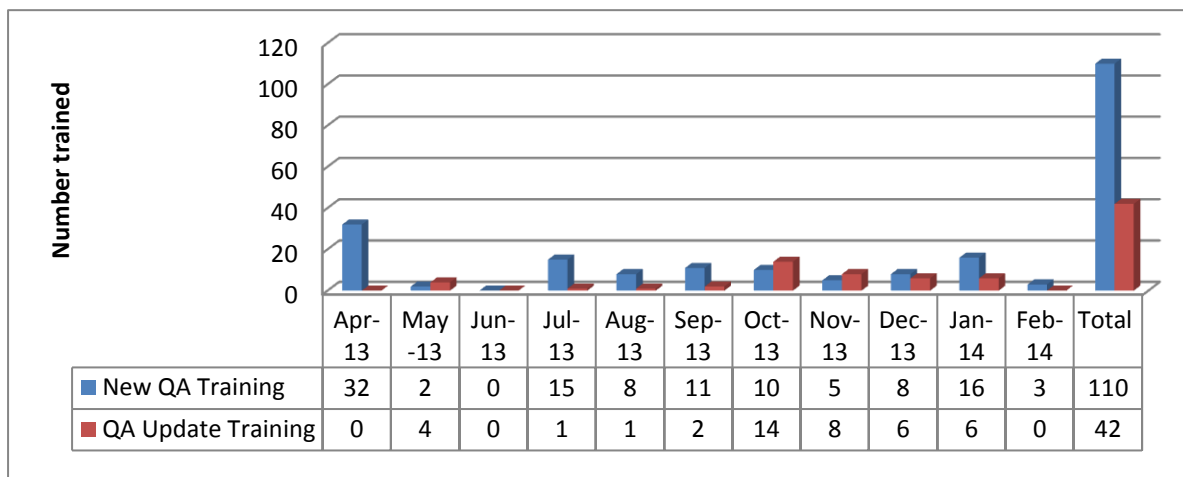
## 6. Governance

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. Table (e) provides an overview of the staff training provided by the R&D Directorate to maintain clinical indemnity and patient safety.

### 6.1 GCP/QA Training

Staff engaged in research activity require specialist training to maintain regulatory compliance and Good Clinical Practice (GCP). Quality assurance (QA) training is a combination of GCP, local policy and standard operating procedure (SOP) compliance. Table (e) illustrates the monthly training activity for new researchers trained during the period alongside the 2 yearly refresher training provided for existing researcher staff.

**Table (e) Training Delivered**



## 6.2 Monitor Feedback

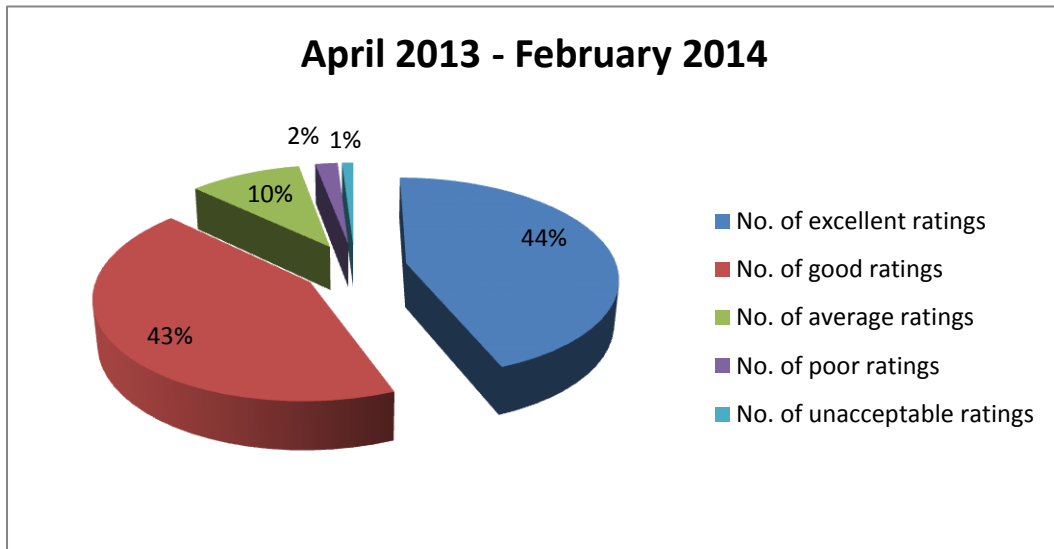
An increase in trial activity inevitably leads to an increase in external sponsor monitoring visits. Table (f) provides a breakdown of the number of monitoring visits completed during the period. The monitoring visits are undertaken by Pharmaceutical Companies, Charitable Organisations and University sponsors.

**Table (f)**

Period	Number of Visits
April	29
May	25
June	22
July	27
August	17
September	20
October	39
November	23
December	19
January	19
February	15
<b>TOTAL</b>	<b>255</b>

Monitors continued to welcome the monitoring feedback forms which provide the R&D management team with an independent level of quality assurance. The conduct and performance of a research trial must be in accordance with GCP standards and sponsor expectations. Monitors are able to rate the Trust across a wide range of activities. Table (g) provides a summary of the forms received to date.

**Table (g) Monitoring Feedback Summary**



## 7. HR & Workforce

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

## 8. Claims/Complaints

There are currently two complaints registered against the R&D Directorate. The Trust secretary has been involved and legal representation agreed. No patient safety complaints/claims registered.

<u>Nature of Complaints registered</u>	<u>Complainant</u>	<u>Parties involved</u>
1) Breach of contract	Company	RWHT/UW
2) Breach of PID data	Patient x1	RWT/Sponsor

## 9. Forthcoming Events

The Royal Wolverhampton NHS Trust Research & Development Annual General Meeting will be held on Wednesday 7<sup>th</sup> May, 1-4pm in the West Midlands Medical Institute.

## 10. Wolverhampton University/RWT Update

During 2013-2014 the Professor for Clinical Practice and Innovation, Magi Sque, working in partnership with the Royal Wolverhampton NHS Trust and University of Wolverhampton researchers delivered:



- 1) A multidisciplinary group of 22 Trust candidates enrolled in a pilot course of seven introductory Master Classes in Research. The purpose of the course was to: i) further develop the ethos of research mindedness and innovation amongst healthcare practitioners in the caring sciences; ii) continuously improve patients' experiences and outcomes through focused evidence based care delivery; iii) make access to research education as easy as possible, encouraging participation.
- 2) A drop in Research Advice Day was carried out at New Cross Hospital, with staff from the NIHR Research Design Service at Keele University. It was well attended by staff from the Trust and University of Wolverhampton. Three projects, specific to the caring sciences, i.e. two concerning dementia and one on organ donation were discussed.
- 3) Two major projects of interest to RWT were completed during the year; *Bereaved families' experiences of organ and tissue donation, and perceived influences on their decision making* led by Prof. Sque and funded by the DH reported in June 2013. The report was favourably received and is feeding into the implementation of NHS Blood and Transplant's new strategy *Taking Organ Transplantation to 2020*.
- 4) Also completed; *'Recognising the gift of organ and tissue donation: The views and preferences of donor families,'* a study led by Dr. Wendy Walker from the University of Wolverhampton and funded by the Trust's Organ Donation Committee. A Working Group has been convened to move this project to implementation i.e. to oversee creation of an artwork to honour 'the gift of life' organ donors give to society.

Project implementation and development continues in a number of other fields including: improving the experiences of colorectal cancer survivors, dementia care, organ donation after circulatory death, and an EU funded Innovative Training Network.

- 5) Six students completed a two day pilot pathway placements within the Research and Development Directorate. It is understood that students found the experience enriching. Care was taken to match students with research nurses working on projects within their current clinical placement areas.
- 5) A land mark Summit Meeting of Nursing Professors in the West Midlands and the Re-launch of the RCN Research Society is to be held at the University of Wolverhampton Science Park on the 20<sup>th</sup> June 2014. The meeting is jointly supported by Royal Wolverhampton NHS Trust, the University of Wolverhampton, and the Royal College of Nursing.

## 11. In Conclusion

RWT performance continues to be on par with large Acute Trusts within the West Midlands region. Our research culture and overall performance continues to be fostered and encouraged. It is noted particularly within the Divisional report (Appendix 1) that there remains a small number of inactive speciality areas. To maintain/improve our performance into 14/15, it will be important for R&D to be developed in these clinical areas alongside standard clinical care. The value of R&D, competency and capacity that will develop within

these clinical areas will provide strength to the Trust competing for new research opportunities.

There are a number of clinical research leads across the Trust who will have the capability and the motivation to explore increased research output.

To strengthen this opportunity, clinical leads will need to take on additional responsibilities, identify time and resources required to extend the Trust R&D capability and recognition. R&D is extremely positive about the number of additional medical researchers in Oncology who have engaged to support current/pending trials in the absence of a senior research lead.

Ensuring that patients are given choice to participate in research trials is a national and local target and is identified by patients as an important clinical choice. Recruitment for 13/14 to date is above 12/13 annual performance with one month recruitment remaining. The clinical team is still striving to meet the ambitious 3777 (29.7% above 12/13 achievement) target but realistically the annual achievement is more likely to be 3400 which will equate to 90% of 13/14 target but an uplift of 16.8% on 12/13 performance.

Whilst the West Midlands research infrastructure and leadership is in a transitional phase, the R&D Management team look forward to the widening of regional collaboration and greater engagement of clinical and non-clinical colleague networks.

**Appendix 1 - Divisional Research Activity – Quarter 3 2013/14**

Quarter 3 – Reporting January 2014	KPI's															
October – December 2013	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
<b>Division 1</b>																
Diagnostic Services Group																
Radiology	✓											1	3	0	0	0
Pathology	✓											0	2	0	0	0
Theatres/ICCU Service Group	✓	4	3	0	n/a	0	n/a	0	n/a	0	n/a	1	2	0	3	1
Cardiology/Cardiothoracic Service Group	✓	10	29	1	0	2	30	2	21	0	n/a	7	16	2	5	0
Surgical Services Group																
General Surgery	✓	2	0	0	n/a	1	4	0	n/a	0	n/a	3	10	0	1	0
Orthopaedics	X											0	0	0	0	0
Urology	✓	1	2	0	n/a	0	n/a	0	n/a	0	n/a	2	1	0	1	1
Obs & Gynae	✓	8	18	0	n/a	5	0	0	n/a	3	0	6	7	0	3	0
Ophthalmology/Head and Neck Services Group	✓	8	72	1	0	1	0	3	0	0	n/a	9	5	3	4	1
<b>Total</b>	<b>8</b>	<b>33</b>	<b>124</b>	<b>2</b>	<b>0</b>	<b>8</b>	<b>34</b>	<b>5</b>	<b>21</b>	<b>3</b>	<b>0</b>	<b>29</b>	<b>46</b>	<b>5</b>	<b>14</b>	<b>2</b>
<b>Division 2</b>																
Children's Services Group	✓	14	7	2	0	3	0	0	n/a	0	n/a	9	20	0	1	0
Adult Community Services	X											0	4	0	0	0
Rehabilitation & Ambulatory Medical Group	✓	19	86	2	0	0	n/a	0	n/a	1	0	6	8	0	4	2
Medical Group	✓															
Respiratory	✓	9	11	0	n/a	0	n/a	0	n/a	0	n/a	5	7	0	2	1
Gastroenterology	✓	14	10	0	n/a	2	59	0	n/a	0	n/a	2	5	0	2	0
Diabetes	✓	7	17013	0	n/a	0	n/a	0	n/a	0	n/a	4	3	0	2	1
Renal	✓	4	15	0	n/a	3	0	0	n/a	0	n/a	3	5	0	2	1
Nutrition & Dietetics	X											0	0	0	0	0
Emergency Services Group	x											0	3	0	0	0
Therapies & Pharmacies Group	✓											0	0	0	0	0
Oncology & Haematology Group	✓	59	87	8	5	3	15	1	0	0	n/a	17	21	1	9	2
<b>Total</b>	<b>8</b>	<b>126</b>	<b>17229</b>	<b>12</b>	<b>5</b>	<b>11</b>	<b>74</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>46</b>	<b>76</b>	<b>1</b>	<b>22</b>	<b>7</b>
<b>Corporate Division</b>																
Medical Physics	X											0	0	0	0	0
Infection Control	x											0	0	0	0	0

\*PIC – Patient Identification Centre