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| The Royal Wolverhampton NHS Trust | |  |
| Trust Board Report | | |
| Meeting Date: | 27 th October 2014 | |
| 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 September 2014. | |
| Action Requested: | To receive the report for assurance and approve the proposal under item 7. | |
| 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 – Quarters 1 & 2 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 April 2014 up to 30th September 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> | |

Achievements for period April 14 – September 14

- Sustained approval of trials within 30 days.
- 77% of studies approved within 15 days.
- Patient feedback and engagement processes in place.
- Continued high ratings from external study monitors.
- CRN: West Midlands allocation to Trust confirmed at £1,547,482.

Engagement and high returns on feedback surveys with external monitors and trial participants will continue to provide assurance that the R&D Directorate continues to provide a service which is of a high standard. This will continue to attract new research and raise the profile of the Trust and researchers regionally, nationally and internationally

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

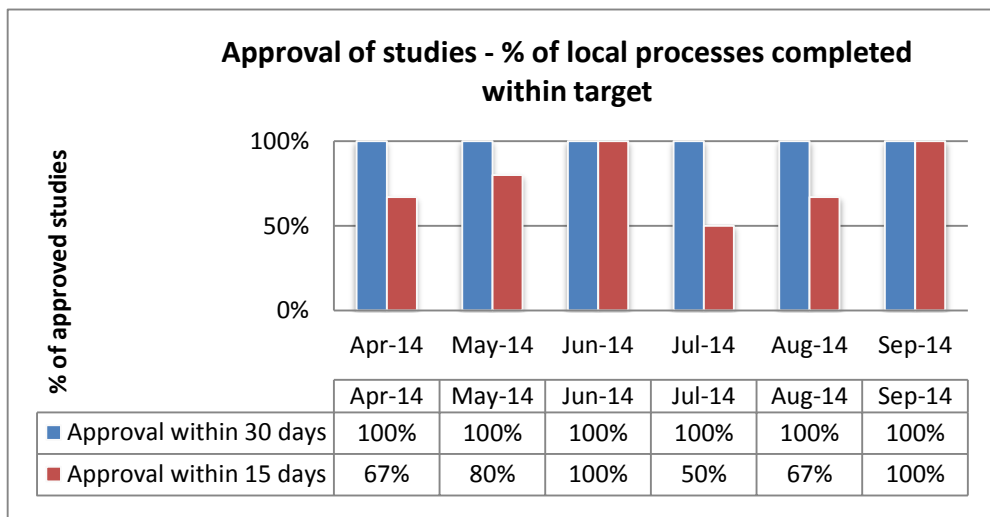
- Increasing recruitment into all research studies
- Increasing medical research capacity
- Increase nursing/AHP research opportunities (Acute/Community care)
- Increasing own account portfolio research
- Motivating inactive clinical services
- Improving recruitment times
- Maintain high levels of patient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

The Trust Board is also asked to approve the proposal that Dr James Cotton, Director of R&D at RWT, should join the LCRN Partnership Group as RWT representative so as to represent the interests of the Trust as an LCRN partner organisation and with delegated authority to represent RWT Trust Board at this forum.

2

NIHR WMN CLRN Performance Targets (RWT)

(a) Trust Approval Times in support of 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 77% against this target for studies approved during 2014/15.

(b) NIHR High level Objective (HLO) 5 – NHS Trust Permission/SIV to First Patient First Visit (30 days)

This HLO is probably the most difficult to achieve, RWT trials are in the main interventional and/or randomised clinical trials (RCT's). During 2014/15, 25% of Trials opened at RWT since April 2014 have achieved the target of First Patient First Visit within 30 days of R&D permission.

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 3777. Table (c) provides the latest recruitment for the Trust into NIHR Portfolio studies, whilst the RWT recruitment into all Trust research activity as at 30/09/14 is presented in Table (d).

Table (c) – Portfolio study Recruitment Report Update

| Target 2014-15 | Number of Participants Recruited 2014-15 | % Recruitment against Target |
|----------------|--|------------------------------|
| 3777 | 504 | 13.3% |

Table (d) – RWT Actual Recruitment 30/09/14

| Study Category | No. of Active Studies (Recruiting/Follow-up) | Recruitment to date 14/15 |
|----------------------------|--|---------------------------|
| Portfolio - non-commercial | 122 | 418* |
| Portfolio - commercial | 39 | 78 |
| Portfolio – own account | 1 | 8 |
| Non-commercial (other) | 21 | 47 |
| Commercial (direct) | 12 | 24 |
| Own account | 8 | 1 |
| Total | 205 | 576 |

* An additional 296 participants were recruited into a non-consenting study which did not require any direct patient contact (UKCRN 8899 - Prevalence of abnormal PrP using appendix tissue).

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|-----------------|--|
| | <p>Research performance across the Trust is illustrated within the Divisional quarterly update attached as Appendix 1.</p> |
| <p>3</p> | <p>Patient & Public Involvement</p> |
| <p>3.1</p> | <p><u>Engagement in Research</u></p> |
| | <p>In addition to the 576 patients recruited into research trials to date during 2014/15, over 10,000 have been screened for eligibility against the over 200 active trials.</p> |
| <p>3.2</p> | <p><u>Research Participant Survey</u></p> |
| | <p>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.</p> <p>During the first two quarters of 2014/15, 43 completed questionnaires were received. These included studies undertaken within Oncology, Diabetes, Ophthalmology, Renal, Respiratory and Stroke services. The results continued to show that participants felt research was important to improve health care (100%), they felt supported during their involvement in research (95%), the majority (72%) would take part in a further study and 91% would recommend involvement to a family member or friend.</p> <p>A number of patients have recorded videos for the R&D Directorate team which will be used to feedback research patient stories to clinical and research staff.</p> |
| <p>3.3</p> | <p><u>Publishing Performance in Initiating and Delivering Clinical Research</u></p> |
| | <p>In accordance with NIHR requirements, RWT provided and published data on performance in initiating and delivering clinical research at the end of July 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> |
| <p>4</p> | <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 – September 2014, 218 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 92% were rated as good or excellent.</p> |
| <p>5</p> | <p>HR & Workforce</p> |
| | <p>A new R&D Directorate Manager, Sarah Glover, came into post in August 2014.</p> |
| <p>6</p> | <p>Claims/Complaints</p> <p>There are currently two complaints registered against the R&D Directorate.</p> |

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 |

7 CRN West Midlands/RWT Update

The LCRN leadership team has agreed that RWT should have representation at the Partnership Group and have suggested that Dr James Cotton, Director of Research and Development RWT be this representative. As such he will act with delegated authority to represent RWT Trust Board at this forum so as to represent the interests of the Trust as an LCRN partner organisation. The RWT board are asked to approve Dr Cotton's position on the partnership group and for him to act with delegated responsibility for the Trust Board.

8 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:

(a) Professor Summit Meeting

A landmark Summit Meeting for nursing professors in the West Midlands was held on the 20 June 2014 at the University of Wolverhampton's Science Park. This was the first meeting of its kind in the UK, bringing together regional leaders of nursing research. The day had a number of important objectives among which were how the professors could work smarter and better together to address health issues in the region, and what they could do to support research engagement, and increase nurse research capacity and capability. There appeared to be some consensus that a Nursing Professoriate for the West Midlands may be a way forward. A follow up meeting is due to take place in December. The day was supported by RWT and the University of Wolverhampton, and funded by the RCN.

(b) Master Classes in Research

A series of 10 Master Classes in Research were delivered on site at New Cross by researchers from the University of Wolverhampton's Centre for Health and Social Care Improvement between 30 April - 2 July 2014. Classes were attended by 18 delegates drawn from disciplines across the Trust. The aims of the classes were to further develop the ethos of research mindedness and innovation amongst healthcare practitioners in the caring sciences. The classes were positively evaluated.

(c) Two-day clinical research pathway for students

Six 3rd year nurses undertook placements with R&D clinical research nurses

in July. A workbook for the pathway has been developed and is ready to pilot.

(d) West Midlands Clinical Academic Internship Programme

Prof. Sque is working with the above programme (for NHS staff) which runs from October 2014-March 2015. The taught element of the programme is structured to enable interns to develop skills in the design and delivery of clinical research. Each intern is assigned a clinical academic supervisor. A matching scheme approach is taken to ensure each intern is partnered with the best supervisor for them, taking into account both areas of interest as well as practical considerations. Interns are expected to carry out a small project or desk research as part of their programme.

Appendix 1 - Divisional Research Activity – Quarters 1&2 2014/15

| April – September 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 | Active CI's in dept | Linked Research Nurses | Linked CTAs/AHP's |
|--|-----------------|------------------------------|---------------------------|-------------------------------|-----------------------|------------------------------|---------------------------|---------------------------|------------------------|-------------------------------|---------------------|-------------|---------------------|------------------------|-------------------|
| Division 1 | | | | | | | | | | | | | | | |
| Diagnostic Services Group | | | | | | | | | | | | | | | |
| Radiology | Y | | | | | | | | | | | | | | |
| Pathology | Y | | | | | | | | | | | | | | |
| Theatres/ICCU Service Group | Y | 1 | 87 | - | - | - | - | - | - | 1 | 0 | 1 | 0 | 2 | 1 |
| Cardiology/Cardiothoracic Service Group | Y | 14 | 34 | 1 | 18 | - | - | 2 | 0 | - | - | 7 | 2 | 4 | 0 |
| Surgical Services Group | | | | | | | | | | | | | | | |
| General Surgery | Y | 4 | 63 | - | - | 1 | 0 | - | - | - | - | 4 | 0 | 3 | 0 |
| Orthopaedics | N | | | | | | | | | | | | | | |
| Urology | Y | 2 | 0 | 1 | 1 | - | - | - | - | - | - | 2 | 0 | 2 | 1 |
| Obs & Gynae | Y | 12 | 20 | - | - | 4 | 0 | - | - | - | - | 9 | 0 | 3 | 1 |
| Ophthalmology/Head and Neck Services Group | Y | 10 | 3 | - | - | 1 | 0 | 5 | 0 | - | - | 6 | 3 | 2 | 1 |
| Total | | 43 | 207 | 2 | 19 | 6 | 0 | 7 | 0 | 1 | 0 | 29 | 5 | 16 | 4 |
| Children's Services Group | | | | | | | | | | | | | | | |
| Children's Services Group | Y | 11 | 7 | 1 | 5 | 4 | 0 | - | - | - | - | 10 | 0 | 2 | 1 |
| Adult Community Services | N | | | | | | | | | | | | | | |
| Rehabilitation & Ambulatory Medical Group | Y | 9 | 14 | - | - | 1 | 0 | - | - | - | - | 5 | 0 | 3 | 1 |
| Medical Group | | | | | | | | | | | | | | | |
| Respiratory | Y | 8 | 46 | - | - | - | - | - | - | - | - | 5 | 0 | 3 | 1 |
| Gastroenterology | Y | 12 | 326** | - | - | 3 | 11 | 1 | 1 | - | - | 5 | 1 | 2 | 0 |
| Diabetes | Y | 7 | 22 | - | - | - | - | - | - | - | - | 4 | 0 | 4 | 1 |
| Renal | Y | 5 | 28 | - | - | 3 | 0 | - | - | - | - | 4 | 0 | 3 | 1 |
| Rheumatology | Y | 10 | 14 | 2 | 0 | - | - | - | - | 1 | 0 | 2 | 0 | 3 | 0 |
| Dermatology | Y | 4 | 16 | - | - | - | - | - | - | - | - | 3 | 0 | 3 | 0 |
| Sexual Health | Y | 1 | 0 | - | - | - | - | - | - | - | - | 1 | 0 | 0 | 1 |
| Nutrition & Dietetics | N | | | | | | | | | | | | | | |
| Emergency Services Group | | | | | | | | | | | | | | | |
| Therapies & Pharmacies Group | Y | - | - | - | - | 1 | 0 | - | - | - | - | 1 | 1 | 0 | 0 |
| Oncology & Haematology Group | Y | 52 | 120 | 7 | 0 | 3 | 36 | 0 | 0 | 0 | 0 | 14 | 0 | 11 | 5 |
| Total | | 119 | 593 | 10 | 5 | 15 | 47 | 1 | 1 | 1 | 0 | 54 | 2 | 33 | 11 |
| Medical Physics | | | | | | | | | | | | | | | |
| Medical Physics | Y | | | | | | | | | | | | | | |
| Infection Control | | | | | | | | | | | | | | | |
| Infection Control | N | | | | | | | | | | | | | | |

** Includes 296 participants recruited into a non-consenting study (UKCRN 8899 - Prevalence of abnormal PrP using appendix tissue).