Trust Board Meeting

Date of Meeting	25/11/2013
Title of Report:	R&D Directorate Report
Author	Dr J Cotton, Research & Development Director
Summary:	Performance Update

Action Required by the receiving committee:	□ Decision Approval □ **Receive for Information** X **Receive for Assurance**	Decision of Committee (to be entered after the meeting)

Implications	
Clinical	Without R&D the Trust will be unable to fulfil its obligations to give research opportunities to NHS patients. Staff will not gain the benefit of research training and experience of improving care through clinical trials.
Patients, carers or the public	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.
Resources	Finance, workforce, time, facilities
References	Health and Social Care bill, National Institute for Health Research (NIHR)
Assurances linked to report subject	System Plan, Patient Safety, CQC Registration, NHSLA, Information Governance, Health & Safety, MHRA, NIHR. CQUINS
Assurance framework number	(if on the Board Assurance Framework)

Risks Identified:	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 a few studies and a 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. ALL clinical areas need to be research active.
Include Risk Grade (categorisation matrix/Datix number/Risk Register Number)	AMBER – C3

BACKGROUND DETAILS

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1. Research and Development

During period April - September 2013, the R&D Directorate has continued to:-

- Attract new research opportunities,
- Network nationally with colleagues,
- Work with industry,
- Update members of the local community on the Research and Innovation activity.

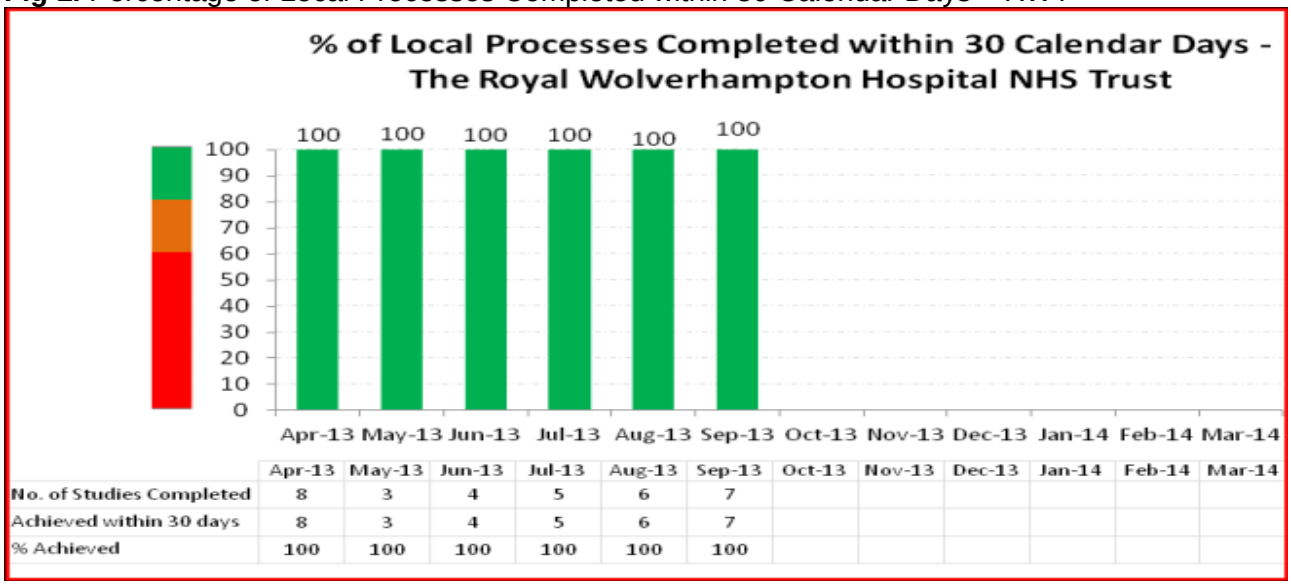
This paper will provide an overview of our performance, achievements and the challenges to be addressed over the coming months.

2. RWT Research Operational Performance Against National Targets

This report provides a summary of operational activity up to the end of September 2013. Performance report tables from the West Midlands North Comprehensive Local Research Network present further validation of performance during the reported period. The R&D Directorate continues to monitor actual performance across the Trust to ensure that the culture of Research continues to evolve across clinical areas of the Trust. We have a clear objective to provide patients with access to research trials and aim to facilitate this activity.

Trust Performance against NIHR Targets – Trust Approval (WMNCLRN Reported)

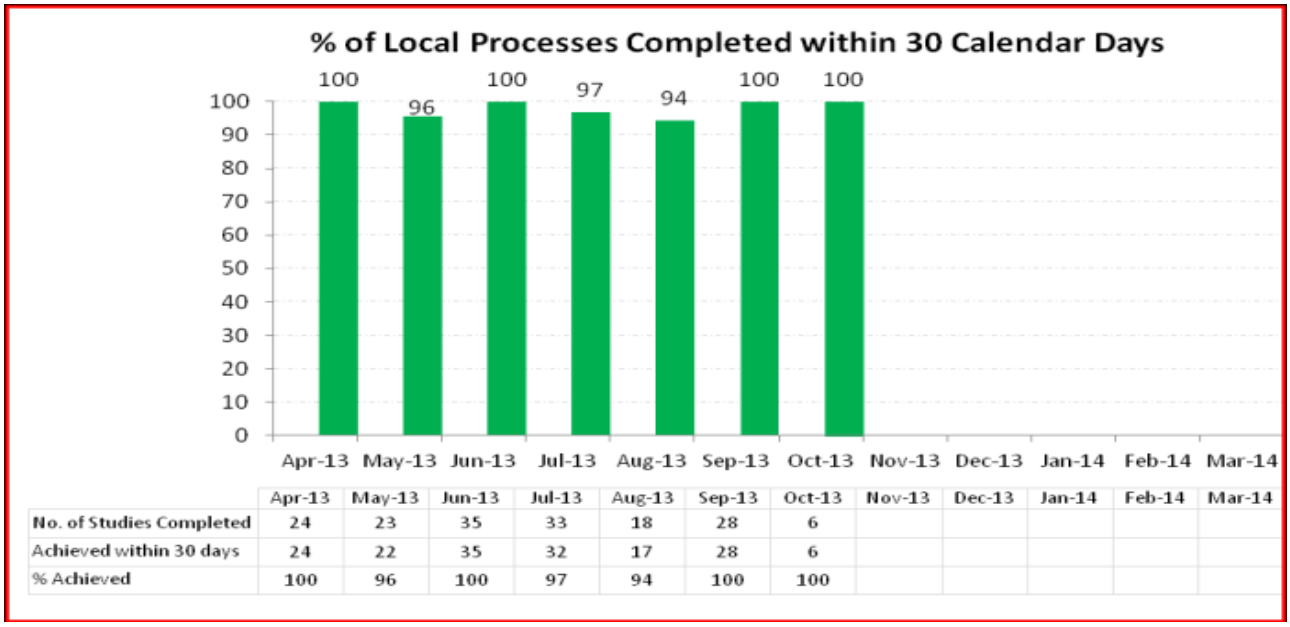
Fig 1. Percentage of Local Processes Completed within 30 Calendar Days – RWT



	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14
No. of Studies Completed	8	3	4	5	6	7						
Achieved within 30 days	8	3	4	5	6	7						
% Achieved	100	100	100	100	100	100						

We are able to report that in comparison to other Trusts, RWT is maintaining consistency in meeting a key national target of approving trials within specified timelines.

Fig 2. Percentage of Local Processes Completed within 30 Calendar Days - WMNCLRN Trusts



	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14
No. of Studies Completed	24	23	35	33	18	28	6					
Achieved within 30 days	24	22	35	32	17	28	6					
% Achieved	100	96	100	97	94	100	100					

The West Midlands North CLRN is currently ranked first nationally for the proportion of study-wide governance reviews completed within the national performance metric (100%) and first nationally for the proportion of local governance reviews completed and NHS permissions granted within the national 30 day local metric (98%).

In the future a national driver will be to continue to reduce governance review times and the duplication of effort across many Trusts geographically. A pilot scheme of 'single assessment service' for commercial trials is underway, specifically focusing on the costing and contractual agreement activities. Through collaborative links the Trust R&D Management team is already networking with colleagues involved in the pilot scheme and information is being shared on the benefits and lessons learned. With this information in hand, it is clear that RWT R&I will be able to play a significant part in achieving this future aspiration of a 'single assessment service' aided by the existing and much enhanced computerised local project management system (LPMS) .

NHS Permission to First Patient First Visit

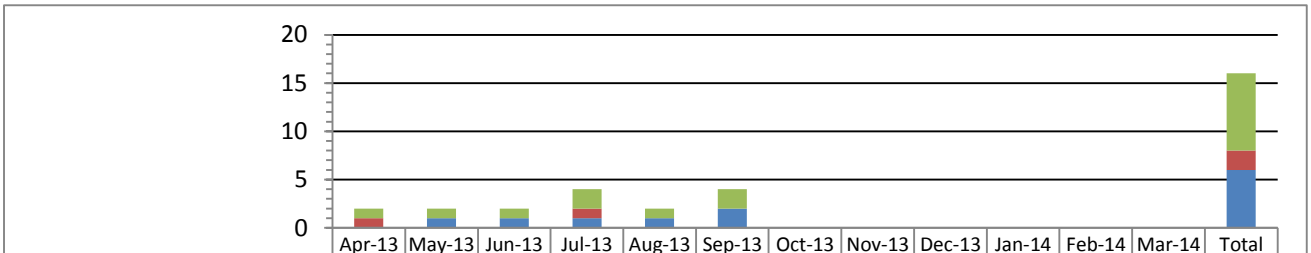
The second important National target is time from NHS Trust permission or site initiation visit (SIV) to first patient visit. The target is 30 days and similarly to most Trusts we are performing poorly against this metric.

Fig 3 provides the external reported position and Fig 4 provides local reported position.

Fig 3. WMNCLRN Reported Commercial Portfolio Performance, 1st Patient, 1st visit within 30 days

CCRN Objective 4: Ensure efficient and effective systems and research delivery models are in place to facilitate the speedy set-up and start of NIHR CRN Portfolio studies		
Links to HLO5: Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies		
Measure	**Assessment Criteria**	**Trust Current RAG Status**
4c) Proportion of all studies achieving NHS permission to first patient first visit within 30 days	≥80% studies achieved 60 – 80% studies achieved <60 % studies achieved	R

Fig.4 Local Reported Commercial Portfolio Performance



	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	Total
No. SIVs	1	1	1	2	1	2							8
No recruited (within 30 days)	1	0	0	1	0	0							2
No. Breach	0	1	1	1	1	2							6

(Fig. 4 confirms that 8 Site initiation visits (SIV) were required and completed, 2 studies meet the 30 day target but 6 failed)

There are a variety of reasons for failing to meet the site approval to first patient enrolled at 30 days, including

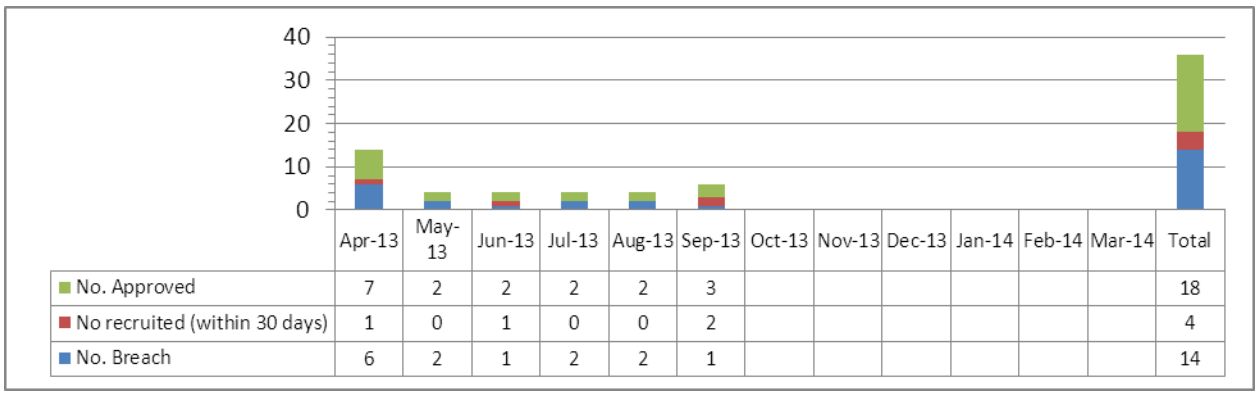
a) Delays from sponsors in providing drugs/equipment post SIV
b) A high proportion of complex interventional trials at RWT with relatively few patients to be recruited
c) Genuine difficulty in recruitment
d) Delays in sponsor Chief sites in uploading data.
e) Pre SIV screening limitations

We have focused action plans on areas within RWT that we can improve including pre NHS Trust approval screening, timeline planning with all staff involved and proactively planning sponsor visits shortly after Trust approval anticipated. With these measures we hope to see an improvement to this important metric locally. In comparison to Commercial trials we are able to report good progress rolling out these plans on non-commercial portfolio trials as shown in Fig. 5 and 6.

Fig 5. Non Commercial Portfolio Trials 1st Patient, 1st visit within 30 days

	Assessment Criteria		September's RAG Status
Ensure portfolio non-commercial studies recruit within 30 days of Trust Approval	< 60% studies achieved 60 – 80% studies achieved ≥ 80% studies achieved		G

Fig 6. Non Commercial Portfolio Trials 1st patient, 1st visit within 30 days



	Apr-13	May-13	Jun-13	Jul-13	Aug-13	Sep-13	Oct-13	Nov-13	Dec-13	Jan-14	Feb-14	Mar-14	Total
No. Approved	7	2	2	2	2	3							18
No recruited (within 30 days)	1	0	1	0	0	2							4
No. Breach	6	2	1	2	2	1							14

(Fig.6 confirms that 18 non-commercial trials were approved, (11 required SIV's) 4 studies meet the 30 day target but 14 failed overall whilst changes are taking effect from September 2013)

Portfolio Recruitment 2013-14

Fig 7

Number of Participants Recruited 2012-13	Number of Participants Recruited 2013-14	Target 2013-14
2911	2624	3777

CCRN Objective 1:	Increase the number of patients recruited into NIHR CRN Portfolio studies	
Links to HLO1:	Double the number of participants recruited into NIHR CRN Portfolio studies	
Measure	**Assessment Criteria**	**CLRN Current RAG Status**
1a) Proportion of agreed recruitment goal being met	RAG :- 100% or more of target 90 – 99% of target Less than 90 %	G

The **actual** portfolio recruitment for April 13 – September 2013 for RWT is 2670 **(70.6%)** of our annual target (3777). There is still a slight timing delay on the uploading verified accruals monthly by sponsors but this is improving. Within the WMN CLRN membership, RWT is the top performing recruitment site and is on target to meeting and superseding its current recruitment target. (See Table 1 for Recruitment summary.)

As one high recruiting portfolio own account study closes to recruitment the Trust is poised to see a new study commence in Diabetes. The technical issues are almost complete and data quality checks are now being undertaken. This study is aiming to recruit 8,000 patients over the next few months and a further 8,000 are to be recruited in the next financial year. This study is not only important to RWT but also to the WMNCLRN as a recent half yearly review meeting indicated that the cumulative accruals forecast for the Network was anticipated to be reduced by 8,000 within WMN CLRN primary care. The aim for RWT is to be within the top 10 single site recruiting centres (by local population) in England by March 2014.

With this information and aspiration RWT continues to be seen as a strong recruitment site and a huge demand continues for studies to be placed at RWT. A request has been submitted to the WMNCLRN to provide interim funds to expand current workforce capacity to support the rise in pending studies due to be approved imminently. The contingency application has been submitted for a further £79,000 (non recurrent) to ensure that we are able to retain trained staff that were employed to cover maternity leave during the period October – March 2014. Clinical areas which are expanding research capability/portfolios do so with limited resources and could perform much more research with the investment requested. Clinical areas of specific interest are Dermatology, Renal, Rheumatology and Diabetes.

Table 1. Summary of Recruitment April – August 2013

Study Category	Recruitment
Portfolio non-commercial	926
Portfolio commercial	60
Portfolio own account	1687
Non-commercial	49
Direct Commercial	19
Own account	41
NIHR Adopted PIC	6
TOTAL	**2788**

Total portfolio trial accruals are 2673, 6 patients identified for other Trusts and a further 109 non portfolio accruals achieved to date.

3. External Quality Assurance

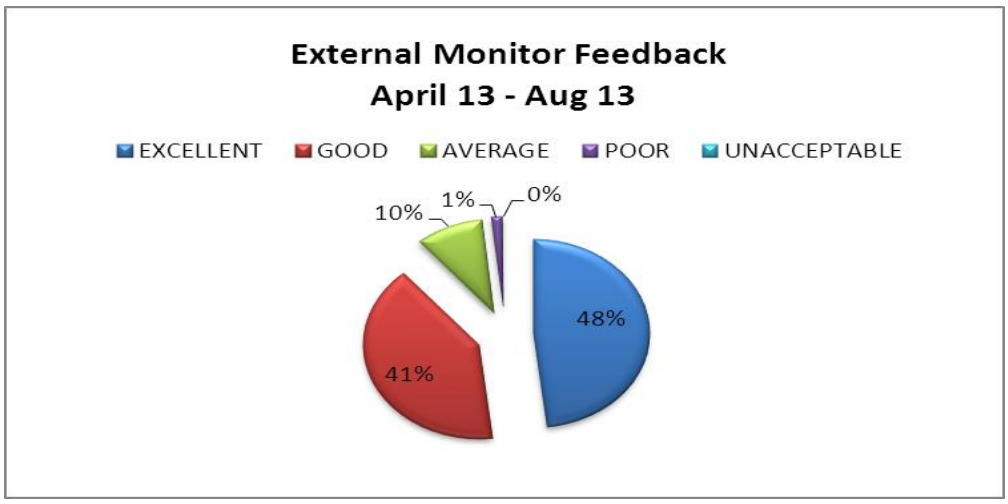
Throughout the recruitment period, external monitors visit the Trust and are able to confirm if there are any concerns regarding recruitment, service, quality and communications. RWT is believed to be the first Trust to implement a local external sponsor monitor feedback form. These forms are now mandatory for all externally sponsored trials. The information gathered provides assurance that we remain proactive in maintaining the high expectations placed of our research teams.

Chart 1 provides confirmation that 89% of sponsors rate RWT as Excellent/Good with a further 10% as average and 1% as poor. The R&D Management team are aiming for 95% as good/excellent and each monitoring form received is crucial to meeting this local target.

Monitors have acknowledged our efforts and have praised us for seeking such feedback.

Patient surveys have been tested and are now incorporated within our local quality monitoring plans. As patients complete their final treatment we will ask for feedback on the care and support they have received and this will enable the R&D Directorate to continually evolve and meet the expectations of all parties directly involved in trials.

Fig 8. Feedback from External Monitors



4. Patient Choice/Involvement and Communications

Nationally it is important that R&D Management teams address the engagement of patients and patient representation in research and therefore the R&D management team have responded following the disappointing 'Secret Shopper' review earlier in the year.

A number of activities have been put into place but new innovative methods will also be tested in support of the "OK' to ask" campaign. The extent of the activities are provided in tables 2 and 3

Table 2. PPI Communication Action Plan

Activity	Location	Status	Impact	Issues
Pop up posters	Main entrances across the Trust	In place	Medium Visual Impact	Easy to walk past
Posters in clinical areas	Research Active areas	In Place	Low Visual Impact	Easy to walk past
Totems	Entrance Areas Presentation slides	In Place	Medium Visual Impact	May not see slide
Web Page	Trust Web Site	In Place	Medium Visual Impact	Not sure of hits to page
Patient Letters	To add R&D statement to letter	Requested	Medium Visual Impact	Likely to be read
3D Virtual Research Nurse	To replace pop up stand at East Entrance	In Development	High Visual Impact	Instant attraction

Media	Local Press and media	Pending	Medium Impact	Target population not yet needing Trust services
PALS	OK to Ask poster General information supplied	In place	Medium Impact	General Enquiries
Email	Designated email address For patient enquiries	In Place	Medium Impact	General remote enquiries

A local campaign to develop Research Patient/Carer Ambassadors is underway with the first meeting scheduled for the 28th October 2013. This will provide an avenue for research patients and their carers/friends relatives to engage further within research. Expressed interest in working and promoting research will enable R&D to structure four levels of research ambassador scheme.

Table 3 Research Ambassador Scheme (PPI Engagement Plan)

Level	Engagement	Activity	Time Required
1	Engaged with R&D Management team as PPI representatives	Attend meetings as Lead PPI representative	4 days per month
2	PPI representation at Research Groups	Patient support /perspective	1/5 day per month
3	PPI representation	Trial design	When required
4	PPI representation	Research Awareness Campaign	3 hours per month

Through detailed reporting we are able to report to the Trust Board that that patients' are actively being considered, approached and engaged in research trials. As Illustrated in Table 4 confirmation of activity provides an overview of how many patients were screened and directly involved in active trials. This table also provides some clarity on the complexity and nature of research as patients screened for suitability may not meet trial specific inclusion criteria. The recruitment status at the half year position equates to 32.9% of all patients screened. Total number of patients screened, consented and in followed up for the period was 12,444.

Research Active Departments: We are currently aiming to encourage research in all clinical areas. Successful areas and areas not performing research can be seen in table 4 below.

Table 4. Giving Patients Choice to Participate in Research Trials (April – September 2013)

SUPPORTING PATIENT CHOICE	Follow Up 2013/14	Screening Total 2013/14	Recruitment total	Quarter 2 Total
Cardiology	46	446	**107**	**599**
Stroke (Care of the Elderly)	37	880	**18**	**935**
Respiratory	101	514	**42**	**657**
Accident & Emergency	0	0	**0**	**0**
Critical Care (ITU)	39	395	**26**	**460**
Dementia	0	0	**0**	**0**
Audiology	0	0	**0**	**0**
Diabetes	26	361	**18**	**405**
Sexual Health	0	0	**395**	**395**
Renal	50	35	**36**	**121**
Gastro	509	1336	**158**	**2003**
Surgery	3	0	**3**	**6**
Orthopaedic	0	0	**0**	**0**
Ophthalmology	343	31	**72**	**446**
Rheumatology	39	73	**6**	**118**
Dermatology	0	0	**0**	**0**
Oncology	353	164	**104**	**621**
Haematology	0	0	**1736**	**1736**
Obstetrics	2	38	**32**	**72**
Reproductive Health	7	33	**9**	**49**
Paediatrics	28	4162	**26**	**4216**
Mental Health	0	0	**0**	**0**
Total	**1,583**	**8468**	**2788**	**12,444**

5. Academic Partnership

The R&D Directorate is co-ordinating the formation of an enhanced academic partnership with University of Wolverhampton. A framework has been agreed and a formal report will follow in the near future. Other academic links with Universities of Liverpool, Aston and Oxford continue to flourish.

Own account research is usually developed in conjunction with an academic or industry partners and this is an area which needs further development. As noted in Table 5, the Trust has had some

success in securing portfolio status for two own account trials thereby raising the reputation of the Trust nationally. There is significant room for the development of this important area and we are currently pursuing strategies to facilitate this with the Trust executive.

Table 5. Own Account Research Recorded April – August 2013

		Portfolio	Non-Portfolio
Consultant	Approved	**2**	**2**
	Pending	0	**1**
	Registered	0	**1**
	Suspended	0	**1**
SPR	Approved	0	**1**
	Pending	0	0
	Registered	0	**1**
	Suspended	0	0
Nurse	Approved	0	0
	Pending	0	0
	Registered	0	0
	Suspended	0	0
Allied Health Professional	Approved	0	0
	Pending	0	0
	Registered	0	**1**
	Suspended	0	0
Student	Approved	0	0
	Pending	0	0
	Registered	0	0
	Suspended	0	0

6. Any other Matters

New Appointments – A Deputy R&D Manager has appointed and will commence on the 25th November 2013. This individual will have responsibility for developing reporting schedules to accurately reflect the clinical, research and financial impact of the Research and Innovation directorate.

External Visits/Reputation - Continued interest in the R&D Directorate Local Project Management Systems is increasing steadily from across the UK. This has been assisted greatly with the NIHR confirming that the R&D Directorate software is one of three nationally preferred systems.

Events - R&D took part in the Trust AGM Health Market event at the end of September 2013.

Divisional Reporting Structures – R&D have now restructured the reporting of operational activity by Division and will seek to demonstrate the value of research to the Trust.