TRUST BOARD

Date of Meeting	25 February 2013
Title of Report:	Research and Development at RWT
Author	Dr J Cotton, Research & Development Director
Summary:	This report aims to update the Trust Board on the current status of Research and Development in the NHS, the political impetus for research within the NHS and the value of research success to RWT. This report will also outline the current position of R&D at RWT and suggest a strategy for increased research success.

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

Implications

Clinical	Without R&D patient choice will be directly affected, clinicians will be less engaged in modernisation agenda and unable to influence through evidenced based methodologies advancements in their specialist field.
Patients, carers or the public	Patients and Carers opt to participate in research to help themselves 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 and option.
Resources	Finance, workforce, time, facilities
References	Health and Social Care bill, NIHR
Assurances linked to report subject	System Plan, Patient Safety, CQC Registration, NHSLA, Information Governance, Health & Safety, MHRA, NIHR.
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 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.
Include Risk Grade (categorisation matrix/Datix number/Risk Register Number)	HIGH AMBER – C4

BACKGROUND DETAILS

.

1. Research and Development

Clinical Research (along with education) is one of the main drivers of increased quality in clinical healthcare. It has been well documented that institutions that participate in clinical research have better results, better outcomes and that research active clinical staff are more likely to be aware of both innovative clinical developments and national best practice. Furthermore research active departments attract and retain high quality staff.

As well as being central to the Department of Health's (DOH) quality agenda, there is a major focus on securing the collaboration with the health sciences industry in and outside of the UK. In order to avoid further loss of valuable commercial healthcare and life sciences companies from the UK, the current and previous governments have developed a system to streamline research nationally so as to attract clinical trials (both academic and commercial) to the NHS.

The National Institute of Health Research (NIHR) has the strategic aim "To improve the Health and Wealth of the Nation through Research" to this end it has set up a series of clinical research networks (CRNs). The NIHR Clinical Research Network (CRN) has developed since the establishment of the National Cancer Research Network in 2001 with the subsequent establishment of 5 other Topic Specific Networks (Mental Health, Diabetes, Medicines for Children, Dementias and Neurodegenerative Diseases, and Stroke), followed by the Primary Care Research Network and Comprehensive Clinical Research Networks in 2007. The Comprehensive Clinical Research Network provides support for all areas of clinical need not covered by the Topic and Primary Care Networks and its portfolio has been organised into 23 "specialties" each led by a National Specialty Group. The NIHR runs a single portfolio of approved academic and commercial trials. Funds are available to support these trials within NHS institutions via the local networks.

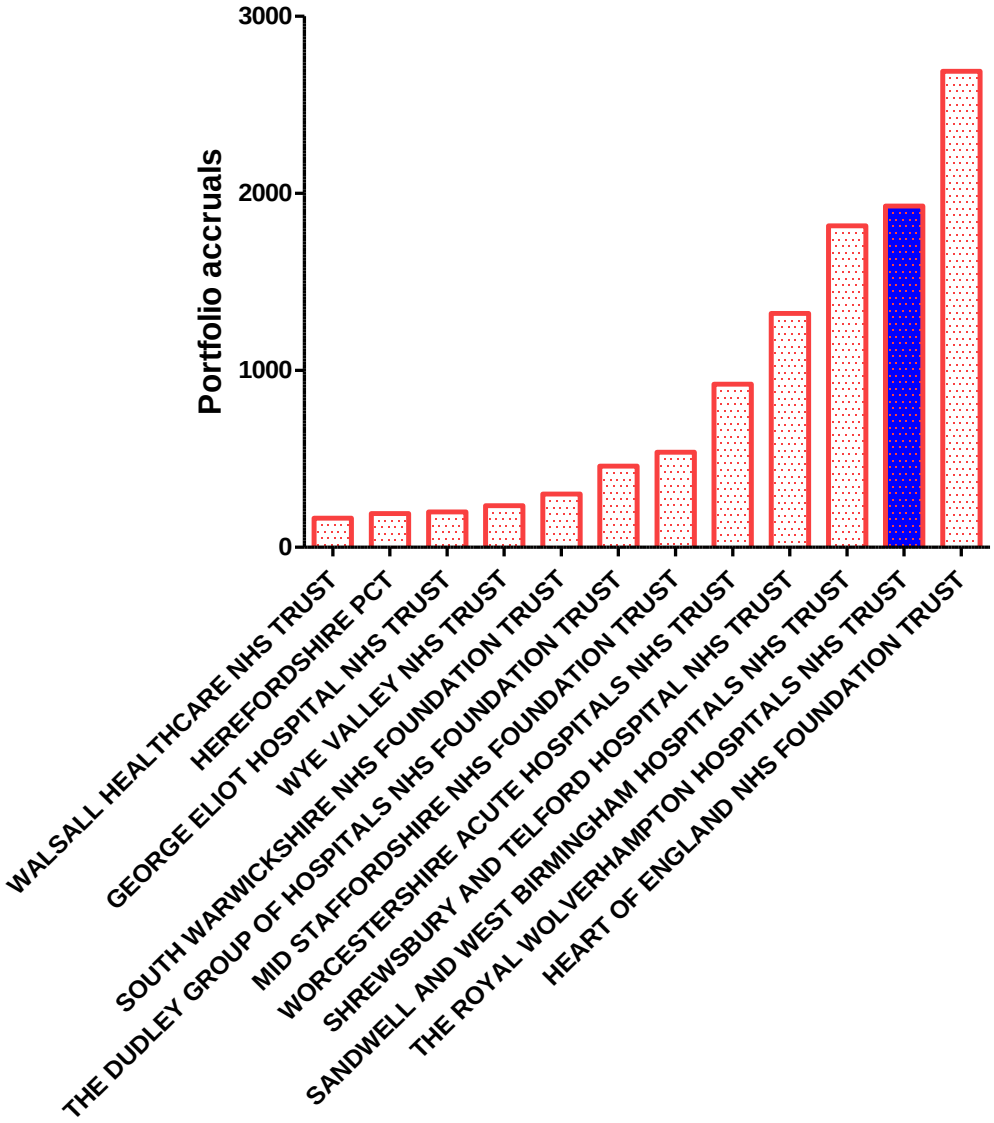
In Feb 2010 Andrew Lansley laid out the DOH's view of the NHS as "An NHS which sees Research and Development (R&D) as central to being the best healthcare." And this focus has remained with R&D now being a constitutional requirement (Health and Social Care Bill and Trust compliance to Annual Care Quality Commission (CQC) reporting for clinical care to be commissioned where ALL patients have availability to seek and access clinical trials. The implications for research active Trusts are clear.

2. Current Trust R &D position:

The Trust holds a strong position in the region in terms of trial management, research leadership and recruitment. We currently have 4000+ patients in 465 clinical trials within the Trust.

The relative recruitment and number of trials compared with West Midland North District General Hospitals (DGH's) and West Midlands Teaching hospitals are shown in Figs 1-3.

Fig 1: Patients recruited to NIHR portfolio trials 2011-12 by West Midlands DGHs



RWT hosts the Greater Midland Cancer research network and has a number of clinical leads for research within the WMN CLRN:

- GMCRN: Prof D Ferry
- Ophthalmology Prof Y Yang
- Respiratory Dr L Dowson
- Diabetes Dr D Singh
- Critical Care Dr S Gopal
- Cardiothoracic Dr J Cotton
- Gastroenterology Dr M Brookes

Fig 2. No. of Patients Enrolled into NIHR Portfolio Trials - RWT vs. Local Teaching Hospitals

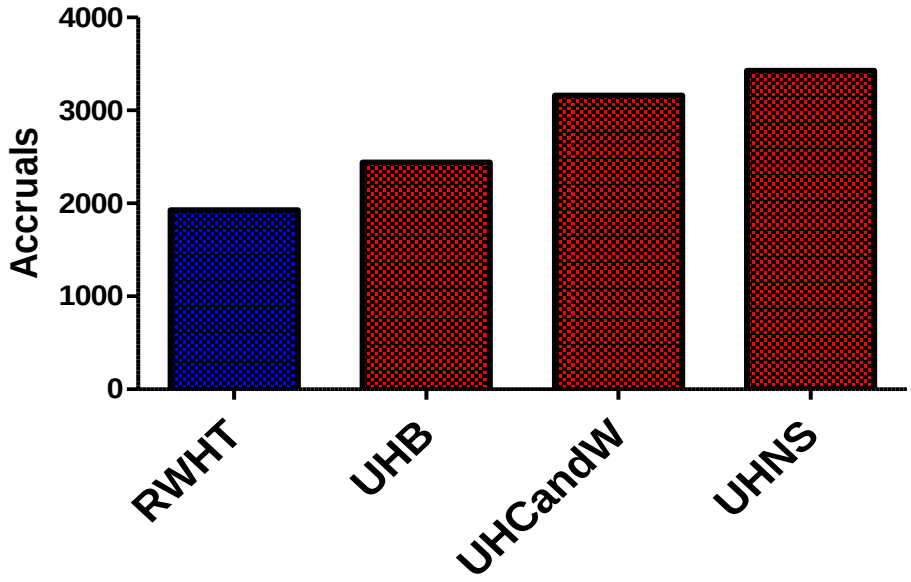
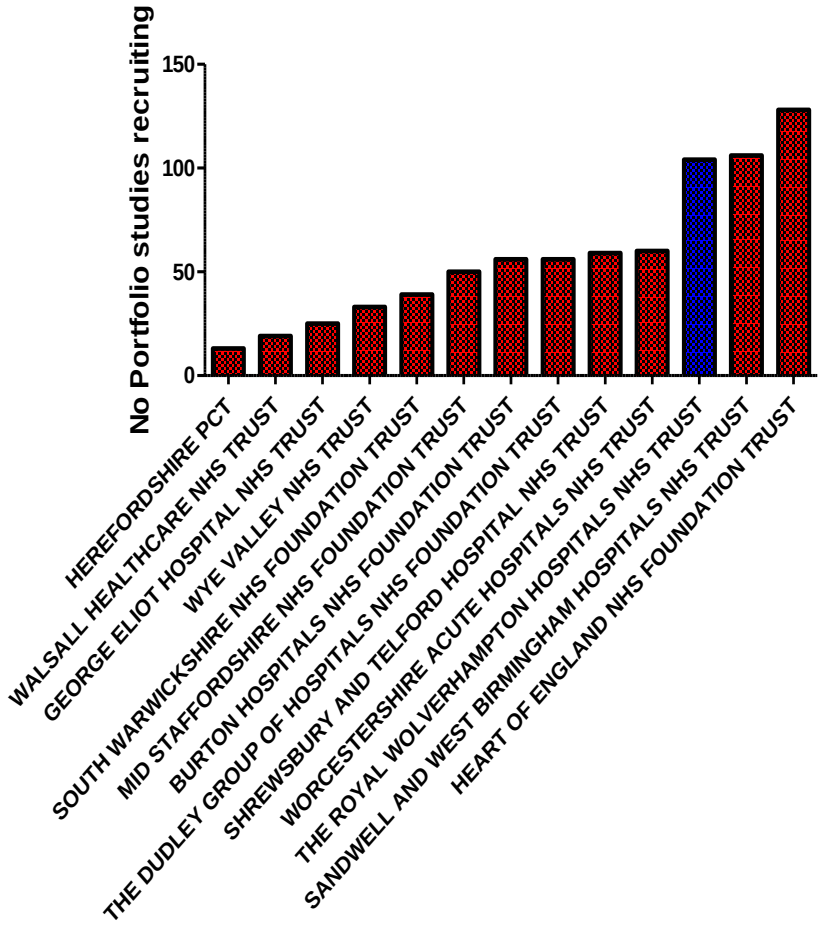


Fig 3: No of portfolio trials open. DGH Hospitals West Mids 2011-12



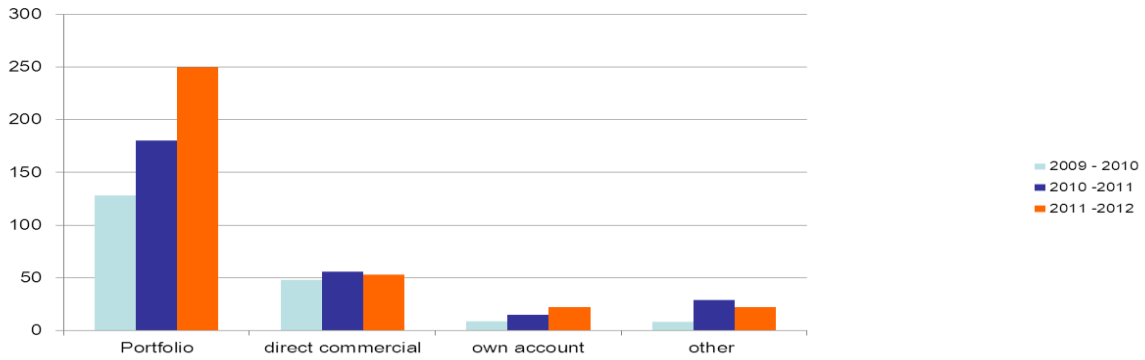
Drs Gopal and Brookes have both developed and delivered their own NIHR Portfolio trials as Chief Investigators over the past year. In addition Dr Basu (Haematology and Dr Lodwick) are running a very successful adopted NIHR portfolio trial in the emergency admission unit. Dr Singh has recently attracted a prestigious BMA grant for a clinical trial that should be adopted onto the portfolio. Each of the above demonstrated a personal track record in attracting research and managing research with a marked increase in accrual rate.

Table 1: Recruitment to NIHR Portfolio Trials 2012-13.

Note: current recruitment to one new trial is circa 210 per month so end of year variance will reduce.

Department	No. of Projects	Total Accruals
A&E	1	17
Cardiovascular	10	116
Care of the Elderly	6	44
Critical Care	2	33
Diabetes	8	12
Gastrointestinal	18	134
Genitourinary	1	0
Haematology	24	259
Histopathology	1	0
Infection	1	0
Max Fax	1	0
Neurology	2	0
Obstetrics	1	0
Oncology	58	287
Ophthalmology	8	78
Paediatrics	12	65
Renal	4	34
Repro Health	7	68
Respiratory	10	31
Stroke	2	35
Surgery	3	0
Urology	3	10
	186	**+1223**
CLRN TARGET		**3000**
Variance +/-		**-1777**

Fig.4 Overview of R&D Portfolio from 2009 - 2012



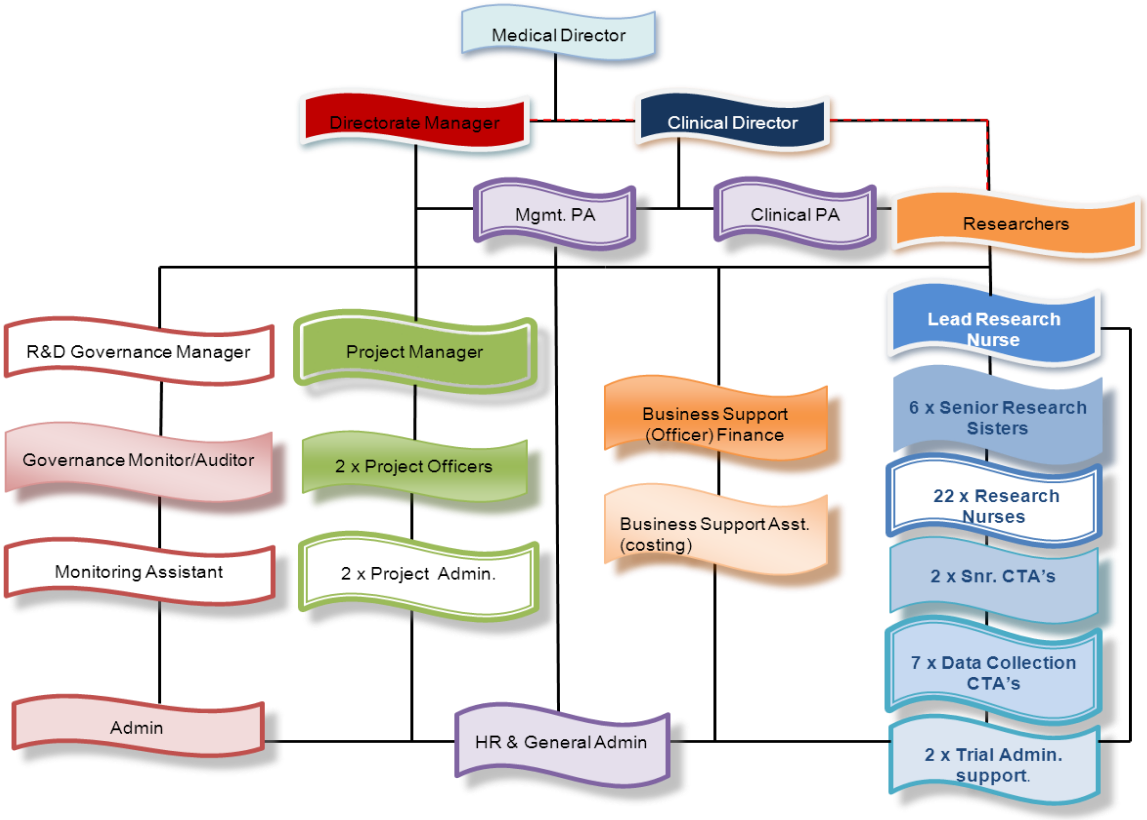
3. Staffing and financial structure:

The R&D Directorate currently employs 57 staff, the structure is shown in figure 4 however the research team consists of:-

- Research Management Team - 14
- Research Nurses - 30
- Clinical Trials Assistants – 13
- Active Researchers across the Trust – 118

•

Fig. 4. R&D Staff Structure

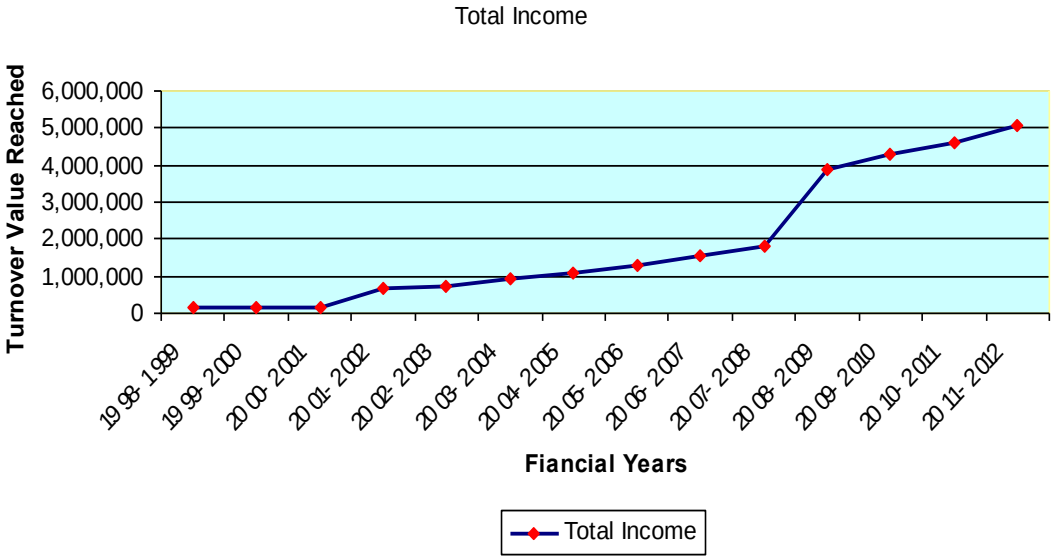


Strategically our plan is to become the highest recruiting site in the West Midlands by 2015, this would give us an increased income stream and significant influence in terms of research management. To do this we will need to grow our own account research portfolio and develop clinical trials at RWT which are adopted onto the portfolio. We will also need to support our high level researchers to develop into chief investigators.

4. Revenue

There has been a year on year growth in revenue since the inception of R&D in 1998 and this trend is now being affected by the reduction in direct commercial trials. The NIHR has been extremely successful in increasing the number of industry studies adopted onto the portfolio thus leading to a decrease in profit margins. We anticipate that commercial trials profitability is likely to fall sharply with a probable reduction in annual revenue.

Fig 5a Historical Growth of R&D Turnover 1998 - 2012

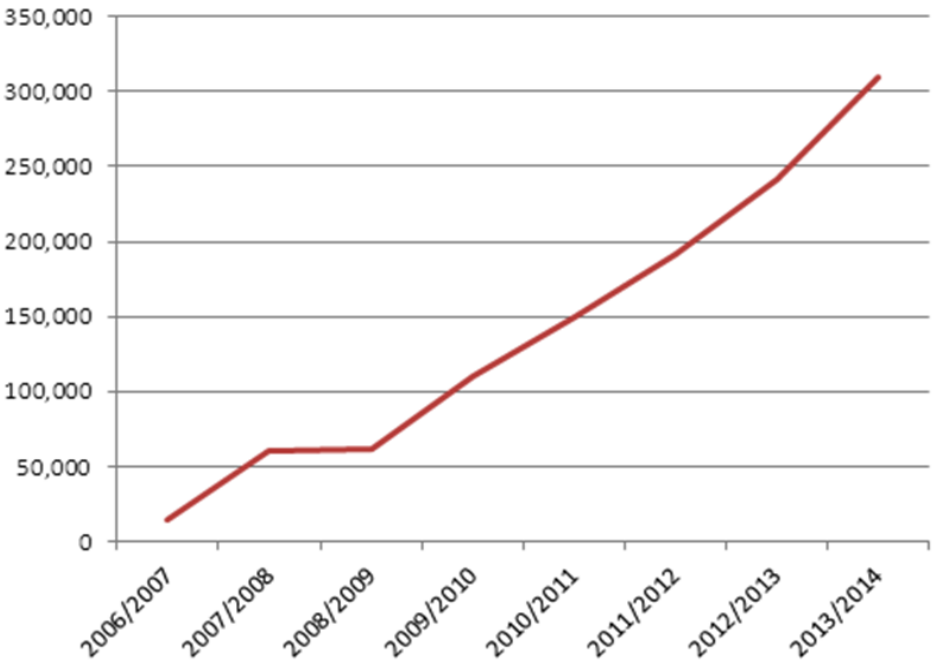


The R & D Directorate financially supports RWT in a number of ways:

1) Access to free drugs for most clinical trial patients undergoing NHS treatment.
2) Direct funding for clinical staff also undertaking research activity.
3) Development revenue
4) CIP contribution.

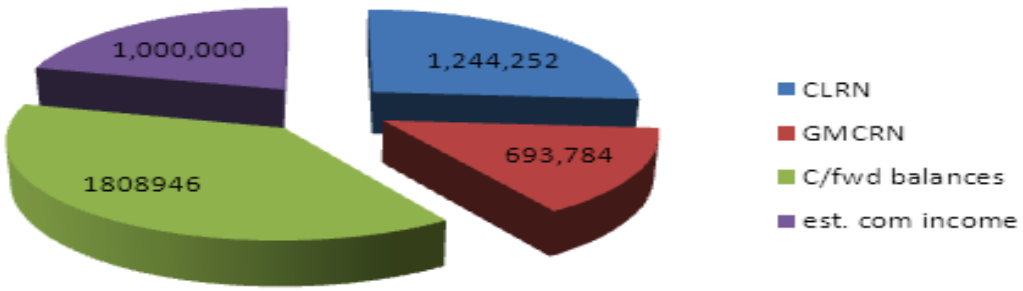
CIP contribution is linked to uncommitted income against each account held within the R&D Directorate Trading Account. No CIP can be attributed to funds from NIHR. The Trust MUST also demonstrate investment of industry profit into supporting research capacity. The R&D Directorate NIHR funds received do not fund non pay costs.

Fig 5b. CIP Contribution Year on Year 2006 - 2015



The R&D Directorate has struggled with CIP but has met targets each year by reducing valuable developmental funds and has scaled down its innovation activities.

Fig 5c: Income source R and D 2012-13



Income for 2012-13 is less than in previous years, the start of a downward trend unless new clinical areas are opened up to research and alternative funding sources are found. Fig 5d provides clarity on how much funding is invested back into Trust budgets.

In total, including CIP 2012 – 2013, R&D will contribute £410,696 directly to exchequer accounts and a further £420,683 to underpin additional research clinical via trading accounts for pay and diagnostic costs. This does not include R&D Directorate pay costs for Research Management, Research Nurses or Clinical Trail assistants.

Table 2. Summary of Research Income by Department April – Jan 2013

Commercial Income		TRADINIG ACCOUNTS ADDITIONAL FUNDING TRIALS AND STAFF				
Department	Income	PA Sessons	Capacity	Support	CIP	**Total**
A&E	265.44	0	0	0	0	**265.44**
Cardiology overall	9049.5	0	0	36584	0	**45633.5**
Clinical Chemistry	11520.83	0	9663	8661	0	**29844.83**
Diabetes	1875.17	0	0	0	0	**1875.17**
Haematology	111.3	2498	0	30000	0	**32609.3**
Haematology Labs	3911.64	0	0	0	0	**3911.64**
Infection Prevention	1124.64	0	0	0	0	**1124.64**
Lung Function	1217.41	0	25579	0	0	**26796.41**
Medical Physics	336.71	0	11,294	0	0	**11630.71**
Microbiology	8680.37	0	0	0	0	**8680.37**
O/T West Park	188.54	0	36741	0	0	**36929.54**
Oncology	29797.24	50,517	0	0	0	**80314.24**
Ophthalmology	19851	9600	0	0	0	**29451**
Pharmacy	28231.46	0	63356	0	0	**91587.46**
Radiology	44845	0	32000	0	0	**76845**
Respiratory	1810.28	35479	0	0	0	**37289.28**
Rheumatology	1871.31	0	0	0	0	**1871.31**
Gastroenterology	0	8493	0	0	0	**8493**
Cardiovascular	0	24228	0	0	0	**24228**
stroke	0	0	0	0	0	**0**
chemotherapy	0	0	22000	0	0	**22000**
radiographer	0	0	20000	0	0	**20000**
R&D Directorate CIP	0	0	0	0	240,000*	**240,000**
Total	**164687.84**	**130815**	**220633**	**75245**	**240,000**	**831380.8**

CIP journal being processed currently to balance end of year commitment

5. Development Plans

For research and Development to flourish in the Trust there are a number of specific organisational changes required:-

- R&D needs to become fully integrated within the corporate reporting structure.
- Research activity needs to be embedded in all parts of the clinical service.
- We need to build capacity for R&D expansion and clinical capacity to see clinical research patients without compromising throughput of clinical cases.

- Clinicians and particularly research active PIs will need to have research time in their job plans so that there is a coordinated approach to delivering at least some research activity in every Directorate.
- R&D current accommodation needs to be addressed.

5.1 Clinical and Financial Integration: Suggested plans

Currently R&D contributes annually to CIP. This has risen considerably year on year (see Fig 5b) and in the absence of an increase in income will deflate the Department and reduce available funds to the Trust over the short and medium term: This is a considerable risk given R&D's limited disposable income and have no call on exchequer funds. One proposal would be to replace CIP with a plan to markedly increase the Trusts funding from R&D by supporting expansion. This could be achieved by:

a) Supporting R&D in every Directorate (currently a large number are not active or are only minimally active). To do this each Directorate would need to find at least one research "champion" and support them in the job planning process to have enough time to develop and perform research. It is anticipated that very active research individuals should have 1 or 2 PAs in their job plan for research: there are currently 7 individuals in the Trust that fulfil this remit and are being or need to be supported in terms of time.

b) Increasing the Trust take from research profits. It might be possible to levy a set percentage of money (perhaps 20 %) paid for each trial for Trust funds in place of CIP. This would lead to greater revenue for the Trust (than current CIP) without the deflationary pressure on the department. Following this plan, more funds would be generated by the Trust supporting an increase in research. This would need agreement from researchers and the Trust Board.

c) Allow R&D to re-invest CIP back into the Trust to expand capacity and increase medium and long term funding to the Trust.

Structural changes to R&D

- A new senior lead research nurse has been appointed.

- We will co-opt a patient/public representative to sit on the R&D management board. This will build on our current plan to survey all patients following research participation.
- Develop the role of a communications manager/Development manager to increase awareness of the R&D Directorate both inside and outside the Trust. This individual will foster relationships with researchers and local industry.
- Develop a new operational business manager with a main focus being the accuracy and quality of KPI data and reporting thereof.

d) Develop a new role of trial support officer, an experienced individual who can help clinical researchers in the Trust develop their research ideas with a plan to increase the number of principal and chief investigators in the Trust.

6. General Recommendations to the Board

For research and Development to flourish in the Trust there are a number of specific organisational changes required:-

- R&D needs to become fully integrated within the corporate reporting structure.
- Research activity needs to be embedded in all parts of the clinical service.
- We need to build capacity for R&D expansion and clinical capacity to see clinical research patients without compromising throughput of clinical cases.

- Clinicians and particularly research active PIs will need to have research time in their job plans so that there is a coordinated approach to delivering at least some research activity in every Directorate.
- R&D current accommodation needs to be addressed.

Key recommendations to Board

6.1 Corporate integration:

Suggested measures: As previously R&D Director will report quarterly to the Trust management team. In addition R&D Director will report KPIs and progress bi-monthly to the Trust Board: this reporting is now, in itself, a measured key performance indicator for the research networks.

Suggested KPIs to be reported are divided into centrally reported (to the Networks and NIHR) and locally reported.

Centrally reported:

a) Number (and %) portfolio trials achieving Trust assessment and approval within 30 days of R&D receiving all of the required information and valid site specific information (SSI form).
b) Number (and %) portfolio trials achieving recruitment of first subject within 40 days of R &D giving approval or from time of the site initiation visit.

c) Annual Trust accrual vs. the network target set in the yearly business planning process.
d) Number of trials failing to recruit any patients.

Locally Reported:

e) Management approval times for each Directorate and Division.
f) Cumulative annual R &D income for each directorate and division.
g) Cumulative annual R&D income for each support service (eg. radiology, pathology and medical physics).
h) Number of research trained individuals in Trust.
i) Number of research active consultants by Directorate and Division.
j) Number of research trials open in each Directorate and Division.
k) Number of accruals by Directorate and Division.
l) Number of innovations registered by Directorate and Division.

6.2 Nomination of a Non Executive Director with responsibility for R and D

Given the central importance of R&D to a healthy and successful Trust in the future, it would be beneficial to strengthen links with the Trust Board by allocating a Non-Executive Director with specific responsibility for R&D. This individual would attend monthly R&D management meetings and help to guide the strategic development of the Directorate.

6.3 Bid for NEW Combined Regional CRN

With the development of the Network system under the auspices of the NIHR there are currently over 100 networks with management structures in the UK. Plans are now in place to reorganize these into no more than 15 “super networks” in the UK. In the West Midlands this will mean amalgamating 3 CLRNs (our own, West Midlands North, with Birmingham and Black Country and West Midlands South) as well as the 6 local topic specific networks. The new Network will have an operating turnover of approximately £30M.

Each new Network will not be a full legal entity and will need an NHS Host. Currently negotiations are starting regarding the West Midlands host organisation. The NIHR have stated a preference for each of the local organisations to nominate a preferred host. This is unlikely to occur in the West Midlands and it is more likely that a bidding process will be undertaken. The New host will have management commitment to the new Network with a key member of the Trust on the Board of the new Network. The host will also have some responsibilities for performance management in addition to financial management.

There would be considerable advantages to RWT being the host of the new network, not least the ability to have an input into the dispersal of research funding

to different organisations. We could ensure equitable allocation of funding between research organisations following research activity. There is a perceived risk that centralizing the funding to one of the large academic institution could lead to a reduction in support for large research active DGHs such as our own.

We had a successful visit from Jonathan Sheffield, chief executive of the NIHR, to RWT in Nov 2012 with a number of research presentations. He was clear that successful research organisations and not just academic organisations would be considered as hosts. As a result of this visit Jonathan Sheffield has positively requested his Chief Information Officer to visit the R&D Directorate. A visit date has been confirmed as the 4th March 2013.

In preparation of the forthcoming announcement for host applications a project team under the leadership of Maxine Espley is being formalised with a view to placing a high quality cogent bid when the timelines and rules of the process are made clear from the centre.

The board is asked to reflect on the information contained in this report and provide clarity on their strategic ambition for research in the Trust in terms of the value and opportunity that R&D can make in the short, medium and long term.