

Trust Board Meeting : Wednesday 13 November 2013

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Title	Research & Development Annual Report 2012/13
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Status	For Information
History	This is an annual report to the Trust Board.

Board Lead(s)	Professor Edward Baker, Medical Director			
Key purpose	Strategy	Assurance	Policy	Performance

Executive Summary

<p>1. The BRC and BRU are in the second year of work since their renewals, and will undertake a detailed review of progress and future direction during 2014, in order to prepare for the next NIHR funding round. This is expected to be announced in 2016.</p>
<p>2. The BRC Working Groups have made important progress in a number of key areas. Molecular Diagnostics and Clinical Informatics have achieved notable early successes, but require strategic prioritisation if they are to achieve nationally leading success for the OUH/OU Partnership. BRC Translational Pathology is the focus of a fundamental review.</p>
<p>3. Mandatory reporting of clinical research performance metrics to NIHR has been introduced over the last year, highlighting the need to accelerate clinical study initiation and recruitment. Sustained improvements in OUH performance will require increased strategic and operational support of clinical research across the OUH Divisions and OU Clinical Departments. The recent reconfiguration of the OUH Divisions provides an opportunity to prioritise clinical research performance within the organisation.</p>
<p>4. The Joint Research Office, comprising over 80 members of staff from both OUH and OU, supports all joint research across the partnership, currently including more than 1200 clinical studies and dealing with over 2000 research contracts annually.</p>
<p>5. Clinical Research plays an important role in strategic developments including the AHSN, the AHSC bid and recent successes in award of an NIHR CLAHRC, and designation of OUH as host of the new NIHR Local Clinical Research Networks (LCRN) for the Thames Valley and South Midlands. Currently the CLRN is ranked 3rd in England for commercial study performance and 5th for network recruitment, with OUH itself being the second highest recruiting trust in the country.</p>
<p>6. Recommendation</p> <p>The Trust Board is asked to receive the report and note the contents.</p>

1. BRC and BRU Progress

- 1.1 During the first year of the post-renewal BRC programme, the 14 Research Themes and 7 Working Groups have established and consolidated their programmes. All of the Themes and Working Groups reported on progress, and milestones achieved, at a review by the BRC Steering Committee on 24th April 2013. This review, and examples of research successes drawn from the Themes' reports, formed the basis of the BRC annual report to NIHR submitted in May 2013. NIHR feedback on the annual report was satisfactory.
- 1.2 All BRC Themes have been supported in continuing with their research programmes through 2013/2014, dependent upon satisfactory review of progress by the Steering Committee. However, in 2014 there will be a more strategic review of BRC Themes, incorporating external scientific advice, in order to identify the new priorities for the Themes. This will be a full two years before the anticipated submission of the bid in the next round of competitive BRC funding, expected in 2016 for initiation in 2017.
- 1.3 The musculoskeletal BRU, based at the Nuffield Orthopaedic Centre, has established themes in the areas of rheumatology and inflammatory joint disease; orthopaedics, surgical innovation and evaluation; epidemiology and disease prevention; sarcoma; and rehabilitation. Notably, the BRU is developing and evaluating novel surgical and tissue engineering therapies (with filed patents) and is working closely with the BRC in establishing a Trials Unit supported by the Royal College of Surgeons (SITU). Work is on-going to align tissue banking and bioresources. Professor Sallie Lamb (previously Director of the Warwick CTU) has been recruited to lead a programme in trials of rehabilitation. The BRU away day and review is scheduled for 18 November 2013.

2. Developing strategic priorities through the BRC Working Groups and other initiatives

- 2.1. The BRC Working Groups were established to identify and support areas of new strategic priority for the OUH-OU partnership, in areas including molecular diagnostics, clinical informatics, clinical trials units, cognitive health, transplantation, education and training and patient involvement. Of these working groups, two have made particular progress in the early steps towards establishing new programmes of activity. However, this initial operational progress has highlighted a pressing need to agree the strategic objectives. The Board is asked to specifically consider two areas, Clinical Informatics, and Molecular Diagnostic and Pathology.

Clinical Informatics:

- 2.2. Better use of clinical patient-related data, gathered through EPR systems, is critical to underpinning clinical research programmes, particularly across distributed clinical pathways and networks. The BRC has made initial investments in providing leadership. Professor Jim Davies, Department of Computer Science, is Chairman of the BRC Clinical Informatics Working Group and has been co-opted to the BRC in a 0.5WTE role as the BRC Director of Clinical Informatics, in

conjunction with the OU Department of Computer Science. The Clinical Informatics Working Group brings together investigators who have already established clinical research programmes that entrain clinical data sets. Greater investment will be needed to achieve more effective use of clinical data to support research. It is likely that further additions to lead clinical informatics across specific therapeutic areas in the OUH-OU Partnership, and across the AHSN, will be required, complemented by technical and operational changes within the respective EPRs.

- 2.3. The NIHR Health Informatics Collaborative (NIHR HIC) has been funded by NIHR, against the proposal submitted by the Chief Executives of the 5 large BRC Trusts in Summer 2012. Each of the five BRC Trusts has received £400k revenue and £400k capital per year for two years to develop systems and governance frameworks to share clinical data between the BRC Trusts in support of clinical research programmes in a number of exemplar areas. The OUH-OU Partnership supports leadership aspects of the NIHR HIC, by hosting the Programme Manager and the Director of Informatics (Prof. J Davies) who has coordinated the collaborative programme. The work of the NIHR HIC has been successful in establishing 5 themes of data collection and sharing across the 5 large BRCs, to support clinical research. Each theme is led by one of the BRCs- Cancer (Ovarian) [Cambridge]; Transplantation [Guys/St. Thomas']; Intensive Care [UCLH]; Acute Coronary Syndromes [Imperial] and Hepatitis C [Oxford].
- 2.4. The work of the NIHR HIC is particularly relevant to the developments in genomics, both locally and nationally. Genomics England (GeL), a company set up with the Department of Health to run the 100,000 genomes programme, has enlisted support from the NIHR HIC, and in particular from Oxford, to assist with early set up, at the request of the Chief Medical Officer and from Sir John Chisholm (the CEO of GeL).

Molecular Diagnostics and Pathology:

- 2.5. The BRC Molecular Diagnostics Working Group has built on previous programmes established by the Blood Theme and Genomic Medicine Theme to establish an increasing number of clinical diagnostic tests based on genomic technologies particularly in haematology and oncology. A substantial volume of diagnostic testing to support both NHS clinical activity and clinical trials is being delivered through a CPA accredited molecular diagnostic laboratory, the Oxford Molecular Diagnostics Centre, hosted within the Laboratory Medicine Directorate of the OUH based at the John Radcliffe and at the Churchill Hospital. In addition to substantial BRC funding, the molecular diagnostics laboratory is supported by competitive external grant income from the Technology Strategy Board and from the Health Innovation Challenge Fund (HICF). The future growth of the Molecular Diagnostics Centre, beyond a proof of concept that has already been achieved, will be dependent upon an appropriate business model that reflects the need for flexible recruitment of staff, the need to direct revenues towards growing new areas of activity, and the differences that arise from specialised diagnostic testing underpinning regional and national patient referral pathways, and specialist clinical trials, as distinct from large volume routine diagnostic testing, e.g. in haematology and biochemistry.

- 2.6. The success of molecular diagnostics is also critically dependent upon support from Pathology, in order to provide and process cellular and tumour material from patients, for molecular diagnosis. Attempts to ensure that molecular diagnostics and clinical research are supported by Pathology have so far not proven to be effective. The BRC supported the creation of a new post of Director of Translational Pathology three years ago, but this has not had a major systematic effect on Pathology support of molecular diagnostics.
- 2.7. A new strategic approach to translational pathology is to be presented to the Strategic Partnership Board in November 2013 and developed in conjunction with the BRC Steering Committee, and the respective BRC Themes and Working Groups.

3. OUH-OU Joint Research Office

- 3.1 The OUH-OU Joint Research Office (JRO) was formed in May 2011, bringing together the OU Medical Sciences Division Research Services Office (RSO), Business Development Team and Clinical Trials Research Governance with OUH R&D, OUH Contracts and R&D Finance and the BRC Management Team, co-located in refurbished space in the Churchill Hospital provided by OUH. The co-location of the JRO teams has greatly facilitated partnership working and efficiency gains. The JRO now incorporates more than 80 staff (with over 60 qualified to first degree, 20 at masters level, 2 MBA and 17 to PhD), and the added value of co-location attracts other groups, including research management groups (e.g. cancer), NIHR Clinical Research Network Teams and external partners.
- 3.2 Over the past year the focus of the operational development within the JRO has been to align the functions of the above teams to increase efficiency of research management. A major component of this work has been working with the Heads of Teams to map out where joint working currently occurs, where it should be encouraged and also where separation of function is a natural position between two organisations.
- 3.3 The piece of work has now been completed and will culminate in an away day for the JRO during which 'improvement projects' will be announced and planned to deliver any changes to JRO business process as identified by the Heads of Teams.
- 3.4 In addition to this internal work, the University Deputy Director of research services and the OUH Associate Director of R&D have met with other joint research offices to learn from their experiences of setting up such an enterprise. This has identified several models for a JRO and these are being considered further.
- 3.5 Space for accommodating any JRO expansion is already extremely limited. Additional NIHR RCF funding to support a small expansion in accommodation, working with OUH Estates is being directed towards medium term portacabin accommodation. Greater synergies and external revenues, e.g. through interaction with industry, could be realised if the JRO vision could be supported by substantial provision of new space. The business development functions and clinical research links with industry would be greatly enhanced by co-location of

JRO groups, for example within the proposed Facilities Building and/or BioEscalator projects. Inclusion of JRO functions within these new projects could form an important component of the business plan.

3.6 The Board is asked to note proposals to develop OUH-OU partnership working through the JRO in the Facilities Building and BioEscalator projects, to be developed through TME and the Strategic Partnership Board.

4. New OUH Clinical Divisions Reconfiguration

4.1 The recent reconfiguration of the OUH Divisional structure, reducing the number of clinical Divisions from seven to five, has important implications for partnership working in clinical research. The two former OUH clinical Divisions incorporating rheumatology and orthopaedics, and cardiac and vascular have now been incorporated in other Divisions. Both of these clinical domains are important components of the Musculoskeletal BRU, the Cardiovascular BRC Theme and for engagement with the respective University Departments. Recent discussions with the OUH CEO and Director of Clinical Operations have emphasised the importance of maintaining prominence for musculoskeletal and cardiovascular clinical research within the new re-configured OUH Divisional structure.

4.2 The reconfiguration of the OUH Clinical Divisions provides an opportunity to re-emphasise the importance of clinical research management, governance and performance. To ensure effective partnership working, it is proposed that each of the five new OUH Divisional management groups should include two representatives from respective OU MSD Departments, one of whom should also be a BRC Theme Leader. The OU-OUH Joint R&D Committee has requested that the OUH Clinical Divisions identify a Divisional R&D Lead who will take responsibility for coordinating clinical research studies and ensuring satisfactory performance in study initiation and recruitment.

4.3 The Board is asked to note plans to strengthen clinical research management, governance and performance within each of the proposed OUH Divisional Management Groups.

5. Clinical Research Performance Reporting:

5.1 The Government's Plan for Growth, published in March 2011, aimed to increase efficiency in initiation and delivery of clinical research, focusing on recruitment of the first patient to clinical trials within 70 days of receiving a valid protocol – the '70 Day Benchmark'; and delivery of commercial clinical trials to time and target.

5.2 NIHR has placed renewed emphasis on reporting metrics for the approvals and initiation of clinical studies, which will be used for monitoring the R&D performance of NHS Trusts. Attainment of key metrics is a requirement for NIHR funding, including BRCs/BRUs, and performance metrics are published for each NHS Trust receiving NIHR funding.

5.3 All NHS Trusts in England receiving NIHR funding are required to submit performance metrics to NIHR each quarter. The fifth quarterly report of data was submitted on 30th July 2013. A summary of this submission is provided below. Similar reports will be submitted to the Trust Management Executive on a quarterly basis, with a recommendation that regular reports are submitted to the Trust Board.

6. Summary of Performance for Q1 2013/2014

6.1 Performance should be considered in the context of the volume of research undertaken at OUH (both as host and sponsor). The Trust is involved in approx. 1250 trials including over 20,000 patients, representing a significant challenge to ensure all necessary approvals and performance. Nevertheless, there is a trend of improvement; JRO staff continue to work with researchers to identify efficiencies in R&D approvals and patient recruitment.

6.2 The 70 day Benchmark metric applies to all interventional trials and relates to the time taken to set up a study and grant permission within a Trust (target 30 calendar days); and, once that permission has been granted, the time by the investigator team to recruit the first patient (target 40 calendar days). Since the beginning of the reporting period, the percentage of reported OUH studies meeting the target timelines has shown gradual improvement. In the context of metrics for all 48 NHS Trusts in England reporting to NIHR, published in October 2013, OUH ranks in 'League 1' (i.e. upper quartile) of Trusts based on number of studies, and 5th position within this quartile in time to study initiation.

	% meeting benchmark
Q1 12/13	13.5
Q2 12/13	24.7
Q3 12/13	23.6
Q4 12/13	20
Q1 13/14	27.7

6.3 Reasons for failure to meet these targets include some delays in initial approvals and contract negotiations. However, failure to identify eligible patients for recruitment after approval of the study is also a frequent cause for delay, suggesting a lack of readiness, capacity or coordination with patient pathways for conducting the research.

6.4 Commercial Trials Recruitment to Time and Target

This metric applies to trials with a commercial sponsor and relates to recruitment numbers within the time period specified in the contract.

6.5 The number of trials reaching target recruitment by or before the target date has shown no real improvement over the past three quarters, although OUH remains one of the highest performing NHS Trusts for commercial studies recruitment.

	Number of reported trials	% meeting recruitment target
Q3 12/13	150	46.6
Q4 12/13	157	52.3
Q1 13/14	162	50.5

6.6 From Q3 12/13, a marked change in reporting requirements and criteria was introduced, making comparison between the first two quarters and later ones difficult. As they lack equivalence with approximately 100 extra trials reported in Q3 12/13, these figures have not been included within this table.

6.7 As mentioned above, one of the major factors contributing to the failure to meet the 70 day benchmark is the recruitment of patients to trials.

6.8 The Joint Research Office is exploring measures to improve the clinical research performance metrics, including:

- 6.8.1 Requiring researchers within the Trust and University to plan recruitment of the first patient prospectively, and not to approach the Trust for NHS permission until all arrangements with service support departments and plans for study initiation are in place. These issues are to be overseen by R&D leads within each of the OUH Clinical Divisions, reporting to the Divisional Director.
- 6.8.2 Ensuring that projected recruitment is sufficiently feasible to enable recruitment to time and target.
- 6.8.3 Giving consideration to withdrawal of Trust approval for studies where research performance is persistently poor.
- 6.8.4 Consideration of new requests for NHS permission in the light of the previous success of a Principal Investigator in achieving study initiation and recruitment targets.

6.9 Improved operational support of clinical research studies will be required from both OUH and OU teams within the Joint Research Office in order to achieve these demanding performance targets. Potential sources of major delay in study initiation include contract negotiations (typically undertaken by the OU Research Services office), and clinical costings (required from OUH clinical Directorates, Divisions, and clinical services such as laboratory medicine, pharmacy and radiology).

6.10 Recruitment to clinical trials remains a challenge that needs to be addressed on a Trust-wide basis, and can be addressed through the reconfiguration of the OUH Divisions by appointment of Divisional R&D leads and ensuring that clinical research performance metrics are an integral part of Divisional performance management.

7. NIHR Local Clinical Research Networks

7.1 OUH is the host organisation for what is currently the Thames Valley Comprehensive Local Research Network (CLRN), working closely both locally and nationally with other disease specific networks to support research. OUH

will, from April 2014, host the new Thames Valley and South Midlands Local Comprehensive Research Network.

7.2 The CLRN has overachieved against recruitment objectives, with 28,846 recruits over the 5 year period, well in excess of the CCRN target to double activity. In 2012/13 this comprised recruitment to 518 different studies across 13 NHS trusts. OUH is listed in the recently released Guardian League Table as second highest recruiting NHS Trust nationally, with over 16,000 recruits.

7.3 The CLRN is also subject to NIHR performance monitoring, with a focus on RM&G, and has achieved consistent progress. The CLRN overachieved the median target performance required for the complete 2012/13 financial year both for local and study wide checks, with reported 2012/13 mean timelines of 24 days and 21 days respectively.

7.4 The commercial study activity in the TVCLRN portfolio has grown significantly during the year, reflecting the emphasis we have placed on supporting the Life Sciences Industry and the expansion of local Specialties. As at year end, the CLRN achieved its highest ranking to date (3rd) in the Commercial Open Study Performance ranking and is now ranked 5th in Network-Supported Sites for Studies that Closed in 2012/13.

7.5 The OUH competed successfully in the recent national competition to host the new NIHR Local Clinical Research Network (LCRN), being designated the Host Organisation for the Thames Valley & South Midlands LCRN from April 2014.

7.6 The new LCRN replaces the existing Thames Valley Local Comprehensive Research Network (TVCLRN) and topic-specific networks in Diabetes, Stroke, Cancer and Neurodegeneration (DENDRON), incorporating these activities in to 6 new clinical research divisions covering all therapeutic areas. The LCRN depends on participation from all NHS Trusts across the LCRN region, which is coincident with the Oxford AHSN, but the governance and responsibility for the management and performance of the LCRN rests with the Board of Host Organisation, working through a designated Executive Director (the OUH Medical Director), and the LCRN Clinical Director and Chief Operating Officer. An operational manager 'Transition Lead' has been appointed by NIHR to facilitate the transition from the existing NIHR networks to the new LCRN. The new management arrangements and indicative budget allocations pose some particular challenges for the OUH and the new LCRN, which have been brought to the attention of Dr. Jonathan Sheffield, CEO of the NIHR LCRNs.

8. R&D Finance

8.1 The R&D Finance team provides management accounting and business support services to those researchers undertaking or applying to undertake research activity within OUH. The team manages circa £45m of R&D Funding annually within the Trust and a further £5m of funding in the role of as NIHR Thames Valley Network Hosting Trust.

8.2 Specifically, the team provides management accounting and business support functions for a range of different funding streams, including, BRC, BRU, Clinical

Research Facilities (CRFs), NIHR Research Capability Funding (RCF), NIHR Networks (both as host and participant), Study & Grant Funding, Commercially funded studies.

8.3 Research Capability Funding (RCF)

8.3.1 As a result of its success in attracting NIHR funding, OUH received £5.5m of NIHR RCF in 2012-13. Over the past year, R&D staff have worked very closely with OUH Director of Finance, and colleagues, to develop models of financial management that has allowed OUH to use these funds to support strategic initiatives, greatly enhancing the potential for growth of research within the Trust.

8.3.2 RCF is distributed in a structured way:

- 8.3.2.1 £2.2m has been provided to underpin research efforts and costs within the Trust. In addition, researchers are able to apply for modest support from RCF on an *ad hoc* basis.
- 8.3.2.2 A call for proposals was made for applications for strategic recruitment across the partnership and the first round has just completed. RCF funds will be used to support these key appointments.
- 8.3.2.3 In October 2013, a call was opened for proposals to fund specific research activities, in keeping with NIHR criteria for the use of RCF, during 2014/15.

8.4 Costings model

Members of the OUH R&D team are currently undertaking a review of costs of research across the Trust, included working with the PLICS initiative. This project seeks to identify the baseline costs for research activities in the Trust to support grant applications and attracting industry research in an increasingly competitive market. The costing model aims to provide more accurate and rapid reimbursement of research costs within the OUH Divisions, and support of core research infrastructure and support.

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