

Trust Board Meeting in Public: Wednesday 18 January 2017

TB2017.18

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| Title | Research and Development Governance and Performance Report |
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| Status | For information |
| History | This is an Annual Report |

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| Board Lead | Dr Tony Berendt, Medical Director | | | |
| Key purpose | Strategy | Assurance | Policy | Performance |

Executive Summary

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| <p>1. This paper presents the Research and Development Governance and Performance Report.</p> |
| <p>2. Clinical research is of major strategic and reputational importance to the Trust. OUH is highly active in clinical research, with ongoing clinical research studies in all Divisions. The Trust has a close partnership with the University of Oxford in clinical research, exemplified by the renewal of the NIHR Biomedical Research Centre (BRC), incorporating the Biomedical Research Unit (BRU), and hosting of the NIHR Local Comprehensive Research Network and the Academic Health Sciences Network. Through the Oxford Academic Health Sciences Centre the OUH has a framework for joint working between the University of Oxford, Oxford Health NHS Foundation Trust and Oxford Brookes University.</p> |
| <p>3. The Oxford BRC Annual Report 2015-16 was submitted to the NIHR, demonstrating impressive scope and scale of translational research. A successful Oxford BRC public open day was held in April 2016 to celebrate Biomedical Research in Oxford and showcase the work of the BRC. The Oxford BRC was one of the 20 successful BRCs throughout England to receive funding for 2017 to 2022. This partnership has been awarded new funding of almost £114m over the next five years, to address major NHS and global healthcare challenges, and to take advantage of new research opportunities and technologies.</p> |
| <p>4. The OUH hosts more than 1800 clinical research studies, including more than 500 clinical trials. OUH R&D activities are supported by annual revenues approaching £50m. Operationally, the Joint Research Office, comprising over 80 members of staff from both OUH and University of Oxford, supports all joint research across the partnership. There is an opportunity to develop a new strategic plan for the future development of the JRO, following decisions about the location of office accommodation.</p> |
| <p>5. The focus on clinical research performance by the NIHR remains an important priority for the OUH and the University of Oxford. OUH R&D significantly reduced the time taken to grant NHS Permissions (TMA) as well as achieving the first recruitment to such trials within the target timelines. Our recent performance in the 70-day study initiation benchmark has improved substantially, with OUH now ranked first nationally out of the most research-active NHS Trusts, with a 100% record in most of the recent reporting periods, now sustained over more than 1 year.</p> |
| <p>6. The introduction of the Health Research Authority (HRA) approvals process, which aims to simplify and accelerate NHS approvals for clinical research, has caused implementation problems that have had a significant and often detrimental consequence for Oxford researchers and for the Joint Research Office.</p> |
| <p>7. Recommendation</p> <p>The Trust Board is asked to note this report.</p> |

1. Strategic Importance of Research to Oxford University Hospitals (OUH)

One of OUH's six strategic objectives is to deliver the benefits of research and innovation to patients; developing durable partnerships with academic, health and social care partners and the life sciences industry to facilitate discovery and implement its benefits. Enabling and undertaking research in OUH also aligns the Trust with regional and national agendas to deliver evidence-based medicine in the NHS, and to create health and wealth through research and innovation. Moreover, the scale, scope and quality of clinical research activity across the Trust adds national profile to OUH as one of England's leading University Hospital Trusts, and has important beneficial impacts on clinical services, quality of care, and the recruitment and retention of clinical staff.

OUH is a highly active research organisation, with clinical research taking place in every Clinical Division. This includes both OUH-initiated studies and studies in close partnership with the University of Oxford (UoO), helping contribute to the University achieving top ranking in the world for medical and health teaching and research for the sixth year running in the Times Higher Education World University Rankings.

OUH receives a wide spectrum of funding to support clinical research, and either hosts or is a partner in key local and regional research infrastructure. The OUH R&D revenues, approaching £50m per annum, come from a variety of sources including charities, industry and public sector funders and this budget is proportionately distributed across the clinical divisions. The budget supports clinicians, nursing staff and allied health professionals across the organisation.

Maintaining a vibrant and growing research environment within OUH is central to our involvement in the initiatives listed above and to securing a leading position in the region. Moreover, the scale of our activities attracts world-class clinicians, clinician scientists and other clinical and non-clinical staff to Oxford, and contributes significantly to retention and career development.

Key partnerships for OUH in clinical research include:

The NIHR Oxford Biomedical Research Centre (BRC).

The National Institute for Health Research (NIHR) Oxford Biomedical Research Centre (BRC) is a partnership that brings together the research expertise of the University of Oxford and the clinical skills of staff of Oxford University Hospitals NHS Foundation Trust, with the aim of supporting translational research and innovation to improve healthcare for patients.

The NIHR Oxford BRC undertakes 'translational research', taking laboratory research into a clinical setting (from the bench to the bedside). This kind of research is about first-time studies of medical innovations in patients, which are intended to improve healthcare delivery for the benefit of all patients. The NIHR Oxford BRC is characterised by creative connections and collaborative relationships. These are facilitated between different research themes, with other local research resources connected by the Strategic Partnership Board. Broader connections with other NIHR Biomedical Research Centres/units, Clinical Networks and experimental medical facilities have also been developed.

BRC Leadership Workshop

The first Leadership Workshop for senior investigators and partners has been held by the NIHR Oxford Biomedical Research Centre. Sue Dopson, Rhodes Trust Professor of Organisational Behaviour and Associate Dean of Faculty at Saïd Business School, led the event. More than 35 senior investigators funded by the BRC and partner organisations such as Oxford University Innovation and the Oxford Academic Health Science Network attended the event at St Catherine's College, Oxford on 26th October 2015.

BRC Principal Fellow Competition

In January 2016, Oxford BRC and BRU announced the successful applicants for their first Principal Fellow Competition. A total of 15 researchers will each receive £15,000 a year over

three years to support their work in areas such as genetics, childhood vaccines, eye surgery, skin conditions and nursing. In addition to this, they will also receive opportunities for senior leadership training.

NIHR Oxford BRC Open Day 2016

The BRC held an open day for the public at the John Radcliffe Hospital entitled “Celebrating Biomedical Research in Oxford” on Thursday 21st April 2016. The event showcased the work of the NIHR Oxford Biomedical Research Centre (BRC). It included more than 30 stands about the work of the BRC and its partners with interactive demonstrations such as extracting DNA from strawberries, an artistic way to make a healthy beta cell to learn about diabetes and even a chance to play the classic game Operation for budding surgeons. There was also a panelled debate about the opportunities and challenges presented by the sharing of large amounts of patient data and clinician-led talks about new ways to treat cancer and the future of meningitis vaccines.

The Director of the BRC Prof Keith Channon said: “The BRC Open Day clearly demonstrated the enormous scale and scope of the research partnership between the Oxford University Hospitals and the University of Oxford. Members of the public, patients and their families were highly interested to see how scientific research, supported by the BRC, has led to new diagnostic tests and treatments that are already impacting on NHS patient care across Oxfordshire, and beyond.”

Comprehensive and up to date information about the BRC Open Day, as well as public lectures, events and Principal Fellow Competition, is available at the BRC website (<http://oxfordbrc.nihr.ac.uk/>).

ISO Accreditation

The BRC operations team achieved a further renewal of the ISO9001 designation in 2015, this extends until 2018 and will have an annual external audit against the standard.

NIHR Oxford BRC Annual Report 2015/16 Financial Year

The NIHR Oxford BRC submitted the 2015/16 annual report on the 29th July 2016 to the National Institute for Health Research. All 14 research Themes of the NIHR Oxford BRC have made excellent progress in addressing the aims and objectives of the BRC. There have been no changes to the strategy. The Themes have published **>550 papers** acknowledging the NIHR Oxford Biomedical Research Centre in peer reviewed journals during 2015-16 including papers in Nature, Nature Genetics, The Lancet, BMJ and New England Journal of Medicine and have attracted over £100M of external funding.

Oxford BRC funding award 2017-2022

The NIHR which is funded through the Department for Health, announced on the 14th September 2016 that the NIHR Oxford BRC is one of 20 successful BRCs throughout England to receive funding for 2017 to 2022 following a competitive bidding process worth a record £816M. The Oxford University Hospitals –University of Oxford BRC has been awarded new funding of almost £114M over the next 5 years. This is a further increase in funding compared with the current £94M BRC + £10M BRU awards - an excellent outcome in a highly competitive process. The Oxford Health BRC was also awarded £12.8M to support the new BRC in mental health and dementia – bringing the total NIHR BRC funding to Oxford to £126m – a 20% increase compared to the funding in the previous round.

The Oxford BRC includes **20 Research and Cross-Cutting Themes** to address major NHS and global healthcare challenges and to take advantage of new research opportunities and technologies. The full list of Themes for the Oxford BRC for 2017 to 2022 are:

- Cardiovascular
- Diabetes and Metabolism
- Gastroenterology and Mucosal Immunity
- Genomic Medicine
- Haematology and Stem Cells
- Antimicrobial Resistance and Modernising Microbiology
- Multi-modal Cancer Therapies
- Multimorbidity and Long-Term Conditions

- Neurological Conditions
- Musculoskeletal
- Stroke and Vascular Dementia
- Surgical Innovation and Evaluation
- Technology and Digital Health
- Vaccines for Emerging and Endemic Diseases
- Obesity, Diet and Lifestyle
- Respiratory
- Molecular Diagnostics
- Clinical Informatics and Big Data
- Imaging
- Partnerships for Wealth, Health and Innovation

The BRC Themes will form 'Clusters', in order to foster more effective collaboration, more efficient use of resources, platforms and manpower, greater opportunity for budget flexibility, and more systematic Theme representation and governance. A schematic showing the BRC Themes and Theme Clusters is presented in Appendix 1.

The NIHR Oxford Musculoskeletal Biomedical Research Unit (BRU). The Oxford BRU is hosted by OUH in partnership with Oxford University and was awarded £9.8m over five years from 2012-2017 and undertakes translational research in three key musculoskeletal areas: (a) epidemiology and risk factors for osteoarthritis and osteoporosis; (b) orthopaedic surgery; and (c) inflammatory arthritis (rheumatology).

The NIHR announced during the BRC Funding competition that BRUs would no longer exist. The Oxford BRC funding award for 2017-2022 has incorporated the Musculoskeletal specialty as a Research Theme.

The Thames Valley and South Midlands Local Comprehensive Research Network (LCRN).

The OUH was awarded £13.5m/year for 5 years, from April 2014, to host the LCRN and to support its activity across the Region, with six 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 the designated Executive Director (the OUH Medical Director), LCRN Clinical Director and Chief Operating Officer.

The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Oxford.

Although hosted by Oxford Health NHS Foundation Trust, OUH is a partner in, and contributor to, the Oxford CLAHRC. Through strong collaborative leadership, the NIHR CLAHRC Oxford aims to address areas of high importance and relevance for patients as well as key NHS priorities: delivering the most effective and best value services and focusing on those with greatest need – the frail elderly presenting to acute medical services, people with dementia in care homes, and those with chronic enduring illnesses and comorbidities; the highest users of NHS services.

The Oxford Academic Health Science Centre (AHSC). The Oxford AHSC was launched in April 2014 for five years. The AHSC is a partnership comprising OUH, Oxford Health NHS Foundation Trust, University of Oxford and Oxford Brookes University to bring together research, teaching and clinical care activities in the four organisations to address some of the greatest strategic challenges to health care systems here in the UK and globally. Core to this programme is six interconnected themes that focus on strategic issues which the partners believe are central to sustaining a successful healthcare system:

- Big Data: Delivering the Digital Medicine Revolution
- Building Novel NHS, University and Industry Relationships
- Modulating the Immune Response for Patient Benefit
- Managing the Epidemic of Chronic Disease

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- Emerging Infections and Antimicrobial Resistance
 - Cognitive Health: Maintaining Cognitive Function in Health and Disease.

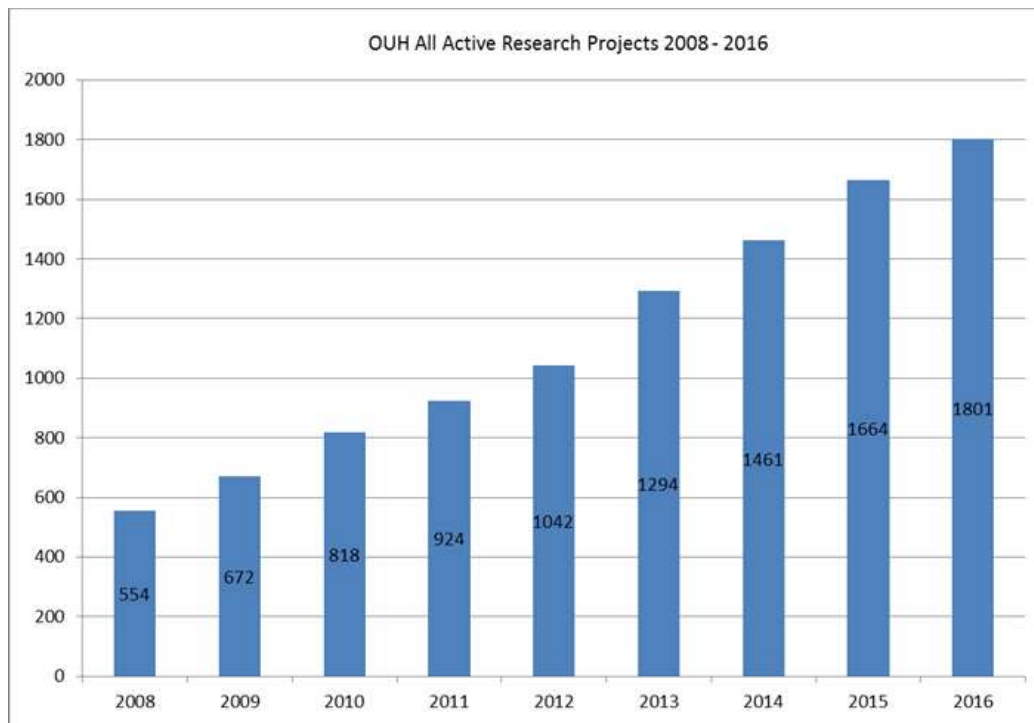
The Oxford Academic Health Science Network (AHSN). The Oxford Academic Health Science Network is one of 15 AHSNs licensed in 2013 for five years by the NHS, with the vision of 'Best health for our population and prosperity for our region'. The Oxford AHSN will support collaboration, research and innovation across the NHS, universities and business, building on our strengths to deliver exemplary care and create the strongest life science cluster. The Oxford AHSN area covers a population of 3.3 million living in Berkshire, Buckinghamshire, Milton Keynes, Oxfordshire and Bedfordshire. The NHS spends £5bn a year in this region and employs 65,000 people. The Oxford AHSN will:

- Focus on the needs of patients and local populations – support and work in partnership with commissioners and public health bodies to identify and address unmet health and social care needs, whilst promoting health equality and best practice.
- Speed up adoption of innovation into practice to improve clinical outcomes and patient experience – support the identification and more rapid uptake and spread of research evidence and innovation at pace and scale to improve patient care and local population health.
- Build a culture of partnership and collaboration – promote inclusivity, partnership and collaboration to consider and address local, regional and national priorities.
- Create wealth through co-development, testing, evaluation and early adoption and spread of new products and services.

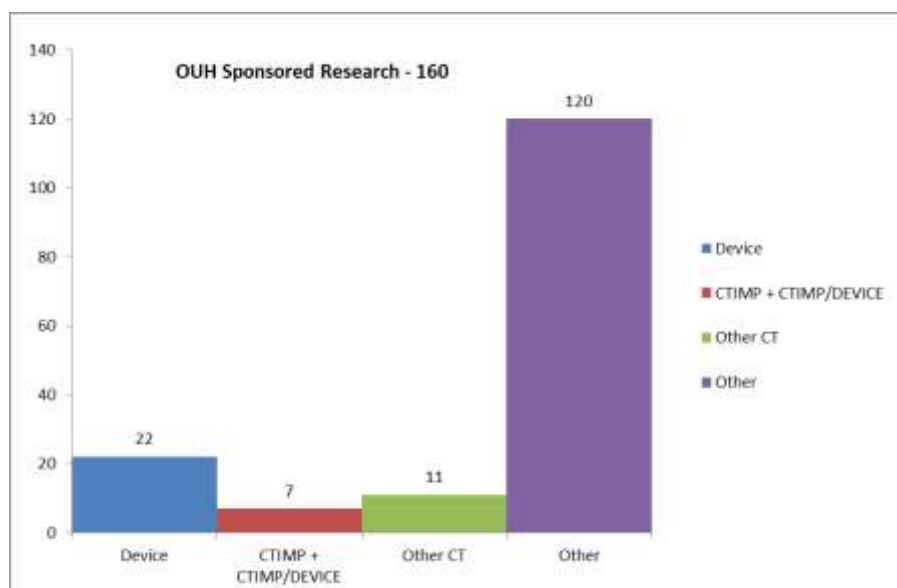
The 100,000 Genomes Project. OUH and the University of Oxford continue to play a central role in the 100,000 Genomes Project, working alongside both NHS England and Genomics England, and building on the designation of the Genomic Medicine Centre (GMC).

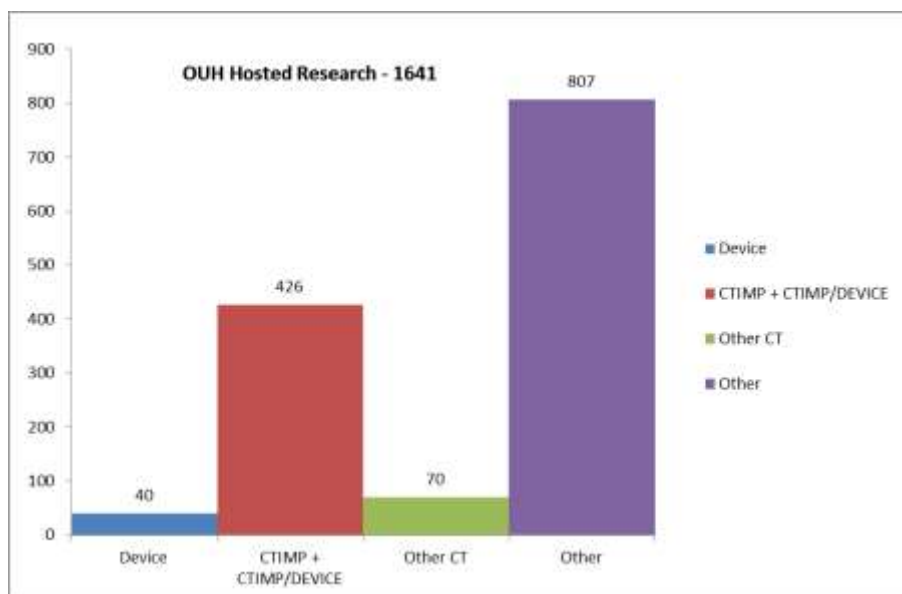
2. OUH Clinical Research Activity

The volume of active research studies has increased progressively in recent years, with a tripling of research studies of all types, since 2008, such that OUH now hosts more than 1800 active research studies. These figures are summarised in the graph below:



This number of studies can be analysed according to the nature of the research and whether it is **hosted** (i.e. OUH is the NHS organisation providing the clinical environment, capabilities and patient care) or **Sponsored** (i.e. OUH takes legal responsibility for the conduct of the study, as well as hosting), and whether the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP), or is a non- interventional study. These are shown in the graphs below. The majority of OUH hosted studies are not CTIMPs, and are sponsored by organisations other than OUH (e.g. University of Oxford, commercial partners, other NHS Trusts, other universities).





The OUHT sponsored CTIMPs are the most resource intensive to the Governance team; with all interventional trials (sponsored and hosted) being the primary focus for reporting of OUHT performance to NIHR.

3. Clinical Research Performance

3.1 Background

The Government's Plan for Growth, published in March 2011, aims 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; and delivery of commercial clinical trials to time and target.

Since June 2012, the NIHR has required that the Trust report on performance to these targets on a quarterly basis. Attainment of key metrics is a requirement for NIHR funding.

The Trust is also required to publish its own performance to these metrics on a readily accessible page on the website.

The current assessment of performance indicates that the Trust is now achieving the standards set by the National Institute for Health Research for initiation of research with 100% of evaluable trials meeting the target. Improvement is still required in meeting the standards of delivery of research to time and target.

The Department of Health threatened the imposition of financial penalties on Trusts failing to meet the initiation targets by withholding NIHR funding. Due to consistent improvement in performance, it has been confirmed Oxford University Hospitals will not be suffering any financial penalty for 2016/17.

The Department of Health has stated that similar financial penalties will still be a possibility for the 2017/18 RCF allocation, though this remains unconfirmed.

3.2 NIHR Clinical Trials Performance Indicators

3.2.1 70 day Benchmark for initiation of clinical trials:

This metric applies to all interventional trials and relates to the time taken to set up a study and grant permission within a Trust; and, once that permission has been granted, the time by the research team to recruit the first patient (with a combined target of up to 70 calendar days).

Data submitted is assessed and 'adjusted' according to the reasons provided for not meeting the benchmark. For example, if a trial involving rare diseases fails to recruit to the benchmark, this reason is deemed by NIHR to be acceptable and is therefore 'adjusted' out

of the performance data. This 'adjustment' serves to ensure that there is no pressure on the Trust to avoid undertaking research into rare diseases; thus maintaining our reputation as a centre of excellence for the treatment of, and research into, rare diseases.

R&D staff work with study teams to ensure that they recruit within the required timescale prior to each NIHR submission. A summary table of OUH 70 day performance figures is shown below:

| | Unadjusted % meeting benchmark | Adjusted % meeting benchmark |
|----------|--------------------------------|------------------------------|
| Q3 13/14 | 21.7 | 34.7 |
| Q4 13/14 | 25.9 | 42.4 |
| Q1 14/15 | 30.6 | 53.3 |
| Q2 14/15 | 42.2 | 70.3 |
| Q3 14/15 | 54.2 | 95.0 |
| Q4 14/15 | 55.1 | 100 |
| Q1 15/16 | 64.2 | 100 |
| Q2 15/16 | 60.1 | 100 |
| Q3 15/16 | 63.4 | 100 |
| Q4 15/16 | 71.7 | 99 |
| Q1 16/17 | 69.5 | 100 |

Since the last annual report there have been five more reports to the NIHR. Once the data had been analyzed by the NIHR only one trial in all five reports failed to include a reason for not meeting the benchmark. This trial was not excluded from the report and the performance dipped to 99% for reasons not meeting the benchmark being accepted by the NIHR. This is indicative of the data quality now being provided by R&D as well as the enhanced communication channels, opened and maintained across departments, and the diligence with which these reasons are verified.

In 'League 1', consisting of the most research-active NHS Trusts, **OUH is the only Trust to have continued to achieve near-100% compliance with the 70 day target.**

Whilst this achievement is unlikely to be repeated in each Quarter, a consistently high percentage, such as that achieved in each of the last six reporting periods, is considered to be sustainably attainable; a reflection of the processes and tools which have driven the observable improvement.

Please note that the way that the performance of the Trust is reported will change as more studies are submitted through the HRA Approval process (see 5.1). New guidelines have been issued that require new time-points to be collected and reported from which the metrics will be generated.

3.2.2. Commercial Trials Recruitment to Time and Target

This delivery metric is based specifically on commercially-sponsored clinical trials, which must recruit to time and target; calculated from the total number of patients and the duration of the recruitment period, as set out in the study contract.

The number of trials achieving their target recruitment by or before the target date now shows a steady improvement, as shown in the table below, although much remains to be achieved. Please note that from reporting period Q4 15/16 the required dataset to be reported was changed. Additionally as more studies complete their lifecycle through the HRA Approval route, their time points will also change, according to the new guidelines as mentioned above.

| | Number of reported trials | % of evaluable trials meeting recruitment target |
|----------|---------------------------|--|
| Q3 12/13 | 150 | 46.6 |
| Q4 12/13 | 157 | 52.3 |
| Q1 13/14 | 162 | 50.5 |
| Q2 13/14 | 191 | 47.4 |
| Q3 13/14 | 198 | 46.0 |
| Q4 13/14 | 181 | 40.5 |
| Q1 14/15 | 186 | 49.0 |
| Q2 14/15 | 176 | 55.0 |
| Q3 14/15 | 171 | 59.2 |
| Q4 14/15 | 204 | 64.7 |
| Q1 15/16 | 224 | 58.4 |
| Q2 15/16 | 226 | 57.9 |
| Q3 15/16 | 220 | 61.4 |
| | | % Trials Meeting Time and Target / Total Trials |
| Q4 15/16 | 53 (change of dataset) | 49.1 |
| Q1 16/17 | 69 | 57.6 |

Accurate feasibility assessments optimize the chance of successful recruitment to target. Early involvement with the research teams is used to ensure achievable recruitment targets are agreed in workable timelines, reflecting OUH capacity and capability. R&D teams maintain robust communication channels with research teams, to monitor ongoing recruitment figures and review feasibility, where significant changes have been made to trial arrangements, whether through substantial amendment to the protocol or arising from resource challenges.

4 Strategies to Enhance and Accelerate Clinical Trials Performance

The R&D Team continues to develop new strategies and processes, working with new national initiatives as they are implemented. The overall objective being to continue to maintain and improve the OUH performance in respect of the NIHR metrics for the initiation and delivery of clinical research:

4.1 Measures to improve rapid data management and tracking

The very large scale of the OUH clinical research portfolio requires systems that can track and alert both R&D teams and investigators within the short timelines required by the NIHR metrics.

The Research Portfolio Manager (RPM) system was upgraded in September, and continues to be developed. It is proving to be an invaluable tool for the management of clinical research performance, by more rapidly highlighting timelines in the performance of the JRO and clinical research teams. The RPM facilitates a proactive approach to the management of data, so that outliers can be identified and addressed, within a time period that will impact upon the data submitted to NIHR.

The RPM is subject to on-going development, with the intention to expand access to relevant data across the Trust, so that real time data can be monitored and potential breaches of time targets highlighted promptly to the relevant PI and Divisional Director. Thus, prompt action to rectify the situation can be implemented by the research teams. This will affect both the 70 day benchmark and the recruitment to time and target metric. Such a development will also serve to create a shared sense of ownership of clinical research performance across the Trust.

The R&D staff have developed a proactive and outward facing approach to research; the JRO ethos is of an integrated team to support clinical research across the Trust. R&D team members attend steering committees and individuals are identified as key contacts for the various Divisional groups and Clinical Trials Units.

This latest release of the RPM has enabled the Thames Valley Clinical Research Network to adopt the system as their 'Local Portfolio Management System'. This will further enhance communication and sharing of data, with the aim of avoiding duplication of effort, wherever possible. There are plans to roll out this system to the other trusts in the Thames Valley area.

4.2 Prioritising Clinical Research Performance in the OUH Clinical Divisions

TME receives a quarterly report of OUH Clinical research performance. The OUH Clinical Divisions are crucial to effective clinical research management, governance and performance, since the clinical activity and patient flows are embedded within Divisions, and research study PIs work as either substantive or Honorary Contract holders within the Clinical Division. Work is underway to appoint Divisional R&D Managers across OUH, who will take responsibility for coordinating the clinical research portfolio and ensuring overall satisfactory performance in feasibility, study initiation and recruitment within each Division. Embedded within, and professionally accountable to the Divisions, there will be a reporting line into the Joint Research Office. Two managers are now in post, in Surgery and Oncology and in the Clinical Support Services Divisions.

4.3 Incorporation of Clinical Research Performance in Statutory & Mandatory Training, and in Consultant Appraisal

The R&D Team provide both face-to-face and on-line training modules in Good Clinical Practice (GCP) for all clinical research PIs and for other researchers, to be undertaken in accordance with OUH policies. Greater 'visibility' for GCP training, and the opportunity to introduce specific aspects of clinical research performance that are relevant to both PIs and to wider groups of OUH clinical staff, could be achieved by including research training modules in the OUH Statutory & Mandatory Training requirements. Discussions have been initiated with the Learning and Development Department to establish what should be covered within the mandatory training undertaken by all new OUH staff.

OUH local requirements for consultant medical appraisal have incorporated some aspects of reporting and assessing clinical research activity, for example evidence of up-to-date training in GCP. Working with the Medical Director, there is an opportunity to modify these local requirements to include more systematic and objective information on clinical research performance for all consultants who are PIs in research studies, for example by a requirement to include listings of all studies, with performance metrics, which are made available through the JRO's Research Portfolio Management system (RPM).

The issues of both first patient recruitment and recruitment to time and target are highlighted whenever formal training is delivered to researchers. As part of their routine support role, the

R&D Team also ensure that OUH PIs, research teams and clinical staff (and their managers) are reminded at every opportunity of the importance of maintaining the highest standards in these key performance metrics.

5. Forthcoming challenges

5.1 The Health Research Authority Approvals Process

The Health Research Authority (HRA) Approval Process was implemented fully in April 2016. This is the new process for research approval in the NHS in England, that brings together review of governance and legislative compliance with the independent ethics review. The HRA states that “the new system simplifies the approvals process for research, making it easier for research studies to be set up.” However, this does not remove the role of local R&D offices, as the HRA requires their focus to change to ensuring that Trusts have appropriate Capacity and Capability to undertake each project as it is submitted.

HRA approvals represent a significant change to research governance nationally, and has already had a dramatic effect on the business of the Joint Research Office (JRO), both for the University and Trust. There remain many problems in the HRA process at this stage in its implementation: Lack of clarity in communications by HRA with researchers, sponsors and R&D offices; errors in the HRA assessments; inconsistencies in implementation of processes, and development of informal procedures that undercut transparency and equity. For example, work is prioritised according to who raises concerns with the greatest vigor. Provision of support to researchers by JRO staff, in order to address these issues, is time-consuming and impacts adversely on expected timelines.

In order to support the HRA, managers in the JRO take every opportunity to be involved in consultations and updates on the process at a national level: Oxford is represented in groups such as the NIHR Research Champions; the Research & Development Forum Strategic Group; The HRA Sponsor Reference Group; HRA Amendment Working Group and the HRA model Non-Commercial Agreement (mNCA) redraft group. The Head of Research Governance has recently attended the Academy of Medical Sciences’ review of the current situation, in order to highlight the concerns of researchers, the University of Oxford and OUH..

5.2 Additional requirements in metrics reporting

The NIHR implemented an additional metric reporting studies receiving financial support from NIHR Biomedical Research Centre (BRC); NIHR Biomedical Research Unit (BRU) and from the NIHR Clinical Research Facility (CRF). Each such study has to report Quarterly on their recruitment that quarter. The implementation of this report has been complex and is still being refined.

5.3 Maintaining good research practice

Successful recruitment must not be at the expense of good and ethical research practice, ensuring that approach and recruitment is always appropriate. The R&D Governance team undertakes monitoring, risk based audits and more brief compliance checks on interventional trials and research studies, to ensure this.

6. Research Management and Governance

6.1 Background – NHS Research Governance

Research governance refers to the framework in OUH to manage the research process from end to end, to ensure that research is undertaken in a safe, appropriate and ethical manner, in accordance with national guidance and applicable laws to ensure that maximum benefit is derived from research of public and patients. These include:

- **The Health Research Authority (HRA)** that has responsibility for both the HRA Approval Process in England and the National Research Ethics Service (NRES), which is responsible for all Research Ethics Committees (RECs).
- **The NHS Research Governance Framework (RGF)** that sets out a framework for the

governance of research in health and social care. This includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. The HRA intends to replace the RGF with a new simplified framework, the timelines for this are not clear.

- **EU Clinical Trials Directive** (2001/20/EC) provides a framework which sets out how clinical trials investigating the safety or efficacy of a medicinal product in humans must be conducted. The EU Clinical Trials Directive was transposed into UK Law as the Medicines for Human Use (Clinical Trials) Regulations 2004 and came into force on 1st May 2004, forming the basis for the UK Clinical Trials Regulations 2004.

6.2 Local Frameworks for R&D Governance, Training and Monitoring

Locally, clinical research is governed by a number of OUH Trust policies:

- Safety Reporting in Clinical Research
- Sponsorship of Clinical Research Studies
- Trust Management Approval for Clinical Research
- Research Protocol Amendments
- Monitoring and Audit of Research Studies
- Research Grants Policy and Procedures
- Management of Intellectual Property
- Integrity in Research
- Receipt, Storage and Handling of Investigational Medicinal Products

These policies are underpinned by a suite of Standard Operating Procedures (SOP) within R&D. Policies and SOPs are updated in response to national and local developments.

The policies are all available on the OUH website and specific attention is drawn to them during Good Clinical Practice (GCP) training. The content and requirements of the policies are also covered within this training. Through collaboration with the University of Oxford Clinical Trials and Research Governance team (CTRG), GCP training is provided to cover all research-related legislation and GCP; courses being designed for both staff new to trials and an update for experienced researchers. GCP training is a legal requirement of the Regulations and the Research Governance Framework. All researchers, in the Trust and the University, are required to have undertaken this training every three years as a minimum.

A training course is provided for clinical researchers, specifically designed for those not engaged in the conduct of a CTIMP. Informal training is provided in the form of advice and support to researchers and their teams.

The R&D Governance team ensure that all Clinical Trials of Investigational Medicinal Products (CTIMP) and device trials, for which the Trust has taken on the role of Sponsor, are monitored, to assure the Trust of compliance with the relevant regulations. In addition, a number of hosted CTIMPs are selected for audit, either where concerns have been raised, or according to a risk assessment. For a selection of research studies, compliance checks are undertaken periodically. Such checks involve assessing levels of compliance in specific areas of research conduct, e.g. informed consent procedures and safety reporting requirements.

6.3 Strengthening Research Governance in OUH

OUHT has a very large research portfolio and has established a robust approach to governance in accordance with national standards.

To maintain the highest standards, all members of staff involved in research must be aware of the need to comply with the policies and procedures for research governance in the Trust. This is most easily achieved by ensuring that R&D activities are fully integrated, reported and monitored in the Clinical Divisions. Divisional R&D Managers have been appointed with a mandate to promote research, oversee performance and ensure that research active staff have adequate training to undertake trials and studies in a safe manner. This effective local/divisional implementation and monitoring of governance policies will promote patient safety in OUHT.

Greater awareness of R&D governance, for training in GCP and the requirements of R&D SOPs and policies could be achieved through Statutory and Mandatory Training, through Appraisal and through Divisional audit and training activities, the goal being to ensure that the vast majority of clinicians are able to support well governed research by understanding the processes that should be demonstrable by investigators in the clinical environment.

7 Research Management and the Joint Research Office (JRO)

7.1 R & D Finance

7.1.1 Year End Financial Position

The Trust obtained Foundation Trust status on 1 October 2015.

For the financial year, 2015-16, the OUH reported a breakeven financial position for Research and Development. The budget includes income and spend for major OUH-OU NIHR infrastructure programmes (BRC, BRU, LCRN etc).

As detailed in the table below, in total for Research and Development for the Trust, actual income of £46.2m was recovered and expenditure of an equal amount was committed (£46.2m).

| OUH R&D Only | Outturn 2015-16 | | |
|--------------------------|-----------------|---------------|----------------|
| | Plan £m | Actual £m | Variance £m |
| Income | | | |
| Other Income | 45.3 | 46.2 | 0.9 |
| Total Income | 45.3 | 46.2 | 0.9 |
| Expenditure | | | |
| Pay | (34.7) | (35.5) | (0.8) |
| Non-Pay | (10.6) | (10.6) | (0.1) |
| Total Expenditure | (45.3) | (46.2) | (0.9) |
| EBITDA | 0 | 0 | 0 |

7.1.2 Financial Planning for 2015-16

For the financial year, the Trust has set an annual income and expenditure plan of £52.6m for Research and Development. The plan represents:

- NIHR funded schemes of £43.6m (83% of total budget)
- And £9.0m for balances generated from R&D activities and infrastructure costs

The overall plan for 2016-17 reflects:

- A reduction to NIHR funding levels of circa £0.9m from 2015-16. This is due in part to a) known variation in contract values of £0.4m, b) changes to level of market forces factor and RCF applied to LCRN budget and c) a reduction of funding received for Trust Research Capability Funding (see below).
- An annual plan for R&D income and expenditure relating to study/grant activity has been set (£8.0m). A budget was not previously set.

7.1.3 Research Capability Funding

Research Capability Funding (RCF) is allocated to research active NHS organisations in respect of major NIHR programmes, and for the NIHR Senior Investigators associated with the Trust. The Trust has received an annual allocation of £5,471k for the financial year 2016-17.

This funding has been reduced by 5.5% compared to the funding received in 2015-16 (£5,787k). The reduction was not, in any part, due to any performance metric or benchmark, but reflects the pressure on NIHR budgets leading to a reduction in all RCF awards from NIHR this year.

RCF will be used across the OUH-UoO partnership in line with NIHR policy and guidelines.

Funding decisions and commitments against the funding will be managed against the background of potential changes to R&D funding and particularly the transition between BRC2 and BRC3 funding allocations. In managing and minimising any emerging financial risks, it is anticipated that the allocation will be fully committed.

7.2 R&D Recruitment

The OUH Head of R&D Operations, Dr Christopher Bray commenced employment with the Trust on 5th September 2016. He is responsible for the OUH R&D management functions through the Joint Research Office (JRO) and will oversee the delivery of services to facilitate and support high quality clinical and translational research within the OUH-UoO Partnership and its collaborators.

The role of OUH Research and Development Lead has been promoted to Head of Research Governance and will continue to ensure that the Trust is compliant with all relevant research governance legislation and guidance relating to the conduct of clinical trials and research studies, in its role as research sponsor and host organization. The Head of Research Governance will directly be responsible for the leadership and direction of the R&D Governance teams.

These two senior roles will align to establish and lead the effective joint working of R&D teams within the JRO, working closely with the Deputy Director of UoO Research Services.

It is expected that up to three additional R&D Divisional Managers will be recruited to extend the specialist local support provided to all the OUH Divisions, working closely with the JRO.

7.3 Accommodation for the Joint Research Office

The JRO's current accommodation at Block 60, Churchill Hospital is in a poor state of repair and is due to be demolished as part of a major redevelopment plan. OUH does not wish to invest further in the building, so Block 60 therefore needs to be vacated in an orderly manner. OUH has alternative accommodation available now at Unipart House, Cowley and the University (UoO) will have additional accommodation available at Boundary Brook House (BBH) next year. Neither provides an ideal standalone solution to meet either our current or our future needs, but the options for new accommodation also brings significant opportunities for the future development of the JRO.

Developing a 'Greater JRO' would enable more effective partnership working with other related groups in Oxford including Oxford Health NSH FT, the AHSC and the Thames Valley and South Midlands LCRN (hosted by OUH). This would be facilitated significantly by co-locating these groups. However, it is uncertain whether BBH would be able to accommodate all the staff working in the current JRO, and even if feasible to do so, there would be no possibility of further expansion, including those from the other groups expected to join a Greater JRO.

The overall plan is therefore to use both of the buildings available. The JRO's OUH staff will move as soon as possible (by the end of 2016) to Cowley, which will also become the main base for the new groups joining the Greater JRO. The JRO's UoO staff will move to BBH when it becomes available next year. Maintaining the existing effective relationships between OUH and UoO staff, as well as OUH staff and researchers on the clinical campuses will be given a high priority. This will require some new working practices and careful utilisation of the shared facilities that will be available at each site for hot-desking and meetings. Additional resources such as videoconferencing facilities for small group use may also be required at both sites.

Recommendation

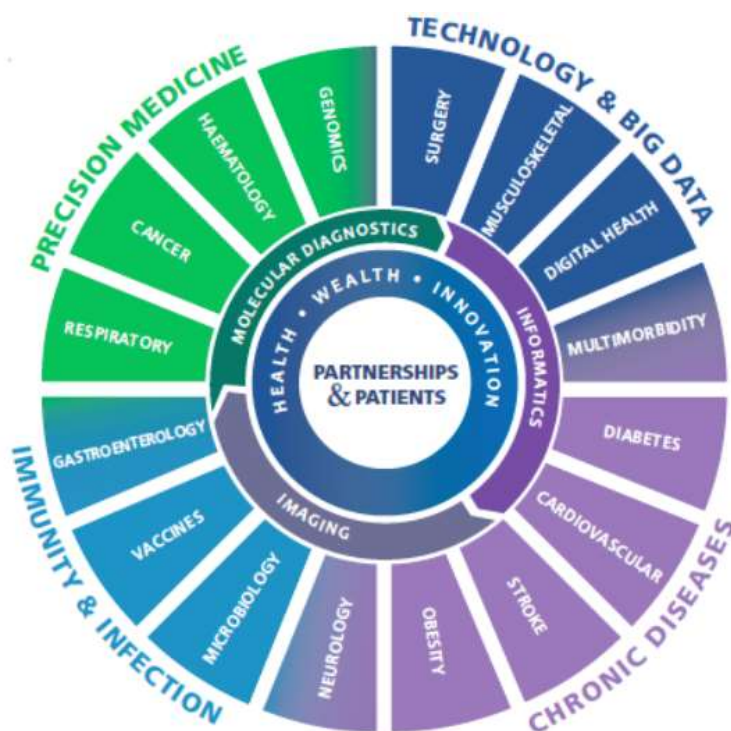
The Trust Board is asked to note this report.

Dr Tony Berendt
Medical Director

January 2017

Report prepared by:
Professor Keith Channon
OUH Director of R&D

Appendix 1 – Schematic of Oxford BRC Themes and Theme Clusters



THEME CLUSTERS:

PRECISION MEDICINE

- Respiratory
- Multi-modal Cancer Therapies
- Haematology & Stem Cells
- Genomic Medicine

TECHNOLOGY AND BIG DATA

- Surgical Innovation & Evaluation
- Musculoskeletal
- Technology & Digital Health

CHRONIC DISEASES

- Multimorbidity & Long Term Conditions
- Diabetes & Metabolism
- Cardiovascular
- Stroke & Vascular Dementia
- Obesity, Diet & Lifestyle
- Neurological Conditions

IMMUNITY & INFECTION

- Gastroenterology & Mucosal Immunity
- Vaccines for Emerging & Endemic Diseases
- Antimicrobial Resistance & Modernising Microbiology