

**Report to the Meeting of the**

**Oxford Health NHS Foundation Trust**

**Board of Directors**

**27 September 2017**

**Research and Development Report**

[1 Clinical Quality and Care 4](#_Toc493081342)

[2 Networks and Collaborations 4](#_Toc493081343)

[2.1 Oxford Academic Health Science Network (OAHSN) 4](#_Toc493081344)

[2.2 Oxford Academic Health Sciences Centre (AHSC) 7](#_Toc493081345)

[3 National Institute of Health Research Infrastructure 7](#_Toc493081346)

[3.1 NIHR Collaboration in Leadership in Applied Health Research and Care (CLAHRC) 7](#_Toc493081347)

[3.2 NIHR Diagnostic Evidence Co-operative (DEC) 8](#_Toc493081348)

[3.3 NIHR MedTech and In Vitro Diagnostic Co-operatives (MIC) 9](#_Toc493081349)

[3.4 NIHR Oxford cognitive health Clinical Research Facility (CRF) 10](#_Toc493081350)

[3.5 NIHR Biomedical Research Centre (BRC) 13](#_Toc493081351)

[3.6 NIHR Clinical Research Network (CRN) 17](#_Toc493081352)

[4 Research Set Up, Management and Governance 17](#_Toc493081353)

[4.1 Pipeline Group Meetings 17](#_Toc493081354)

[4.2 HRA Approvals 17](#_Toc493081355)

[4.3 Capacity and Capability 18](#_Toc493081356)

[4.4 Contracts and Confidentially Disclosure Agreements 18](#_Toc493081357)

[4.5 Costings 18](#_Toc493081358)

[4.6 Study Data Capture 18](#_Toc493081359)

[4.7 Monitoring and Auditing of Research Projects 19](#_Toc493081360)

[4.8 Studies and Participant Recruitment 19](#_Toc493081361)

[5 Pharmacy 20](#_Toc493081362)

[6 Case Records Interactive Search (CRIS) 20](#_Toc493081363)

[7 Trust Governance and Reporting Mechanisms 21](#_Toc493081364)

[7.1 Reporting and Governance 21](#_Toc493081365)

[8 Finance 22](#_Toc493081366)

[8.1 Income 22](#_Toc493081367)

[8.2 FY18 Performance 23](#_Toc493081368)

[8.3 Collaboration in Leadership in Applied Health Research & Care (CLAHRC) 23](#_Toc493081369)

[8.4 Biomedical Research Centre (BRC) 24](#_Toc493081370)

[8.5 Research Capability Funding (RCF) 24](#_Toc493081371)

[8.6 NIHR Study Income 25](#_Toc493081372)

[8.7 Clinical Research Facility (CRF) 25](#_Toc493081373)

[8.8 Subcontracted study income 26](#_Toc493081374)

[8.9 DEC \ MIC 26](#_Toc493081375)

[8.10 Clinical Research Network: Thames Valley and South Midlands (CRN) 26](#_Toc493081376)

[8.11 Grant Applications 26](#_Toc493081377)

[8.12 Risks - Redundancy Costs 27](#_Toc493081378)

[8.13 Oxford Academic Health Science Network (OAHSN) 27](#_Toc493081379)

[8.14 Summary of Funding Timeframes 28](#_Toc493081380)

[9 Staffing 28](#_Toc493081381)

[10 Estates 29](#_Toc493081382)

[11 Communications 29](#_Toc493081383)

[11.1 Significant Communications 29](#_Toc493081384)

[11.2 Additional communications activities: 31](#_Toc493081385)

# Clinical Quality and Care

Participation in research produces widespread benefits for patients and, more generally, improvements in quality of care. A Censuswide comsumer poll of 3,000 people in England, commissioned by the NIHR published data in September 2014 saying that 95% of those as responding stated that it is very important that the NHS carries out clinical research, with 85% or people agreeing that they would be very or somewhat willing to take part if they were diagnosed with a medical condition or disease. This accounted for the main factor that was most likely to motivate them into taking part, along with if a friend/family member was taken seriously ill and didn’t have the treatment they needed. The majority of those surveyed said that clinical research takes place within the NHS, Universities and Clinical Trials Units. Oxford health NHS FT has strong links to the University of Oxford, which has been rated as the world’s best university for clinical, pre-clinical and health subjects for the past 5 years (2011- 2016 THE World University Rankings), top ranked in the Research Excellence Framework 2014 for research quality in Psychology, Psychiatry and Neuroscience and third highest University in the areas of mental health and dementia in the RAND report commissioned by NIHR in 2015. In addition Oxford Health NHS Foundation Trust was the top ranked mental health Trust in the Mental Health Highlight Area in the NIHR RAND report

# Networks and Collaborations

## Oxford Academic Health Science Network (OAHSN)

Following the decision by the Board to reduce funding in January, restructuring of Best Care is complete. The Best Care team has worked hard to find new sources of funding (£500k), enabling five of the eight affected networks to continue, with the redeployment of most of those affected. Thanks goes to the HR teams in Oxford Health and Oxford University Hospitals. <http://www.oxfordahsn.org/wp-content/uploads/2017/07/170704_Year-5-Q1-Oxford-AHSN-FINAL.pdf>

Oxford Health NHS FT is hosting three OAHSN themes;

* Early intervention led by Prof Belinda Lennox and Dr Matthew Broome for the Thames Valley, Matt Williams (Manager)
* Anxiety and Depression led by Prof David Clark and Ineke Wolsey (Manager)
* Dementia led by Dr Rupert McShane
  + 1. **Early Intervention Theme**

Most NHS mental health services have high variability coupled with patchy record-keeping. However, by using a common assessment tool with providers’ electronic health records, early intervention in psychosis (EIP) services in the Oxford AHSN region are working towards unrivalled data quality and completeness leading to higher standards and reduced variation. The new matrix tool is helping ensure more people with first episode psychosis get specialist help first time. An audit published in March 2017 showed that patients receiving treatment within 14 days increased from 64% (Sept 2015) to 83% (Sept 2016).

The programme developed an innovative real-time data analytics and visualisation tool called the EIP Matrix to help benchmark the quality of services. It is aligned to NICE key performance indicators including, duration of undiagnosed psychosis, interventions delivered, physical health and employment and education.

The Oxford AHSN Early Intervention in Psychosis Clinical Network has developed a shared approach since 2014, hosting the NHS England (South) Early Intervention in Psychosis (EIP) preparedness and assurance function. This involves working with NHS mental health service providers across the south of England (five AHSN areas), Wessex AHSN, third sector, NHS England, Public Health England, NIHR CLAHRC Oxford and carers. This includes 30+ organisations across 50 CCG areas from Kent to Cornwall.

Locally-based quality champions were appointed to own local data quality and completeness. Regular data reviews around an evidence-based, validated dataset were carried out and workshops and shared learning events took place. Peer reviews were organised to enable teams to learn from each other's strengths.

Best practice case studies were captured along with a video which has been viewed over 36,000 in 12 months: <https://www.youtube.com/watch?v=hGP_7cEP5cI>

This is leading to better quality care and reduced symptoms. Annual savings across southern England are estimated at £16m based on a £4,000 saving per patient per year for those accessing EIP services compared to standard care (from health economic analysis - Tsiachristas et al BMJ Open, 2016).

There has been a significant increase in patients referred to smoking cessation services, from 21% in 2015 to 66% in 2016. Over the same period there has also been a 46% increase in individuals and families accessing family interventions, (from a 17% baseline to 24.9%). Almost half (42%) of people accessing EIP are in employment and/or education, whilst 72% are in settled accommodation.

### Anxiety and Depression Theme

The focus for the last 6 months has been on 3 projects:

#### Improving Access to Psychological Therapies

Continuous Performance Improvement of all our Improving Access to Psychological Therapies (IAPT) services (Berkshire, Buckinghamshire, Oxfordshire and Milton Keynes) to maintain current high recovery rates (consistently some 5% higher than the national average and requirement) and support increased number of patients who will move to recovery following their treatment. Recovery rates average for Q1 this financial year for Thames Valley and Milton Keynes holding at 56.4% despite considerable upheaval within our services as they are recruiting new staff into the new Integrated IAPT services. Importantly, services are also increasing number of patients who have moved to recovery month on month from 938 in April to 1159 in June 2017. We have now also achieved a completion rate for ICD 10 recording of a problem descriptor of between 93% and 97% which, as we know, is directly related to higher recovery rates.

Careful analysis of monthly performance data, identifying areas for improvement and supporting the implementation of improvement plans. Focus these last 6 months has been on increasing ICD coding and improving use of paired Anxiety Disorder Specific Measures (ADSMs) as the data has helped us understand that using the generic assessment tools only (PHQ9 and GAD7) may show a patient as having moved to recovery when, in fact, they have not recovered from the specific symptoms associated with their specific anxiety disorder including Post-traumatic stress disorder (PTSD), Obsessive compulsive disorder (OCD), Agoraphobia and panic disorders. So it is very important for all clinicians to use paired ADSMs to ensure full recovery and prevent relapse. Other areas for focus have been initiating additional, highly specialised skills training by world leading experts to improve recovery rates for specific disorders including OCD and Social Anxiety Disorder.

#### Durability of Clinical Gains

A number of patients who agreed to participate in this project across Thames Valley and Milton Keynes and who were discharged in June 2016 have now completed two follow-up questionnaires assessing depression and anxiety scores since discharge at 6 months and 12 months. It is only a small sample and data is currently being processed and a paper will be available in the next couple of months on outcomes of this pilot. In addition there is hope to obtain funding for phase 2 of this project which will consist of developing an app for follow-up studies.

Maintaining therapeutic gains: this work stream is part of the durability of clinical gains project and is run by our Patient Forum members (ex-service users and appointed PPI staff from all TV and MK services). It aims to find out what support patients need following discharge to stay well. We have now signed off the questionnaire to be sent out to all ex-service users on the various ‘people banks’ within Thames Valley and Milton Keynes in October pending audit committee approval.

#### Health economics evaluation

Health care utilisation evaluation of additional, integrated and co-located IAPT services for patients with Long Term Conditions (LTCs) and co-morbid depression and/or anxiety has been ongoing. All Thames Valley IAPT services were successful in being awarded Early Implementer status and funding as well as national funding for a Thames Valley wide health care utilisation evaluation. The Anxiety and Depression (A&D) Network is working with Professor David Stuckler, Professor of Sociology and Political Economy at the University of Oxford. Across the Thames Valley work has continued to the same service evaluation protocol and design within both a stepped wedge design comparison (health care services utilisation at a given point in time when one patient cohort has started treatment and another hasn’t) as well as pre and post treatment healthcare utilisation evaluation. Working across TV in a consistent manner means will enable to both evaluate services locally (specific information for local commissioners and providers) as well as across TV (which will boost numbers and provide opportunities for additional analysis).

### Dementia Theme

Health Education England Thames Valley is supporting the Oxford AHSN Dementia Clinical Network to deliver education and training for staff across the region:

* Continue with educational webinars (CPD)
* Sustain care home in-reach team Best Practice Network
* Sustain post-diagnostic support Best Practice Network
* Primary care (including GP education)
* Annual learning event

## Oxford Academic Health Sciences Centre (AHSC)

The ASHC will submit a separate report to the Board regarding activity across the four partner organization in Oxford. These reports will be on a biannual basis

# National Institute of Health Research Infrastructure

## NIHR Collaboration in Leadership in Applied Health Research and Care (CLAHRC) Theme Updates

### Theme 1

All projects on target to complete December 31, 2018

Newly adopted/funded projects

* Dementia Network - Webinar programme to maintain and increase Thames Valley and reduce variation in diagnostic and prescribing practice in memory services. Patient and carer quality of life questionnaire evaluation (Theme 3 collaboration) evaluating questionnaire to assess patient and carer well-being. Care homes in-reach teams - best practice network brought together health teams that 'in-reach' into care homes across Thame Valley to share good practice relating to care home residents living with dementia, and to build on the knowledge gained from the Well-being and Health for People with Dementia (WHELD) study. Complementary to the ongoing Care Home work in Theme 1 (Fossey.J). Driving and cognitive impairment - feasibility study for computerised cognitive test battery called Driveable to assess if a patient needs an on-road assessment. Pilot is underway. Telematics - working with an SME, to assess the effectiveness of 12v car cigarette lighter dongles to capture real-time driving behaviour data of people with cognitive impairment to identify high risk driving patterns. Computerised analysis of brain images (Oxford Mental Health BRC collaboration) - introduction of a software package to read brain scans.
* Anxiety & Depression Network - Enhancing Recovery rates through understanding variability and increasing number of patients successfully treated for anxiety and depression disorders within our Improving Access to Psychological Therapies services (IAPT) - overall objective for this project is that more patients will recover following treatment. Durability of clinical gains study: what are the longer term benefits to patients who achieve recovery? the durability of gains obtained in IAPT is largely unknown as services are not required to routinely follow-up discharged patients. This study looks at how we can best obtain robust follow-up data from patients who have completed a course of psychological therapy and what the long-term benefits are of treatment. What is the benefit of integrated IAPT interventions for people suffering with Long Term Conditions and co-morbid anxiety/depression? All Thames Valley CCGs in partnership with their providers successfully applied to become Early Implementers and are setting up additional, integrated and co-located services. A core requirement for funding was outcome data collection from the start of the project (clinical as well as health economics across primary and secondary care).and the ability of Early Implementer sites to link data. We have committed to work with Professor Stuckler and project manage a robust health economics evaluation on behalf of all TV CCGs and provider services for national dissemination.
* CAMHS Evaluation - Evaluation of the reconfigured CAMHS service across the Thames Valley
* Evaluation of street triage service - Street triage is an NHS commissioned service where mental health workers support police officers to reduce the detention of those with mental illness in police stations, supporting the most vulnerable in society. CLAHRC is evaluating the outcome of this service in the Thames Valley, using routinely collected data from the police and NHS records systems.
* Understanding patient trajectories and predicting risk of poor long term outcomes in patients discharged from Early Intervention in Psychosis care: These services are time limited intervention, with treatment given for up to three years, and little is known about the clinical pathways and long-term outcomes of patients following their discharge. There is some evidence to suggest that the greater improvement made by those who have early intervention care may not be sustained once they have left the service. This study will identify and describe the clinical trajectories of thousands of early intervention patients, and model the clinical and sociodemographic factors associated with a risk of poor outcomes in this population. Through identifying patients who have a high risk of relapse this research has the potential to help with the creation of targeted interventions to improve the transition process and aftercare of patients following discharge from early intervention.
* Cost of Self Harm Project Update - A press release was issued on September 7 2017 and was picked up by the Oxford Mail. The coverage was extremely positive <http://www.oxfordmail.co.uk/news/news_bites/15526483.Self_harm_cost_to_NHS_set_at___162m/> . Further information is provided below.

### Theme 2

All projects on target to complete December 31, 2018

### Theme 3

The PPI function of the CLAHRC has now been embedded in this Theme. A PPI steering group chaired by Professor Ray Fitzpatrick has been set up and meets quarterly. The CLAHRC are in discussion with both BRC's regarding an overarching PPI stream of research which will encompass all 3 infrastructure awards. This is at an early stage.

### Theme 4

All projects on target to complete December 31, 2018

### Theme 5

All projects on target to complete December 31, 2018

DPhil SNAP-HT trial is now completed and the results are due to be published before Christmas

### Theme 6

DROPLET Trial (bolt on project) and the Meal Replacement Systematic Review are now complete and have been submitted for publication.

Despite lengthy delays due to issues with Tesco's research liaisons team, the final contract is now with the University and is expected to be signed in the next 2 weeks. The announcement of the collaboration is embargoed until the contract is signed. The project as a whole has not been delayed as a result of this as slippage was foreseen and factored into the design

### Cost of Self Harm

Professor Keith Hawton and Dr Apostolos Tsiachristas have published the results of their CLAHRC supported project ‘Cost of Self Harm’ in Lancet Psychiatry. In conjunction with OH NHSFT, University of Oxford, London School of Economics and the Department of Health, a press release was issued on September 7, 2017:

The hospital costs of self-harm: Study from Oxford reveals the health service costs for hospital care of people who self-harm, emphasising the need for effective clinical services and prevention initiatives.

Self-harm by intentional poisoning or self-injury is a very common reason for presentation to hospital, especially in young people. It is often repeated and carries a significant risk of future suicide. Self-harm was included as a key issue in England’s National Suicide Prevention Strategy for the first time this year. Until now very little information has been available on the costs of hospital care for people who self-harm.

Researchers from the University of Oxford and the London School of Economics have linked information from a register of people presenting to a large general hospital following self-harm to financial records in order to estimate the economic costs of their medical and psychiatric care while in hospital. In a report published in The Lancet Psychiatry they showed that the average cost for each episode of self-harm was £809, with higher costs for adolescents than adults. They estimated that if such costs apply to all self-harm episodes presenting to hospitals in England the overall cost to the NHS amounts to £162 million each year.

Professor Keith Hawton, the senior author of the report and Director of the Centre for Suicide Research based at the University of Oxford’s Department of Psychiatry, said “the findings of this study highlight the need for high quality services for people who self-harm to provide effective medical care and to ensure that patients receive careful psychiatric assessment in order to plan suitable aftercare. The findings also underline the need for large-scale initiatives to prevent self-harm, such as school-based psychological well-being classes and other community programmes aimed at improving emotional health.”

This research was supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Oxford and the Department of Health.

The paper is available via this link: <http://www.thelancet.com/journals/lanpsy/article/PIIS2215-0366(17)30367-X/fulltext?elsca1=tlxpr>

### Forward Look and High Profile Developments

The next CLAHRC Annual Symposium will be held September/October 2018.

## NIHR Diagnostic Evidence Co-operative (DEC)

* There have been approximately 14 formal company interactions in the last six months, covering wound management, respiratory disease management, infection and antimicrobial prescribing, wearable patient monitoring, and smart drug delivery.
* The DEC has prepared a paper entitled ‘Common evidence gaps in point-of-care diagnostic test evaluation: a review of horizon scan reports’. This paper has been accepted for publication by BMJ Open and will be published in the near future.
* Dr Philip Turner visited the HQ of the British In-Vitro Diagnostics Association on two occasions during the reporting period to present the work of the DEC and to discuss antimicrobial resistance with the external affairs and AMR working parties respectively.
* Innovate UK Small Business Research Initiative Phase II project: We supported our phase I industry collaborator Mologic Ltd to apply for Phase II funding. The application was funded to £2m, with the second phase covering the continued development and trialing of the proposed diagnostic for COPD exacerbations. The DEC will provide academic clinical guidance and will revise and update the health economics model which was developed in the first phase.
* The health economics modelling exercise from the Innovate UK SBRI phase I project (above) is being prepared for publication by DEC researchers.
* Ongoing projects include the METRIC (MEasuring TempeRature In Children) trial, which is a methods comparison study of different thermometry devices.
* The 2017 UK Diagnostics Forum took place on the 16-17 May 2017 at Lady Margaret Hall with the theme 'Diagnostics in Times of Change'. The event featured a number of very high profile speakers and was rated very positively by attendees.
* The Diagnostic Evidence Workshop is due to be held at Worcester College in September 2017. We have awarded five full bursaries to SMEs to attend this event through open competition. The bursaries have been provided through an award made to the DEC from the MRC’s Proximity to Discovery fund.
* The DEC in collaboration with the NIHR WoundTec HTC held a wound management workshop at St Anne’s College Oxford in July. The event featured clinicians/academics from Oxford, Cardiff and Birmingham, with representatives from four specialist wound-management companies who are developing diagnostics and POC imaging devices. The Oxford Health Tissue Viability Team lead was present together with a senior nurse from the chronic wound management team and representatives from plastics.
* The DEC Health Technology for Tomorrow seminar series which was funded through the MRC Proximity to Discovery fund completed during this reporting period. These seminars covered e-health, wearable technologies and imaging devices for use in acute community settings. Companies developing exciting technologies were invited to present at the seminars, which were followed by panel discussions and networking lunches. Two of the seminars were held in association with the EurOOHnet (European Out of Hours Network) and SW-SAPC conferences (Society for Academic Primary Care, Southwest Region); both high profile events. The seminars have resulted in ongoing interactions between seminar speakers and the DEC.

## NIHR MedTech and In Vitro Diagnostic Co-operatives (MIC)

It has been announced that the NIHR Community Healthcare Medtech and In Vitro Diagnostic Co-operative application, submitted earlier this year has been successful, with Oxford Health NHS FT hosting the award - £1.24 million over five years, starting in January 2018. The Oxford MIC is one of 11 newly funded NIHR MICs announced in September by Health Secretary Jeremy Hunt to coincide with the publication of the Life Science Industrial Strategy

University of Oxford researchers will lead a medical diagnostics co-operative that will drive forward the development, evaluation and uptake of new medical diagnostic technologies to improve outcomes for patients in the community. It will partner with commercial medical technology developers to ensure new concepts are rigorously evaluated, applicable in the NHS and have far-reaching clinical benefit.

The MIC will bring together and synergise experienced health researchers, end users, and clinical experts skilled in the development and evaluation of diagnostic tests.

By focusing on key NHS priorities, the new initiative aims to speed up the development, evaluation, and deployment of diagnostic tests that support healthcare professionals to make better decisions for their patients in areas such as antibiotic prescribing, child health and chronic illness. The focus will be on home and community care, including GP surgeries, acute medical centre, out-of-hours care and home visits.

The MIC will be led by the Clinical Director, Professor Chris Butler, who is Professor of Primary Care Health Sciences at the University of Oxford’s Nuffield Department of Primary Care Health Sciences. Dr Gail Hayward, will be the MIC’s Deputy Director.

The Nottingham-based MindTech Healthcare Technology Co-operative, a national centre focussing on the development, adoption and evaluation of new technologies for mental healthcare and dementia has been refunded as a MIC – and has a formal collaboration with the NIHR Oxford Health Biomedical Research Centre.

## NIHR Oxford cognitive health Clinical Research Facility (CRF)

The CRF is a single managed entity hosted by OUH in partnership with OHFT. The CRF provides a flexible and integrated neuroscience resource that facilitates the efficient and timely conduct of experimental neuroscience including high intensity early phase experimental medicine research and early phase clinical trials. The CRF’s aim is to be fully aligned with the strategies of both the NIHR BRCs based in Oxford to enable, encourage and facilitate high intensity research in neuroscience and to work with principal investigators and commercial partners both established and new to achieve this aim.

The main research areas include; Adult Mental Health Disorders, Dementia and Neurological Conditions.

### Outputs

Data submitted for the annual return on activity between 1st April 2016 and 31st March 2017 shows that 32 studies were undertaken and 34 peer-reviewed articles were published where either CRF staff were contributing authors or the research was carried out on the CRF.

The CRF provides specialist clinical research study and trial support for many activities for a range of studies, including both commercial and non-commercial sponsors studies, with a focus on experimental medicine.

Key examples of studies currently active:

* A clinical biomarker study of immunological phenotypes associated with monoaminergic anti-depressant response, and the brain and cognitive phenotypes associated with variation in peripheral C-reactive protein (CRP) levels, in patients with major depressive disorder (MDD), BIOmarkers in Depression study (BIOdep). BIOdep is a ‘Wellcome Trust Consortium for Neuroimmunology of Mood Disorders and Alzheimer’s Disease’ study a public-private partnership with collaborations between 7 academic and 4 industry partners looking at the effect of inflammation on Alzheimer’s disease and treatment-resistant depression. We successfully reached target recruitment for Cohort 1 in 2016-17 and are currently recruiting to Cohort 2. The data from cohort 1 will be available later this year for analyses and publication.
* Exploration of the short-term physical and psychological effects of lithium in mood instability. The Oxford Lithium Trial (OXLITH) is a double-blind, randomised, placebo-controlled study of 6-week lithium treatment in participants with bipolar disorder and mood instability, designed to develop a valid experimental medicine model for bipolar disorder. The aim is to identify early clinical, neurocognitive and biological effects that may predict treatment response and inform drug development. The capacity to deliver this trial is an example of the CRF being central to the integration of both translational neuroscience and the clinical service, e.g. specialist scanning expertise and facilities are on site as is the Bipolar Disorder Research Clinic.
* The primary objective of the PREVention of dementia by ENvironmental intervention and Therapy (PREVENT) study, funded by the Alzheimer’s Society, is to describe the interaction of Alzheimer’s Disease (AD) risk (based on genetics and family history) and biological markers of AD in middle age. We will do this by comparing high and low AD risk participants in the 40-59 age range in terms of a variety of AD biomarkers. A secondary objective of the study is to establish a trial-ready cohort that will at a later stage be used to test the benefit of an intervention program based on multiple risk factors. The study may result in the identification of intermediary biomarkers of AD risk in middle age and will enable further targeted research in AD. The study is recruiting to target on the CRF.
* Three high intensity commercially sponsored (Janssen Cilag) studies using intranasal esketamine for depression. The primary objective of these studies is to assess the safety and tolerability of intranasal esketamine in subjects with TRD. These studies demonstrate the capability of the CRF to coordinate high intensity trials over a prolonged period.

### Studies in set up and due to open within the next 6 months include:

* The European Prevention of Alzheimer’s Dementia (EPAD) study. EPAD is a research initiative that provides a platform to investigate new treatments that aim to prevent or delay the onset of clinical symptoms in people at risk of developing AD. It involves more than 36 organizations across Europe including universities, pharmaceutical companies and patient organizations and is supported by the European Innovative Medicines Initiative. It is also working closely with other, similar initiatives worldwide, including the US-based Global Alzheimer’s Platform. The EPAD longitudinal cohort study (LCS) will draw on existing national and regional registers of people at risk of developing AD to create a single, pan-European EPAD register of around 24, 000 people. Of these, the 6 000 deemed to be at greatest risk of AD will be invited to join an EPAD cohort of ‘at risk’ subjects. This group will undergo a wide range of assessments and imaging over time. The project will select around 1 500 people from the cohort to take part in early stage ‘adaptive’ clinical trials of drugs designed to prevent AD. All data collected from the EPAD cohort and trial will be made publicly available for analysis to help researchers everywhere improve their understanding of the early, pre-dementia phase of AD. Ultimately, the hope is that this project will reinvigorate the development of treatments for one of the most challenging diseases facing our ageing societies.
* Deep and Frequent Phenotyping (DFP) study funded by the Medical Research Council. The DFP study will both track and predict change over time in preclinical AD and healthy controls. It will do this by measuring pathology using a number of different methods (brain imaging, CSF collection, cognition change) over time. We predict the study data will be the largest, openly available dataset on preclinical Alzheimer’s disease thereby providing a rich data source for research into both understanding AD better and informing treatment trials for new drug development
* Bipolar disorder (BD) has a strong genetic component and calcium signalling is considered to be a key part of its pathophysiology. The Oxford calcium channel antagonist study: exploration of the role L-type calcium channels in cognition and sleep (OxCaMS) is designed to find out more about the short-term effects of a calcium channel blocker called nicardipine. This OH-BRC experimental medicine study will compare the effects of nicardipine and placebo. The results may help to decide whether calcium channel blockers are likely to benefit individuals with mood instability and bipolar disorder. They may also facilitate the search for new medicines that are more effective, safer and easier to tolerate. We are also interested in whether people’s genes influence the effects of calcium channel blockers. The gene we are interested in is CACNA1C which codes for a part of the calcium channel.

### Occupancy

2016/17 Occupancy (Apr 16 – Mar 17).The occupancy reported in the 2016/17 NIHR annual report was 56% and reflected the three sites which at that time made up the Oxford cognitive health Clinical Research Facility. This was an increase on the 47% reported for 2015/16. The 2016/17 Warneford site occupancy of 59% was a significant increase on the prior year level of 44%.

For 2017/18 Q1 (Apr-Jun) occupancy at the Warneford site was 64% which was in line with the same period in 2016/17. The predicted full year occupancy is expected to show a further increase on the 59% reported last year.

### Renewal of CRF funding

The NIHR Oxford cognitive health CRF was awarded renewal of NIHR funding (3.7M over 5 yrs) commencing April 2017, hosted by OUH. The CRF renewal included resource to expand the facilities at the JRH. The CRF team has been working closed with the Acute Vascular Imaging Centre (AVIC), Nuffield Dept of Neurosciences, and the OUH Executive Team and R&D Dept to determine the optimal way of achieving this aim. We anticipate that space for the new facility will be identified in September 2017 and a joint CRF-OUH working group will then move quickly to staff the site, to enable opening by end 2017.

### Strategy and Research Objectives

The primary objective is to deliver new therapies tailored to the needs of individual patients by breaking down disciplinary boundaries, taking advantage of scientific, technical and infrastructural capabilities that cut across disorders.

#### Short-term objectives

Short-term objectives: to build further our capability in translational neuroscience, to support the objectives of OH-BRC, to expand facilities at the JRH, to finalise the PPI/E strategy for the CRF.

#### Medium-term objectives:

To realise plans for purpose built integrated and coordinated neuroscience research and clinical facilities across Oxford. Work has been initiated for a joint University-NHS Masterplan to develop the Warneford as a Brain Health Centre for translational neuroscience. The Masterplan is driving the joint development, the first stage of which is the £4.5 million upgrade of the Oxford Centre for Human Brain Activity, now part of the newly opened Wellcome Centre for Integrative Neuroimaging.

#### Long-term objective

To deliver an efficient translational pipeline fuelled by Oxford’s unrivalled scientific infrastructure and expertise and deploying the very best science to deliver new therapies for patients’ mental, cognitive and neurological disorders.

## NIHR Biomedical Research Centre (BRC)

The successful Oxford Health BRC, a partnership between OHFT and University of Oxford has commenced with funding started in April 2017, £12.8 million over 5 years with 50% of the annual budget being awarded within the first year.

The hub of the new centre will be based at OHFT Warneford Hospital site. The site also houses the University of Oxford’s Department of Psychiatry and its associated research centres and facilities.

The strategy is to bring the best science to the complex problems facing research into mental disorders and dementia with the aim to use digital and other new technologies to produce scalable solutions with global application and transform our discovery science into new treatments and diagnostic tools, delivering precision care that is strongly informed by patient involvement, ethical and economic consideration

### Operational Progress

* **BRC Theme leaders meetings** have been established. The group meets on a monthly basis to discuss and optimize budgets and synergies across the themes in order to maximize outputs.
* **BRC Steering Committee** has been established. Thecommittee is responsible for the operational, strategic and scientific direction of the NIHR Oxford Health BRC.
* **Operational budgets** have been set and are issued monthly. These are to be used to form to forecast the year end position, thus allowing for the identification of any cost pressures or underspend.
* **Governance Structures** have been established. The newly established Research Management Group (RMG) will receive quarterly reports from the BRC and provide an opportunity for additional strategic collaborations across NIHR infrastructure in Oxford.
* **Contracting.** The NIHR BRC contract has been negotiated and signed
* **Reporting and Metrics.** Work is to start on the mechanisms for data collection for the NIHR quarterly and annual returns. Discussion taking place with OUH to establish a potential mechanism using existing data capture tools.
* **Collaborations with other BRCs.** Contact has been made with other BRCs to look at synergies and ways of collaborating across the NIHR infrastructure.
* **Launch Event.** A very successful launch event was held on 31st of March to officially open the OH BRC. There were a number of key figures from UO, OHFT, OUH and OBU in attendance. Louise Wood from DH, Tony Soterio from NIHR and Nicola Blackwood, local MP, gave short talks. Louise Wood in particular gave a challenging and thought provoking talk. Nicola Canning, service user and a research advocate also gave a talk on the Patient’s perspective and importance of research and Oxford experience. The event was received very positively
* **Signs.** New signs are now being displayed around the Warneford site to direct people to the appropriate locations.
* **BRC Website.** A new BRC website is live.

### BRC Themes

* ***Adult Mental Health: Innovation in Diagnosis and Treatment (Theme Lead: Professor Paul Harrison)***

The Adult Mental Health theme has rapidly got up to speed. By June we had appointed to the three posts budgeted for in Y1: a research coordinator (shared with Experimental Medicine theme), a lab manager (shared with the Aging and Dementia theme) and a computational neuroscientist (co-funded by the new Wellcome Centre for Integrative Neuroimaging). All three appointments have proved successful and the post-holders are driving forward the work of the Theme. A template has been circulated to formalise the process for adopting existing and proposed studies within the Theme, making clear that the access to BRC support also comes with requirements of researchers to ensure compliance with NIHR regulations. A separate template has been circulated for staff wishing to request financial support from the Theme for pilot studies. Examples of studies already adopted within the theme are the OxLith clinical trial in bipolar disorder, and the OxCAMS study of mood instability. The rest of the Y1 Theme budget is committed to activities within the Clinical Research Facility, the ketamine clinic, and for running costs and infrastructure for the BRC laboratory work. Discussions are underway to plan the expanded portfolio which will be possible with the increased budget for Y2 and beyond.

In addition a DPhil post in experimental medicine (2018-2021), is being cofounded by this theme and the Wolfson College (the Wolfson Marriott Studentship).

* ***Older adults and dementia (Theme Lead: Professor Clare Mackay***) –

In June, twenty-seven researchers attended a kick-start meeting for the Older Adults and Dementia Theme, and representatives were assigned to the four sub-themes of Pharmacological Interventions, Non-Pharmacological Interventions, Patient and Public Involvement, and The Brain Health Centre.

Our focus over the first six months of the BRC has been primarily on the first three of these sub-themes. Within the Pharmacological Interventions sub-theme, the Deep and Frequent Phenotyping Study, European Prevention of Alzheimer’s Dementia Study, and PREVENT Dementia study are building trial-ready cohorts for future treatments. Within the non-pharmacological sub-theme, we have published papers examining the effects of mobility1 and sleep2 on brain structure. We have also published a protocol paper outlining the Defining the Impact of improved Sleep on COgnitive function (DISCO) study, which is investigating the impact of a digital Cognitive Behavioural Therapy programme for insomnia on cognitive functioning.3 Finally, within the Public and Patient Involvement sub-theme, we have worked with the PPI theme to survey researchers on their current activities and training needs. We are also running a series of focus groups to develop a strategy to reinvigorate the Friends of Oxford Dementia and Ageing Research (OxDARE) registry of interested research participants.

Three papers have been published

1. Demnitz, N. et al. Associations between Mobility, Cognition, and Brain Structure in Healthy Older Adults. Front. Aging Neurosci. 9, 155 (2017).
2. Sexton, C. E. et al. Associations between self-reported sleep quality and white matter in community-dwelling older adults: A prospective cohort study. Hum. Brain Mapp. (2017). doi:10.1002/hbm.23739
3. Kyle, S. D. et al. Effects of digital Cognitive Behavioural Therapy for Insomnia on cognitive function: study protocol for a randomised controlled trial. Trials 18, 281 (2017).

* ***Precision Psychological Treatments (Theme Lead: Professor Anke Ehlers)*** –

The theme made progress with building infrastructure (staff recruitment), development of content for online treatments, PPI strategy, development of training materials for therapists and randomized controlled trials of digital interventions.

A virtual reality (VR) specialist (Dr. Avitor Rovira) has been appointed and is working with Professor Daniel Freeman on the use of VR in the treatment of paranoia. A randomized controlled trial of a digital cognitive behaviour therapy for insomnia showed significant effects on paranoia and hallucinations that were mediated by changes in insomnia (Freeman et al., Lancet, 2017, http://dx.doi.org/10.1016/ S2215-0366(17)30328-0).

A web developer is currently being recruited who will develop the proposed platform for delivery of online psychological therapies.

Content for online versions of cognitive therapy and stress management therapy for PTSD has been created. A randomized controlled trial will compare the efficacy of the treatments.

A PPI coordinator for the theme (Dr. Hannah Murray) has been appointed.

Videos that demonstrate core treatment procedures in cognitive therapy for social anxiety disorder and PTSD have been created and will be made available online to therapists. Materials for other disorders are in the planning phase.

* + 1. **BRC Cross Cutting Themes**
* ***Informatics/digital health (Theme Lead: Professor Simon Lovestone)***

The theme has be streamlined into three sub-themes – Digital Health, led by Chris Hinds and will continue to support and develop True Colours as a primary Function, Clinical Informatics, Led by Tanya Smith and will drive the use of the Case Records Interactive Search (CRIS) within the research arena and clinical audit within the Trust and Bioinformaitics, led by Prof Caleb Webber.

* ***Neuroimaging and Cognitive Neuroscience (Theme Lead: Professor Kia Nobre) –***

The theme has been streamlined into sub-themes of Magnetic Resonance Imaging (MRI), Magnetoencephalography (MEG), and Cognition, with the aims of developing standardized assessments, applying assessments across research studies, and translating assessments into clinical settings. Work within this Theme is closely aligned to the recently established Wellcome Centre for Integrative Neuroimaging – and includes a number of joint appointments. For example, Nicola Filippini has been appointed as Magnetic Resonance Imaging manager at the Oxford Centre for Human Brain Imaging, and will facilitate translational neuroimaging research and standardization of MRI assessments. A second radiographer position is currently being advertised, and we are also in the process of revamping the MEG personnel.

* ***Clinical research infrastructure and experimental medicine (Theme Lead: Professor Catherine Harmer)***

Following the success of the BRC award this theme has secured the following grants

* MRC industrial partnership grant. Grant received for a 3 year project to study the effects of a 5-HT4 agonist on emotional processing in depressed patients. The company Pfizer supplied the 5-HT4 agonist through an asset sharing initiative. Key investigators: Catherine Harmer and Phil Cowen.
* UCB grant, for a 2 year study aimed at developing and validating implicit measures of cognition in patients with Parkinson's Disease. Key investigators: Catherine Harmer, Susannah Murphy and Corinna Klinge.
* Janssen Pharmaceutical grant, for a Phase One study investigating the effects of a novel glutamatergic compound on experimental medicine models of antidepressant action. Key investigators: Catherine Harmer and Susannah Murphy.
* **Patient and Public Involvement and Ethics (Lead: Professor Ilina Singh)**

The PPI stream has recruited a highly experienced PPI Manager for the BRC/CRF, who came into post on May 1st, 2017. We have also identified PPI liaisons within all the BRC themes. The PPI Manager has been holding conversations with a range of stakeholders and has reviewed the literature in order to prepare a background document that will inform PPI strategy development. The development of the strategy engages actively with the Patients and Research Group (PAR), set up in 2016. A patient Co-Chair has been recruited to lead the PAR Group and a timeline for strategy development has been drafted with the Co-Chair. PPI assistance has informed the TRD EME-re-application. An ongoing relationship with OUH BRC, specifically the Partnerships for Health, Wealth and Innovation theme, has been established in order to identify links for joint research and to share learning from practical experience across the two BRCs. The PPI Manager also mentors the PPI liaison from the Oxford Academic Health Science Centre.

* ***Education and Training (Lead: Professor Elizabeth Tunbridge)***

The funding for the Education and Training theme fundamentally starts in 2018 and progress is being made to create and recruit to a new Training Coordinator to support the theme.

## NIHR Clinical Research Network (CRN)

According to NIHR CRN performance metrics, in FY 2016/17, OHFT was the highest recruiting mental health trust on the measure of participant recruitment (2537 participants) and second highest on number of studies recruiting (60 studies). This met and exceeded performance in FY2015/16 (2576 participants and 48 studies).

The range of studies supported has grown by 25% and participant recruitment numbers are similar. Studies cover the following range of conditions: mild cognitive impairment (MCI), prodromal Alzheimer Disease (AD), mild/moderate AD, bipolar, schizophrenia, MDD and depression, sleep disorders, psychosis, anxiety, eating disorders, autism, staff and carer surveys.

The vast majority of studies meet recruitment targets, notably a commercial AD trial recruited over target (5/3 recruited), and was the highest recruiting NHS site for that trial. A complex commercial trial of intranasal ketamine for Major Depressive Disorder (MDD) successfully recruited its target of 4. A commercial dementia study is still recruiting, and has currently recruited 16 participants vs a target of 7.

Recruitment to dementia studies remains strong, with all studies routinely meeting or exceeding recruitment targets. The dementia research nursing team work closely with memory clinics to support referrals to research, and have supported MSNAP accreditation of memory clinic services.

# Research Set Up, Management and Governance

## Pipeline Group Meetings

New processes are being established to streamline a committee approach to setting up studies within the Trust due to the potential increased number of studies as a result of the successful BRC. A Pipeline Group meets regularly to determine whether studies are of scientific, strategic, patient value and whether there is capacity to undertake the study in the Trust and where the study could take place. It is key that a Principal Investigator (PI) is identified early in the process that can lead the study set up and delivery. The Pipeline Group will establish whether the study is appropriate to be developed in terms of undertaking costings, contract negotiations, capacity and capability (completion of HRA Statement of Activities) as part of the set up process thus enabling a more transparent and collective approach to research to ensure study targets can be met and that there is no overburdening of certain patient populations.

## HRA Approvals

HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments’ Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study

## Capacity and Capability

One aspect of HRA Approval is ensuring that there is clarity on the resource implications for participating NHS organisations and others delivering research within an NHS care setting.

For non-commercially sponsored studies a Schedule of Events and Statement of Activities forms are used to capture all information around study activities being undertaken at a local level as part of the approvals process.

For commercially sponsored studies a completed NIHR Industry Costing Template and template agreement are used to prior to local NHS approvals that the sponsor intends to use with host organisations.

The R&D office will work with researchers and sponsors to ensure a swift process of confirming the Trust’s capacity and capability to deliver the study to time and target. The team require that authorisation has been obtained from the appropriate Service Director, responsible for the Directorate where the research activity will take place before Trust Management Approval is provided to the research team.

## Contracts and Confidentially Disclosure Agreements

An agreement between OHFT and OUH to undertake the review of research contracts and contracts Confidentially Disclosure Agreements (CDA) from a legal perspective to ensure the Trust obligations are appropriate is ongoing and working effectively.

Recently concerns were raised regarding the terminology within legal agreements over the liability. The Trust has agreed at a no contract or CDA should have unlimited liability. Internal processes are now being established to assess and monitor risk

## Costings

The Head of R&D leads the costings process and works closely with research and clinical teams to provide accurate information on the timing and cost of undertaking specific protocol driven activity, including the set up and management of studies to ensure that the studies are run in a cost neutral manner within the NHS.

## Study Data Capture

The R&D office received an updated version of the Research Portfolio Management System (RPMS) in January 2017. The RPMS runs on the OXNET server, a secure NHS server system. The updated database has some new and enhanced functions and will be used to its full potential to provide reports and data on research activity, including recruitment, to ensure a more robust and accurate understanding of research activity taking place within the Trust. Work is being undertake to include functionality for identifying BRC studies.

## Monitoring and Auditing of Research Projects

The auditing and monitoring of research projects is currently on hold due to staff shortages and limited resource

## Studies and Participant Recruitment

The NIHR publishes league tables on an annual basis for NIHR portfolio adopted studies. There may be slight discrepancies in the data when comparing to internally data capture due to reporting differences and potential lag time.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **2014/2015** | **2015/2016** | **2016/2017** |
| Number of Studies | 40 | 48 | 60 |
| Number of Participants | 2012 | 2576 | 2537 |

### NIHR Metrics and Targets

Performance in initiating (70 Day target) for clinical trials and Performance in Delivering (Time to Target) for commercial clinical trials

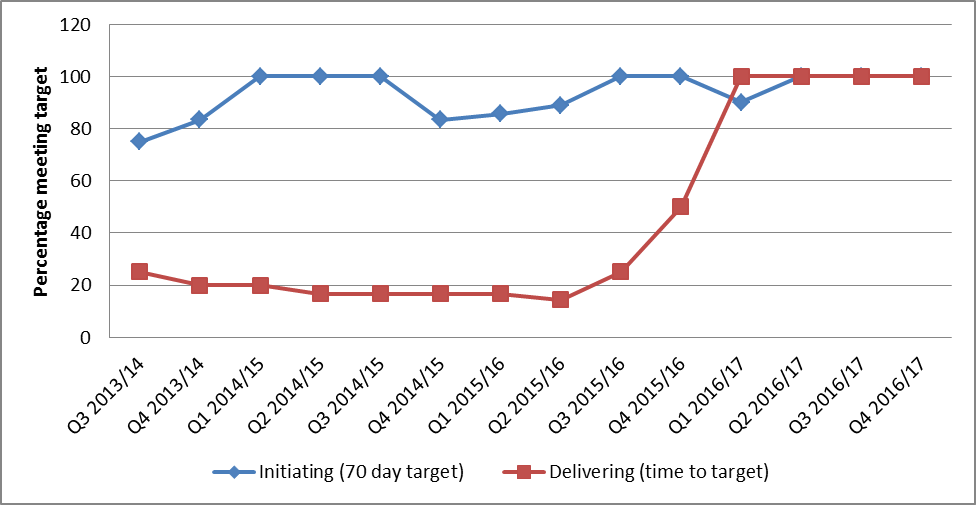
### Initiating studies

The Trust is still maintaining a 100% compliance in ensuring clinical trials are opened in a timely fashion and that the first patient is recruited within 70 days. The number of studies this metrics is captured for is generally limited to approximately 10. Therefore if one study does not meet the target the percentage can change dramatically

### Delivering Time to Target

OHFT is maintaining 100% compliance for delivering the stated number of participant in the allocated recruitment period for commercial clinical trials. Currently the number of studies closing to recruitment is 2. Therefore if one study does not meet the target the percentage can change dramatically.

When comparing to other MH Trusts OHFT are joint 7th in terms of number of commercial clinical trials where we meet the target for recruitment. The data suggests that of the 52 MHS Trusts, 24 Trusts do not submit data, 21 Trusts closed 1 o 2 studies, 6 Trusts closed 3 to 5 studies, 2 Trusts closed 6 to 8 studies and 1 Trust closed more than 9 studies. The Trust that closed 9 studies have acknowledged that the higher number is due to a number of non mental health community based studies (especially in diabetes) and that the MH ones are on par with other organisations. The data suggested that there are few commercial clinical trials taking place within the mental health area



# Pharmacy

There are currently 14 Clinical trials of Investigational Medicinal Products (CTIMPs) open for recruitment, with another three in set up. Of these studies 9 are commercially sponsored studies and 5 are non-commercial. Most of the medicines for these studies are stored at CPSU in Kennington, where they are managed by the pharmacy clinical trials team.

The Lead pharmacist has agreed initial plans for costing and delivering BRC adopted studies based on BRC funding for the pharmacy team. This will be reviewed as BRC research develops over the coming years as support for the BRC increases

Pharmacy clinical trials team has invested in transit bags with ambient cool packs which maintain the contents of the bag at ambient temperature for several hours. This means that there is a better guarantee of appropriate storage of IMP during transit, which in turn allows us to extend the distance that we can reliably send dispensed IMP.

# Case Records Interactive Search (CRIS)

UK CRIS went live in March 2017. Our CRIS data is now attached to CareNotes and will be updated on a monthly basis.

The CRIS coordinator (Tanya Smith) who is also the Digital Theme Leader of Ox-CRIS and UK-CRIS for NIHR Oxford Health Biomedical Research Centre supports the Ox-CRIS infrastructure, facilitating users, both within the clinical audit and service enhancement teams in the Trust and researchers in the BRC to use CRIS. She also contributes to the leadership of UK-CRIS as the key contact for the other UK CRIS NHS Trusts. There are currently 11 UK CRIS Trusts and 3 DCRIS Trusts, which together create the CRIS Network.

The Oxford CRIS Oversight Group meetings are held monthly to discuss submitted applications and monitor the audit of CRIS searches. The group is chaired by the Medical Director and Caldicott Guardian and is attended by the CRIS Coordinator, Director of IT, Head of Information Governance, Head of R&D, two carer/patient representatives, representatives from the trust Clinical Directorates, Trust Audit Team and academic leads from the University.

To date the CRIS Oversight have approved 22 applications, 17 of which were research questions, one service evaluation, three clinical audit questions and one feasibility application, which has so far consisted of 8 sub searches. We have 8 active CRIS searches and 12 active CRIS users.

We are progressing well will with our natural language processing (NLP) capabilities and further collaborations are now also in progress. These will provide the CRIS users with an automatic text reading facility for extracting and bringing into context relevant data from free text fields within CRIS. Agreements have been set up via the research passport system for our collaborators at Manchester University and a data processing contract is now in progress with a German academic institution who specialise in text mining, SCAI Fraunhofer, to provide NLP expertise for CRIS free text data. All authorised researchers are provided with a virtual desktop environment, created by the Trust IT department, which restricts both access to the data and prevents the data from being removed from the Trust firewalls.

Consent for re-contact is our next focus. CareNotes has been updated to allow this information to be captured and we would also like to extend this process to include bio resource linked to the electronic medical record (EMR) via CRIS as well as novel participant recruitment of non-patient citizens via NHS, using digital engagement and routine clinical/real world data.

# Trust Governance and Reporting Mechanisms

The Research Management Group (RMG) was established in November 2016 and continues to meet on a monthly basis. It is a stakeholder committee of those involved in research across the geographical coverage of Oxford Health NHS FT and is represented by a number of partners and collaborators across the region including Trust R&D and clinical directorate leads, BRC, CRF, CLAHRC, DEC, CRN, University of Oxford, Oxford University Hospitals NHS Foundation Trust, AHSN and AHSC.

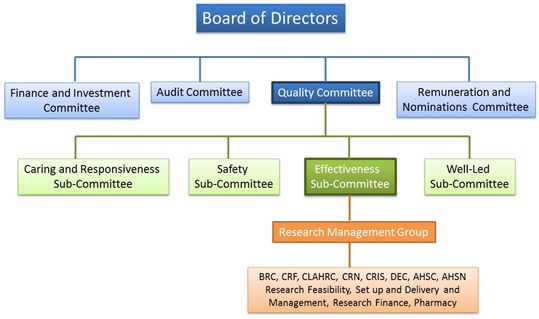
## Reporting and Governance

The RMG is a high level committee established to drive the collaborative research strategy across the Trust. It is responsible for the strategic and scientific direction of the research undertaken with or in partnership with OHFT.

The RMG oversees and monitors the financial position of research where there is involvement of the Trust and receive reports from the Head of R&D Finance which will highlight major areas of expenditure, anticipated changes or impacts on budgets and related funding. In addition it is accountable for the assurances made to the Trust to ensure fulfilment of its responsibilities as a host organisation

The RMG receives information and assurances from the various research activities undertaken in conjunction with OHFT, including dashboard reports on the OHFT BRC, CRF, CLAHRC, DEC, TV&SM CRN, Case Records Interactive Search (CRIS), Research Feasibility, Set-Up, Delivery and Management (including quality assurance), Pharmacy and Research Finance.

A summary of these reports is submitted to the Quality Sub Committee: Effectiveness on a quarterly basis.



# Finance

## Income

The Trust receives research funding from various commercial and non-commercial organisations. These funding streams are outlined in the table below along with the FY18 budgeted values.

|  |  |  |
| --- | --- | --- |
| **Type** |  | **FY18 (£k)** |
| **National Institute for Health Research (NIHR)** |  |  |
| Collaboration in Leadership in Applied Health Research & Care | CLAHRC | 2,000 |
| Biomedical Research Centre | BRC | 1,495 |
| Research Capability Funding | RCF | 1,036 |
| Study income |  | 846 |
| Clinical Research Facility (OUH hosted) | CRF | 582 |
| Subcontracted study income |  | 224 |
| Diagnostic Evidence Collaborative | DEC | 208 |
| **Total** |  | **6,391** |
| **Other Funding** |  |  |
| Clinical Research Network : Thames Valley & South Midlands Core Funding | CRN:TV&SM | 842 |
| Other income (Non-NIHR Grants and studies) |  | 531 |
| CRN:TV&SM Network Funding | CRN:TV&SM | 312 |
| Non-NIHR CRF Income |  | 71 |
| **Total** |  | **8,147** |

The NIHR, Department of Health and CRN:TV&SM require the completion of detailed quarterly and annual returns to ensure all funding is used appropriately and within the year awarded. Any unused funding would need to be returned to the relevant funding organisation. Quarterly and annual forecasts are also required by these organisations to demonstrate the need for continued funding

## FY18 Performance

At the end of July (period 4) the R&D performance was £14k favourable against budget due to vacancies. This is expected to increase slightly by the year end.

*Note: The deadline for this report meant that the last complete period was period 4*

## Collaboration in Leadership in Applied Health Research & Care (CLAHRC)

The CLAHRC commenced in January 2014 will run until December 2018. It is led by Professor Richard Hobbs from the University of Oxford, Department of Primary Care.

The CLAHRC theme budgets have been allocated in two phases, Phase 1 in 2014 for 2 ¼ years and Phase 2 in 2015 following a mid-term review for the remaining 2 ¾ years.

The budgets are detailed below (£k):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Phase 1 Budgets** | **Theme Lead** | **FY14 \*** | **FY15** | **FY16** |
| Better Management of Psychiatric comorbidities | Mike Sharpe | 14 | 161 | 370 |
| Health Behavior and Behavioral Interventions | Sarah Lamb | 38 | 168 | 336 |
| Early Intervention and Service Innovation | John Geddes | 16 | 144 | 318 |
| Patient Self-Management (Chronic Disease) | Richard McManus | 46 | 226 | 380 |
| Patient experience and PROMS | Ray Fitzpatrick | 55 | 187 | 346 |
| Central and Support Costs | Richard Hobbs | 81 | 364 | 250 |
| **Total** |  | **250** | **1,250** | **2,000** |

*Note: FY14 was 3 months*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Phase 2 Budgets** | **Theme Lead** | **FY17** | **FY18** | **FY19 \*** | **Total** |
| Service redesign | Belinda Lennox | 312 | 135 | 104 | 551 |
| Behavior change – exercise and rehab | Sarah Lamb | 267 | 248 | 160 | 677 |
| PROMS | Ray Fitzpatrick | 191 | 229 | 182 | 601 |
| Multi-morbidity | Mike Sharpe | 123 | 118 | 101 | 342 |
| Patient self-management | Richard McManus | 362 | 356 | 175 | 893 |
| Behavior change – weight and obesity | Susan Jepp | 268 | 217 | 155 | 641 |
| Central and Support Costs | Richard Hobbs | 477 | 697 | 623 | 1,795 |
| Total |  | **2,000** | **2,000** | **1,500** | **5,500** |

*Note: FY19 is 9 months*

### Performance

The actual expenditure is forecast to be in line with budget for FY18

### Matched Funding

A fundamental requirement of the CLAHRC is the need to demonstrate matched funding committed by other organizations linked to CLAHRC activities. This needs to be at least to the same level as the NIHR funding. Identification of this funding is an on-going process involving the senior management team and theme leads.

## Biomedical Research Centre (BRC)

BRC funding commenced in April 2017 and will continue for five years based on the profile below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **£k** | **FY18** | **FY19** | **FY20** | **FY21** | **FY22** | **Total** |
| Funding | **1,499** | **2,844** | **2,848** | **2,814** | **2,819** | **12,824** |

BRC funding is based on £1m per year per theme. The Oxford Health BRC contains three themes but funding in year one for new BRC’s is limited to 50%. The slight shortfall on £3m per year was due to a national reduction by the NIHR post award.

The annual indicative budgets are set out below (£k), however the actual expenditure will be reviewed regularly to ensure best value for money is being achieved. This may lead to reallocations as and when appropriate. One of the key features of the BRC is that wherever possible individuals are not funded 100% and matched or shared funding is sought.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary** | **Lead** | **FY18** | **FY19** | **FY20** | **F Y21** | **FY22** | **Total** |
| **BRC Themes** |  |  |  |  |  |  |  |
| Adult Mental Health | Paul Harrison | 237 | 458 | 464 | 464 | 464 | 2,086 |
| Older Adult Mental Health | Clare Mackay | 326 | 541 | 541 | 541 | 541 | 2,490 |
| Psychological Treatments | Anke Ehlers | 306 | 504 | 483 | 445 | 439 | 2,176 |
| **Cross-cutting Themes** |  |  |  |  |  |  |  |
| Neuroimaging & cog. neuroscience | Kia Nobre | 112 | 288 | 288 | 288 | 288 | 1,266 |
| Informatics & Digital | Simon Lovestone | 172 | 480 | 476 | 476 | 472 | 2,076 |
| Infrastructure & exp. Medicine | Catherine Harmer | 159 | 242 | 242 | 242 | 247 | 1,132 |
| PPI&E | Ilina Singh | 58 | 125 | 145 | 147 | 150 | 625 |
| Training | Liz Tunbridge | 20 | 53 | 55 | 57 | 60 | 245 |
| Core Costs | John Geddes | 109 | 153 | 155 | 155 | 158 | 730 |
| **Total** |  | **1,499** | **2,844** | **2,848** | **2,814** | **2,819** | **12,824** |

## Research Capability Funding (RCF)

Research active NHS organisations receive RCF to enable them to meet some, or all, of the research-related component of the salary of their researchers and research support staff working on clinical and applied health research, where that component is not already provided by another funding source.

The annual RCF allocation combines a percentage of the NIHR funding received in the previous calendar year with an allowance for each Senior Investigator associated with Trust.

The FY18 RCF allocation was £1.036m, a reduction of £0.009m on FY17 due to a reduction in the infrastructure rate (-£13k) only partially off-set by increased study related RCF (£4k)

The Trust splits its RCF income between that earned by the Trust and Department of Psychiatry and that from the Department of Primary Care, the breakdown and year on year movements are shown in the table below:

|  |  |  |  |
| --- | --- | --- | --- |
| **FY18 (£k)** | **Department of Psychiatry \ Trust (including CLAHRC)** | **Department of Primary Care** | **Total** |
| Senior Investigators (SI) | Guy Goodwin, John Geddes, Mike Sharpe | Sue Ziebland, David Mant, Trisha Greenhalgh, Andrew Farmer, Chris Butler |  |
| SI related RCF (£75k) | £0.225m | £0.375m | £0.600m |
| Study funding | £0.077m | £0.227m |  |
| Study related RCF | £0.025m | £0.074m | £0.099m |
| Infrastructure   * CLAHRC * DEC | £2.000m | £0.248m |  |
| Infrastructure related RCF | £0.300m | £0.037m | £0.337m |
| Strategic contribution | £0.049m | (£0.049m) | - |
| Total | £0.599m | £0.437m | £1,036m |
| FY17 | £0.740m | £0.305m | £1,045m |
| Increase \ (Decrease) on FY16 | (£0.141m) | £0.132m | (£0.009m) |

## NIHR Study Income

The NIHR study income is made up of two awards linked to the Department of Primary Care. These are NIHR program grants awarded to Professor Richard McManus (£518k in FY18) and Professor Andrew Farmer (£327k in FY18).

## Clinical Research Facility (CRF)

CRF funding commenced in April 2017 and will continue for five years profiled as follows;

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **£k** | **FY18** | **FY19** | **FY20** | **FY21** | **FY22** | **Total** |
| Funding | **740** | **744** | **748** | **751** | **755** | **3,738** |

The award is hosted by OUH but the bulk of the funding will be used to support the CRF on the Warneford site. Some funding will be used to for development of CRF facilities at OUH.

The BRC requirements for experimental medicine has lead to later phase studies being displaced from the Warneford CRF due to lack of capacity. To address this work is taking place to make the ECT suite at the Whiteleaf research ready to undertake clinical research studies

## Subcontracted study income

This includes Health Foundation founded studies and an MRC study in collaboration with Cambridge University

## DEC \ MIC

The existing DEC which is lead by Gail Hayward from the Department of Primary Care has been extended until December 2017. The NIHR are replacing DEC’s with MIC’s NIHR (Medtech and In vitro diagnostic Co-operative) and the Trust hosted an application from the Department of Primary Care. The Trust was invited to interview and await the outcome.

## Clinical Research Network: Thames Valley and South Midlands (CRN)

The budgeted FY18 funding from the CRN of £842k for core staff and £312k for hosted network staff is shown in the table below along with the forecast year end position.

|  |  |  |  |
| --- | --- | --- | --- |
| **Division** | **Specialty** | **FY18 Budget**  **(£k)** | **Forecast(**  **£k)** |
| **Core Allocation** |  |  |  |
| Division 4 | Mental Health | 376 | 363 |
|  | Dendron and Neurological disorders (Dendron) | 275 | 208 |
|  | Division-wide (Division 4) | 140 | 113 |
| Cross-Divisional | Non-Pay, Overheads & Other | 51 | 47 |
| **Total** |  | **842** | **731** |
| **Network staff** |  |  |  |
| Division 4 | Mental Health | 13 | 13 |
|  | Dendron and Neurological disorders (Dendron) | 13 | 13 |
| Division 5 | Primary Care | 247 | 249 |
| Cross-Divisional |  | 39 | 40 |
| **Total** |  | **312** | **315** |

## Grant Applications

Grant applications take place on a regular basis submitted by various individuals and to a number of different funding bodies, activity since November 2014 is shown in the table below;

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **FY15**  **(Nov-Mar)** | **FY16** | **FY17** | **FY18**  **(Mar-Aug)** | **Total** |
| Outcomes of Grants submitted |  |  |  |  |  |
| Awarded | 1 | 11 | 10 |  | 22 |
| Unsuccessful | 14 | 18 | 17 | 1 | 50 |
| Submitted |  |  | 6 | 3 | 9 |
| Work in progress |  |  | 1 | 2 | 3 |
| On-hold |  |  | 1 |  | 1 |
| **Total** | **15** | **29** | **35** | **6** | **85** |
| Funding applications |  |  |  |  |  |
| NIHR | 6 | 12 | 9 | 1 | 28 |
| Health Foundation | 2 | 1 | 2 | 2 | 7 |
| OHSRC | 2 | 1 | - |  | 3 |
| CSO, Scotland | - | 1 | - |  | 1 |
| Research Councils UK (RCUK) | 1 | - | - |  | 1 |
| MRC | - | - | 1 |  | 1 |
| Parkinson’s UK |  |  | 1 |  | 1 |
| Sub-contracted | 4 | 14 | 22 | 3 | 43 |
| **Total** | **15** | **29** | **35** | **6** | **85** |
| Funding Requested (£k) |  |  |  |  |  |
| NIHR | 3,295 | 9,058 | 21,526 | 256 | 34,135 |
| The Health Foundation | 575 | 75 | 106 | 579 | 1,335 |
| OSRC | 14 | 2 | - |  | 16 |
| CSO, Scotland | - | 34 | - |  | 34 |
| Research Councils UK (RCUK) | 50 | - | - |  | 50 |
| MRC |  |  | 149 |  | 149 |
| Parkinson’s UK |  |  | 13 |  | 13 |
| Sub-contracted | 50 | 2,536 | 1,037 | 140 | 3,763 |
| **Total** | **3,984** | **11,705** | **22,831** | **975** | **39,495** |
| Grants Awarded |  |  |  |  |  |
| NIHR | - | 2 | 2 | - | 4 |
| Health Foundation | 1 | 1 | 1 | - | 3 |
| OHSRC | - | 1 | - | - | 1 |
| CSO, Scotland | - | 1 | - | - | 1 |
| Sub-contracted | - | 6 | 3 | - | 9 |
| **Total** | **1** | **11** | **6** | **-** | **18** |
| Funding Awarded (£k) |  |  |  |  |  |
| NIHR | - | 5,078 | 16,563 | - | 21,641 |
| The Health Foundation | 75 | 75 | 107 | - | 257 |
| OSRC | - | 2 | - | - | 2 |
| CSO, Scotland | - | 34 | - | - | 34 |
| Sub-contracted | - | 1,539 | 75 | - | 1,614 |
| **Total** | **75** | **6,728** | **16,745** | **-** | **23,548** |

## Risks - Redundancy Costs

Where staff are funded from time limited awards there is a potential redundancy risk. This has always been monitored along with HR to identify and mitigate the risk on a case-by-case basis

The CRN reduced their level of funding for the R&D Governance team for FY18 where £131k was requested but only £65k funded and pharmacy support where £28k was reallocated from the senior research pharmacist to create a new pharmacist post at the Whiteleaf. This latter post may not be required and would need supervision which the senior pharmacist cannot provide on the reduced hours funded.

## Oxford Academic Health Science Network (OAHSN)

Oxford Health hosts the Dementia, Early Intervention in Mental Health and Anxiety and Depression OAHSN Clinical Networks.

These networks are planned to continue until March 2018 and will be funded from a combination of the AHSN, CLAHRC and Berkshire CCG, as detailed below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Network** | **Lead** | **FY18 funding** | **Total** |
| Dementia | Rupert McShane | FY17 funding carried forward £8k, CLAHRC funding £15k, Final AHSN funding £69k | £93k |
| Anxiety & Depression | David Clark | FY17 funding carried forward £15k, CLAHRC funding £15k, Final AHSN funding £28k, Berkshire CCG £11k | £69k |
| Early Intervention in MH | Belinda Lennox | Final AHSN funding £39k | £39k |

There will be a financial pressure of £100k in FY18 due to the Trust agreeing to fund a senior member of the AHSN with no budget identified. There is also a financial risk of redundancy for staff currently funded.

The OASHN is seen as a clinical development rather than research and is reported separately in the finance report to the Board.

## Summary of Funding Timeframes

|  |  |  |
| --- | --- | --- |
| **Infrastructure/Award** | **Current funding timeframe** | **Renewal/relicensing timeframes** |
| AHSN | 2013 to 2018 | March 2018, although funding may now cease in July 2017 with limited renewal |
| AHSC | 2014 to 2019 | 2019 |
| CLAHRC | Jan 2013 to Dec 2018  *(9 months extension confirmed but level of funding yet to be advised*) | To be confirmed. Potential call for renewal in late 2017 |
| DEC | Extended until Dec 2017 | Replaced by MIC |
| MIC | NA | Jan 218 to Dec 2022 |
| CRF | Sept 2012 to March 2017 | April 2017 to March 2022 |
| BRC | NA | April 2017 to March 2022 |
| CRN | April 2014 to March 2019 | To be confirmed |

# Staffing

Professor Andrea Cipriani has been appointed as the Associate Director of R&D. The post has been created within the Trust to work with the Director of R&D, Head of R&D and Head of R&D Finance as the R&D Senior Management Team (SMT) to shape R&D going forward.

Emma Stratful, the Head of R&D is now the R&D representative on the Trust Extended Executive Team. This will help support the R&D agenda at a senior level, particularly as the Trust embarks on the new BRC and NHS infrastructure and integrating research and clinical services across the organisation.

A new Patient and Public Involvement (PPI) Manger, Sandra Regan has been appointed to support the BRC, CRF and R&D within the Trust. Sandra joins the Trust with a wealth of experience from OUH BRC.

A number of staff from pharmacy, the R&D Office and two research assistants are currently on or expected to be on maternity leave over the coming months.

There are current difficulties in recruiting to clinical trials pharmacy team following two unsuccessful rounds of advertising and interviewing.

The Research Support Manager has resigned from her position. Her role is currently being covered by the Head of R&D and support team while the SMT look at opportunities to reshape the role.

The new Research Implementation Manager is settled and is performing well in post, managing the team of research assistants. There has been high turnover in the team, with two staff having been accepted onto the clinical psychology doctorate. All staff have been replaced and the team is up to full strength.

# Estates

The joint research office (JRO) between Oxford University Hospitals NHS FT (OUH) and the University of Oxford relocated from the Churchill hospital to UNIPART in Cowley, Oxford at the end of August. This move is an opportunity for OHFT R&D team to join the JRO to help support the streamlining of research set up and management across the organisations. This will enable closer working relationships within the research arena for the benefit of researchers, patients and staff across organisation in order to streamline and speed up current processes.

The consultation of staff has been completed it has been agreed that due to staff shortages within the core R&D team there will be a delay in relocating OHFT staff at this time.

There has been an increase in the number of experimental medicine studies taking place on the CRF, in addition to the BRC pipeline that will flow through the CRF, therefore it is becoming increasingly difficult to accommodate later phase research on the CRF due to the funding restrictions on the NIHR CRF infrastructure and occupancy rates within the facility. In order for the Trust to continue to undertake late phase and in particular commercial studies alternative space is being explored. One option is to undertake moderate refurbishment of some clinical space at the Whiteleaf Centre in Aylesbury that could be used to conduct research activity when not in clinical used. Work is progressing with this option.

# Communications

## Significant Communications

The communications team put out a number of research-related stories over the last six months, and collaborated with partner organisations to manage and promote other stories. Below is a brief list: items marked with an \* were also sent out to local and/or national press.

All of these stories were also supported by outreach on social media, and where applicable, highlighted on the NIHR Oxford Health BRC website:

* CBT for insomnia can reduce anxiety, depression and paranoia symptoms <http://www.oxfordhealth.nhs.uk/news/treating-insomnia-may-reduce-mental-health-problems/>
* Oxford Health/Department of Psychiatry staff awarded Associate Professorships: <http://www.oxfordhealth.nhs.uk/news/oxford-health-staff-awarded-associate-professorships/>
* £1.24 million for new medical diagnostics hub\* <http://www.oxfordhealth.nhs.uk/news/1-24-million-for-new-medical-diagnostics-hub/>
* Two of our clinical psychologists nominated for British Psychological Society awards <http://www.oxfordhealth.nhs.uk/news/clinical-psychologists-recognised-for-their-work-with-older-people/>
* New mobile app tackles paranoia (this story was also sent out the local press) <http://www.oxfordhealth.nhs.uk/news/new-mobile-app-tackles-paranoia/>
* Figures show rise in Oxfordshire NHS research\* <http://www.oxfordhealth.nhs.uk/news/figures-show-rise-in-oxfordshire-nhs-research/>
* Health visitors hope to recruit 300th family into study\* <http://www.oxfordhealth.nhs.uk/news/oxford-health-visitors-hope-to-recruit-300th-family-to-research-study/>
* Oxford health at top of the table for most people recruited to take part in research studies\* <http://www.oxfordhealth.nhs.uk/news/oxford-health-tops-table-for-recruitment-to-research/>
* Free drop-in public event about NHS research\* <http://www.oxfordhealth.nhs.uk/news/research-in-the-nhs/>
* Dr Dan Freeman interviewed about VR as a healthcare tool <http://www.oxfordhealth.nhs.uk/news/virtual-reality-as-a-healthcare-tool/>
* Grandmother with dementia on why she is taking part in Oxford Health research\* <http://www.oxfordhealth.nhs.uk/news/oxford-health-patient-on-research-hopes/>
* Push for recruitment to Lithium versus Quetiapine study\* <http://www.oxfordhealth.nhs.uk/news/lqd-study/>
* Ilina Singh/Rupert McShane paper on responsibly testing ketamine treatment for depression\* (received extensive media coverage) <http://www.oxfordhealth.nhs.uk/news/researchers-highlight-need-for-responsible-development-of-ketamine-for-severe-depression/>
* The NIHR Oxford Health Biomedical Research Centre officially launches on 1st April 2017\* <http://www.oxfordhealth.nhs.uk/news/the-future-in-mind/>
* Oxford Health to spearhead development of digital technology in mental healthcare nationally\* <http://www.oxfordhealth.nhs.uk/news/oxford-health-named-as-global-digital-exemplar/>
* Major research grant to study how VR can help with persecutory delusions\* <http://www.oxfordhealth.nhs.uk/news/new-funding-for-virtual-reality-treatments-for-mental-health-problems/>

## Additional communications activities:

* Following the extensive media interest in the paper about the responsible testing of ketamine for depression, the communications team organised a number of interviews with current patients, making sure that the patients’ interests were protected and that the work was responsibly reported. Patients were interviewed on BBC Radio 4, BBC television, local radio stations and the Guardian. Examples of some of this coverage are below:

<http://www.bbc.co.uk/news/av/health-39510932/i-ve-been-taking-ketamine-for-my-depression>

<https://www.theguardian.com/society/2017/jun/02/i-can-stop-and-breathe-the-people-taking-ketamine-for-depression>

* The communications team are currently also managing a BBC documentary into the experience of another patient case-study of ketamine for treatment-resistant depression.
* The communications team helped organise the successful launch event for the NIHR Oxford Health BRC. Including attendance from Nicola Blackwood MP, and coverage about the event on local ITV news.
* The NIHR Oxford Health BRC website was launched: https://oxfordhealthbrc.nihr.ac.uk/
* The NIHR Oxford Health BRC twitter account was also launched during this period.
* The communications team negotiated a correction to a story in the Daily Mail which incorrectly reported work by one of the NIHR Oxford Health BRC theme leads.
* The communications team also advised on possible risks in the publication of a potentially high-profile biography by a patient currently being treated at the depression clinic.
* Excellent relationships developed with NIHR Communications team and the NIHR Oxford Biomedical Research Centre.

**Authors and Title:** Professor John Geddes, Emma Stratful & Dr Mark Hancock

**Lead Executive Director:** Dr Mark Hancock

1. *A risk assessment has been undertaken around the legal issues that this paper presents and there are no issues that need to be referred to the Trust Solicitors.*
2. *This paper (including all appendices) has been assessed against the Freedom of Information Act and the following applies:*

* *THIS PAPER MAY BE PUBLISHED UNDER FOI*

1. *This paper provides assurance and evidence against various Care Quality Commission Outcomes*