

**BOD 37/2019**

(Agenda item: 13)

**Report to the Meeting of the**

**Oxford Health NHS Foundation Trust**

**Board of Directors**

**27 March 2019**

**Research and Development Report**

**For information**

**Executive Summary**

The last six months has seen the consolidation and expansion of the National Institute of Health Research (NIHR) Oxford Health Biomedical Research Centre (BRC) from year one where only 50% of the funding was available. This has included joint clinical-research activities such as a pilot to establish a Brain Health Centre (BHC).

The NIHR Clinical Research Facility (CRF) continues as the heart of research on the Warneford and in the last quarter of 2018 saw a further expansion of the services it provides with the first intravenous infusions taking place on the unit.

The Oxford NIHR Collaboration in Leadership in Applied Health Research and Care (CLAHRC) led by Professor Richard Hobbs continues to make good progress. This infrastructure funding stream comes to an end in Sept 2018 is to be replaced by Applied Research Collaboratives (ARCs) for which Oxford Health has supported the submission of a robust application for funding due to start in 2019.

The NIHR Community Healthcare MedTech and IVD Co-operative (MIC) is continuing to make progress against its objectives and has had 15 formal company interactions/consultations in the last six months, covering infection (UTI, respiratory, STI), chronic disease, remote monitoring of patients, and diagnostic platforms.

The Research Management Group is proving a value asset in steering the strategic and scientific direction of research undertaken within OHFT and its partners by bringing together key stakeholders from the various NIHR infrastructures, AHSC, AHSN, University of Oxford, Oxford Brookes University and the clinical services

The Trust continues to provide robust research support to enable researcher to conduct studies within OHFT, with regular pipeline meetings to establish feasibility for each study taking into consideration scientific and strategic importance to patients, the organisations and its partners.

Work on the consent for recontact initiative has recently restarted with a review of the pilot data

CRIS continues to support researchers undertaking studies within the organisation in addition to increasing the support for clinical audit within the Trust.

R&D will report a favorable financial variance for FY19

OHFT continues support the Oxford Academic Health Science Network with developments in Mental Health

**Governance Route/Approval Process**

The is a biannual update report to the Board for Research and Development taking place or being hosted within the Trust and is for information

**Statutory or Regulatory responsibilities**

Research and Development is aligned to its regulatory responsibilities in undertaking research and is compliant with contractual obligations

**Recommendation**

The Board is asked to note the report.

**Author and Title:** Bill Wells and John Geddes

**Lead Executive Director:** Mark Hancock, Medical Director

1. ***Strategic Objectives*** *– this report relates to or provides assurance and evidence against the following Strategic Objective(s) of the Trust*

*1) Driving Quality Improvement*

*(Goals: patients will be safe from harm; patients will achieve the clinical outcomes they want; and patients and carers will have an excellent experience)*

*2) Delivering Operational Excellence*

*(Goals: our services will be effective and efficient; information will be translated into knowledge; and our planned surplus will be delivered)*

*3) Delivering Innovation, Learning and Teaching*

*(Goals: the impact of the AHSN, AHSC and CLAHRC will be maximised; we will collaborate in research and innovation; and we will deliver high quality teaching)*

*4) Developing Our Business through Collaboration and Partnerships*

*(Goals: we will work in collaborative partnerships; we will maintain and grow our services where we add value; and we will have strong relationship with our stakeholders)*

*5) Developing Leadership, People and Culture*

*(Goals: staff satisfaction will be in the top 20% of Trusts nationally; our staff and teams will be high-performing; and we will recruit and retain an excellent workforce)*

*6) Getting the most out of Technology*

*(Goals: our patients and staff will have the right technology available; our workforce will have the necessary IT skills to do their jobs well; and an outstanding IT service will be delivered)*

*7) Using our Estate efficiently*

*(Goals: patients and staff will benefit from safe and appropriate environments; our estate will be sustainable and environmentally-friendly; and our estate will be cost-effective)*

[1 Introduction 7](#_Toc3283590)

[2 Networks and Collaborations 7](#_Toc3283591)

[2.1 Oxford Academic Health Science Network (OAHSN) 7](#_Toc3283592)

[2.1 Oxford AHSN Anxiety and Depression (A&D) Network 7](#_Toc3283593)

[2.2 Dementia 8](#_Toc3283594)

[2.3 Mental Health Care for Emergency Department Frequent Attenders - Regional Collaborative 8](#_Toc3283595)

[2.4 Integrated mental health care and policing teams (SIM) 8](#_Toc3283596)

[2.5 Early Intervention in Psychosis: Improving Quality and Safety during transfers 9](#_Toc3283597)

[2.6 Sleepio 9](#_Toc3283598)

[2.7 Industry 9](#_Toc3283599)

[2.8 Oxford Academic Health Sciences Centre (AHSC) 9](#_Toc3283600)

[2.9 Oxford Institute of Nursing, Midwifery and Allied Health Research 9](#_Toc3283601)

[3 National Institute of Health Research Infrastructure 11](#_Toc3283602)

[3.1 NIHR Collaboration in Leadership in Applied Health Research and Care (CLAHRC) Theme Updates 11](#_Toc3283603)

[3.2 NIHR MedTech and In Vitro Diagnostic Co-operatives (MIC) 13](#_Toc3283604)

[3.3 NIHR Oxford cognitive health Clinical Research Facility (CRF) 14](#_Toc3283605)

[3.4 NIHR Biomedical Research Centre (BRC) 16](#_Toc3283606)

[3.5 NIHR Clinical Research Network (CRN) based performance 23](#_Toc3283607)

[4 Research Set Up, Management and Governance 23](#_Toc3283608)

[4.1 Research Set Up 23](#_Toc3283609)

[4.2 Pipeline Group Meetings 23](#_Toc3283610)

[4.3 Health Research Authority (HRA) 24](#_Toc3283611)

[4.4 Capacity and Capability 24](#_Toc3283612)

[4.5 Contracts and Confidentially Disclosure Agreements 24](#_Toc3283613)

[4.6 Costings 24](#_Toc3283614)

[4.7 Study Data Capture 24](#_Toc3283615)

[4.8 Monitoring and Auditing of Research Projects 24](#_Toc3283616)

[4.9 Studies and Participant Recruitment 25](#_Toc3283617)

[4.10 Case Records Interactive Search (CRIS) 25](#_Toc3283618)

[4.11 Consent for re-contact 26](#_Toc3283619)

[5 Trust Governance and Reporting Mechanisms 27](#_Toc3283620)

[5.1 Reporting and Governance 27](#_Toc3283621)

[6 Staffing 27](#_Toc3283622)

[7 Estates 27](#_Toc3283623)

[8 Communications 27](#_Toc3283624)

[9 Intellectual Property 28](#_Toc3283625)

[10 Finance 28](#_Toc3283626)

[10.1 Research Income 28](#_Toc3283627)

[10.2 FY19 Income Budget 29](#_Toc3283628)

[10.3 Performance 29](#_Toc3283629)

[10.4 Collaboration in Leadership in Applied Health Research & Care (CLAHRC) 30](#_Toc3283630)

[10.5 Medtech and In vitro diagnostic Co-operative (MIC) 30](#_Toc3283631)

[10.6 Clinical Research Facility (CRF) 30](#_Toc3283632)

[10.7 Biomedical Research Centre (BRC) 30](#_Toc3283633)

[10.8 Clinical Research Network: Thames Valley and South Midlands (CRN) 30](#_Toc3283634)

[10.9 Research Capability Funding (RCF) 30](#_Toc3283635)

[10.10 Grant Income 31](#_Toc3283636)

[10.11 I4I 31](#_Toc3283637)

[10.12 Study Delivery 31](#_Toc3283638)

[10.13 Oxford Academic Health Science Network (OAHSN) 32](#_Toc3283639)

[10.14 Infrastructure Funding Timeframes 32](#_Toc3283640)

[10.15 Audits 32](#_Toc3283641)

# Introduction

Participation in research produces widespread benefits for patients and, more generally, improvements in quality of care. A Census wide consumer 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. 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)

Oxford AHSN works to ensure that mental health has a significant focus in its work. Below we highlight mental health work that is either hosted within OHFT or of relevance to the trust.

## Oxford AHSN Anxiety and Depression (A&D) Network

This existing network is hosted by OHFT with Professor David Clark as Clinical Lead and Ineke Wolsey as Network Manager and all IAPT services across Thames Valley and Milton Keynes are members. The Anxiety and Depression Network can report the following progress on some of its projects:

**IAPT services patient outcomes:** The network supports all services in continuously improving patient outcomes and, to date, all TV IAPT services have performed extremely well and are recognized as amongst the best in the country with recovery rates consistently some 6% above the national average. Looking ahead and acknowledging unprecedented cost pressures for both CCGs and provider trusts across the patch, it is anticipated that, for the first time since rolling out IAPT services across TV, it is likely that services won’t be able to achieve the access targets or waiting times targets set nationally. It is also possible that recovery rates will suffer.

**Relapse prevention:** This work has progressedgreatly in the past 6 months and all services across Thames Valley and Milton Keynes will start introducing a much improved, new protocol focused on supporting patients to stay well after step 2 IAPT treatment.

**The health economics evaluation** of the Integrated IAPT programme: first report now available on the Oxford AHSN, Anxiety and Depression Network website. Savings of £1,870 demonstrated for every patient suffering with a Long-term physical health Condition and co-morbid depression/ anxiety who received the adapted, primary care-based, multi-disciplinary IAPT-LTC treatment. Savings calculated over a 2 year period and mainly based on a reduction in A&E and in-patient spells as well as visits to GPs.

**The therapy support and follow app**: this is now in pre-Beta testing phase and so far has been very well received. It will serve as a personal storage device for all IAPT patients (to support them to stay well after discharge) and also as a follow-up tool to enable services to keep track of their patients’ progress after discharge so that support can be offered when needed in a timely fashion.

**New digital therapies: T**he A&D Network is supporting the roll-out of a number of digital web-based therapies which have shown to be as effective in clinical trials as face to face therapy. To date these include Social Anxiety Disorder and PTSD (currently as part of a clinical trial).

## Dementia

Some dementia work continues within the AHSN though the Dementia Clinical Network no longer exists in its previous form.

**Dementia webinars** This programme launched in 2014, with the aim of building a culture of collaborative working across the Oxford AHSN region and reducing variation in diagnostic and prescribing practice following initial referral to memory services. Webinars can be watched live or on-demand and over the years it has been running over 50 webinars have taken place, with over 1,000 live attendees and over 900 views of webinar recordings.

**Best practice network for Care homes in-reach teams** This network is aimed at supporting the health teams (including OHFT’s Care Home Support Service) that in-reach into care homes, helping care homes to provide better care to people living with dementia. Within the network, teams share best practice and support each other to take initiatives forward. CPD topics within network meetings have included Nutrition, hydration, depression in older people, the WHELD study, and diabetes in care homes. care homes to provide quality care to people living with dementia

## Mental Health Care for Emergency Department Frequent Attenders - Regional Collaborative

A collaboration between Emergency Departments (EDs) in the Thames Valley region has been funded by the Health Foundation through the Q Exchange programme. This collaborative, which runs from November 2018 to November 2019, is aimed at improving ED mental healthcare for frequently attending patients through peer support of teams across the Thames Valley, incorporating the following objectives:

1. Analysing data on attendance patterns to identify variation and overlap between departments throughout the region (including where patients are attending more than one ED)
2. Sharing of Frequent Attenders Programme models across the Thames Valley region aiming to identify and implement best practice and looking at which interventions may be particularly effective
3. Involving service users to devise strategies to understand and better meet their needs

Dr Deon Louw, Consultant in ED at OUHFT is the clinical lead. The project has been liaising with OHFT teams involved in this area of work. A multi-disciplinary event is to be held in Oxford on 2nd May 2019.

## Integrated mental health care and policing teams (SIM)

This is a national initiative being rolled out by AHSNs, in which police are integrated within a mental health team, working together to empower and mentor high impact users of services towards safer and healthier lives. It brings a structured proactive approach, and where SIM has been implemented there have been some major successes with service users reducing or ceasing their high impact patterns and greatly reducing their contacts including with the criminal justice system. We are exploring whether this is an initiative that could be rolled out within Oxford AHSN’s area and we recently organised for a team from OHFT and Thames Valley Police to attend a video meeting with Oxleas NHS Foundation Trust a current SIM site, to determine whether SIM would be beneficial for this area.

The Oxford AHSN is participating in National SIM teleconferences and meetings which are proving very valuable.

## Early Intervention in Psychosis: Improving Quality and Safety during transfers

The AHSN is supporting a project within the Early Intervention in Psychosis Thames Valley network on improving quality and safety during patient transfers. The project will work with teams to explore incidents concerning transfers, to establish best practice in this area, and to develop and embed new procedures. A survey has been completed by Thames Valley teams to investigate the extent of issues with transfers between teams and between different elements of the NHS, for example referrals from other services such as primary care. This work is due to be completed in March 2019.

## Sleepio

Innovate UK has funded a collaborative partnership which has enabled free direct access to Sleepio, an evidence-based sleep improvement programme, for 2.7 million adults across the Oxford AHSN footprint.  This project (the ‘Sleepio project’) is jointly delivered by Oxford AHSN and Big Health and is supported by NHS England.  The AHSN is working in partnership with Big Health to explore the best ways for people experiencing insomnia to access Sleepio. The project went ‘live’ on World Mental Health Day (10 October 2018) and people living in the Thames Valley can access Sleepio via this link [www.sleepio.com/nhs](http://www.sleepio.com/nhs) . Oxford AHSN is working with GPs, and primary and mental health NHS staff, local employers, and third sector organisations, to explore how the NHS can expand the provision of digital medicines, like Sleepio, at scale. A health economic evaluation will be conducted at the end of the project later this year. A variety of large organisations have now rolled-out Sleepio to their staff and contacts.

## Industry

The Strategic and Industry Partnerships element of the AHSN supports the development of partnerships between academia, industry and the NHS across the development pathway for new products and services. In practice this covers new medicines, diagnostics, medtech and digital health innovations. This includes supporting new products and services which have potential to improve mental health services.

## 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

## Oxford Institute of Nursing, Midwifery and Allied Health Research

The Oxford Institute of Nursing, Midwifery and Allied Health Research (OxINMAHR) is an Oxford Brookes University led partnership between key stakeholders to lead and participate in world-class research and evidence-based practice. We have a particular interest in innovation and best practice at the point of care.

OxINMAHR researchers take a broad, holistic view of health, to encompass physical, psychological, emotional, spiritual, cultural and social elements; and, consider health and illness to occur in the context of family life. Thus, health issues and challenges are viewed as being concerns for individuals, as well as their families and communities. OxINMAHR has a specialist focus on research that; (i) Enhances patient safety and well-being; (ii) Enhances health equity and social justice; and, (iii) Promotes health workforce resilience and sustainability.

OxINMAHR is currently in a state of transition while the process of recruitment of a new Institute Director is ongoing; Prof Helen Dawes is currently the interim Director.

Within OxINMAHR, research activity continues to contribute to both strategic and operational objectives for Oxford Health Foundation Trust. OBU are keen to continue to collaborate with OHFT to create and develop clinical academic appointments for nurses and AHPs. Work is underway to identify areas within OHFT/OBU where these appointments may be created and successfully sustained.

Across OxINMAHR, public involvement (including patients, carers and families) is viewed as a key aspect of research, which is encouraged at each stage of the research process. There are two distinct areas of Public Involvement to meet both AHP and Nursing programmes of research.

For AHP, the MOReS team has two vibrant groups for children and adults and include an ideas factory. Activities include a registered Freestyle Project (led by Dr Shelly Coe) which follows the recently launched National Standards for Public Involvement. For Nursing, the PPI group is co-chaired by Cathy Henshall and Jo Brett and seeks to engage and involve patients and the public from a diverse range of backgrounds in research. CH and JB are hosting an OxINMAHR PPI research event in early November to shape ideas for future PPI involvement in research moving forward.' These activities make significant contribution to ensure that research themes, topics and studies are developed from a range of sources and from the bottom up to improve the quality of care.

Many joint collaborations and research projects are ongoing with members of Oxford Health including Dr Beatrix Ruckli working with Dr Johnny Collett on a CRIS data project. Early findings indicate that patients who have a diagnosis of Autistic Spectrum Disorder, Personality Disorder and Asperger’s are likely to have a higher risk of self-harm when compared to patients with other mental disorders, admitted to local acute mental health in-patient wards. This is a clinically significant finding and their collaborative work aims to inform the development of staff training sessions to improve patient care. MOReS affiliate Dr Richard Baskerville is currently involved in exercise and self-management for diabetes care with regular organised walks around Oxford with patients and has been very recently appointed as Oxford City Locality Diabetes Coordinator for Oxfordshire Clinical Commissioning Group with huge potential for developing strong relationships to create a positive impact on patient care and research.

Ongoing project work with the Oxford Centre for Spirituality and Wellbeing led by Prof Debra Jackson and Dr Guy Harrison relates to supporting leaders to maintain positive culture for clinical team through a survey of senior clinicians within the Thames Valley region. The purpose of this survey is to assess the need for training/ CPD in spiritually integrated patient care.

The recently formed Nursing and Midwifery Excellence UK (NAME-UK) is an informal network of UK health care organisations and individuals (including OHFT) who are interested in pursuing Magnet® or Pathway to Excellence® recognition with the American Nurses Credentialing Center for quality patient care, nursing and midwifery excellence and innovations in professional nursing and midwifery practice.

The International Dementia and Culture Collaborative (IDCC) is led by Dr Joanne Brooke and was set up with current projects to consider the impact of culture on nurses understanding dementia and how this may impact on their provision of person-centred care.

Research from the Children and Families Research Group led by Jane Appleton, involves children within the prenatal period, up to age 18. It includes areas such as safeguarding, child protection, child health, looked-after children, and the role of the family unit including parenting, school, and community influence on child wellbeing.

Current projects with a focus on patient care include: i) stand up for cerebral palsy ii) occupational therapy and young people with emerging mental health issues iii) movement, physical activity and mental and physical health and wellbeing iv) factors relating to safe driving performance and mental health.

Across OxINMAHR a wide range of research degrees are undertaken and supervised through the involved Centres and research groups in collaboration with both OHFT

The Centre for Movement, Occupational and Rehabilitation Sciences (MOReS) led by Prof Helen Dawes has developed strong research links with teams across the Trust and have been named in a draft of ‘A strategy to develop the capacity, impact and profile of Allied Health Professionals in Oxford Health NHS Foundation Trust 2018-2023’. This documents a commitment to recruit and retain high quality staff to embrace and embed new ways of working to enhance clinical practice and maximise the health and wellbeing of Trust staff. The team work in close contact with OHFT (Rebecca Kelly and Dr Beatrix Ruckli) to develop and evaluate staff training workshops.

Possible areas of strategic direction being considered are

* Recruitment of AHP to PhD studentships
* Exploring the potential for clinical academic roles
* Engagement of clinical staff in research and support from management teams
* Developing the theme of adolescent/young people mental health
* Developing AHP and Nursing research (from BSc to Fellow) and translation into practice

# National Institute of Health Research Infrastructure

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

### Governance

At its meeting in September 2018, the CLAHRC Management Board initiated a series of theme reviews to:

* Dive deeper than the quarterly metrics into what has worked well, when and how
* Check accuracy of the metrics to date for drafting the final report to NIHR;
* Confirm and inform the activities for the final 9 months of the CLAHRC term
* Enable sharing ideas for future programmes and implementation planning

By way of preparation, Theme Leads prepared an additional report, structured to describe progress in two parts - research and implementation – and identifying key impacts.

The first two themes (4 and 6) reported in December 2018, others are scheduled for 4 March (1 and 5) and 4 June (2 and 3).

### Theme 4– Better Management of medical-psychiatric multimorbidity – Prof Michael Sharpe

Project figures were too small to map cost saving, and health economics effectively. Confidence intervals are wide. Potential follow up with Cancer alliances was recommended to the team.

The Board asked about economic analysis; this had not been possible within the time and resources available.

A multicentre grant on the back of CLAHRC work showing promises for change.

Too few people with depression in diabetes to move forward with feasibility study.

Actions still pending – publication of outputs by September 2019

### Theme 6 - Behavior Change: Diet and Obesity – Prof Susan Jebb

*Weight management:* Extensive engagement nationally, the group discussed local relevance. Fat and sugar reduction results pending.

*Food purchasing projects* – are hard to get funded elsewhere, CLAHRC funding was essential for this work. A Robust trial is nearing conclusion. Relationships with retailers and national impact has been significant. Theme lead reported various opportunities to contribute to and advise policy and evaluation forums.

PC-Shop project: the primary outcome, to reduce people’s saturated fat intake and is reliant on Population Health for analysis, the secondary outcome is cholesterol reduction, which can be done in the Primary Care department.

Ideas for the future include work towards a diabetes prevention program, work around self-management of obesity, and trying to get credible evidence into the NHS. T

Theme lead is considering setting up network within SPCR for interventions for obesity/lifestyle.

This theme has several extensions and BRC pull through projects in progress and is proposed for development in the NIHR ARC (see 1.1.6 below)

### Operations

A systematic review (by CLAHRC administration and Oxford Health Trust finance staff) was initiated in November 2018. This is now complete in readiness for the financial year end. Where required, adjustments have been made to ensure all projects are on track to complete by 30 September 2019.

Funds to support open access publication, communications enhancement and dissemination through conferences etc. has been made available to the CLAHRC community.

NIHR will require an annual report to March 2019 as previously. Templates likely to be provided in early April 2019.

### Events

**CLAHRC Annual Stakeholder Symposium:** Held 15 February 2019 at Saïd Business School included a series of presentations and an informative discussion based on the NHS long term plan (published 7 Jan 2019) among 60+ stakeholders and a panel of regional leaders.

Details at https://www.clahrc-oxford.nihr.ac.uk/upcoming-events/clahrc-stakeholder-symposium-2019

**National CLAHRC Directors’ meetings** since January 2019, these have been organised on behalf of all CLAHRCs by East of England and East Midlands and include all prospective ARCs. This approach has been well received is more cost effective than the outsourced option previously; next meeting 18 June 2019.

**Discovery to Application** – the CLAHRC is co-convening a session with the Oxford BRC Long term conditions and multimorbidity theme at the BRC cluster event 26 March 2019. Expert panel will include: Kathy Hall - OUH Director of Strategy; Tracey Marriot -Director of Innovation Adoption Oxford AHSN; Stuart Bell -Oxford Health CE; Kiren Collison - Oxfordshire CCG Clinical Chair.

### NIHR Applied Research Collaboration Oxford and Thames Valley (OTV ARC):

Decisions, originally expected in December 2018, were delayed to January. A number of ARC proposals nationally, including Oxford and Thames Valley, were recommended for ARC designation conditionally. Others were funded and NIHR anticipates national coverage with an ARC in each of the 15 AHSNs.

OTV was required to provide:

* increased focus on how its work programme has been informed by and will address the needs of the local population, including increased evidence of engagement and involvement of public health and social care
* revised strategy for the ‘Community and Social Care Improvement’ Theme with clear aims, outputs and deliverables
* plan and timeline, for leadership recruitment or succession should the Director choose to step down during the funding period to 2024

Engagement from proposed ARC partners regionally has been strong. Responses required and additional business planning narrative were duly submitted to NIHR 26 February. Final decisions are expected by May 2019 and, if successful, a 5 year award for the full £9m with a review at the end of the first year is anticipated.

### Projects

More information at <https://www.clahrc-oxford.nihr.ac.uk/research>

A detailed project update will be provided in the next briefing to the Trust Board in September 2019

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

### Industry consultations

The NIHR Community Healthcare MedTech and IVD Co-operative has had more than 15 formal company interactions/consultations in the last six months, covering infection (UTI, respiratory, STI), chronic disease, remote monitoring of patients, and diagnostic platforms.

### Publications

The MIC team has published the following papers since the submission of the last report

* Lee JL, Verbakel JY, Goyder CR, Ananthakumar T, Tan PS, Turner PJ, Hayward G, Van den Bruel A. The clinical utility of point-of-care tests for influenza in ambulatory care: A systematic review and meta-analysis. Clinical Infectious Diseases 2018 ciy837 <https://doi.org/10.1093/cid/ciy837>
* Yang Y, Abel L, Buchanan J, Fanshawe T, Shinkins B. Use of decision modelling in economic evaluations of diagnostic tests: An appraisal and review of Health Technology Assessments in the UK. PharmacoEconomics Open 2018. <https://doi.org/10.1007/s41669-018-0109-9>
* Verbakel JY, Lee JJ, Goyder C, Tan PS, Ananthakumar T, Turner PJ, Hayward G, Van den Bruel A. Impact of point-of-care C reactive protein in ambulatory care: a systematic review and meta-analysis. BMJOpen 2019. <https://bmjopen.bmj.com/content/9/1/e025036>

### Events

* Hosted by the MIC Precision Antimicrobial Prescribing clinical theme under the leadership of Professor Hayward, the MIC AMR Café took place on the 29th November 2018 at Trinity College Oxford. Four diagnostics companies were selected through open competition to join the MIC expert panel. Discussions covered the development of novel diagnostics for infectious diseases and the application of existing technologies. The MIC has continued discussions with the majority of attendees, with an intention to provide further support.
* The Acute Adult Ambulatory Care and Future Hospital clinical theme (Professor Dan Lasserson lead) will deliver a workshop entitled ‘Ultrasound: Delivering the Diagnostics Strategy of the Future’. The workshop will take place on the 28th March 2019 in Birmingham, with key talks delivered by Dr Tony Newman-Sanders (NHSE National Clinical Director for Diagnostics) and Professor Alison Noble (Technikos Professor of Biomedical Engineering, University of Oxford). The event will incorporate an interactive session where attendees will have the opportunity to try a number of point-of-care ultrasound systems. The event has sold out at 100 tickets.
* The MIC is supporting an Academic Industry Meeting Day (AIMday) which will be hosted by the Medical Sciences Division and will focus on antimicrobial resistance. The day will support four subthemes, including diagnostics, medical technologies, vaccines and medicines. The AIMday will take place on the 4th of July. MIC Clinical Director, Professor Chris Butler will deliver one of the opening talks which will focus on the challenges of addressing this global health problem from a community healthcare perspective.
* The MIC Acute Paediatrics Clinical Theme will host a workshop on the 2nd of May 2019 at Trinity College Oxford to discuss potential solutions to the challenge of collecting clean-catch urine samples from paediatric patients. The workshop will be delivered in collaboration with the NIHR Children and Young People MIC, which is based in Sheffield.

### Recent funding

* A consortium led by the MIC has been awarded €590k through the EIT Health funding scheme for a project to refine and clinically evaluate a novel diagnostic approach to guide the treatment of urinary tract infections in the community. This project is a collaboration between the MIC (Nuffield Department of Primary Care and the Primary Care Clinical Trials Unity), Public Health Wales Specialist Antimicrobial Chemotherapy Unit, Region Uppsala Municipality (Sweden), and Astrego Diagnostics AB (Sweden).
* Professors Butler and Hayward are part of a large consortium which has successfully applied for an EU IMI grant for approximately €10m to focus on diagnostics for respiratory infections. As part of the project, Professor Butler will lead a 10 EU country adaptive platform trial to evaluate candidate diagnostics, with approximately €4m coming to Oxford.

### Projects

* Innovate UK Small Business Research Initiative Phase II project: The MIC is continuing to support Mologic Ltd in their development of a point-of-care diagnostic test to stratify patients to the most appropriate treatment during acute exacerbations of their condition.
* NIHR i4i funded collaborative projects: The MIC has begun work on a project together with the Bristol Urological Institute, University of the West of England and the NIHR Devices for Dignity MIC. This Product Development Award (PDA) project concerns the development and evaluation of a novel diagnostic for urinary tract infection, with the MIC providing health economic and clinical input (ongoing). Work on a second PDA project began with Cambridge Respiratory Innovations Ltd and the University of Portsmouth in November 2018 to evaluate the performance of the CRiL N-Tidal platform in asthmatics.
* The NIHR HTA funded METRIC (MEasuring TempeRature In Children) study, which is a methods comparison study of different thermometry devices completed recruitment in August 2018. The data analysis phase of the project has been largely completed, with the manuscript now in preparation.
* The MIC Acute Paediatric Ambulatory Care theme has begun a service evaluation in paediatric ED at the John Radcliffe to examine the impact of two point-of-care tests on the pathway for children presenting with suspected appendicitis. The foci of this evaluation will be length of stay and time to clinical decision.
* In collaboration with the Department of Clinical Biochemistry (OUH), the MIC Methods theme is working on a project funded by Becton Dickinson to explore pre-analytical error associated with point-of-care testing in routine clinical practice. This project is utilizing both quantitative and qualitative (ethnographic) methodology.
* Working with Professor Belinda Lennox (key researcher MIC Long-Term Conditions clinical theme), the MIC is carrying out a project based in OHFT which is focusing on improving access to physical healthcare screening (lipids and HbA1c) for patients with severe mental illness. The CARMEN project is underpinned by community delivery of these tests through a portable point-of-care diagnostic system which can be taken to patients’ homes. A number of related projects are also in the planning stages.
* Funded by NHSE, the MIC is collaborating with researchers at the University of Leeds to map the clinical pathway for the diagnosis and management of patients who present to primary care with symptoms of urinary tract infection.

## 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

Activity data for the annual return (1st Apr 17-31st Mar 18) shows 43 studies were undertaken and 64 peer-reviewed articles published where CRF staff were authors or the research was carried out on the CRF.

The CRF provides specialist clinical research study and trial support for a range of studies, including commercial and non-commercial sponsors’ studies, with a focus on experimental medicine. Key examples of studies currently active:

* The Oxford calcium channel antagonist study: exploration of the role L-type calcium channels in cognition and sleep (OxCaMS) compares effects of a calcium channel blocker, nicardipine, versus placebo; results may help decide whether calcium channel blockers benefit individuals with mood instability and bipolar disorder and may facilitate the search for medicines that are more effective, safer and easier to tolerate. OxCAMS opened in late 2017; we have recruited 21 participants.
* PREVENT’s (Alzheimer’s Society) aims to describe the interaction of AD risk (based on genetics and family history) and biological markers in middle age. It will establish a trial-ready cohort to test the benefit of an intervention program based on many risk factors. Findings may result in identification of intermediary biomarkers of AD risk in middle age and will enable further targeted research. The study recruited to target (n=68). Assessments and lumbar punctures are undertaken on the CRF.
* EPAD investigates new treatments that aim to prevent or delay the onset of clinical symptoms of AD. It involves >36 organizations across Europe, including universities, pharmaceutical companies and patient organizations, and is supported by the European Innovative Medicines Initiative. It works closely with other, similar initiatives worldwide, including the US-based Global Alzheimer’s Platform. EPAD opened to recruitment in 2018 and has recruited 56 participants to date.
* SINAPPS2 is an MRC funded, randomised, phase II, double-blinded, placebo-controlled trial aiming to test the efficacy and safety of intravenous immunoglobulin (IVIG) and rituximab versus placebo treatment for antibody-associated psychosis in addition to the current psychiatric standard of care. Patients with antibody positive psychosis will receive either IVIG and rituximab, or placebo infusions. The primary outcome is time to remission sustained for six months. The main SINAPPS2 site is OUHFT; however, IVIG/placebo infusions are delivered at the CRF. All registered nurses and medics are trained to deliver IV medications. Three participants have been treated at the CRF.
* Research on Emotional effects of SeroTonin Agonism in Non-medicated Depression (RESTAND) and in ResistanT depression – medicated (RESTART) (MRC): investigate effects of activating serotonin-4 (5HT4) receptors on emotion processing in depressed patients, to aid understanding of the mechanisms underlying antidepressant treatment. RESTAND/RESTART are RCTs, with some participants allocated to receive a drug activating 5HT4 receptors. RESTAND opened in Jul 2018, with 21 participants screened. RESTART opened in Aug 2018; 14 participants have been recruited.

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

* New Therapeutics in Alzheimer’s disease (NTAD). This highly-focused biomarker study combines established and novel markers to identify a marker set for measuring outcomes in prodromal disease proof of concept trials and to establish a sample bank for further exploratory studies.
* Deep and Frequent Phenotyping (MRC). DFP will track and predict change over time in preclinical AD and healthy controls by measuring pathology using a number of different methods (brain imaging, CSF collection, cognition change). We predict study data will be the largest, openly available dataset on preclinical AD, providing a rich data source for research into understanding AD better and informing treatment trials for new drug development.
* **A**ntidepressant **T**rial with **P**2X7 Antagonist JNJ-54175446. This is a Phase 2 RCT, from a public – private partnership and a continuation of the Wellcome Trust’s Neuroimmunology of Mood Disorders and Alzheimer's Disease consortium. It trials the antidepressant efficacy of a novel CNS-penetrant P2X7 receptor antagonist, as an adjunct therapy for people with incomplete response to conventional antidepressants and a biomarker profile predictive of active P2X7 signaling.
* Pramipexole trial for Bipolar Disorder. A multi-centre, randomised, double-blind, placebo-controlled trial of pramipexole plus mood stabilisers for patients with treatment resistant bipolar disorder. It aims to evaluate the clinical effectiveness of pramipexole over 12 weeks alongside standard mood stabilising medication, in managing patients with treatment resistant bipolar disorder.
* Pramipexole trial for Depression. An NIHR funded, multi-centre, randomised placebo-controlled trial evaluating the efficacy and mechanism of pramipexole as add-on treatment for people with treatment resistant depression. Compares efficacy of pramipexole and placebo after 12 weeks.

### Renewal of CRF funding

The NIHR OHCRF 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. However, an appropriate location at the JRH was not identified, largely due to space issues. As a result, alternative options for the CRF’s governance and reporting structures are now being considered. This includes the potential for two NIHR funded CRFs, one at OUH and one at OH. This will be discussed at the Academic Health Science Centre meeting in Spring 2019.

**1.1.5 Strategy and Research Objectives**

Primary objective: deliver new therapies tailored to individual patient needs by breaking down disciplinary boundaries, capitalizing on scientific, technical and infrastructural capabilities that cut across disorders.

Short-term objectives: To build further our capability in translational neuroscience, to facilitate the objectives of OH-BRC.

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 fueled 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 Oxford Health BRC, a partnership between OHFT and University of Oxford has commenced with funding starting in April 2017, £12.8 million over 5 years. In FY19 an additional £1m was awarded for FY19 to provide a sustainable solution to UK-CRIS.

The hub of the new center is at OHFT Warneford Hospital site. The site also houses the University of Oxford’s Department of Psychiatry and its associated research centers 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.

### Overview of Activity

We have:

* a formal governance and reporting structure which includes the BRC steering committee to oversee the strategic direction of the BRC and the BRC theme leaders meeting to support the operational management of the award. This latter group increases collaboration and synergies across themes, which facilitates staff to be funded and managed across themes. The BRC is represented on the Research Management Group by both the Director and Manager
* supported 83 studies during the first year and leveraged and received £16,371,358 in-year project funding as a result of the infrastructure and vision provided by the BRC.
* undertaken considerable work developing the Patient and Public Involvement and Engagement (PPIE) strategy, which has been co-produced with involvement from the Patients And Research (PAR) group, Oxford Health BRC and Oxford cognitive health CRF.
* been working with BRCs nationally and NOCRI to establish a Mental Health Translational Research Collaborative (TRC) to drive the exceptional work in the mental health arena across the country through the BRC network and in Mike Browning we have the national lead for the work on Treatment Resistant Depression

Plans are now being developed for the second annual return

### BRC Themes

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

Over the past six months, the theme has been active across all domains of its activity.

We have expanded our support for research infrastructure, jointly with the Experimental Medicine cross-cutting theme. We have now adopted over 40 studies in total, including 6 new ones since September 2018. The support has taken various forms, including help with neuroimaging data analysis, statistical and ethics advice, encapsulation and randomisation, experimental design and analysis, advice on sample transport and storage, and access to Standard Operating Procedures (SOPs). We have also provided laboratory-based support in the form of sample processing, equipment maintenance, genotyping and various immunoassays. As part of our competitive seed funding application scheme, we have provided financial support to 2 additional pilot studies since September 2018, enhancing their competitiveness for subsequent larger-scale external funding.

In collaboration with the Experimental Medicine cross-cutting theme, we have also expanded our library of SOPs (15 currently in place, with 5 developed or in development since September 2018). The SOPs are aimed at implementing standardised procedures and guidelines on key research topics within the BRC, such as: informed consent; collection and processing of cortisol; ordering, storage and disposing of medication; management of clinical waste; risk assessment; safety reporting, etc.

In collaboration with the Neuroimaging cross-cutting theme and Older Adults and Dementia themes, we have also contributed to an expansion of the resources available for neuroimaging analysis support, including documents on how to conduct data analysis on resting state, region-of-interest and seed-based analysis, functional connectivity, and task-based fMRI.

We are also working closely with our PPI/E cross-cutting theme in several areas, especially promoting the active involvement of patients, carers and public members into the early stages of study design. One of our theme members (Dr. Liliana Capitao) is the staff co-chair of the Patient and Research (PAR) group and PPI liaison for our theme. Liliana has been working together with the PPI manager, the patient co-chair of the PAR group, and Prof. Ilina Singh to promote and increase the visibility of PPI within the OH BRC. Accordingly, we have incorporated PPI as an important element of consideration in the application form for our BRC study adoption scheme.

Several theme-supported papers have been published over the past six months, including a detailed analysis of the psychiatric features of NMDA receptor encephalitis, published recently in *Lancet Psychiatry* and featured on BBC TV.

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

Progress towards the establishment of the Brain Health Centre (BHC) has continued to gain momentum in recent months. Since September, the BHC has resulted in a number of joint clinical-research roles:

* Dr Lola Martos, clinical lead for the BHC and director of Older Adult services has been appointed as an Honorary Senior Clinical Lecturer in the Department of Psychiatry
* Clare Hamblin, Memory Clinic Nurse, has been engaged by the University to work on the BHC project for two days a month
* Maureen Cundell, Memory Clinic Nurse, and Lucy Garrod, Psychological Services Therapist, also contribute time to support the BHC project
* Several members of BHC research staff now have OH honorary contracts
* Plans are in place to recruit to new joint clinical-research positions to support the BHC, including a clinical psychologist post, and specialty doctor position, both part-funded by the OH BRC.

These joint clinical-research activities, as well as further meetings with senior representatives from University of Oxford Research Services, Risk and Liability, and Legal Services, the Oxford Health Chief Operations Officer, Head of Service, Medical Director, and Caldicott Guardian, as well as the Oxford University Hospitals Senior PACS/RIS manager*,* have led to a number of key infrastructural achievements for the BHC:

* A Memorandum of Understanding (MOU) has been drafted that outlines the responsibilities and agreements in regard to the BHC between the University of Oxford and Oxford Health NHS Foundation Trust, who operate the memory clinic service.
* The necessary infrastructure has recently been put in place to connect the Oxford Centre for Human Brain Activity (OHBA, where the BHC will be based) to NHS IT networks, providing essential access to NHS electronic patient records and picture archiving/communication systems.

The BHC has also appointed a PPI (public and patient involvement) representative to the working group, and has established a BHC PPI advisory panel, made up of people living with dementia, carers and interested members of the public. To date, the BHC advisory panel has developed a PPI strategy for the BHC, reformed the ethical application documentation, and co-developed an abstract on the importance of public involvement to the success of the BHC that was accepted for presentation at the Alzheimer’s society conference.

A key new appointment for the theme has been Brain Health Centre Administrator Karen Lindsey, who will support the running and operations of the Brain Health Centre and Oxford Centre for Human Brain Activity. Other recent appointments include Tony Thayanandan and Nyla Haque, both based in the Department of Psychiatry, who will work as trial coordinators for a number of ongoing and upcoming studies within the Older Adults and Dementia theme.

Of the ongoing studies, the DPUK (Dementias Platform UK) Clinical Studies Register (CSR), now named GreatMinds, has started to recruit to their register of highly characterised individuals for recruitment to clinical trials. The Deep and Frequent Phenotyping (DFP) study is still yet to commence, having been delayed due to challenges in establishing the governance arrangements for use of existing cohort members. Eight new projects have expanded to the portfolio of Older Adults and Dementia research studies.

The Friends of OxDARE (Oxford Ageing and Dementia Research) registry has established links with the NIHR Clinical Research Network (CRN) Patient Research Ambassador (PRA) scheme, to support the recruitment of Friends of OxDARE Ambassadors who will help promote dementia and ageing research in Oxford and surrounding areas. The Friends of OxDARE registry continues to support ongoing research studies in this and other BRC themes, and a public event will be held in the summer to feed back to the Friends on the results of research they have taken part in. Other public engagement activities that OxDARE has been involved in include:

* The development of a public engagement package, in collaboration with the EPAD (European study for the Prevention of Alzheimer’s Disease) project, to educate older adults about evidence-based actions they can take to help promote ‘brain fitness’
* Provision of an ‘Older Person’ representative for the Wellcome Centre for Integrative Neuroimaging (WIN) Public Engagement external advisory board
* Collaboration with the Ashmolean Museum on their ‘Meet Me at the Museum’ campaign to improve the museum’s provisions for older adults, particularly those living with dementia.
* A public research event organised by OxDARE for relatives at a local care home for people with dementia
* Several public events throughout March 2019 related to dementia, brain donation and stroke, as well as national science festivals

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

The Precision Psychological Therapies Theme has initiated several new virtual reality (VR) projects at the BRC-supported VR laboratory at the Warneford Hospital. Freeman’s group started a VR treatment trial of automated therapy for patients with psychosis who have persecutory delusions (the THRIVE trial). They have also worked with patients to design a new VR automated treatment for patients with psychosis who have withdrawn from everyday activities. A large multi-centre trial, funded by the NIHR i4i programme, will start in July 2019. The trial will be the largest ever VR treatment trial. Stein’s group are working on the development of a VR programme for parents with depression or anxiety in the perinatal period, in order to enhance their responses to infant facial expressions. Murphy and Rovira aim to develop a novel digital method using virtual reality to complement the treatment of eating disorders, and are piloting the validity, feasibility and acceptability of a virtual reality scenario.

Further progress has been made with the development and evaluation of several internet-delivered psychological treatments. Fairburn and Murphy (CREDO) have created a new version of an internet treatment for eating disorders, termed “Digital CBTe”, which is being piloted. Ehlers’s group are working on the development of internet-delivered treatments for prolonged grief and PTSD in veterans and are running the STOP-PTSD RCT of internet-delivered cognitive therapy and stress management therapy for PTSD. Clark’s group are running a study of the implementation of internet-delivered cognitive therapy for social anxiety disorder in local IAPT services. Wild is evaluating a training programme for paramedics that aims to reduce the risk of developing PTSD or depression in response to stressors at work in a RCT.

Furthermore, online resources for health professionals have been developed. Stein’s group have developed an online version of the behavioural activation manual and materials for depression from their Insika Yomama trial for HIV-positive mothers with perinatal depression. Ehlers and Clark’s group have developed online training materials for cognitive therapy for social anxiety disorders and PTSD. Kuyken’s group have developed digital resources for mindfulness cognitive therapy for young people and an implementation resource for health service settings.

* + 1. **BRC Cross Cutting Themes**

#### Informatics/digital health (Theme Lead: Professor Simon Lovestone)

We have received additional funding for UK-CRIS this financial year and are establishing an expert advisory group to oversee the national UK-CRIS platform and provide national leadership in information governance for real world clinical data.

We have established a core group of informaticians at Oxford which is becoming fully trained in the analysis of complex multi-modal biomolecular data for biomarker studies. This group is working with others on a test data set (AddNeuroMed) and has successfully established pipelines for metabolomics QTL analysis to nominate target biomarkers. A paper is in generation. We are now assembling a wider collaborative group for replication and extension studies across other data sources

We have made progress in establishing, testing and refining a suite of apps for use on smartphones for assessment of cognition in preclinical Alzheimer’s. These will be implemented in clinical studies in 2018/19

We are working with Johnson and Johnson and have completed an agreement to work together to establish a centre for mental health and dementia to encompass the BRC Digital theme and other initiatives. As part of this agreement we have received funding for three programmes of work from Johnson and Johnson, one on drug development for Alzheimer’s disease, one on experimental medicine for treatment resistant depression and one on informatics for dementia risk and mechanism.

The BRC has provided a platform for the successful Pathfinder grant (£1 million starting in April 2018) in the Mental Health Data Platform programme. This will enable us to establish a very exciting programme of infrastructure development and projects using both clinical and molecular data in studies that will help us to understand, find biomarkers for, nominate targets for therapeutics and establish platforms for clinical trials. We will have a strong focus on mood disorders

UK-CRIS has been used as an example of real-world observational data, to understand the relationship between cardiovascular, metabolic disease and Alzheimer’s Disease onset and progression with a view to nominating targets for development.

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

A key infrastructural development for the Neuroimaging and Cognitive Neuroscience theme is the installation of a new MEG (magnetoencephalography) scanner at OHBA. The new scanner was received in January 2019 and installation is due to be completed after Easter 2019. This new scanner will include a helium-recapture function that will remove the need for weekly helium fills.

Other infrastructural updates include installation of electromyography (EMG) equipment in the OHBA MRI scanner to allow small muscle movements to be measured during MRI scans, for use in research with patients with movement disorders such as amyotrophic lateral sclerosis (ALS). A new computerized booking system (Calpendo) has also been launched across the Wellcome Centre for Integrative Neuroimaging (WIN), including OHBA, to streamline the booking of the MRI and MEG scanners, TMS and EEG labs, and other facilities. OHBA’s Linux workstations, used for MEG analysis, have recently received software upgrades that will improve the support offered by existing IT teams. The number of mains and network ports at OHBA has also been increased to support the growing number of researchers and support staff.

As a cross-cutting theme, the Neuroimaging and Cognitive Neuroscience theme has collaborated across the OH BRC, as well as the WIN, to achieve the following in the last 6 months:

* The establishment of a neuroimaging journal club for translational research, in collaboration with the Experimental Medicine theme, to provide an opportunity for BRC-supported researchers to share and discuss the latest MRI analysis approaches
* The establishment of an MRI analysis drop-in clinic for BRC-supported researchers, in collaboration with the Experimental Medicine theme, to provide a dedicated time for researchers across all themes to get advice on their analyses.
* A tour of neuroimaging facilities at OHBA (MEG scanner, MRI scanner, TMS lab) as part of the Oxford Short Course in Experimental Medicine for Mental Health (OxCEMM), organised by the Training and Experimental Medicine BRC themes.
* Support for streaming WIN Wednesday research and educational seminars in the Department of Psychiatry/OHBA.

Key appointments for this BRC theme include EEG/TMS lab manager Mark Roberts, who will manage the labs in the Department of Experimental Psychology, Imaging IT Officer Duncan Smith, who will help develop and administer informatics infrastructure for neuroimaging data, and Dejan Draschkow, a post-doctoral researcher who will work on developing and refining digital cognitive tests.

A number of studies in the Neuroimaging and Cognitive Neuroscience theme have recently completed data collection, including studies looking at cognitive phenotypes in Parkinson’s disease (PD) and the effect of medication on timing in PD, as well as a large-scale project that tested over 2000 participants from the NIHR BioResources with tablet-based cognitive tests.

New projects have also started in the last 6 months, including work to put refined and validated cognitive tests onto a web-platform, and a study testing participants from the Oxford Biobank with mobile phone-based cognitive tests to investigate the effect of APOE genotype, a risk factor for Alzheimer’s disease, on working memory and long-term memory. The latter study was also awarded a pump-priming award from the Alzheimer’s Research UK (ARUK) local research network. The anticipated start of the NTAD (New Therapeutics in Alzheimer’s disease) study was delayed due to the installation of the new MEG scanner.

In relation to the Brain Health Centre (BHC), initial plans are in place to work with OUH consultant neuroradiologists to improve the quality and consistency of the clinical reports produced for MRI scans conducted on memory clinic patients. Pilot testing of sensitive cognitive tests that will form part of the BHC research cognitive assessment is underway, supported by OxDARE research assistants (Older Adults and Dementia theme).

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

The Experimental Medicine theme has made significant progress over the past six months.

Jointly with Adult Mental Health, we have expanded our support for research infrastructure. We have now adopted over 40 studies in total, including 6 new ones since September 2018. The support has taken various forms, including help with neuroimaging data analysis, statistical and ethics advice, encapsulation and randomisation, experimental design and analysis, advice on sample transport and storage, and access to Standard Operating Procedures (SOPs). As part of our competitive seed funding application scheme, we have provided financial support to 2 additional pilot studies since September 2018 on the pathway to fellowship or larger scale funding applications.

In collaboration with the Adult Mental Health theme, we have also expanded our library of SOPs (15 currently in place, with 5 developed or in development since September 2018). The SOPs are aimed at implementing standardised procedures and guidelines on key research topics within the BRC, such as: informed consent; collection and processing of cortisol; ordering, storage and disposing of medication; management of clinical waste; risk assessment; safety reporting, etc.

One of the key areas that has developed extensively over the past 6 months is the neuroimaging data analysis support provided by Dr. Cassandra Gould van Praag. Cassandra has organised a series of workshops designed to guide and support new OH BRC researchers through the process of conducting analysis of MRI data on the computer cluster, with a focus on computer programming, version control and best practice in maintaining records. Cassandra has also been working closely with the Information Technology (IT) team at the Wellcome Centre for Integrative Neuroimaging (WIN) as well as with the OH BRC Neuroimaging cross-cutting theme and Older Adults and Dementia, in order to improve our theme’s access to educational resources to enable efficient, transparent and reproducible neuroimaging analysis. Specific activities reflecting these ongoing collaborations are: 1) the establishment of a monthly OH BRC Translational Neuroimaging Journal Club (in association with OH BRC members from other themes) where we discuss analysis methods appropriate for our research areas; 2) a monthly OH BRC Neuroimaging Support Drop-in Session (in association with OH BRC members from other themes), where members of the OH BRC can receive one-to-one advice and guidance on technical or theoretical issues regarding their neuroimaging research; 3) initiating, promoting and supporting the live broadcast of WIN seminars held at the John Radcliff Hospital, to improve access to discussions about leading edge imaging research for members based at the Department of Psychiatry/Warneford Hospital site.

We are also working closely with our PPI/E cross-cutting theme in several areas, especially promoting the active involvement of patients, carers and public members into the early stages of study design. One of our theme members (Dr. Liliana Capitao) is the staff co-chair of the Patient and Research (PAR) group and PPI liaison for our theme. Liliana has been working together with the PPI manager, the patient co-chair of the PAR group, and Prof. Ilina Singh to promote and increase the visibility of PPI within the OH BRC. Accordingly, we have incorporated PPI as an important element of consideration in the application form for our BRC study adoption scheme.

Several theme-supported papers have been published over the past six months, including a detailed analysis of the future of psychological treatments, published recently in the Lancet Psychiatry.

Finally, we highlight the *MRC Experimental Medicine challenge grant* recently awarded to our theme (£1.2 million), in collaboration with Janssen Pharmaceuticals, to test a new experimental medicine model for fast acting antidepressant drug treatment in treatment-resistant depression.

#### **Patient and Public Involvement and Ethics (Lead: Professor Ilina Singh)**

The BRC Patients and Research Group (PAR Group) and Clinical Research Facility (CRF) ENGAGE Group have met regularly during this period, bringing research staff together with lay representatives to inform patient and public involvement in research.

The BRC PPI Theme is working with the Oxford CLAHRC and Oxford BRC to deliver a series of 8 workshops for patients, carers and members of the public on the research cycle, and how people can get involved in shaping research. The workshops are running between January and August 2019.

 A pilot small grants scheme has been launched to encourage and support Oxford Health BRC researchers to include PPI in their projects from an early stage.

The PPI Manager co-delivered a training session with a patient representative and researcher, as part of the Oxford Short Course in Experimental Medicine for Mental Health.

The PPI Manager and the CRF Manager met with the NEUROSEC Young Person’s Advisory Group (part of Neuroscience, Ethics and Society team at the Oxford University Department of Psychiatry) to discuss engaging young people in research.

The PPI and Ethics Lead is developing a paper on the Ethics of PPI in Mental Health and Wellbeing with the Ethics team in the Oxford BRC

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

We have recently successfully delivered the first round of our bespoke training course - the Oxford Short Course in Experimental Medicine for Mental Health (OxCEMM). OxCEMM ran from 6-8th January 2019 and was a huge success – we achieved our aim of attracting a group of 25 individuals from diverse backgrounds (basic scientists, clinicians, nurses and other allied health professionals, etc.) The course gave attendees a comprehensive, practical introduction to experimental medicine. Feedback from participants was excellent and all attendees wished to stay in touch and be involved in our Experimental Medicine Network (see below). OxCEMM will rerun in January 2020, and we are considering how we might further support funding applications from early career researchers, highlighted as an area of significant need by OxCEMM attendees.

The other central component of our capacity development plan is the development of the Experimental Medicine Network (EMN). The EMN will provide all relevant staff and trainees with access to continued training, and a forum to share experiences and ideas. We have completed a scoping exercise, in collaboration with our local partners, and are in the early stages of establishing the EMN, which will likely focus on the use of Slack to foster communication between EMN researchers.

## NIHR Clinical Research Network (CRN) based performance

Building on the success seen since FY16, in FY18 OHFT was the 5th highest recruiting mental health trust across all specialties, with 2349 participants recruited to a total of 62 portfolio studies. In FY18 OHFT was the 2nd highest recruiting trust to studies on the Mental Health portfolio with 2101 participants recruited to 45 studies. This trend continues in FY19 to date with Oxford Health currently being the 3rd highest recruiting trust to the Mental Health portfolio (recruiting 2238 participants across 43 studies).

In FY18, OHFT was ranked 29th out of all NHS trusts reporting recruitment to the Dementia and Neurodegenerative diseases (DeNDRoN) portfolio with 219 participants recruited to 13 studies. At the end of the first nine months of FY19 OHFT was ranked 30th out of 162 Trusts and reported recruitment of 185 participants to 9 studies.

In FY18 Thames Valley and South Midlands CRN was ranked 8th out of 15 CRNs in terms of participant recruitment to the Mental Health and Dementia and Neurodegeneration portfolios. This includes activity across all trusts in the region.

The CRN are proud of their achievement in meeting participant recruitment targets, and in Oxford Health this is also the case. Without fail, all commercial dementia studies have either met or exceeded recruitment targets. There is growth in the mental health commercial portfolio within OHFT.

There are a wide range of studies, commercial drug trials, non-commercial trials including repurposed medications, tele-care, patient and carer surveys and genetic studies.

Drs Andrew Molodynski and Rohan Vanderputt continue in their respective roles as CRN Mental Health lead and CRN Dementia lead across the Thames Valley region. Helen Collins, CRN Research Delivery Manager for Division 4, continues to work with the Prof Andrea Cipriani as Associate Director of R&D, to enable OHFT to support NIHR portfolio studies.

New PIs are supporting the portfolio: three Old Age Psychiatrists have recently become actively involved as PIs or sub-investigators, and via the CRN green shoots initiative, further Adult Psychiatrists have been funded to take on clinical research responsibilities.

# Research Set Up, Management and Governance

## Research Set Up

In order to ensure that research is fully embedded in the Trust in line with the national agenda to support the development and delivery of evidence-based medicine, we are currently streamlining our research set up activities to ensure that they are truly efficient and easily accessible to teams across our care portfolio.

These newly reviewed processes will be communicated widely in the coming months to ensure that all groups, even those not historically involved in research, know how to get a research project started and delivered. This will be done to attract and develop new principle investigators (PIs) from around the Trust, thereby enhancing our capacity to deliver evidence-based patient care.

## Pipeline Group Meetings

The Pipeline Group, chaired by Prof Andrea Cipriani, Associate Director of R&D, meets regularly to determine whether proposed studies are appropriate to be developed and whether or not there is capacity in the Trust to deliver, enabling a more collective approach to research. This approach has helped to ensure that study targets can be met while also preventing the overburdening of patient groups.

A Mini Pipeline Group has been established to meet bi-monthly to discuss expressions of interest coming in to the Trust and potential Oxford Health NHS Foundation Trust sponsored studies.

## Health Research Authority (HRA)

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. Since its introduction in April 2016 the changes have been embedded within the Research Support Office HRA Approvals.

## 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. The Research Support Team work with researchers and sponsors to ensure a swift process of confirming the Trust’s capacity and capability to deliver studies 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. Directorate contact is now required before the study is presented to the Pipeline Group.

## Contracts and Confidentially Disclosure Agreements

An agreement is in place for OUH to undertake the review of research contracts and Confidential Disclosure Agreements (CDAs) from a legal perspective to ensure the Trust obligations are appropriate. A standard operating procedure is being drafted by OUH and once approved will be adopted in OHFT with an appendix detailing local Trust requirements

## Costings

The R&D Finance team 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 Research Support Office received a database system called Studyline in May 2017. Studyline 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 and surrounding Trusts. The Research Support Team are working with the Data Manager to streamline the reporting process.

## Monitoring and Auditing of Research Projects

The R&D Support Team audited four hosted studies in 2017/18; only one study was audited in 2018/19 due to staff shortages.

In 2018, the monitoring process was put on hold due to staff shortages. Starting from Q1 2019-2020, we will begin a process to bring the Trust up to date in its monitoring activities. Once this has been achieved, we will implement a new internal standard operating procedure to ensure ongoing compliance.

## 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** | **2017/2018** | **2018/2019** |
| Number of Open Studies | 40 | 48 | 77 | 74 | 112 |
| Number of Participants | 2012 | 2576 | 1994 | 2456 | 1886 |

### NIHR Metrics and Targets

Our focus remains on transparency, accuracy, and meeting sponsor expectations. The Research and Development Department are working to ensure that delays getting patients in to studies are minimised.

**Number of Expressions of Interest (EOI) and Feasibility**

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Expressions of Interest** | **Number of Studies approved via Feasibility** | **Number of Studies abandoned during Set Up** |
| 2016-2017 | 82 | 66 | 20 |
| 2017-2018 | 82 | 27 | 29 |
| 2018-2019 (10 months) ??? | 56 | 26 | 19 |

## Case Records Interactive Search (CRIS)

Tanya Smith is the CRIS Manager and Digital Theme Leader of Ox-CRIS for NIHR Oxford Health Biomedical Research Centre. The Oxford team includes a CRIS Data Administrator who supports new users of CRIS to set up their accounts and projects and conduct the audits and 2 CRIS Academic Support and Data Analysts who provide support to CRIS researchers in framing their CRIS question and also running more complex searches and extracting relevant data for users to subsequently analyse.

Tanya started a 6-month secondment in September as the UK CRIS National Training and Support Lead, promoting the effective use of CRIS between 11 UKCRIS partner sites and has been developing a training programme, to meet the needs of local Trusts.

The Oxford CRIS Oversight Group meetings are held bi-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, a carer/patient representative, representatives from the trust Clinical Directorates, Trust Audit Team, Trust Pharmacy team and academic leads from the University.

To date the CRIS Oversight have approved 56 UK CRIS applications, 33 of which were research questions, 11 service evaluation, 12 clinical audit questions. We currently have 34 active CRIS searches and 43 active CRIS users.

**Natural Language Processing (NLP) work** - This will provide CRIS users with an automatic text reading facility for extracting and bringing into context relevant data currently only available within the free text fields of the medical record.

Work continues locating all mentions of drugs within the clinical notes and whether they are being prescribed, mentioned or ‘PRN’ along with their dose. The plan will then be to enable all CRIS Network Trusts to run across their data to benefit from this work. We are also now able to locate MMSE and MOCA cognitive scores.

**CRIS SQL Training** – Oxford have been instrumental in developing the recent SQL training workshops as well as supporting with additional external linkage work.

Suzanne Fisher and Adam Pill have been developing a 2-day programme to train CRIS researchers across our Network. They will be delivering the workshops, with Tanya’s support in March.

**Virtual Desktop Environment** - We continue to offer a virtual desktop environment, created by Oxford Health Trust IT department, for authorised non-NHS researchers to access CRIS. This restricts access to both the data and prevents it removal from the Trust firewalls without prior permission. This will shortly be moving to a facility at Swansea University - UK Secure Research Platform - UK SeRP which will provide additional analysis and NLP tool facilities.

**Consent for re-contact** pilot is currently under review. There is now a form in CareNotes and patients were being asked whether they are interested in being contacted about research in the future. Once the review has taken place and the lessons learnt have been recognised, the next steps to this process will then be established.

**Improving Access to Psychological Therapies (IAPT) linkage to CRIS** – CRIS will soon be linked to IAPT data in Oxford within the CRIS system. The development work has been supported by Suzanne Fisher in the Oxford CRIS team who has been working closely with the UK CRIS Programme team and members from the IAPT service too. We are shortly commencing the User Acceptance Testing (UAT) and hope to go live in the next few weeks.

## Consent for re-contact

Andrea Cipriani is now the interim lead of the Informatics/Digital Theme of the Oxford Health BRC and in collaboration with Mike Denis and Sophie Walker, he will be directly responsible of the progress of C4RC.

In Jan 19 a meeting was held to restate the C4RC purpose and review the C4RC pilot study (Andrea Cipriani, Sophie Walker, Mike Denis, Tanya Smith, Helen Jones, Bill Wells, Jen Potts).

The following starting points were discussed and agreed upon: (1) getting patients involved with research improves services and care for everyone and it is a priority for our Trust; (2) we should make the most of the consents gained from patients in out Trust and be transparent about what is done with their data; (3) OH should be in the fast lane for showing how to be a research active Trust (especially because in Oxford we have the 2nd mental health BRC in the country). We will look to create a leaflet about what the Trust does with patients’ data

The feedback from the four pilot sites was mixed: main areas of consideration were the form itself, how it was embedded into Carenotes and how it could be implemented into routine clinical services. The group discussed the feedback and agreed that the pilot demonstrated considerable difficulties with an opt-in approach (both in terms of logistics and attitudes of clinicians). Sophie and Mike Denis met the Information Governance (IG) team, who are in the process of thinking of suitable GDPR alternatives to our current model and are writing a 4-page review of opt in versus opt out approaches form an IG perspective. This will be valuable information to be presented and discussed during the next meeting of the C4RC group. As part of this a visit other Trusts which have done an opt out approach is being planned

The Informatics/Digital Theme of the Oxford Health BRC will also fund a series of focus groups at each site with a key contact from the pilot, with support from Claire Murray (PPI lead). Key contacts have been asked to start approaching 4-6 patients from their service and to find a date to conduct it by the end of March.

The group finally agreed to summarise and present the results of the survey and the focus groups in an article to be published in a peer-reviewed scientific journal (Evidence Based Mental Health – BMJ Group). The Director of the Oxford Health BRC (John Geddes), the Medical Director of Oxford Health NHS FT (Mark Hancock) and the Chief Executive Officer of Oxford Health NHS FT have agreed to be co-authors of this paper.

# Trust Governance and Reporting Mechanisms

## Reporting and Governance

The Research Management Group (RMG) is a high-level committee established to drive the collaborative research strategy across the Trust and local areas. It is responsible for the strategic and scientific direction of the research undertaken with or in partnership with OHFT.

The meetings bring together academics and clinical services with mutual interest in particular projects or work streams to increase engagement between clinical services and research for open discussion about the synergistic and collaborative working to deliver patient benefit through research endeavors.

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.

The RMG was noted by the NIHR BRC feedback as noteworthy and worth sharing with colleges nationally.

# Staffing

Andrea Cipriani took up a role as NIHR Professor in October and Cathy Henshall has been awarded NIHR funding through its 70@70 competition. We are fortunate that these two nationally recognised individuals will continue as part of the Research Senior Management Team.

Emma Stratful (Deputy Director of Research Strategy and Operations) left the Trust at Christmas and Bill Wells, previously the Head of R&D Finance is covering this role on an interim basis.

Helen Jones has been appointed as Research Delivery Manager to lead the Adult, Older Adult and CRF study delivery teams, each lead by a band 7 operational manager. Helen reports into Cathy Henshall (Nurse Lead for Research/CRF Manager) and Andrea Cipriani (Associate Director of R&D), who are responsible for the strategic direction and oversight of the three teams and they work closely with the NIHR and CRN to ensure that their requirements are met.

A new role of patient engagement manager was created recently, and Jen Potts will be covering this role on an interim basis when she returns from maternity leave in April. This role will be key to the Consent for re-contact process.

Francesca Hatton, the Research Support manager left the Trust in January. She has been replaced by Brandy Coote who joined in January.

# Estates

We are now running research studies at the Whiteleaf centre in Aylesbury which provides greater opportunities to staff and patients in Buckinghamshire to get involved in research.

Work has been initiated between R&D, Estates and Clinical Services to look for additional opportunities across the geographical area of the Trust to be able to conduct research.

# Communications

The BRC is sponsoring a dedicated communications manager to work as part of the Oxford Health communications team to publicise and engage the public, media, staff and patients in the centre’s research agenda. The role will work closely and collaboratively with BRC theme leads and the University of Oxford Department of Psychiatry communications lead to build and enhance understanding and support for the centre’s work.

In the meanwhile, the BRC will commission a communications agency to support the delivery of a short-term project designed to help raise awareness of its work and support the wider public in understanding science and research in mental health and how this contributes to better patient care and experience. Using the 6 themes of the BRC and including the CRF, the agency will source and write up 7 ‘good news’ stories, which can be used in the annual report, posted on the website and shared online. Additionally, 7 short film clips will be produced offering a catchy, interactive, engaging way to communicate the science in plain English. Again, these will be posted on the BRC website and shared. These resources will support the next step in expanding the materials available online while supporting further engagement and knowledge sharing among the PPI groups and other people interested in this important work.

In December, [Professor John Geddes introduced the new Translational Research Collaboration for Mental Health to National Health Executive](http://www.nationalhealthexecutive.com/Comment/leading-the-way-the-translational-research-collaboration-for-mental-health) online. The NIHR TRC-MH brings together BRCs (London, Oxford, Cambridge, Bristol, Nottingham, University College London), with Clinical Research Facility hosting sites in Manchester, Newcastle and Exeter, and comparable developments in Cardiff and Edinburgh. It provides a single point of contact for partners such as industry and medical research charities to work with the 11 participating centres of excellence, speeding up contract and agreement negotiations. It will coordinate from first contact through to research project delivery. The initial focus of the TRC-MH will be on new therapies for treatment-resistant depression and for people ‘at risk’ of developing mental illness to help develop preventive strategies. The TRC-MH will also develop well-defined cohorts of patients who have consented to be re-contacted to participate in research studies.

On February 12, Professor Andrea Cipriani led a news briefing with the Science Media Centre on his published paper, Association of cannabis use in adolescence and risk of depression, anxiety and suicidality in young adulthood: A systematic review and meta-analysis, which was published in [JAMA Psychiatry](https://protect-eu.mimecast.com/s/Zx9_CEq4MizxREHNdD1B?domain=jamanetwork.com). The excellent coverage included national newspapers, The Times, The Daily Mirror, The Sun, The Guardian, The Daily Telegraph, The Independent Daily Edition and Daily Express. Online news sites - BBC news, Reuters and Daily Mail online. International news - NBC, Global News Canada, The Globe and Mail, CBC Health, The Canadian Press (English and French), Montreal Gazetter, Le Devoir and The Philadelphia Inquirer. Broadcast - BBC World Service, BBC Radio 4, regional stations, LBC and Sky News.

# Intellectual Property

In Oct 2017 the Framework Intellectual Property Agreement (FIPA) was sent to the NIHR for review and in the Summer of 2018 the Director of Research Services at Oxford University, the Chief Operating Officer at Oxford University Innovations and the Trust Medical Director signed the agreement.

Since the start of 2019 a lot of activity has taken place between all parties and the NIHR. The Trust led by the Director of Finance and the Director of Corporate Affairs are now considering the best way to operationalise this agreement to ensure maximum benefit to the Trust and NHS.

IP now appears in research contracts including the BRC, MIC, CLAHRC and most grants

# Finance

## Research Income

During the last ten years, OHFT income generated from research activity has grown from just over £1m in FY09 to an FY19 budget of £12m.

Income over the period FY10 to FY14 was largely from a small number of grants but over the last five years these have been replaced by infrastructure awards providing the opportunity to support more research activity and generate leveraged income.

The FY19 income budget has benefitted from a non-recurrent £1m award for the development of UK CRIS as part of the BRC. FY20 will see the existing CLAHRC award come in an end in October resulting in a £1m reduction although it is hoped that the bulk of this will be mitigated by a successful ARC application.

## FY19 Income Budget

The FY19 Income budget of £12m is made-up and managed as follows:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FY19 Income Budget** | **Management of Funds** | | | **£k** |
| **Source** | **R&D SMT *(note 1)*** | **Primary Care** | **Other** | **Total** |
| **National Institute for Health Research (NIHR)** |  |  |  |  |
| Biomedical Research Centre (BRC) | 3,846 |  |  | 3,846 |
| Collaboration in Leadership in Applied Health Research & Care (CLAHRC) |  | 2,000 |  | 2,000 |
| Research Capability Funding (RCF) | 672 | 534 |  | 1,206 |
| Study income | 111 | 969 |  | 1,080 |
| Clinical Research Facility (CRF) | 744 |  |  | 744 |
| I4I | 982 |  |  | 982 |
| MIC |  | 249 |  | 249 |
| **Total** | **6,355** | **3,751** | **-** | **10,106** |
| **Other Funding** |  |  |  |  |
| Clinical Research Network: Core Funding | 792 |  |  | 792 |
| Clinical Research Network: Hosting of Network staff |  |  | 314 | 314 |
| Study Delivery | 349 |  |  | 349 |
| Other Grants | 436 |  |  | 436 |
| **Total** | **7,932** | **3,751** | **314** | **11,997** |

Note 1: The R&D SMT is made up of Prof. John Geddes (R&D Director), Bill Wells (Interim Deputy Director of Research), Prof. Andrea Cipriani Associate Director of R&D) and Dr Cathy Henshall (CRF Manager).

## Performance

R&D performance for FY19, as at month 10 (Jan 2019) is showing a contribution to overheads of £114k, compared to budgeted cost of £97k, generating a £211k favourable variance. This has occurred due to greater than budgeted study income £94k, staffing vacancies £103k and an underutilisation on Excess Treatment Costs (ETCs). As of October 2018, each Trust needs to meet a threshold, prior to the local Clinical research Network funding ETCs.

The year end position is forecast to be showing a contribution to overheads of £120k, compared to a budgeted cost of £129k, showing a forecasted Year End of £249k Favourable Variance

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

The CLAHRC commenced in January 2014 and following a successful extension application it will now run until September 2019. FY19 Funding is £2m and FY20 reduces to £1m due to the award coming to an end in 2019. It is hoped that the CLAHRC will be replaced by the ARC where funding of £9m over five years would start in October 2019. The ARC application was submitted in August, and following interviews in October, the Department of Health and Social Care, feedback was received in January, requesting further information. A revised application was submitted in February and confirmation on selected NIHR ARC’s is now expected in May.

## Medtech and In vitro diagnostic Co-operative (MIC)

The NIHR funded MIC started in January 2018 and is led by Gail Hayward from the Department of Primary Care (£1.2m, FY19 250k)

## Clinical Research Facility (CRF)

CRF funding commenced in April 2017 (£3.7m, FY19 £744k). This award is hosted by OUH but managed in its entirety by OHFT with the bulk of the funding being used to activity at the Warneford. Funding was planned to be used for development of CRF facilities at the OUH however due to problems in identifying suitable space funding was reallocated to other areas selected as part of a completion in FY18. A similar process took place recently with £27k awarded to NDCN to develop Oxford Health’s CRF capacity for nuclear imaging and £45k awarded to the Acute Vascular Imaging Centre at OUH to support innovative new areas of work requiring intensive nursing inputs.

## Biomedical Research Centre (BRC)

The BRC commenced in April 2017 and is led by Professor John Geddes from the University of Oxford, Department of Psychiatry. FY18 expenditure was in line with the £1.4m funding awarded. The original FY19 funding of £2.8m has been increased to £3.8m by the NIHR to support the development of UK CRIS as noted above.

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

The FY19 core CRN budget of £791k funds Service Support Activity (primarily patient recruitment). It is currently predicted that only £690k will be utilised by OHFT with the balance being returned to the CRN.

CRN Network staff such as the Thames Valley Primary Care Research Partnership are hosted by the Trust but not under the management of the R&D Senior Management Team. their costs are recovered on a direct cost basis from the CRN (FY19 budget £314k)

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

The FY19 RCF allocation of £1,205m showed an increase of £168k on FY18 with an extra £88k driven by higher infrastructure awards and £80k driven by increased grant related income. FY19 was split between the Trust & Department of Psychiatry (including CLAHRC) £672k and the Department of Primary Care £533k.

Following a review of RCF future funding will see the amounts based on Infrastructure awards reducing, the Senior Investigators element being removed with the Grants element remaining at a similar level. These changes will be phased in over future years.

Despite this, with additional RCF received from the BRC Infrastructure award, we expect Trust RCF to increase in FY20, to approximately £1.5 million

## Grant Income

The NIHR study income is received for three awards, these are:

* Professor Richard McManus (Department of Primary Care). “Optimising the monitoring and management of raised blood pressure during and after pregnancy” (£2.5m, FY19 £503k)
* Professor Andrew Farmer (Department of Primary Care). “Supporting people with type 2 diabetes in effective use of their medicine through a system comprising mobile health technology integrated with clinical care” (£2.5m, FY19 £463k)
* Dr. Valeria Frighi (Department of Psychiatry) “Fractures in people with intellectual disabilities” (£152k, FY19 £111)

In 2018 a further NIHR grant was awarded, that will start later in 2019:

* Professor Paul Stallard (University of Bath). “A comparison of usual care versus usual care plus a smartphone self-harm prevention app (Blue Ice) in Young adolescents aged 12-17 who self-harm” (£350k over 3 years)

In 2019 Professor Cathy Creswell will be joining the Department of Psychiatry and transferrin a previously awarded Programme grant to the Oxford Health (£2.5m over 5 years) entitled “Development and evaluation of a pathway from ‘Universal screening’ to online intervention for children with anxiety problems”

In addition to several small sub-contracted applications three have been submitted with OHFT as lead, these are detailed in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigator | Organisation | Study Title | Funder | Funding |
| Claire Friedman Smith | Dept. of Primary Care, University of Oxford | Safety Netting in Primary Care: A realistic review of the contexts and mechanisms of its effectiveness | NIHR | 149,803 |
| Felicity Waite | Dept. of Psychiatry, University of Oxford | Preventing psychosis ‘in young people at ultra-high-risk attending NHS Mental Health Services | NIHR | 249,990 |
| Ben Goldacre | Dept. of Primary Care, University of Oxford | 0418-10130 Identifying, explaining and addressing unwarranted variation in GP prescribing | NIHR | 327,743 |

## I4I

The I4I award “Immersive virtual reality to transform the lives of patients with psychosis” (£3,9m, FY19 £1.1m) commenced in June 2018, will run for three years and is led by Professor Daniel Freeman (Department of Psychiatry).

## Study Delivery

The Study delivery function is led by Prof. Andrea Cipriani (Associate Director of R&D), Dr. Cathy Henshall (CRF Manager) and Helen Jones (Study delivery manager). This brings together commercial and non-commercial study income generated from resources funded by the CRN, CRF and BRC. The NIHR funders expect income generated to be recycled for the benefit of research. This area is under new management and provides the opportunity for greater utilisation of resources and the development of new investigators.

## Oxford Academic Health Science Network (OAHSN)

The Anxiety and Depression network will be funded in FY19 by the AHSN & others £77k and CLAHRC £61k with a further £62k available from the CLAHRC in FY20 and FY21.

## Infrastructure Funding Timeframes

|  |  |  |
| --- | --- | --- |
| **Infrastructure or Award** | **Current funding timeframe** | **Total Value** |
| CLAHRC | Jan 2013 to Sep 2019 | £10.5m |
| MIC | Jan 2018 to Dec 2022 | £1.2m |
| CRF | April 2017 to March 2022 | £3.7m |
| BRC | April 2017 to March 2022 | £13.5m |

## Audits

During FY19 the Trust was selected by the NIHR for a Funding review. This involved a paper-based exercise and two day visit in December for an NIHR Audit. Feedback was very positive indeed and the NIHR were enormously impressed by the integration, team working and academic/financial engagement. In January 2019 the Trust was also selected by the Local Clinical Research Network for a Financial Controls Monitoring visit, again the feedback was positive.

**Authors and Title:** Professor John Geddes, Director of R&D, BRC and CRF

Bill Wells, Interim Deputy Director Research Strategy and operations, Senior Manager for NIHR BRC

Dr Mark Hancock, Medical Director

**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*