

# PAPER

[This will be input by secretariat]

**Report to the Meeting of the**

**Oxford Health NHS Foundation Trust**

**Board of Directors**

**January 2014**

**Research and Development Report**

# Clinical Quality and Care

It is increasingly recognised that participation in research produces widespread benefits for patients and, more generally, improvements in quality of care. A Censuswide comsumer poll of 3,000 people in England, commissioned by the NIHR published data in September 2014 saying that 95% of those as responding stated that it is very important that the NHS carries out clinical research, with 85% or people agreeing that they would be very or somewhat willing to take part if they were diagnosed with a medical condition or disease. This accounted for the main factor that was most likely to motivate them into taking part, along with if a friend/family member was taken seriously ill and didn’t have the treatment they needed. The majority of those surveyed said that clinical research takes place within the NHS, Universities and Clinical Trials Units. Oxford health NHS FT has strong links to the University of Oxford, a thriving R&D department and Clinical Research facility to enable high quality research to take place and provide opportunities for patients and carers.

# Networks and Collaborations

## AHSN

Oxford Health NHS FT is hosting three themes;

* Early intervention led by Prof Belinda Lennox and Sarah Amani
* Anxiety and Depression led by Prof David Clark and Ineke Wolsey
* Dementia led by Dr Rupert McShane

The current management and financing is via R&D although there is discussion being held within the Trust as to whether this should be devolved to the clinical directorates within the organisation as the money is for NHS services.

### Early Intervention Theme

Four working groups with public representatives, clinicians, researchers and managers from across the Thames Valley have been established:

* Developing a common assessment for early intervention in psychosis;
* Reducing unwarranted variation;
* Extending the Early Intervention model to another condition other than psychosis;
* Increasing the number of young people participating in research

The four working groups meet every 2 months to work on and through the above groups, they have established a common set of outcome measures (a common assessment) for all early intervention in psychosis teams;

They are in the process of recruiting four clinicians to be seconded as Band 7 Quality Champions to drive quality through consistent use of the above common assessment;

On behalf of NHS England, they have established a national Expert Reference Group involving psychosis national subject matter experts to establish the first ever mental health Referral to Treatment standards;

Working with the AHSN informatics team, they have mapped the current service provision, service structures and benchmarked outcomes for young people with mental health issues in the Thames Valley including;

* the number served by EIP teams,
* the number who are served by generic CAMHS (Child and Adolescent Mental Health Services) & AMHS (Adult Mental Health Service);
* a range of outcomes including service utilisation, employment & education rates and cost to the local health economy;
* looking at the rate of transition from CAMHS to AMHS

They continue to work in partnership with our partners and are open to exploration of collaborating with other partners who can help the network to achieve its aim to *Improve health and social outcomes for young people with first episode psychosis, including symptom reduction and engagement with education and employment.*

### Anxiety and Depression Theme

#### **Understanding outcome variability and improving recovery rates for Talking Therapies (IAPT)**

Our analyses will quantify variations in access rates and outcomes (recovery and reliable improvement rates) by service, by clinical condition (depression, PTSD, generalised anxiety disorder, social anxiety disorder, obsessive-compulsive disorder, panic disorder, health anxiety, and specific phobias), and by patient demographics (age, ethnicity, etc). These analyses go well beyond the data that is available nationally, which is restricted to overall recovery rates for a service. Once outcome variability has been quantified, we will aim to identify predictors of that variability in terms of service models, procedures, types of interventions, therapist training, etc. The findings will be fed back to services so that they can use them to restructure their service provision, as appropriate, to further enhance outcomes. The aim is a 5% improvement on current average.

#### **Supporting local service innovation and disseminating successes throughout the region.**

This work stream will provide research support for the projects by advising on outcome measures and evaluation. It will also support the leads of the relevant projects to share their learning with other IAPT services within our network so that ALL of the services will be able to implement the new service innovations. The key innovations that are currently underway are:

1. CBT for insomnia treatment protocol
2. Depression and diabetes integrated care projects
3. Heart 2 Heart integrated care project
4. COPD integrated care project
5. Psychological Perspectives in Primary Care (PPiPCare) training programme
6. MUS integrated care pathway project

#### **Improving data completeness in CYP IAPT.**

We will be working with the CAHMS services and the CYP IAPT (Children and Young People’s Improving Access to Psychological Therapies) collaborative to increase the average data completeness of paired outcome data (i.e. pre and post treatment) across the OAHSN patch by 10%.

### Dementia Theme

Webinars are proving to be very successful, level of participation is increasing and first KPI achieved. Despite delays earlier in the year the Data Capture project with True Colours is close to a working solution, ready for trial with a group of 30 carers final details to be agreed in December.  Delta G (Improving palatability of energy drink) work has hit a major stumbling block and it is unclear at this stage, if the energy drink will be progressed for use in health applications. YPWD Younger People With Dementia is progressing well, the 1st KPI achieved ahead of planned date revised KPIs to increase the scope of work to be submitted to Best Care Programme Board

Unwarranted Variation –  Webinars. 7 Webinars held 16th July – 19th November, they have been very successful.  Participation from consultant staff and the multidisciplinary team. December KPI achieved, 15 consultants have attended 29% or more of the sessions. Full programme set until June 2015. Memory Service National Accreditation Programme (MSNAP) 2 services accredited, 1 awaiting result of accreditation visit, 2 in progress and a further 6 funded by AHSN, Oxon x3, Bucks x2 and Milton Keynes, supported by Maureen Cundell

Data Capture Systems  – True Colours. Despite delays earlier in the year, 30 carers have consented to be included in the trial. First test question agreed with SMS carers and submitted to True Colours.  Date to be agreed for the submission of SMS to carers

Delta G – Improving palatability of energy drink. Planned palatability work with the International Food Network delayed by unsuccessful negotiations with a major retailer with an interest in medical foods. At this stage it is unclear if the product will be progressed for use within the dementia patient group

## NIHR CLAHRC

Overall, the CLAHRC projects are progressing well. There have been some delays to the start of projects in Theme 1 - Early Intervention and Service Redesign and Theme 5: Self Management both due to issues with recruiting suitable staff. These issues are in the process of being resolved and will not cause any significant problems going forward. Finances and matched funding are both on track and more avenues of matched funding are being explored as are potential new partnerships.

Theme 4: Comorbidities has produced 3 high profile papers published in the Lancet, Lancet Psychiatry and Lancet Oncology on Cancer and Depression which attracted a large amount of media interest. There have been a significant number of outputs from the other themes including the award of NIHR PGfAR funding, publications and presentations.

In addition, several new projects have been adopted into the CLAHRC portfolio: POPS2 - weight management in pregnancy (collaboration with the University of Birmingham; OUH and part funded by the NIHR School for Primary Care Research); and Foxweb - reduction of the incidence of violence in forensic psychiatric facilities. There are also a number new collaborations being discussed including a potential collaboration with the NIHR CLAHRC North West London and OUH to roll out their successful COPD bundle across the NIHR CLAHRC Oxford area.

Working with partners at the Said Business school, a training programme has been developed to support future leaders within the NIHR CLAHRC Oxford and its partner organisations. This programme will focus on OH and the core CLAHRC partners in the first instance and is planned to start in February 2015.

The first annual NIHR CLAHRC Stakeholder Symposium was held at St Anne’s College, University of Oxford on 11th December 2014. The meeting received overwhelmingly positive feedback and was aimed at not only at strengthening current partnerships but also sharing innovative ideas and best practice and encouraging the formation of new collaborations. Delegates attended representing most of the CLAHRC stakeholder groups; feedback from the day will be disseminated to all CLAHRC Stakeholders. This feedback will also be used to shape next year’s symposium which we hope will prove to be as successful as the first.

## NIHR DEC

Extract from annual report submitted to the NIHR for 2013/2014

### Progress on Short term objectives:

* Identify new In Vitro Diagnostics (IVDs) relevant to primary care: Our horizon scanning programme has produced six new reports on IVDs relevant to primary care.
* Interacted with nine companies who are developing new IVDs to advise them on primary care applicability.
* Produce rapid technology assessments: It has produced six horizon scanning reports on IVDs relevant to primary care. An additional topic has been submitted to the HTA Diagnostic Technologies and Screening Panel.
* Hold annual stakeholder meeting: There was a third Diagnostics Forum in March 2014. This year’s UK Diagnostic Forum focused on changing the landscape of adoption of diagnostics. Running over two days the conference combined talks, panel discussions, debates and small group sessions. The Forum was attended by 110 delegates from industry, academia and representatives from NICE, NOCRI, Department of Health, the Academic Health Science Networks, Technology Strategy Board, BIVDA and the other DECs.
* Hold annual 3-day educational course: The first annual 3-day course will be held in September 2014 (22-24 September, Queens College, Oxford). This course is aimed at all professionals working on diagnostic tests including people working in industry, academia, funding and regulation etc. The course combines talks with hands-on activities. To stimulate interactive discussions and maximise the learning experience, the number of places for this course are limited.
* Identify gaps in clinical needs: A survey has been conducted among general practitioners to assess their clinical needs for IVDs in routine clinical practice. The survey was initially conducted in the UK, and subsequently expanded to the US, Australia, the Netherlands and Belgium. The results of the survey have been presented at national and international conferences, and a manuscript detailing its main results has been submitted to a peer-reviewed journal.
* Produce case studies: A case study has started on the Abingdon Emergency Multidisciplinary Unit (EMU). This unit was awarded the 2013 Guardian Healthcare Innovation Award for novel care delivery using point of care diagnostic technology for frail older patients. The unit has implemented a wide range of point-of-care tests to assist in managing these patients in ambulatory care, the impact of which on patient outcome and clinical decision making we will describe in the case study. <http://www.theguardian.com/healthcare-network/2013/oct/25/university-oxford-service-delivery-innovation-award-winner>
* Engage with relevant stakeholders: In addition to our ongoing engagement with TSB, BIVDA and industry in general, and our contacts at the Diagnostics Forum, we are engaging with the Academic Health Science Network (AHSN) Oxford, the NIHR Oxford Biomedical Research Centre and the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Oxford, to ensure that the DECs research results are translated into practice.

### Progress on Medium term objectives:

* Secure additional external funding: It is involved in three ongoing grant applications: two European Horizon2020 applications, both now selected for stage 2: one in collaboration with a large multinational industrial partner on a new IVD platform that will synergistically integrate three key assay modalities in one platform (immunoassay, chemical and haematological testing) for the diagnostic work-up of frail elderly and heart failure monitoring, and one with a SME on an integrated comorbid diagnostic platform with assays for diabetes, cardiovascular and chronic kidney disease at the point-of-care; the third application is a NIHR Programme Grant for Applied Research application (also selected for stage 2) in collaboration with the NIHR Nottingham Digestive Disease Biomedical Research Unit on identifying chronic liver disease in the community. In addition, we are preparing an application to the TSB Biomedical Catalyst with a SME on the point-of-care diagnosis of acute coronary syndrome in primary care and ambulance services.
* Direct academic and industry research efforts towards unmet needs: The results of the UK and international survey on clinical needs will feed into the other themes of the DEC, including the horizon scanning theme and the methods theme on transferability of evidence. Once the results of the survey are in the public domain through peer-reviewed publication, we will share and discuss the primary care unmet needs with industry to streamline new developments.
* Develop consultation service for industry: data is being collected after each industry interaction, to establish an effective consultation service for industry. Data collected include a description of industry’s objectives for meeting with the DEC, whether these were met and whether the advice given was helpful, suggestions to improve future meetings, immediate further actions.

### Progress on Long term objectives:

* Good progress has been made in setting up our group as the UK ‘go-to’ group for diagnostics industry and becoming a national resource on diagnostics for primary care with our current output in the Horizon Scanning programme, the multiple interactions with industry and the organization of the Diagnostics Forum. By working with clinicians, industry and NHS organisations, to be able to improve the efficiency of care of NHS patients.

## National Institute for Health Research (NIHR) Networks

The Clinical Research Network (CRN) Thames Valley and South Midlands is within the Oxford AHSN area and is hosted by Oxford University Hospitals NHS Trust, with anticipated annual funding of £13 million. Each of the 15 NIHR CRNs will now cover all therapy areas and allow flexible deployment of resources. Each CRN supports six divisions:

Division 1: Cancer

Division 2: Diabetes, stroke, cardiovascular disease, metabolic and endocrine disorders, renal disorders

Division 3: Children, genetics, haematology, reproductive health and childbirth

Division 4: Dementias and neurodegeneration, mental health, neurological disorders

Division 5: Primary care, ageing, health services and delivery research, oral health and dentistry, public health, musculoskeletal disorders, dermatology

Division 6: Anaesthesia/peri-operative medicine and pain management, critical care, injuries/emergencies, surgery, ears/nose/throat, infectious diseases/ microbiology, ophthalmology, respiratory disorders, gastroenterology, epatology.

Progress continues to grow with the dementias and neurodegeneration specialty of Division 4 (previously known as DENDRON) with an increase in the number of expressions of interest being requested, however the Trust is yet to see this converted into the undertaking of the studies. The Clinical Specialty leads for dementia (Dr Rohan Van de Putt) and mental health (Dr Andrew Molodynski) have been appointed from clinical teams within the Trust. CRF continues to support the undertaking of commercial and non-commercial studies being co-ordinated within the field of dementia.

Links are being formed with other Divisional leads (particularly with Division 2 and 5) within the CRN to potentially undertake more community, non-mental health research and primary care.

## NIHR BRC and CRF

Consideration will be given to as to a trust response to the NIHR calls for Biomedical Research Centre(BRC) and Clinical Research Facility (CRF) applications.

# Research Governance

## R&D Governance Group

The R&D Governance committee has recently been renamed following the restructuring of the Trust committee structures in line with the CQC. The now named R&D Governance Group has continued to meet quarterly and minutes are feed into the CEC.

The R&D Governance Group is primarily an assurance group. The Group reviews the R&D finances, appropriate and safe staffing levels for the conduct and governance of research studies ongoing within the organization, the oversight of the sub groups that report into the R&D Governance Group.

Serious Advert Event (SAE) participants encounter whilst taking part on research studies are robustly captured for industry studies. The new R&D Governance Manager, Vicky Rush, who joined the Trust in June 2014 is in the process of setting up a SAE reporting and safety group for the reporting of SAE from non-commercial studies. This is being piloted on a new study and is supported by the R&D Governance Group.

## Contract Review Processes

R&D has an agreement with the OUH legal team to undertake the review of non-standard or modified contracts from a legal perspective to ensure the Trust obligations are appropriate. In addition agreement covers the drawing up of contracts for Oxford Health NHS FT to be able to subcontract services, such as ECG review, scanning etc. The agreement is working very well and is being utilized effectively.

## R&D Data Capture Mechanisms

### Expressions of Interest

Commercial companies are continually looking for new NHS sites in which to conduct their studies. The initial step is to complete an expression of interest which provides key information about the research servicers that the Trust can offer. If a company requires further information they will request confidentially agreements to be signed and the Trust will undertake a feasibility assessment. The number of expressions of interest the Trust has been asked to complete has increased significantly over the last six months. This has led to the decision that the default position is to say yes and if the companies requests further information and extended feasibility.

### Grant Application Process

During the last six months R&D have developed a grant application process to help researchers in the completion of funding applications. This is to support researchers in costing for their research appropriately and within the funding body guidelines in a timely manner to ensure that deadlines are met.

### Pipeline Meetings

Pipeline meetings have established to determine the feasibility of the undertaking of studies both within the CRF and the community. Researchers are requested to complete an R&D designed form detailing the study and its requirements for delivery, this generates a unique study identifier to enable tracking within the department. These studies are discussed at the pipeline meetings, attended by governance, research delivery, finance, CRN, pharmacy staff to ensure an informed decision can be made as to whether the Trust agrees to pursue the conduct of the study, pending appropriate approvals and contracts (including finances).

### R&D Data Capture

The R&D Governance Manager has initiated the redevelopment of the department database for the capture and tracking of research studies and recruitment within the Trust. This is to be aligned to the Research Portfolio system that has been developed at the OUH that will be instated within Oxford Health NHS FT. The database is to help support our internal and external reporting requirements and new pipeline meeting structure to capture all activity rather than just once a study agreed in principle. Discussions between the two organisation are going as there are potential issues if a study is running in both organisations.

### R&D Internal Audit

The R&D department was audited this year, 12 months earlier than anticipated due to change in Trust providers. Initial findings are in line with the capture and tracking of studies which had previously been identified within the R&D governance team and the alignment of cost centers for individual studies. The Trust has returned comments and is awaiting a final report.

# Studies and Participant Recruitment

## Numbers of studies

The Trust currently hosts a number of different research studies, from small student projects to complex commercially sponsored CTIMPs.

The table below shows current research activity ongoing within the Trust. The figures are transient due to projects starting and completing at different times.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Total Number of Studies in OHFT | Commercial CTIMPs | Non-Commercial CTIMPs | Commercial non-CTIMP | Non-Commercial, Non-CTIMP |
| Open | 5 | 5 | 1 | 102 |
| Awaiting Approval | 2 | 6 | 0 | 10 |
| Expression of Interest | 7 | 1 | 0 | 3 |
| Feasibility | 8 | 1 | 0 | 0 |
| Grant Applications | Not applicable | 1 | Not applicable | 8 |
| **Totals** | **22** | **14** | **1** | **123** |

Of the 113 studies open within the Trust 67 are registered on the NIIHR portfolio, nine of which are industry studies. This data is not in line with the external NIHR reports R&D receives via the CRN. External sources suggest that Oxford Health NHS FT has only 31 portfolio studies open within the organisation with only one of those being an industry study. R&D are working hard to resolve these inconsistencies.

## Participant Recruitment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | 2011/2012 | 2012/2013 | 2013/2014 | 2014/2015 |
| Portfolio | 2303 | 1822 | 2763 | 909 |
| Non portfolio | 53\* | 359 | 780 | Data not complete |

R&D records show that 909 participants have been recruited to these 67 portfolio studies since April 2014. Of the 909, 37 participants have been recruited to industry studies and the remaining 870 to non-industry studies. External sources suggest that the number of participants recruited to industry studies is one. This is being reviewed by R&D and the CRN to ensure consistencies with internal and external reporting.

## NIHR Metrics and Targets

NHS organisations are expected to provide the NIHR with quarterly Performance Initiation and Delivery (PID) reports, detailing the number of studies that recruit the first participant into a clinical trial within 70 days of the organisation receiving a valid research application[[1]](#footnote-1) and the number of studies recruiting the expected number of participants (time to target).

Researchers are expected to inform the R&D department of the number of participants recruited to their study, in line with the NHS permission. This data will inform the PID reports that are compiled and published nationally every quarter. The Trust has accountability for delivery of research as the legal entity and consistent failure by Trusts to meet these targets may result in a reduction of up to 5% of Research Capability Funding to NHS organisations.

The table below shows the number of studies initiating research (70 day benchmark)

|  |
| --- |
| **Performance in Initiating CTs** |
| Quarter | NHS Permission granted within the period | Number of studies with valid research application | Number of studies that recruited 1st patient within 70 days | Percentage of studies that recruited 1st patient within 70 days |
| 3 – 2012/13 | 1 Jan 2012 to 31 Dec 2012 | 12 | 4 | 33% |
| 4 – 2012/13 | 1 Apr 2012 to 31 Mar 2013 | 12 | 3 | 25% |
| 1 – 2013/14 | 1 Jul 2012 to 30 Jun 2013 | 12 | 8 | 67% |
| 2 – 2013/14 | 1 Oct 2012 to 30 Sept 2013 | 11 | 8 | 73% |
| 3 – 2013/14 | 1 Jan 2013 to 31 Dec 2013 | 12 | 9 | 75% |
| 4 – 2013/14 | 1 Apr 2013 to 31 Mar 2014 | 12 | 9 | 75% |
| 1 – 2014/15 | 1 Jul 2013 to 30 Jun 2014 | 13 | 8 | 62% |
| 2 – 2014/15 | 1 Oct 2013to 30 Sept 2013 | 10 | 6 | 60% |

The table below shows the time to target for research studies over the last 18 months

|  |
| --- |
| **Performance in Delivering Commercial CTs** |
| Quarter | NHS Permission granted within the period | Number of studies listed | Number of studies not met target | Number of studies met target | Number of studies still open to recruitment |
| 3 – 2012/13 | 1 Jan 2012 to 31 Dec 2012 | 7 | 2 | 0 | 5 |
| 4 – 2012/13 | 1 Apr 2012 to 31 Mar 2013 | 8 | 2 | 0 | 6 |
| 1 – 2013/14 | 1 Jul 2012 to 30 Jun 2013 | 8 | 4\* | 0 | 4 |
| 2 – 2013/14 | 1 Oct 2012 to 30 Sept 2013 | 7 | 4\*\* | 1 | 2 |
| 3 – 2013/14 | 1 Jan 2013 to 31 Dec 2013 | 7 | 3 | 1 | 3 |
| 4 – 2013/14 | 1 Apr 2013 to 31 Mar 2014 | 7 | 3 | 1 | 3 |
| 1 – 2014/15 | 1 Jul 2013 to 30 Jun 2014 | 9 | 5 | 1 | 3 |
| 2 – 2014/15 | 1 Oct 2013to 30 Sept 2013 | 10 | 4 | 6 | na |

\* 2 studies withdrawn by sponsor, 2 did not meet target and are closed to recruitment

\*\*1 study withdrawn by sponsor, 3 did not meet the target and are closed to recruitment

Over the past year the R&D department have been endeavoring to improve performance in these metrics by putting measures in place to ensure that researchers are “research ready” to start their study when they submit their SSI forms and that they have realistically estimated the number of participants that can be recruited to studies.  The R&D department has worked hard to liaise and support researchers, from both non-commercial and commercial sectors, to ensure clear communications and that appropriate processes are followed. More work is required and this is to be addressed at the R&D Strategy Forum in terms of further embedding research into routine clinical practice.

# Recent Research Project Developments

Integrate care home support service (ICHS) is integrating physical and mental health care teams using evidence based research developed by Jane Fossey (Head of Psychological Services) from two previous research studies (FITS Study, on which the WHELD study was based, and CALM AD). Data from the research was published in 2009 and it has taken five years for the practice to be adopted within the services model. There is CLAHRC funding to support the evaluation of the ICHS implementation into clinical services.

The WHELD Study (improving well being and health for people with Dementia), has published two papers in July 2014 and the work is being picked up nationally in a variety of ways, including uptake in general hospital settings.

ReD-KITE: Resistant Depression - Ketamine Infusion Trial Evaluation: a phase I, dose escalation, safety study has closed to recruitment and data has been analysed to determine the safety profile of repeated doses of ketamine infusions and to gain preliminary efficacy data. The data was published in April 2014 and the Trust are discussing the adoption into clinical practice based on the research study of 18 patients enrolled within Oxford Health NHS FT. A summary of this is detailed in Appendix D.

The FRIENDS project, led by Professor Paul Stallard, sponsored by Oxford health NHST and funded by the NIHR Public Health Research Programme award was completed and published in the Lancet Psychiatry in August 2014. The findings suggest that the delivery of anxiety preventing programmes can be effective when used in schools, although the effectiveness is variable depending upon who delivered them.

When research studies that have taken place within the organisation come to an end there can be considerable time before the evidence is translated into practice for patient benefit. This may take years in some cases.

# NIHR Oxford cognitive health Clinical Research Facility (CRF)

The CRF is a joint partnership between Oxford Health NHS FT, Oxford University Hospitals NHS Trust and the University of Oxford.  The annual return required by the NIHR for the CRF award that flows through OUHT reports activity across the four sites of the NIHR CRF (Warneford CRF, Oxford Centre for Anxiety Disorders and Trauma (OxCADAT), the Oxford Cognitive Neuropsychology Centre (CNC) and Charles Wolfson Clinical Neuroscience Facility).  Occupancy for the first 8 months of the year for the activity for the Warneford CRF was 44% based on actual half day units (rather than hours), an increased from last year’s 29%

Details for the other three sites are not currently available but processes will be in place to capture this data for the annual return.

## Nursing staff

Our skill mix within the CRF has continued to evolve with more nursing staff now joining the team to ensure safe administration of trial medication and professional accountability. We have been mindful to ensure psychometric and global rating assessment skills are treated as equally important to meet the demands our industry partners.

## Military Nurse:

The lead R&D Nurse and CRF Matron has initiated conversations with the Military of Defense regarding the facilitation of collaborative working with the military. Discussions continue to look at the feasibility and logistics of the proposal.

# Clinical Records Interactive Search

The use of Electronic Health Records (EHR) makes data extraction feasible. Clinicians provide much of the information contained in the EHR. This information consists of both structured and unstructured data proving difficult for analysis and extraction of information. The richest source of clinical information is more often contained in unstructured fields, such as ‘progress notes’ or documents. Traditionally unstructured data by its nature has been very difficult to search. However, South London and Mausdley NHS FT (SLaM) developed an application **- C**linical **R**ecord **I**nteractive **S**earch (CRIS) - that enables the valuable unstructured information contained in an EHR to be unlocked and transformed so that key clinical data can be interrogated.

The CRIS application takes clinical information from the local, Oxford Health NHS FT (OHFT) EHR, removes patient identifiable information and provides searchable and secure access to data for research and audit purposes. The system allows effective anonymisation and psuedonymisation of data.

CRIS was designed primarily to support three types of usages:

* Type 1: as an anonymised database for secondary analysis
* Type 2: to identify potential recruits to research projects from the clinical population
* Type 3: to provide contextual clinical information for existing research participants

The set up and implementation of the CRIS has moved into R&D. A CRIS Management group has been established to develop key documentation to enable to Trust to submit an ethics application to enable usage within the Trust for research and audit purposes. The CRIS Management Group will morph into the CRIS Oversight Group who will oversee its usage once ethics approval has been granted.

The security model and information governance assurance framework document is near completion. This is a key document that will provide an overview of the specific security model and wider governance framework in OHFT that will maintain the security of clinical information during: the preparation and transfer of the data to CRIS; the transfer of data to NHS Trust partners whilst it’s stored in CRIS; data usage for ongoing audit and research purposes by approved/regulated OHFT staff. This document will provide the framework for the research ethics committee (REC) submission along with patient facing information outlining the CRIS. It is anticipated that the REC will be submitted early 2015.

# Finance

The Trust receives R&D funding from a number of different sources, primarily derived from:

|  |  |
| --- | --- |
| **Source** | **FY15 Budget (£k)** |
| The National Institute for Health Research (NIHR) | 4,722 |
| Clinical Research Network: Thames Valley and South Midlands (CRN) | 1,597 |
| Non-NIHR and Commercial Income | 303 |
| **Total** | **6,622** |

The NIHR and CRN income is expected to be used within year and any underspend returned to the funding organisation.

## Period 7 Year to Date Performance

In FY15 R&D are budgeted to make a contribution to overheads of £126k, at the end of the first 7 months a contribution of £213k had been achieved primary due to higher than budgeted non-NIHR (mainly commercial) income. A breakeven position is forecast over the remaining 5 months which will maintain an £87k favourable variance at year-end.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Income and Expenditure (£k)** | **YTD Budget** | **YTD Actual** | **YTD Var.** | **Full Year Budget** | **Full Year Foreast** | **Full Year Var.** |
| Income | 3,850 | 3,312 | (538) | 6,622 | 6,697 | 75 |
| Expenditure | (3,777) | (3,152) | 625 | (6,496) | (6,484) | 12 |
| **Net Total**  | **73** | **160** | **87** | **126** | **213** | **87** |

The CLRN (via R&D) fund posts within the Pharmacy Department who work on research studies and generate income (at the end of period 7 £6k income was reflected in the accounts). This income is not included in the figures reported above

## National Institute for Health Research (NIHR)

The NIHR Income is broken down as follows:

|  |  |
| --- | --- |
| **FY15 Budget (£k)** | **Type of Income** |
| 1,444 | Direct Study Income (full details of the studies is shown in Appendix A) |
| 108 | Sub-Contracted Study Income (full details of the studies is shown in Appendix A)  |
| 1,112 | Research Capability Funding (RCF) Department of Psychiatry \ Trust driven |
| 90 | Research Capability Funding (RCF) Department of Primary Care driven |
| 717 | Clinical Research Facility (CRF) |
| 1,250 | Collaboration in Leadership in Applied Health Research and Care (CLAHRC) |
| **4,722** | **Total NIHR Income** |

## Research Capability Funding (RCF)

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

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

In FY15 the Trust is running two schemes, one for RCF generated from Department of Psychiatry and Trust based investigators and a new scheme for RCF generated by Department of Primary Care investigators.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **FY14 Department of Psychiatry \ Trust** | **FY15 Department of Psychiatry (DoP) \ Trust** | **FY15 Department of Primary Care (PC)** | **FY15 Total** |
| Senior Investigators (SI)  | Keith Hawton, Guy Goodwin, John Geddes, David Clarke, Alastair Gray | Keith Hawton, Guy Goodwin, John Geddes, David Clarke, Alastair Gray, Charles Vincent, Simon Lovestone | Sue Ziebland |  |
| **SI Funding (£75k)** | **£0.375m** | **£0.525m** | **£0.075m** | **£0.600m** |
| Study Income | £1,592m | £1,338m | £.072m |  |
| Rate | 0.405 | 0.439 | 0.20 ## |  |
| **Study Related RCF** | **£0.645m** | **£0.587m** | **£0.015m** | **£0.602m** |
| **Total RCF** | **£1,020m** | **£1,112m** | **£0.090m** | **£1,202m** |

*## The DEC study in seen as a Centre and attracts a different RCF weighting*

The table below shows the currently proposed FY14 RCF allocation.

|  |  |  |  |
| --- | --- | --- | --- |
| **FY15 RCF (£k)** | **DoP \ Trust** | **PC** | **Total** |
| FY15 Award  | 1,112 | 90 | 1,202 |
| **Current commitments by RCF category** |  |  |  |
| The research-related component of an NIHR Faculty member’s salary, which is not covered by other funding sources | (480) | (90) | (570) |
| Meeting the cost of the time of Faculty members in preparing grant proposals  | (232) | - | (232) |
| The research-related time of NHS-employed scientific, administrative and secretarial staff who support Faculty members in their NIHR-related work (*Includes the mitigation of the cost pressures occurring due to the NIHR withholding final study payments)* | (309) | - | (309) |
| Accommodation costs, finance management costs, and human resource management cost incurred in hosting NIHR-funded research | (91) | - | (91) |
| **Total** | **-** | **-** | **-** |

The use and allocation of RCF is reviewed on a regular basis by the Director of R&D before approval by the R&D Governance Committee. In recent years the drive has been to use RCF strategically for the benefit of research across the Trust, this continued in FY15 but, in addition, individuals were invited to apply for RCF to support research activities and as a result 4 applications were successful receiving a total allocation £79k. This year RCF is being used to the mitigation of the cost pressures occurring due to the NIHR withholding final study payments (mentioned below under Potential Financial Impacts).

## Clinical Research Facility (CRF)

The CRF reporting is split between NIHR and non-NIHR due to its origins and funding sources. On the Warneford site the CRF operates as one unit containing 8 clinical rooms, pharmacy, a meeting room and associated office space. The NIHR CRF encompasses activities taking place at the Department of Experimental Psychology (OxCADAT and OxCNC) and the Charles Wolfson Clinical Neuroscience Facility at the John Radcliffe Hospital as well as those on the Warneford site.

Funding for the unit comes from the NIHR, CLRN and Commercial income. The FY15 budget and forecast outturn position is detailed in the table below.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **FY15 Budget** | **FY15 Forecast** | **Variance** |
| **Expenditure** | **(954)** | **(954)** | **-** |
| NIHR Funding (funding in place until Mar 2017) | 717 | 717 | - |
| CRN: TV SM Funding (funding allocated each year as part of the annual CRN TV SM budget process) | 204 | 204 | - |
| **Non-NIHR Study Income** |  |  |  |
| * Roche
* Lundbeck
* Abbvie
* StemBancc
* Tak
* Sunovion
* Actions
 |  |  |  |
| **Total Non-NIHR income** | **92** | **167** | **75** |
| **Total Income** | **1,013** | **1,088** | **75** |
| **Contribution to overheads** | **59** | **134** | **75** |
| **Margin after recover of CRF Accommodation and Finance Costs**  | **6%** | **12%** |  |

Commercial price negotiations involve the Head of R&D and the Head of R&D Finance with the final sign-off governed by authorisation limits agreed by the Director of Finance.

## Non-NIHR Research Study Income

The table below shows research income reported from non-NIHR studies ongoing in the first 7 months of FY15.

|  |  |  |  |
| --- | --- | --- | --- |
| **Study** | **Sponsor/Clinical Research Organisation** | **£k** | **Funding** |
| FLASHYLYTE RO4917838 in stable patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics - Protocol No. NN25310 | Roche  | 22 | Industry Contract |
| Interventional randomised, double-blind, parallel-group, placebo-controlled, exploratory study investigating the effects of LuAA21004 on cognition and BOLD fMRI signals in subjects remitted from depression and controls | Lundbeck | 1 | Industry Contract |
| Long-term safety and efficacy of ABT-126 in subjects with schizophrenia: a double blind extension study for subjects completing study M10-855 | AbbVie  | 25 | Industry Contract |
| Stem cells for Biological Assays of Novel drugs and predictive toxicology (STEMBANCC | University of Oxford | 17 | Non-Commercial |
| A randomised, double-blind, placebo- controlled, phase 3 study to evaluate the efficacy and safety of once a day, TAK-375 (Ramelteon) tablet for sublingual administration (TAK-375SL tablet) 0.1mg and 0.4mg as an adjunctive therapy in the treatment of acute depressive episodes associated with bipolar 1 disorder in adult subjects (TAK\_301) | Takeda | 5 | Industry Contract |
| A randomised, double-blind, placebo-controlled, single-dose, study of the efects of SEP 363856 and Amisulprode on bold-FMRI signal in healthy male and female volunteers with high or low schizotype characteristics | Sunovion | 38 | Industry Contract |
| Antidepressant controlled trial for negative symptoms in schizophrenia (ACTIONS) | University of Oxford | 22 | Non-Commercial |
|   | **TOTAL** | **130** |  |

*A full list of currently active CRF studies is shown in Appendix B.*

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

The FY15 Income from the CRN is budgeted to be £1,597 which is broken down is the table below, from which a £62k contribution to overheads is expected.

|  |  |  |
| --- | --- | --- |
| **Type**  | **FY15 Budget (£k)** | **Comments** |
| Mental Health \ R&D  | 340 | Trust Governance and support staff and research active individuals within the Trust |
| Clinical Research Facility (CRF) | 374 | Medical and nursing staff employed within the CRF |
| DeNDRoN (CRN Division 4) | 245 | CRN:TV SM Division 4 staff employed by the Trust  |
| Network Staff Hosted by OH | 262 | CRN Network staff employed by the Trust |
| Community Staff | 87 | Community Research Nurses employed by the Trust |
| Thames Valley Primary Care  | 288 | Thames Valley Primary Care Governance and support staff employed by the Trust |
| **Total** | **1,597** |  |

## Potential Financial Risks

### R&D Income Summary FY12-FY17

The level of research funding is predicted to drop next year from its currently forecast level of £6,697k to £6,230k. One of the main areas of concern is the lower RCF in FY17 which would reduce the Trusts flexibility and ability to potentially pump-prime certain areas of research.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Source** | **Type** | **FY12** | **FY13** | **FY14** | **FY15** | **FY16** | **FY17** | **Notes** |
| NIHR | Study income Department of Psychiatry & Trust | 1,605 | 1,768 | 1,827 | **1,164** | - | - |  |
| NIHR | Study income Department of Primary Care | - | - | 106 | **280** | 243 | 243 |  |
| NIHR | Sub-Contracted Study income | 284 | 85 | 389 | **114** | 97 | 92 |  |
| NIHR | Clinical Research Facility | - | 426 | 718 | **718** | 718 | 718 |  |
| NIHR | RCF - Department of Psychiatry \ Trust | 67 | 925 | 990 | **1,112** | 1,118 | 632 | 1 |
| NIHR | RCF - Department of Primary Care | - | - | - | **90** | 124 | 122 | 1 |
| **NIHR** | **Total** | **1,956** | **3,204** | **4,281** | **4,721** | **4,490** | **4,186** |  |
| CRN | TVCLRN \ CRN | 873 | 944 | 2,023 | **1,597** | 1,535 | 1,535 |  |
| Other | Dendron | 159 | 132 | 81 | **106** | 113 | 23 |  |
| Other | Non-NIHR CRF income | 191 | 191 | 150 | **167** | 92 | 92 | 2 |
| Other | Non-NIHR Study income | 509 | 176 | 90 | **105** | - | - | 2 |
|  | **Total** | **3,687** | **4,647** | **6,373** | **6,697** | **6,230** | **5,836** |  |

Notes 1 Assumes similar RCF rates and number of Senior Investigators

2 FY15 based on forecast, FY16 and FY17 based on the FY15 budget. Forecasts are being worked on and will be added once agreed

## Contribution to Overheads

The budgeted contribution to overheads has remained static over the past few years. This will become a challenge to R&D as the funding associated with studies providing generous overhead allowances start to come to an end as illustrated in the Income Summary FY12-FY17 and the flexibility within R&D funding in relation to overheads which existed previously becomes tighter due to new reporting requirements. Overheads from new studies are expected to be covered by a more modest allocation from RCF. Work will take place to identify the forecast contribution to overheads over the next few years.

## Redundancy Costs

There are a few members of staff employed on studies which are coming to an end. This could generate redundancy payments which will not be chargeable to the study. These are being identified and mitigation sought on a case-by-case basis.

## RCF Funding Scenarios

There have been a number of discussions recently concerning the potential reductions in research funding. One of the most vulnerable sources of income is RCF because unlike the infrastructure and grant awards it is based on an annual allocation. For illustrative purposes two scenarios are shown in the table below:

1. A 50% blanket reduction
2. Reductions of 20p on study related RCF, 19p (100%) on infrastructure related and £25,000 per senior investigator.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type** | **Basis** | **Current Rate** | **Total (£)** | **Scenario 1 - Blanket 50%** | **Scenario 2 - Rate Reduction** |
| Studies | 1,446,186 | 0.41 | 592,936 | - 296,468 | -0.20 | - 289,237 |
| Infrastructure | 257,449 | 0.19 | 48,915 | - 24,458 | -0.19 | - 48,915 |
| Senior Investigators | 8 | 75,000 | 600,000 | - 300,000 | -25,000 | - 200,000 |
| **Total** |  |  | **1,241,851** | **- 350,926** |   | **- 538,152**  |

After recently contacting the DH their response was “with pressure on all budgets increasing I should certainly advise taking a cautious approach”

## Study Report and Publication dates

A number of studies have or will come to an end between Oct 14 and Mar 15 where the NIHR contract allows the withholding of the final payments until reports are produced and published. The effect of this is that costs will be incurred this financial year but not recovered until future years. Last year agreement was gained from the DH to fund this from RCF allowing the final payment to be released in the following year on the condition that the funding is used for staff. The studies concerned are shown in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study** | **Finishes** | **Report Required by** | **Worst Case** | **Best Case** |
| Octet | Oct 2014 | Mar 2015 | 30 | 30 |
| Friends | Dec 2014 | Mar 2015 | (65) |  |
| Friends | Dec 2014 | Mar 2015 | (65) | (65) |
| Wheld | Mar 2015 | Mar 2015 | (102) | (102) |
| Octet | Dec 2015 | Mar 2015 | (84) |  |
| **Total** |  |  | **(286)** | **(137)** |

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

In January 2014 the Trust began receiving funding from the NIHR in relation to the CLAHRC which is led by Professor Richard Hobbs from the University of Oxford, Department of Primary Care.

### CLAHRC Budgets

Budgets have been approved and released to the Theme Leads for the first 2 ¼ years ending March 2016. It is planned that there will be a mid-term review by the Executive and Management Board before budgets are released for the final 2 ¾ years.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Budget By Theme (£k)** | **Theme Lead** | ***2013/14 (3 mths)*** | ***2014/15*** | ***2015/16*** | ***2016/17*** | ***2017/18*** | ***2018/19 (9 mths)*** | ***Total*** |
| Better Management of Psychiatric comorbidities | Prof. Mike Sharpe | 14 | 185 | 370 | 373 | 369 | 274 | 1,585 |
| Health Behaviour and Behavioural Interventions | Prof. Sarah Lamb | 38 | 180 | 336 | 331 | 342 | 278 | 1,505 |
| Early Intervention and Service Innovation | Prof. John Geddes | 16 | 217 | 318 | 412 | 348 | 278 | 1,589 |
| Patient Self-Management (Chronic Disease) | Prof. Richard McManus | 46 | 295 | 380 | 321 | 331 | 209 | 1,582 |
| Patient experience and PROMS | Prof. Ray Fitzpatrick | 55 | 216 | 346 | 304 | 301 | 232 | 1,454 |
| Central and Support Costs |  | 81 | 157 | 250 | 259 | 309 | 229 | 1,285 |
| **Total** |  | **250** | **1,250** | **2,000** | **2,000** | **2,000** | **1,500** | **9,000** |

### Quarterly Reviews

Quarterly review meetings take place between the CLAHRC Manager, Head of R&D finance and the theme leads to review spend to date, agree the year end forecast and discuss the allocation of costs to the projects within the theme. To support this and to monitor performance going forward monthly reports have now been developed which will be circulated to the theme leads.

### Matched Funding

A fundamental requirement of the CLAHRC is the need to demonstrate matched funding committed by other organisations which is linked to CLAHRC activities. In total this needs to be at least to the same level as the NIHR funding. Matched funding provides resources to support the proposed themes of research, implementation or a mix of both. Identification of Matched funding is an on-going process involving the CLAHRC Manager and the Head of R&D Finance. Based on current information the amounts shown in the application can be identified.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | ***2013/14 (3 mths)*** | ***2014/15***  | ***2015/16***  | ***2016/17*** | ***2017/18*** | ***2018/19 (9 mths)*** | ***Total*** |
| NIHR Funding | 250 | 1,250 | 2,000 | 2,000 | 2,000 | 1,500 | 9,000 |
| Application Matched Funding | 519 | 2,075 | 2,077 | 2,078 | 2,075 | 1,607 | 10,431 |

## Oxford Academic Health Science Network (AHSN)

Oxford Health is hosting three of the 9 OAHSN Clinical Networks. These are Dementia; Early Intervention in Mental Health; and Anxiety and Depression (detailed below).

Although the OASHN is seen as a clinical development, rather than primarily research related activity, it is combined with R&D when reported in the Finance report to the Board and is, therefore included for completeness. The three networks are budgeted and forecast to breakeven the only concern is the £35k Partnerships fees which the Trust has incurred but didn’t budget for causing an adverse variance.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Network**  | **Lead** | **Projects** | **Total Award** | **End Date** |
| Dementia | Dr Rupert McShane | * *Unwarranted clinical variation*
* *Data capture systems*
* *Development of drink as a potential medical food with a dementia indication*
 | £270k | June 2015 |
| Early Intervention in MH | Prof Belinda Lennox | * *Reduced variation in care*
* *Increase recruitment to Research studies*
* *Enhancing care continuity and extending the model of early intervention*
* *Agreeing a schedule of clinical assessments and criteria for EIS*
 | £210k | June 2015 |
| Anxiety & Depression  | Prof David Clark | * *Understanding outcome variability*
* *Supporting local service innovation & disseminating successes throughout the region*
 | £220k | Oct 2015 |

# Estates

The R&D department has recently vacated the office space within the University Cottage leading to a pressure for staff accommodation. Trust approval has been granted for the R&D staff located adjacent to the executive team to be relocated with the adult mental health management team in the main building of the Warneford Hospital. It is anticipated that the refurbishment of the office space will start at the end of January 2015 following tender for the work. It is hoped that the space will be habitable in February/March 2015

# Staffing

Following three rounds of advertising since August 2013 the Research Implementation Manager post, reporting into the lead R&D Nurse and CRF Matron (Cindy Whitbread), to lead on the recruitment strategy within the Trust has been filled. Alexandra Forrest joined the R&D team in November 2014, replacing Bobbie Sanghera who was undertaking the role as a secondment until a permanent replacement could be found. Alexandra Forrest is supporting seven research assistants (RAs), also recently recruited to help embed and undertake research within the Trust. Two of the RAs (Hayley Sapsford and Thomas Misselbrook)are funded by the CRN and are based in the Oxford and Aylesbury Early Intervention services and will support NIHR portfolio research. The additional five RAs (Rachel Davies, Leah Marriner, Bradley Mullins, Maninder Kaur and Joanna Ciapala), funded by clinical services are to rollout True Colours self-monitoring as 50% of their role and support all research studies within adult mental health services.

There have been significant changes within the Governance team. The team now consists of a Band 6 Research Governance Co-ordinator (Jana Safarikova), part time Research Governance Facilitator (Mel Brookings – currently on maternity leave), R&D administrator (currently being covered temporarily by Parveen Sarbatta, until the newly appointed Natalia Jastrzebska can start in the new year). In addition R&D have secured a part time interim post, Research Governance Support (Tanya Smith, an experienced research co-ordinator, who was at risk of redundancy following the end of the study she was working on). We have secured Tanya support in the development of study and recruitment data capture in line with external reporting mechanisms).

Children and Young People’s services have recruited John Heine, a Research Support Facilitator, to aid in the development of grant applications within the service. This is a 12 month fixed term contract that will be reviewed dependant upon the number of successful applications.

Funding from OUH RCF generated by the NIHR CRF funding has been secured to fund a research nurse to support activity at Charles Wolfson Clinical Neuroscience Facility. Several rounds of interviews have been held with no successful candidates being found. This has lead to the cross cover from CRF delivery staff to support research and increasing training and workforce development across the CRF sites. Two further CRF nurses have joined the CRF team (Elwira Lubos and Akintayo Oladejo) and a health care assistant to support dementia research (Sarsha Wilson) in addition to the promotion of Jethin Benjamin after being within the team six months. After two rounds of advertising and interviews a CRF sister (Adedoyin Adedejui) has been appointed to aid in the day to day running of the CRF and is due to start in January 2015

The current R&D structure is shown below



The Head of R&D (Emma Stratful) has successfully been awarded funding via the OUH BRC and secured a place of the executive MBA at Said Business School at the University of Oxford, starting in January 2015.

# Communications

Work is continuing with the Trust R&D website, but resource and expertise are limited. One of the new RAs has offered to help the R&S Governance Manager take this forward while alternatives are explored. One possibility is a shared Communications post with the University of Oxford, department of Psychiatry.

**Authors and Title:** Professor John Geddes, Emma Stratful & Dr Clive Meux

**Lead Executive Director:** Dr Clive Meux

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*

**Appendix A Non-Commercial funded studies**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study** | **Funder** | **End Date** | **Value** |
| Electroconvulcive therapy: a qualitative study of the experiences of patients and their carers ( healthtalkonline ) | NIHR | 31/12/2014 | £246,656 |
| Aripiprazole treatment for antipsychotic induced hyperprolactinaemia in young patients with severe mental illness and learning disabilities | NIHR | 28/02/2015 | £201,626 |
| Development and evaluation of SMS-based monitoring and management service for people with bipolar disorder | NIHR | 31/12/2014 | £1,660,037 |
| Coercion in MH. Patterns and prevalence of coercion in mental health care and a trial of the effectiveness & costs of Supervised Community Treatment orders | NIHR | 31/07/2014 | £2,072,032 |
| An Optimised Person Centred Intervention to Improve Mental Health and Reduce antiphychotic amongst people with Dementia in Care Homes | NIHR | 31/03/2015 | £2,042,199 |
| Friends | NIHR | 31/12/2014 | £1,306,805 |
| A multi-centre programme of clinical and public health research to guide health service priorities for preventing suicide in England | NIHR via AWP | 30/04/2017 | £562,491 |
| Development of content for an online Cognitive Behavioural Therapy (CBT) platform  | Alzheimer’s Society | TBA | £108,869 |
| Treating insomnia in patients with delusions and hallucinations: a pilot randomized | NIHR | 28/02/2015 | £250,556 |
| NIHR Diagnostic Evidence Co-operative | NIHR | 31/08/2017 | £989,754 |

**Appendix B - CRF Studies**

|  |  |
| --- | --- |
| **Study** | **Sponsor/Clinical Research Organisation** |
| Glutathione Phase 2 study | Glutathione 2 |
| Stem cells for Biological Assays of Novel drugs and predictive toxicology (STEMBANCC) | University of Oxford |
| FLASHYLYTE RO4917838 in stable patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics - Protocol No. NN25310 | Roche |
| A randomised, double-blind, placebo- controlled, phase 3 study to evaluate the efficacy and safety of once a day, TAK-375 (Ramelteon) tablet for sublingual administration (TAK-375SL tablet) 0.1mg and 0.4mg as an adjunctive therapy in the treatment of acute depressive episodes associated with bipolar 1 disorder in adult subjects (TAK\_301) | Takeda |
| A randomised, placebo-controlled, parallel-group, double-blind, efficacy and safety trial of MK-8931 in subjects with mild to moderate alzheimer's disease EPOCH | Merck, Sharpe & Domme |
| Long-term safety and efficacy of ABT-126 in subjects with schizophrenia: a double blind extension study for subjects completing study M10-855 | AbbVie |
| A randomised, double-blind, placebo-controlled, single-dose, study of the efects of SEP 363856 and Amisulprode on bold-FMRI signal in healthy male and female volunteers with high or low schizotype characteristics | P1vital \ Sunovion |
| Interventional randomised, double-blind, parallel-group, placebo-controlled, exploratory study investigating the effects of LuAA21004 on cognition and BOLD fMRI signals in subjects remitted from depression and controls | Lundbeck |
| Mood Action Psychology Programme (MAPP): a case series investigation of brief imagery-focused cognitive therapy (imCT) for Bipolar Disorder | Wellcome Trust |
| Development and evaluation of SMS-based monitoring and management service for people with bipolar disorder (Oxtext) | NIHR |
| A pragmatic randomised double-blind trial of Antipsychotic Treatment of very LAte-onset Schizophrenia-like psychosis (ATLAS) | NIHR |
| Antidepressant controlled trial for negative symptoms in schizophrenia (ACTIONS) | University of Oxford |
| Cognitive Health in Ageing: Investigating the effects of imagery-based cognitive bias modification in older adults | NIHR |
| Mood Action Psychology Programme (MAPP): a case series investigation of brief imagery-focused cognitive therapy (imCT) for Bipolar Disorder | Wellcome Trust |

**Appendix C - October 2014 Pipeline Report**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **ID** | **PI** | **Study Title** | **Type of Funding Organisation** | **Main Funder** | **Est. Value** | **Current Status** |
| PL 002 | Rohan Van Der Putt | Moderate Alzheimer's B2081011 - AD study Site | Commercial | PFIZER | £30k | Site Accepted |
| PL 004 | Rohan Van Der Putt | Randomised, double-blind, parallel-group, placebo-controlled, fixed-dose study of Lu AE58054 in patients with mild-moderate Alzheimer's Disease treated with donepezil STARBEAM | Commercial | Lundbeck | £30k | Site Accepted |
| PL 006 | Jenny McCleery | DaTSCANTM Phase 3b Dementia with Lewy Bodies Registration Study | Commercial | GE Healthcare |   | Feasibility Assessment |
| PL 008 | Belinda Lennox | A randomised Open-label Active Controlled Comparison of Paliperidone Palmitate 1 Month/ 3 Month Formulations versus Oral Atypical Antipsychotics in Subjects with Recent Onset of Schizophrenia (MENT 3596) | Commercial | Janssen |   | Feasibility Assessment |
| PL 015 | tbc | Effects of Modafinil on Cognitive Functioning and Emotional Processing in Patients with Remitted Depression | Non Commercial – NIHR | NIHR |   | Expression of Interest  |
| PL 019 | Maria Turri | Feasibility Randomised Control Trial comparing the cost-effectiveness for a new intervention called the systemic assessment clinic versus standard assessment for psychiatric patients referred to adult mental health | Non Commercial - NIHR | NIHR |   | On Hold |
| PL 020 | tbc | Phase 1 study in healthy volunteers with schizotype characteristics | Commercial | Roche |   | Expression of Interest |
| PL 023 | Daniel Freeman  | The Thinking Well RCT | Non Commercial - NIHR | NIHR - EME | £25k | Grant Submitted |
| PL 025 | Belinda Lennox | A randomised placebo-controlled trial of immunotherapy in patients with first episode psychosis and anti-neuronal membrane auto-antibodies | Non Commercial - other | MRC | £22k | Grant Submitted |
| PL 026 | John Geddes | OxLITH (Conbrio) | Non Commercial - other | Wellcome Trust | £150k | WIP |
| PL 027 | Simon Lovestone | Lithium (Protection for dementia) | Non Commercial - other | Chief Scientist Office, Scottish Government Health & Social | £43k | Grant Submitted |
| PL 028 | Paul Stallard | A randomised controlled trial of Think Feel Do, a computerised cognitive behaviour therapy programme for children with mild/moderate emotional | Non Commercial - NIHR | NIHR | £350k | Grant Submitted |
| PL 029 | Dr Veronika Williams | Delivering support for self-management of dyspnoea-related anxiety in Chronic Obstructive Pulmonary Disease using a digital health platform. | Non Commercial - NIHR | NIHR | £345k | Grant Submitted |
| PL 035 | Dr Alvaro Barrera | Stabilising sleep for patients admitted at acute crisis to psychiatric hospital: a pilot randomised controlled trial | Non Commercial - other | The Health Foundation | £75k | Full Application |
| PL 037 | Stefan Brugger | Grant application (Bayesian Coding, Volatility, and the Formation and Maintenance of Delusions) | Non Commercial - other | OHSRC | £4k | Grant Submitted |
| PL 039 | Jessica Gibson | The Effectiveness and cost-effectiveness of Mother and Baby Units versus general psychiatric Inpatient wards and Crisis Resolution Team services (ESMI) | Non Commercial - other |   |   | Expression of Interest |
| PL 040 | Rohan Van Der Putt | DEME 3749 - CAD106 A2208 | Commercial |   |   | Expression of Interest |
| PL 041 | Rupert McShane | Improving depression treatment: a combined human blood and brain cells ketamine study | Non Commercial - other |   |   | Expression of Interest |
| PL 044 | Veronika Williams and Andrew Farmer | A mixed method study to augment current predictors and definition of exacerbation in COPD through patient experiences, which would then form the basis for an exacerbation predictor tool to be evaluated in a clinical trial. | Non Commercial - NIHR | NIHR | £100k | On Hold |
| PL 045 | Paul Stallard | A pilot study to compare specific cognitive therapy for social anxiety with standard CBT for adolescents. | Non Commercial - other | NIHR | £1m | Grant Submitted |
| PL 048 | Andrew Farmer | A programme to develop, refine and evaluate a system for supporting people with type 2 diabetes in effective use of their medication through use of SMS text-messaging integrated with clinical care | Non Commercial - NIHR | NIHR | £2.5m | Grant Submitted |
| PL 049 | Richard McManus | Programme grant for applied health research application for series of workstreams investigating the monitoring and management of blood pressure in pregnancy.  | Non Commercial - NIHR | NIHR | £2,5m plus SSCs | Expression of Interest |
| PL 050 | Rohan Van Der Putt | A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-Group, Efficacy and Safety Study of Crenezumab in Patients with Mild Alzheimer's Disease (old reference: Monoclonal infusion) | Commercial |   |   | Feasibility Assessment |
| PL 053 | Mary Jane Attenburrow John Geddes | Noven Schizophrenia (Asenapine) | Commercial | Noven |   | Feasibility Assessment |
| PL 060 | Klaus Ebmeier (PI for the UK) | A UK-Brazil exploratory study of transcranial direct current stimulation for late life depression with diffusion tensor imaging measures of white matter tract integrity. | Non Commercial - other | Research Councils UK (RCUK) | £50k | Grant Submitted |
| PL 061 | Mary Jane Attenburrow, John Geddes | Interventional, randomised, double-blind, active-controlled, fixed-dose study of a development compound in patients with treatment-resistant schizophrenia (TBC) | Commercial | Lundbeck |   | Feasibility Assessment |
| *PL 065* | *Jenny McCleery* | *NEW - A drug utilisation study in patients treated with EXELON®/PROMETAX® (rivastigmine) transdermal patch (DEME 3921)* | *Commercial* |  |  | *Expression of Interest* |
| *PL 068* | *Ann Van den Bruel* | *NEW - Developing and evaluating an ambulatory emergency liaison service for the management of acutely ill children*  | *Non Commercial - NIHR* | *NIHR* | *£2.3m* | *Grant Submitted* |
| *PL 069* | *Rupert McShane* | *NEW - A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, 26-Week, Phase 3 Study of Two Doses of EVP-6124 or Placebo in Subjects with Mild to Moderate Alzheimer’s Disease Currently or Previously Receiving an Acetylcholinesterase Inhibitor Medication* | *Commercial* |  |  | *Expression of Interest* |
| *PL 070* | *Rohan Van Der Putt* | *NEW - DEME 3916* | *Commercial* |  |  | *Expression of Interest* |
| *PL 072* | *Phil Cowen* | *NEW - RCT of ebselen in Acute Mania*  | *Charity* | *Stanley Foundation* | *£230k* | *Grant Submitted* |

**Appendix D – Ketamine Trial**

**Background**

Professor Phil Cowen approached Dr Rupert McShane about applying for a research grant to look at ketamine being used as a treatment for ‘treatment resistant depression’ in early 2007. This resulted in two unsuccessful applications to different NIHR programmes before a successful 3rd application for £200k was submitted in 2008. The 30 month research project started in 2009. The co-applicants included Professors Cowen and Geddes, and the Oxford University Hospitals anaesthetists who routinely staff the ECT service.

The successful application was for a study to demonstrate safety and the feasibility of doing ketamine infusion treatments alongside routine ECT patients.

**What the research showed**

As The Huffington Post put it: ‘Yet another study shows ketamine is an antidepressant’. We also showed that two infusions were needed to decide whether or not someone was a responder. The duration of response was variable, but seemed to be longer than in the US studies, perhaps because our patients were also taking routine antidepressants. We got a sense that elderly patients are less likely to be responders. It worked well doing the treatments in the ECT suite.

**What the research led to**

Ketamine is a drug of abuse so managing the publicity around publication was vital. We had excellent advice from the University of Oxford Press Office and ran this through the Wellcome Trust Science and Media Centre. Medical journalists from all major dailies attended. It was picked up by ‘Today’ resulting in global coverage for a couple of days.

In the press release we put a survey monkey link (https://www.surveymonkey.com/s/9RQP5KL) through which we have had 545 responses. This has been an important way of capturing an idea of demand, and in building a community. We set up monthly teleconferences with other NHS and University doctors so that we could form a network. We have helped several clinics to develop protocols. One in particular has started to offer ketamine infusions, as a private service. We have made it possible for others to use the same technological text based mood monitoring instrument as us (True Colours) so we can potentially aggregate data in the future to aid further research in this area. We have successfully applied to become an NIHR mental health network writing group to generate new grant proposals. The whole process was an exemplar for the Oxford Health NHS FT’s Drugs and Therapeutics Committee to develop new processes for managing innovation.

**What next?**

The acute effect of the treatment can be dramatic. It may eventually turn out to be a particularly useful treatment in those who are acutely suicidal. This treatment is innovative so it has been tried primarily on the sickest, most treatment-resistant patients, including a small number of inpatients. The challenges are: how can we best maintain the duration of effect? And how can we use it less severely ill patients? It is difficult to see a future in which ketamine does not have a role to play in the treatment of depression. It may also be useful for other major psychiatric conditions such as anorexia and PTSD.

The support of Trust senior managers and accountants has been vital in turning this research from an interesting study into something that has real clinical impact. By funding a continuation post, it became possible to continue to treat patients after the research finished. Consequently, we are now at the forefront of experience using ketamine treatment worldwide. This clinical exploration has also put us in a position of real strength to make judgements about what research avenues are worth pursuing further in future. It has also attracted commercial research interest.

It is planned that a paid-for service at the Warneford Hospital will start in Spring 2015.

Dr Rupert McShane

Consultant Psychiatrist

Oxford Health NHS Foundation Trust

1. A valid research application is a complete research application that has been received by the NHS organisation following its submission via the Integrated Research Application System (IRAS) that enables review by other agencies (including, but not limited to Research Ethics Committee and MHRA approval) to be conducted in parallel with the work on NHS permission by the contractor. For studies going through the NIHR Coordinated System for gaining NHS Permission (CSP) this will include a valid site specific information ford (SSI) and local associated documents as detailed on the IRAS checklist. Non CSP studies are also required to submit a valid application for both study wide and local reviews as detailed on the IRAS checklist. [↑](#footnote-ref-1)