

# PAPER

BOD 134/2013

(Agenda Item: 14)

# Report to the Meeting of the

# Oxford Health NHS Foundation Trust

# Board of Directors

**27 November 2013**

**Research and Development Report**

**For: Information**

This is the second 6 monthly Research and Development (R&D) Report being presented to the Board of Directors. Its primary aim is to provide, for information, an overview of current R&D activity within the Trust.

**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. Research active clinical services are more likely both to generate and speed access to innovations in health care. The high levels of quality assurance required in research governance and ethical approval procedures can drive up the rigour and quality of routine clinical care. Research often requires cutting edge scientific infrastructure – for example brain imaging facilities - which can also be used for routine clinical care. There is also evidence that more academic clinical organisations are more successful in effectively recruiting and retaining high quality staff. Engagement in R&D activity can increase staff morale, help attract and protect resources and improve the status and profile of a healthcare provider.

# Networks and Collaborations

The Trust continues to engage in research activity, particularly within the area of mental health, where it is acknowledged we are in the top three nationally. The Trust is looking at the remodelling of clinical services including physical and integrated healthcare services. In order to do this successfully, effective involvement in networks and collaborations is key.

There have been a number of major NHS initiatives aimed at increasing research productivity and accelerating the adoption and diffusion of innovation into clinical practice including:

* The creation of Academic Health Sciences Networks (AHSN), which followed the publication of *Innovation Health and Wealth*. The Oxford AHSN has recently successfully been authorised and the Trust is closely involved in the Network which brings a range of new opportunities.
* The creation of Collaboration for Leadership in Applied Health Research and Care (CLAHRC) centres. The Trust is the lead Trust for an Oxford CLAHRC which has recently been awarded.
* The creation of four new Diagnostic Evidence Co-operatives (DEC) to improve the way diseases are diagnosed. The Trust has been awarded one of the four

## Opportunities for further Collaborations include:

* The Trust has played an important role in the development of the Oxford Academic Health Consortium (OAHC) which has fed into the proposed Oxford Academic Health Sciences Centre.
* The Oxford Academic Health Sciences Centre (AHSC). The Trust has played an important role in the recently submitted AHSC application which was shortlisted and interviewed. The process now is:
	+ The Designation Panel has reviewed full applications and interviewed shortlisted NHS provider/university partnerships before making recommendations on AHSC designations to the Department of Health;
	+ November/December 2013: Department of Health confirms selected AHSCs;
	+ April 2014: New designation for selected AHSCs commences.
* The Trust has been approach by Berkshire NHS Foundation Trust and Bath University to consider some form of collaboration. Meetings will take place later in the year to look into the options.

## NIHR Networks

The NIHR infrastructure in England is due to change. Currently there are 25 Comprehensive Local Research Networks in addition to various topic specific networks for cancer, medicines for children, stroke, diabetes, primary care, dementias and neurodegenerative diseases and mental health. From April 2014 these will be replaced by 15 NIHR Local Clinical Research Networks (LCRN) and be responsible for the distribution of £280 million of NIHR funding per year. These LCRNs will have boundary alignment with the AHSN areas. The Thames Valley LCRN is within the Oxford AHSN area and will be hosted by Oxford University Hospitals NHS Trust, with anticipated funding of £13milion. Each of the NIHR LCRNs will now cover all therapy areas and allow flexible deployment of resources.

# Research Governance

Currently R&D reports into the Clinical Effectiveness Committee. The R&D Committee is currently under review in relation to remit, terms of reference and membership. New sub-committees/meetings are being developed that will report into the R&D Committee, including, CRF Board, Finance, Study Review Panel, Monitoring and Auditing, CRF Users and Participant Recruitment Groups. The future of governance for R & D needs further discussion as the trust develops further in this area.

# Studies and Participant Recruitment

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.



Key: PIC – Participant identification centre

 CTIMP – Clinical Trial of Investigational Medicinal Product

 NIHR – National Institute for Health Research

 UKCRN – UK Clinical Research Network

 CSP – Coordinated System for gaining NHS Permission

Within the Trust there is a transient flow of research studies which is typically around 100 at any one time. There has been an increase of 16 studies recruiting participants within the Trust over the last six months. The number of NIHR portfolio adopted studies has increased during the last six months from 50 to 65, the Trust is the lead site for 24 or these studies, a small decrease over the past six months.

The number of participants (patients, carers, staff etc) recruited to studies ongoing within the Trust is a key issue and reasonably consistent at approximately 2000 as shown in the table below:

|  |
| --- |
| **All OHFT Site Studies - Recruitment** |
|   | **2010/2011** | **2011/2012** | **2012/2013** | **2013/2014Estimate** | **2013/2014Actual to date** |
| **Portfolio** | 1919\* | 2303 | 1822 | 2000 e | 1112 |
| **Non-portfolio** | 77\*\* | 53\*\* | 359 | N/A | 216 |

Key: \* because of previous years' inaccuracies this may be higher than actual

\*\* incomplete return

e estimate as submitted to the NIHR

The recruitment of participants to research studies is developed and implemented by individual research teams, with the R&D department collecting the information. The new Research Recruitment Manager will develop and implement a strategy to increase participant recruitment to all research studies throughout the Trust. The post will be supported by five research assistant posts situated within clinical teams throughout the Trust

## 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). These metrics may affect NIHR funding from October 2013, with terms and conditions being incorporated into new contractual agreements for infrastructure and grant funding.

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 table below shows the number of studies initiating research (70 day benchmark) over the last 12 months.

|  |
| --- |
| 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 | 3 | 25% |
| 4 – 2012/13 | 1 Apr 2012 to 31 Mar 2013 | 6 | 1 | 17% |
| 1 – 2013/14 | 1 Jul 2012 to 30 Jun 2013 | 12 | 7 | 58% |
| 2 – 2013/14 | 1 Oct 2012 to 30 Sept 2013 | 11 | 7 | 64% |

The table below shows the time to target for research studies over the last 12 months

|  |
| --- |
| Performance in Delivering Commercial CTs |
| Quarter | NHS Permission granted within the period | \*Number of studies closed to recruitment during period | Number of studies that recruited time to target | Percentage of studies that recruited time to target |
| 3 – 2012/13 | 1 Jan 2012 to 31 Dec 2012 | 3 | 1 | 33% |
| 4 – 2012/13 | 1 Apr 2012 to 31 Mar 2013 | 0 | N/A | N/A |
| 1 – 2013/14 | 1 Jul 2012 to 30 Jun 2013 | 3 | 1 | 33% |
| 2 – 2013/14 | 1 Oct 2012 to 30 Sept 2013 | 4 | 1 | 25% |

\*This does not include studies where the sponsor withdrew.

# Highlights of Research Projects

In March 2013 Prof.Tom Burns and colleagues published the results of the community treatment orders for patients with psychosis (OCTET) randomised controlled trial that showed no benefit to patients on Community Treatment Orders (CTO). It concluded that future use of CTOs should be urgently reviewed, with recommendations being presented to the DoH.

The CRF successfully completed two clinical trials on behalf of an external collaborator in the field of experimental medicine, P1Vital. One study explored whether certain antidepressants have an effect in thinking, perception and memory in healthy volunteers. The other study investigated whether a novel compound potentially to treat depression and anxiety had positive effects on learning and memory. Both studies have only recently closed to recruitment and data analysis is pending. They are in an area of experimental research which is being promoted by the NIHR

ReD-KITE: Resistant Depression - Ketamine Infusion Trial Evaluation: a phase I, dose escalation, safety study has closed to recruitment and data being analysed to determine the safety profile of repeated doses of ketamine infusions and to gain preliminary efficacy data.

A number of studies are ongoing within the field of dementia, in support of the government initiative to tackle the condition.

# Finance

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

* The National Institute for Health Research (NIHR)
* Thames Valley Comprehensive Local Research Network (TVCLRN)
* Commercial Income

The type of income provided by these organsiations is shown below. The NIHR and TVCLRN tables include the FY14 forecast amounts and the Commercial income table includes the actual income at the end of the first 6 months.

##  National Institute for Health Research (NIHR)

|  |  |  |
| --- | --- | --- |
| **Type of income** | **FY14 Forecast (£k)** | **Comments** |
| Study  | 2,465 | To fund successful grant applications *(a full list of currently active studies is shown in Appendix A)* |
| RCF | 1,020 |  (see below) |
| CRF | 718 | Infrastructure funding for NIHR studies taking place within CRF |
| CLAHRC | 250 | CLAHRC Funding starts Jan 2014 |

## 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 funding allocation includes a percentage of NIHR funding received in the previous calendar year plus an allowance for each Senior Investigator registered with the NIHR as being associated with Oxford Health.

The FY14 RCF allocation shows a reduction of £109k on FY13. This movement is made up of a £259k reduction in the study related element which is partially off-set by a £150k increase in the senior investigator element following the inclusion of 2 additional investigators.

|  |  |  |
| --- | --- | --- |
|  | **FY13** | **FY14** |
| Senior Investigators (SI)  | Keith Hawton, Guy GoodwinJohn Geddes | Keith Hawton, Guy GoodwinJohn Geddes, David Clarke, Alastair Gray |
| **SI Funding (£75k)** | **£0.225m** | **£0.375m** |
| Applicable Study Income | £2,056m | £1,592m |
| Rate  | 0.44 | 0.405 |
| **Study Related RCF** | **£0.904m** | **£0.645m** |
| **Total RCF** | **£1,129m** | **£1,020m** |

Uses of the FY13 RCF allocation included:

* RCF fellowships for Dan White whose grant application has got to the second round and Philip Wilkinson who has submitted three applications
* Funding for Belinda Lennox who played a significant role in the CLAHRC application
* 50% funding of a clinical academic within the Children and Families Division

## FY14 RCF Commitments

The table below shows the categories to which the FY14 RCF is currently being allocated; it also shows how the funding is split between the Trust and University.

|  |  |  |  |
| --- | --- | --- | --- |
| **Commitments by category and organization** | **Trust £k** | **University £k** | **Total £k** |
| The research-related component of an NIHR Faculty member’s salary, which is not covered by other funding sources | 87 | 130 | 217 |
| Meeting the cost of the time of Faculty members in preparing grant proposals *Includes 50% funding of the new CAMHS Consultant who is currently preparing a grant application* | 124 | 65 | 189 |
| The research-related time of NHS-employed scientific, administrative and secretarial staff who support Faculty members in their NIHR-related work *Includes IT support in developing True Colours* | 48 | 144 | 192 |
| Accommodation costs, finance management costs, and human resource management cost incurred in hosting NIHR-funded research | 82 | 0 | 82 |
| **Total** | **341** | **339** | **680** |
| Currently unallocated | **340** |

The use and allocation of RCF is reviewed on a regular basis by the Director of R&D and the interim Head of R&D Finance. This allows new options to be considered as and when they arise and helps to maintain flexibility.

The current plan in relation to the £340k unallocated funding is to use as much as possible this financial year to fund the appointment of Simon Lovestone and his team.

## Thames Valley Comprehensive Local Research Network (TVCLRN)

|  |  |  |
| --- | --- | --- |
| **Type**  | **FY14 Forecast (£k)** | **Comments** |
| Core Research Staff and supported Research posts | 700 | To fund core R&D department staff and research active individuals within the Trust |
| Clinical Research Facility (CRF) | 200 | Funds medical and nursing staff employed within the CRF |
| DeNDRoN  | 197 | Funds Thames Valley Dementia and Neurodegenerative Disease Research Network (DeNDRoN) staff employed by the Trust via a service level agreement. |
| Thames Valley Primary Care Research Partnership (TVPCRP) | 1,145 | As of the 1st April 2013 the Trust became the Host to the TVPCRP. TVCLRN funding received is to fund their core staff and to support research active individuals within Primary Care in the Thames Valley. |

## Commercial Research Study Income

The table below shows research income generated from commercial studies ongoing within the CRF during the first 6 months of FY14 in addition to the FY14 Forecast.

|  |  |  |
| --- | --- | --- |
| **Study** | **Sponsor/Clinical Research Organisation** | **FY14 Period 6 YTD £k** |
| A phase III, multi center, randomized, 24 week, double-blind, parallel-group, placebocontralled study to evaluate efficacy and Safety of RO4917838 in stable patients with persistent, predominant negative symptons of schizophrenia | F.Hoffman-La Roche Limited/Quintiles Limited | 33 |
| Evaluation of the effects of agomelatine (25mg and 50mg) and escitalopram 20 mg during eight weeks on emotional blunting, emotional processing and motivation in healthy male and female volunteers.  | Servier/P1Vital | 26 |
| Interventional randomised, double-blind, parallel-group, placebo-controlled, exploratory study investigating the effects of Lu AA21004 on cognition and BOLD fMRI signals in subjects remitted from depression and controls | H.Lundbeck/P1Vital | 60 |
|   | **TOTAL** | **119** |

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

## R&D related Pharmacy Income

|  |  |
| --- | --- |
| **Sponsor/Clinical Research Organisation** | **FY14 Period 6 YTD £k** |
| GW Pharma | 2 |
| Tayrx / QCTR | 2 |
| La Roche Limited / Quintiles Limited | 3 |
| Servier / P1Vital | 2 |
| H.Lundbeck / P1Vital | 2 |
| University of Oxford  | 8 |
| **TOTAL** | **19** |

The main challenge in relation to R&D finance is to maintain the balance between:

* Using the funding within the guidelines provided by the various funding organisations , particularly in relation to contributions to overheads
* Remaining competitive in terms of commercial pricing
* Managing the Trust expectations in terms of contributing toward the EBITDA margin

The interim Head of R&D Finance and the Director of Finance are considering these requirements on a regular basis while trying to agree the Trust approach to R&D financing.

## R&D Pipeline Report

A Pipeline report has been developed to capture potential R&D activity. This report is reviewed on a regular basis by the Study Review Panel. The three extracts below show those studies where completed applications have been submitted and we are waiting for the outcome, applications in progress and potential studies which have been brought to the attention of the review.

## Applications submitted (non-commercial)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigatoror Trust Lead | Study Description | Value £k | Duration | Funder |
| Philip Wilkinson | The effects of transcranial direct current stimultation (tDCS) in late life depression | 252 | 2 years | NIHR\ MRC (E&ME Prog) |
| Dan White, John Geddes | Improved Medicines Adherence using CBT techniques | 205 | 2 years | NIHR |
| John Geddes |  CRF usage as part of a larger Wellcome Trust application being submitted by the University | 66 | 5 years | WellcomeTrust |
| John Powell (Primary Care) | Harnessing user-generated online content to improve NHS services | 2,000k | 5yrs | NIHR  |
| Philip Wilkinson | Mindcare - Mixed method feasibility study of mindfulness based cognitive therapy with dementia couples  | 256 | 2.5 years | NIHR |
| Stuart Bell \ Jill Addis  | Closing the Gap Patient Safety | 275 | 2.5 years | Health Foundation |
| Philip Wilkinson | CareApp - True Colours monitoring by dementia caregivers | 90 | 2 years | Alzheimer’s Society |

## Applications in progress (non-commercial)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigatoror Trust Lead | Study Description | Value £k | Duration | Funder |
| Paul HarrisonJohn Geddes | StemBANCC | 127  | 4yrs | Innovative Medicines Initiative (large EU funder), Sponsored and Insured by University of Oxford? |
| Katharina Wulff | Sleep Study  | Tbc | 9mths | Sleep and Circadium Neuroscience Institute (SCNI) or Wellcome Strategic Award (NIHR funding partner) |
| Rohan Vanderputt | “Minocycline in Alzheimer’s Disease Efficacy” (MADE) | 29 | Tbc | (IOP) Kings College & SLAM |
| Rupert McShane | Technology and Telecare to maintain Independent Living At home for people with dementia” (ATTILA) | 110 | 2yrs | Kings College |

## Applications in progress (commercial)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigatoror Trust Lead | Study Description | Value £ | Duration | Funder |
| John Geddes | Commercial | 152 | 15 mnths | P1Vital / Sunivion |
| John Geddes | TAK375 | 25 | 2yrs | Takeda Global |

## Potential applications (non-commercial)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigatoror Trust Lead | Study Description | Value £ | Duration | Funder |
| Matthew Broome | Autisum | £350k | 2.5yrs | NIHR |
| Katharina Wulff | Sleep Study | tbc  | tbc | MRC |
| John Geddes | True Colours extension | £1.6m | 4yrs | NIHR |
| Tony James | DBT Grant | tbc  | 3yrs | NIHR |
| Digby Quested | Miami extension | Tbc | 3yrs | EME (NIHR \ MCR) |

## Potential applications (non-commercial)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigatoror Trust Lead | Study Description | Value £ | Duration | Funder |
| John Geddes | **Feasibility Study** A double-blind, randomised, placebo-controlled, parallel group study of cannabidiol (CBD)  | tbc  | tbc | GW Pharmaceuticals |

# CLAHRC

## Leadership

Membership of the CLAHRC Executive Group has been agreed as CLAHRC Director, R&D Director and Deputy R&D Director, PPI Lead, Chief Executive of the OAHSN, the Theme Leads, a representative from the Said Business School and the Head of R&D Finance

## Finance

Meetings have taken place involving the CLAHRC Director, Head of R&D, Head of R&D Finance, one of the Theme leads and the University Finance manager to discuss the finance process.

## Legal

The Chief Executive, CLAHRC Director, Medical Directors and the Trust Secretary are due to meet to discuss the management of the CLAHRC. The CLAHRC contract has recently been received from the NIHR and is being reviewed.

## Staffing

Interviews for the CLARHC Manager are scheduled for the 25th November.

# Estates

The Trust R&D Department, including the CRF, is based at the Warneford hospital site. The CRF is now fully operational and eight research rooms are open for researchers to utilise. Some of the core R&D team have moved offices to facilitate the Executive Team’s move but remain on the Warneford site

In collaboration with the Department of Psychiatry in the University of Oxford, the Trust is working towards installing an MRI scanner in the Oxford Centre for Human Brain Activity (OHBA) which, in combination with the existing magnetoencephalography (MEG) scanner and the technical and scientific expertise in the FMRIB facility, will give leading edge scientific and clinical imaging capacity on the Warneford site. This is expected to take place within the next 12 to 18 months

# Staffing

Cindy Whitbread, the new matron for the CRF has now been appointed and started work at the beginning of July 2013.

Dr Andreas Cipriani joined the CRF medical staff in September 2013 to support research within the Trust and in collaboration with the University of Oxford.

Following the resignation of the Research Governance Manager within the R&D department there is a current vacancy. This is a potential risk as the post holder currently manages the NHS permission processes, research passports and letter of access for researchers within the Trust should there be a delay in the identification and recruitment of a suitable replacement. The job description is currently within HR system for rebanding to make the post more strategic and incorporate more responsibility for NIHR metric reports, monitoring and auditing of sponsored and hosted studies and training programmes for researchers.

Additional administrative support has now been recruited to support the R&D department.

Following the resignation of a junior research nurse within the CRF, a replacement post is to be filled. The first recruitment process failed to identify a suitable candidate

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

A new role, Research Recruitment Manager, has been developed within R&D which is currently being advertised.

# Communications

The CRF hosted successful open day on 22nd May 2013 to coincide with International Clinical Trials Day. Throughout the day there were presentations from researchers and research participants in addition to general talks.

The CRF were visited by the NIHR Office for Clinical Research Infrastructure (NOCRI) to discuss progress of the Trust CRF and reporting formats and content.

The R&D department attended the Trust AGM to promote research. Attendance at the Consultants Away Day in October is also scheduled.

A quarterly newsletter is produced and circulated internally and externally. This is currently under review with the thought of an article being included in the Trust monthly Insight publication. This will be supported regular R&D updates generated and circulated by the R&D department.

The NIHR CRF and Trust R&D intranet and internet pages are currently under construction and the content being drafted.

The Head of R&D attended a senior management meeting of the Children and Families division to provide an overview of R&D and presented, with the Medical Director, at the Children and Families Division Research and Development Day on the 14th November 2013

The Head of R&D and the Head of R&D Finance were asked to provide input into an R&D costing project currently being undertaken by Oxford University Hospitals Trust. Links have also been developed with the new Head of Commercial Services

# Uniforms

CRF nurses are now wearing appropriate uniforms in accordance with the dress and uniform policy. Non clinical research staff have selected a grey dress/tunic as standard research uniform, that will be adopted within the trust over time.

**Author 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 | 02/04/2014 | £246,656 |
| Ketamine as an alternative to ECT in treatment | NIHR | 31/08/2012 # | £198,330 |
| Melatonin in Acute Mania Investigation (MIAMI-UK) | NIHR | 30/06/2012 # | £99,918 |
| Aripiprazole treatment for antipsychotic induced hyperprolactinaemia in young patients with severe mental illness and learning disabilities | NIHR | 28/02/2015 | £201,626 |
| Risks, roles and responsibilities: Evaluating falls in inpatient mental healthcare settings for older people | NIHR | 31/05/2013 # | £249,733 |
| Challenge FamCare | Humber NHS FT | 30/09/2013 | £175,989 |
| Development and evaluation of SMS-based monitoring and management service for people with bipolar disorder | NIHR | 31/12/2014 | £1,660,037 |
| Bipolar affective disorder or borderline personality disorder? An exploration of patient and clinician experience | NIHR | 31/07/2013 # | £195,073 |
| Coercion in mental health. 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 peple 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 Avon & Wiltshire  | 30/04/2017 | £562,491 |
| Development of content for an online Cognitive Behavioural Therapy (CBT) platform  | Alzheimer’s Society | TBA | £108,869 |
| Antidepressant Controlled Trial for Negative symptoms in Schizophrenia (ACTIONS) | NIHR via Imperial  |  | £138,814 |
| Treating insomnia in patients with delusions and hallucinations: a pilot randomised | NIHR | 30/09/2014 | £250,556 |
| NIHR Diagnostic Evidence Co-operative | NIHR | 30/09/2017 | £989,754 |

# waiting on final study report

**Commercial funded studies**

|  |  |
| --- | --- |
| Study | Sponsor/Clinical Research Organisation |
| A phase III, multi center, randomized, 24 week, double-blind, parallel-group, placebo contralled study to evaluate efficacy and Safety of RO4917838 in stable patients with persistent, predominant negative symptoms of schizophrenia – NN25310 | F.Hoffman-La Roche Limited/Quintiles Limited |
| A phase III, multi center, randomized, 24 week, double-blind, parallel-group, placebo contralled study to evaluate efficacy and Safety of RO4917838 in patients with sub-optimally controlled symptoms of schizophrenia treated with anticpsychotics – NN25307 | F.Hoffman-La Roche Limited/Quintiles Limited |
| A randomised, double-blind, placebo-controlled, dose-ranging, parallel-group, phase 2 study of the safety and efficacy of ABT-126 in the treatment of cognitive deficits in schizophrenia (CDS) in nonsmokers | AbbVie |

1. A valid research application is a complete research application that has been received by the NHS organisation following its submission via 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)