

**BOD 46/2022**

(Agenda item: 8)

**Report to the Meeting of the**

**Oxford Health NHS Foundation Trust**

**Board of Directors**

**July 2022**

**Research and Development Report**

**For Information**

**Governance Route/Approval Process**

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

**Statutory or Regulatory responsibilities**

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

**Recommendation**

The Board is asked to support these developments.

**Authors and Title:** Vanessa Raymont, Research and Development Director and Karl Marlowe, Chief Medical Officer

**Lead Executive Director: Karl Marlowe**

This is in line with the 4 strategic priorities of the Trust, especially that of Research & Education.

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# Introduction

This report has been produced to provide the Board with additional information requested following the presentation of the R&D Report in March, and to provide a general update on research activities since then. A more comprehensive report will be produced for the September Board.

# Response to March 2022 Board Meeting

Given discussion at the Board meeting in March, more information was requested on the following two areas:

* more about the role of the Joint Research Office so that NEDs can understand the institutional landscape; and
* consideration of how to capture/benefit from commercial opportunities from Research work.  Consider how well equipped the Trust is in terms of the commercial negotiation skills necessary to maximise opportunities from Research

### Oxford Joint Research Office (JRO)

**Background**

The development of the Oxford Joint Research was an Oxford Academic Health Partner (OAHP\*) priority, to enable closer working and coordination for research within the NHS and academia. Bringing together the teams responsible for supporting clinical research across both NHS Trusts and both Universities in Oxford, as part of an initiative was supported at the highest level in each organisation and by the Board of the OAHP, chaired by Professor Sir John Bell.

*\*The OAHP is NIHR Accredited*

**Oxford JRO background**

* The OU/OUH JRO was established 2011, overseen and supported by the Joint R&D Committee (JRDC)
* In December 2021 Oxford Health (OH) and Oxford Brookes University (OBU) became formal partners
* In early 2022 OH and OBU representatives were appointed to JRDC
* In December 2022, Bill Wells (OH) and Boki Savelyich (OBU) joined the JRO’s Partnership and Heads of Teams groups
* In early 2022 a joint external communication was issued

Most JRO’s nationally are one NHS Trust and one university, Oxford is unique in that it contains four partners and covers a large geographic area.

**Note: Formal oversight and reporting arrangements for JRO teams continue to be through their own organisations**

**OH’s developments in relation to the JRO**

* Reported to the OH Board in March 2022
* Dr Vanessa Raymont (OH R&D Director) joined JRDC
* OH, identified the following functions as falling within the JRO remit
  + Study set-up, governance & sponsorship​
  + Finance & Grant applications support​
  + Information Governance​ & EHR searches​
  + BRC & CRF Management​
  + Contracts ​& Intellectual Property Management​
  + Quality Assurance
* The OH Head of R&D presented “An overview of Research at Oxford Health” to the JRO in March
* OH, Heads of Teams now attend the monthly JRO Heads of Teams meetings

OH, have already worked with the JRO in several ways, including sharing “consent for contact” information, Research Informatics (IG) guidance, and aligning study set-up checklists with OUH.

In December 2021, the NIHR removed the requirement for Trust sign-off on grant applications. Following discussions across the JRO the OH Head of R&D was invited to discuss the implications of this change with the NIHR. This was an opportunity to have “one voice” from Oxford.

**JRO opportunities in the future could include items such as**

* Working with OUH to improve the provision of services to deliver OH Research
* Further alignment of study set-up processes across the 4 partners, making Oxford more attractive to industry
* Simplifying processes, to increase participant recruitment to Oxford led studies
* The potential for increasing the number of joint/aligned SOPs
* Streamlining processes for grant submissions across the 4 partners
* Streamlining contract negotiation between the 4 partners
* Development of data sharing agreements
* Joint training
* Joint development of Studyline (Research system). OH, are members of the Studyline Steering group and will be setting up a user group

Both of Oxford BRC’s and CRF’s have or will work together, with a lot of this joint working involving members of the JRO.

A JRO event took place in June 2022. Chris Birdsall (OH Research Comms lead) reported on the event

***Around 100 JRO members from the four Oxford organisations met this week to look at how they can work together to benefit healthcare.***

*The Joint Research Office away day, held on Tuesday (June7th) examined how its member organisations could collaborate on research projects by sharing ideas, expertise, and resources.*

*It was the first time they had all got together since (Oxford Health) and Brookes University joined the JRO in December 2021.*

*Bill Wells our Head of Research and Development started proceedings by joining colleagues from the other three organisations to talk about the evolution of the JRO and other significant developments in research.*

*This was followed by a presentation from Oxford Health clinical psychologist Sinead Lambe on the gameChange project, an automated virtual reality (VR)therapy for psychosis.*

*In the largest ever clinical trial of VR for mental health, the automated therapy was shown to work well for patients diagnosed with psychosis, with those with the most challenging psychological problems getting the most benefit*

*Sinead explained how this project had involved a great amount of collaboration involving 90 people from 15 different organisations over a 4 year period and was supported by members of the JRO.*

*During the update from the Directors of the Oxford BRCs and Clinical Research Facilities*

*John Geddes, the Director of Oxford Health Biomedical Research Centre (BRC) explained the coverage of the BRC’s work extended beyond Oxford and that it was looking to establish an infrastructure across the UK.*

*Andrea Cipriani, Director of Oxford Health CRF said joining the JRO had been a fantastic learning curve and that combining resources would move things forward.*

***National and international leaders***

*A lively panel discussion showed there was great enthusiasm for collaboration*

*Oxford Health Director of Research and development Vanessa Raymont told delegates that Oxford Health had been placing an emphasis on transitional research where research was used to improve clinical services for patients.  She added that this would act as an incentive for more people to become involved in research if they could see the benefits to patient.*

*Delegates also heard from the panel that clinical research in Oxford was an important resource for the country, and that it had national prominence and was seen as an exemplar of what can be achieved.*

*Breakout groups convened after lunch to discuss how information, expertise and training could be shared and communicated between the four member organisations of the JRO.*

*The final presentation of the day was given by Dr Peter Wright (Oxford Brookes University), Head of Development of novel Technology Applications in Rehabilitation at FORTEe, a collaborative international exercise intervention for children and adolescents undergoing anti-cancer treatment*

***Take away messages from the event included***

* ***“Oxford research is not just in Oxford; it is led by Oxford but relevant to the whole country”***
* ***“Diversity of researchers is important as well as diversity of participants.”***
* ***“We are moving away from competition to collaboration”***

***OH Reaction***

*John Geddes said: “It was great to see such enthusiasm for collaboration.” “There were some inspiring examples of how the expanded JRO has already delivered faster and more powerful research to benefit patients”. “It was good to see cross-Oxford (and beyond) inter-disciplinarity and commitment to capacity building.”*

*Bill Wells said: “The event was supported by many senior people from the whole Oxford infrastructure (Universities/Trusts) who acknowledged how important the JRO is in making research happen.”*

**Commercial opportunities from research work**

Pricing for commercial studies is based on an Interactive Costing Tool (ITC), which combines study procedures, timings, visits, and non-procedural activities. Prices use nationally agreed hourly rates and are subject to the relevant Market Forces Factor (MFF).

OH Process

* R&D finance liaises with clinical staff to validate procedures, timings and visit data
* Non-procedural activities are negotiated based on previous experience
* Where OH plan to sub-contract research activities to other originations, prices are agreed with the supplier(s) and sponsor (customer)
* The price per participant is combined with the number of participants to calculate the potential total income
* Total income is compared to the deliver cost and financial sign-off is sought based on Trust SFI’s
* Once agree the ICT is locked and elements extracted to include in the contract

The R&D Finance team negotiate all elements with the sponsor, with input from the clinical teams.

Commercial income is used to support the cost of the team delivering the study, for CRF (experimental medicine) based studies, income is allocated to the CRF and for later phase studies, income is used to fund R&D staff. Any overall surplus is used where possible for the benefit of research.

The CRF also provides services to the University\BRC to deliver studies, with prices being negotiated based on the type of funder and the benefit to the CRF in delivering the study.

The opportunity for the Trust to benefit from commercial activity is currently limited more by the lack of capacity to deliver studies than commercial negotiation skills.

We have previously agreed an income allocation process with another Trust to deliver a study. A similar model could be implemented for any OH clinical service involved in a delivering a study.

The national costing review is currently being reviewed and OH have fed into the consultation process

Other areas to make OH more attractive to industry are greater availability of externally provided research services, such as scanning and more contracting capacity.

**Intellectual Property**

The management of IP generated in relation to research takes place in accordance with the guidance set out in the Framework Intellectual Property Agreements (FIPA) between; Oxford Health NHS Foundation Trust (OHFT), The University of Oxford and Oxford University Innovation (Effective date 1st October 2017).

The current process is being presented to the Finance and investment Committee on 12th July for review.

Other opportunities for sustaining and increasing translational research models, such as the Brain Health Centre are described in a separate document submitted with this report.

# Research activity update

## COVID-19

The Novavax study closed in May 2022.

## Communications \ Events

**INSPIRE Event**

More than 150 people dialled in to the latest Inspire Network session on 9th June 2022 to hear how research is leading to better care for patients within the Trust. The 3-hour event provided a whistle stop tour of some of the research currently being carried out with a packed programme of presentations, case studies, and comments. It highlighted current unique and patient-focused initiatives and introduced the new Trust’s R&D strategic aims of i) increasing clinician-led translational research; ii) growing community-based research; iii) highlighting the Trust’s unique clinical trials facilities to attract further trials leadership opportunities.

One of the key aims the event was to establish a working group to develop more directorate-driven translational research and we will have a follow up event later in the year to report back on progress.

Following the various talks, questions, and breakout sessions our Chief Medical Officer Karl Marlowe said it was an important time for research in the Trust, which should be aligned to and support clinical priorities. He added the session would inform the future research strategy of the Trust.

Our R&D Director Vanessa Raymont who chaired the event said: “I really hope it demonstrated all the great, very translational research that is already going on across OH, as well as how we can help drive more research to ensure we are providing the best care for our patients. I look forward to seeing how the working group we are setting up progresses.'

## NIHR Local Clinical Research Network (LCRN) Thames Valley and South Midlands

**Contract Renewal**

William Van’t Hoff, Chief Executive Officer of the NIHR Clinical Research Network, recently shared details regarding the new geographical configuration of the Network post March 2024.

From April 2024, the 15 current Local Clinical Research Networks (LCRNs) will be replaced by 12 NIHR Regional Research Delivery Networks (RRDN), each mapped onto the NHS England Regional Office boundaries and those of the Integrated Care Systems (ICSs) operating within the regions, also coterminous with most local authority boundaries. This will provide even more focus on regional collaboration, influence and development with the local NHS and care system, to meet the needs of people within a region, while facilitating joint working with the NHS and ICSs.

This means a substantial change to the CRN in which OH sits.  Much of the current footprint will join up with Hampshire and Isle of Wight to form the new South-East Central Network. It will lose the area around Milton Keynes to the East of England region in line with the established NHSE boundaries and the new patch will cover the whole of the Frimley ICS, some of which is currently mapped to the Kent, Surrey and Sussex LCRN.

CRN CC will publish further details regarding the process for selection of future hosts for the NIHR Regional Research Delivery Networks ahead of the process commencing in October 2022. We expect that process to be completed by March 2023 with the new networks going ‘live’ on 1st April 2024.

## NIHR Oxford Health Biomedical Research Centre (BRC)

**Top three achievements in 2021/2022**

1. **gameChange Virtual Reality (VR) programme**. This NIHR funded study is the largest ever clinical trial of VR for mental health, recruiting patients diagnosed with psychosis, particularly those with intense fears about being outside in everyday situations. The gameChange trial (see PMID: 31462489) found that VR led to significant reductions in the avoidance of everyday situations and in distress with results published in May 2022 (PMID: 35395204)- see the press release associated with the publication (<https://www.oxfordhealth.nhs.uk/news/breakthrough-success-in-provision-of-automated-psychological-therapy-using-virtual-reality-vr/>)
2. **Transfer of True Colours to Oxford Health NHS FT**: We transferred the management of the **True Colours** Digital platform from Oxford University to Oxford Health NHS FT, ensuring full embedding in the clinical service, providing direct patient benefit as well as expanded opportunities for research. This completed the translational pathway from early-stage research and innovation to patient care. The BRC provided £50k to support this development
3. **Research during the COVID-19 pandemic**. Work in **vaccine hesitancy** and the **increased risk of common mental disorders after Covid-19 infection** was undertaken, particularly in those hospitalized during the acute infection. Outputs include high impact papers from the Adult Mental Health Theme with five major policy documents including three for WHO and the UK parliament. BRC funded work tracked children’s and parents’ mental health during the pandemic, including a rapid evidence review for Department of Education (DoE). The findings were included in PHE/DoE reports and referenced in both Houses of Parliament. The OxWell School Survey collected data to inform policy and identify schools needing additional mental health support.

**Joint BRC’s open day**

An open day showcasing Oxford’s world-class research to patients and the public was held at Oxford Town Hall on Tuesday 5 July.

The event included an interactive exhibition, up to 3 public talks and careers stand for local schools. This year the event is taking place at Oxford Town Hall.

The objectives were:

* to raise awareness of health research in Oxford, demonstrate its benefits for patients and encourage more members of the public to participate or get involved in research.
* to promote careers in research to school audiences

It has been organised jointly the NIHR Oxford and Oxford Health Biomedical Research Centres.

**BRC Renewal**

At the time of writing, the result of the renewal application is known, but currently under embargo until NIHR makes the outcomes public.

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

**Top three achievements:**

1. Completing the Novavax COVID-19 vaccination study to time and target despite significant changes and additions to the protocol (addition of crossover extension, allowing unblinding for purposes of vaccine passports, facilitating protocol amendments and additional vaccinations to enable travel) and the changing COVID-19 landscape (delays in licensing Novavax which has now been completed, legislation on recording of approved vaccines, surges and reductions in case numbers and IPC regulations).
2. In collaboration with Janssen, we have implemented a novel approach to treatment trials (MDD 3009, MDD 3010). These are the first studies to use data-science technologies to enrich recruitment using electronic health record (EHR) data. The participants will provide real-world evidence on tolerability, treatment outcomes and safety in the NHS for patients having treatment-as-usual (standard of care), which will be the external control arm for the Phase III seltorexant studies.  In addition, the collaboration with Janssen has extended our age range (MDD 1016) in a phase 1b exploratory study of Seltorexant as an adjunctive therapy to antidepressants in adolescents with major depressive disorder who have had an inadequate response to initial treatment.
3. During COVID-19 the CH-CRF continued to conduct high intensity, early phase studies (for example including a programme of IV ketamine studies (including Relaks) and opening a phase 1b study (Synergy)). In addition, the positive learning points achieved during the pandemic (close cross-working with other teams and within OHFT R and D, flexible hours, streamlined processes for set up of high priority studies) were adopted and integrated into standard working practices.

## NIHR Applied Research Collaboration Oxford and Thames Valley (OxTV)

**Implementation, evaluation and AHSN collaboration**

Key activities during the last 6 months include:

* ARC contributed to the AHSN NHSE visit (December 2021). Shared how the research on blood pressure self-monitoring and self-management (Theme 2) supported the system work on cardiovascular disease (CVD).
* ARC/ AHSN Implementation Oversight meeting (October 2021). ARC projects are now RAG rated both for project progress and also progress with dissemination, implementation and impact. Red rated projects will be discussed at ARC Strategy Board to identify what support can be provided. Currently the AHSN are integrated with three themes (2, 5 and 6) and responsive to requests from the other three. This is due to either the current stage of the projects or the projects are not for AHSN implementation support. However, there may still be opportunities for the AHSN to offer guidance, alongside working with the ARC Implementation Manager.

**Other key activities include:**

1. **NHS Insights Prioritisation Programme (NIPP) project:**

Virtual clinics for managing transient ischaemic attack and minor stroke – developing a safe and effective model for post pandemic working.

Secured an additional £275,000 of funding to partner with the AHSN to deliver rapid insights.

* Objectives for the project are:
  + Describe what a good pathway looks like for face to face, virtual and hybrid TIA clinics and which patients are best suited for each model
  + Determine the current availability of data on TIA services and work with partners to identify improvements to enhance quality monitoring of services
  + Describe the views and experiences of patients and healthcare professionals for the different models of TIA clinic.

The project is progressing well with good buy-in from the South East Integrated Stroke Delivery Networks and due to report in March 2023.

1. **Monitoring and supporting health and well-being of residents of care homes: RESTORE2**

RESTORE2 is a multifaceted ‘tool’ that assesses health status of potentially deteriorating person and helps mobilise relevant intervention. RESTORE2 is considered highly relevant to care homes although it currently has a very weak evidence base. This work is championed by AHSNs and we are working locally on the implementation with Oxford AHSN. Access to care homes has been achieved via Oxford Health’s Care Home Support Unit and equivalents in other counties. The interview data coupled with a dashboard of selected NHS Indicators for all care homes in the region will provide an independent measurement of impact on the NHS.

After a significant delay due to the pandemic and a redesign the project is progressing well and information will also link in with the Virtual Wards work the AHSN is leading on.

1. **Capacity Development Programmes**

A core element of the ARC is to build research capacity and capabilities across the system and we have several mechanisms through which we are achieving this:

* A dedicated Masters Course in Applied Digital Health (first cohort starts in October).
* Newly developed Masters in Applied Social Care Research with Oxford Brookes (Launching this summer).
* Awarded an additional £286,224 to run two post-doctoral clinical academic fellowships in dementia.
* Public Health Practitioner Research Training being delivered in the summer.
* Global Healthcare Leadership Masters starting in October.
* Co-applicant on the Health Determinants Research Collaboration funding bid lead by Oxfordshire County Council.
* Four new internships awarded through an additional £41,000 Health Education England funding.
* Five new PhD students started with another four awarded
* Developing with our local infrastructure partners an accredited course for public involvement staff as there is a system-wide need for this with initial additional £28,000 funding from NIHR Centre for Engagement and Dissemination.

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

**Top three achievements of the MIC from 1 April 2021 to 31 March 2022.**

1. Completion of a multi-site retrospective evaluation of the accuracy of rapid diagnostics for malaria in returning paediatric travellers with fever. This has the potential to improve diagnostic algorithms nationwide for children and parents.
2. Completion of 2 community based rapid diagnostic evaluations in the RAPTOR-C19 study within the CONDOR programme, providing the first UK community-based evidence for performance of these tests, likely to be critical in informing diagnostic testing moving forwards into the winter now that testing centres and self-testing are discontinued. In addition, the CONDOR programme contributed significantly to UKHSA and government regulatory strategy.
3. The MIC supported the development of a biobank for samples taken from patients presenting in primary care with vague non-specific symptoms who were referred into the SCAN cancer pathway (<https://www.ouh.nhs.uk/services/referrals/radiology/scan-pathway.aspx>), through a successful application for funding in 2018. Work on these samples has underpinned a significant publication and a university spin-out company (Oxomics <https://www.oxomics.com/>), which we are now working with to support next steps in development.

## Research Management Team (RMT)

Over the past 4 months 10 new studies have opened and 13 have closed, this is reflected in the table below:

|  |  |  |
| --- | --- | --- |
| **Site type** | **As of March 22** | **As of June 22** |
| Recruiting site | 82 | 77 |
| PIC | 13 | 15 |
| Other non-recruiting | 1 | 1 |
| Research database | 3 | 3 |
| **Grand total** | **99** | **96** |

## Research Informatics (RI)

The RI Manager and Head of R&D have recently been involved in discussions on both the redevelopment of True Colours from a research perspective and the development of a Trusted Research Environment (TRE). Both are still at an early stage.

## Financial Performance

**2021-22 Performance**

R&D reported a contribution to the Trust of £260k, which compared to the adjusted budget of £318k resulted in a favourable variance of £578k. The budget of £318k was after transferring £150k to IT to support the development of True Colours. This £150k was in addition to the £50k contribution from the BRC.

**2022-23 Forecast**

The next financial year will see a £1m reduction in Research Capability Funding, non-recurrence of the Novavax surplus and potential cost pressures within the CRF. This will reduce our flexibility and limit our response to new opportunities. We will also be in transition from the current CRF to a new award starting in September and hopefully from the existing BRC to a new expanded BRC.

## Research Active Workforce

**NIHR 70@70**

NIHR James Lind Alliance in Community Nursing: this ARC funded project involved undertaking a priority setting partnership in community nursing to identify the top 10 evidence uncertainties in this area. The NIHR ARC TVSM has committed to hosting a workshop in late Summer 2022 to identify which of the evidence uncertainties can be supported and prioritised through the ARC.

R&D created secondment opportunities for nurses and allied health professionals working in clinical settings to allow them to spend up to 12 months working within the R&D department and we are currently supporting an NMAHP colleague who has taken on Associate PI responsibilities on the PRINCIPLE trial, as part of the NIHR Associate PI scheme.

## Estates

The CRF Director and Manager recently met with the Executive Director for Digital & Transformation to try and identify additional space for the CRF. We are currently awaiting feedback on its availability.

**Authors and Title:** Dr Vanessa Raymont, Research and Development Director

**Lead Executive Director:** Dr Karl Marlowe