

Cover Sheet

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Title: Research & Development Governance and Performance Report
2023-24

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Board Lead: Chief Medical Officer
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Confidential: No
Key Purpose: Performance

Executive Summary

1. This paper presents the Oxford University Hospitals NHS Foundation Trust's (OUH) Research and Development Governance and Performance Report for 2023-24.
2. With a portfolio of over 1500 active clinical research studies, OUH is one of the largest and most productive research-active university hospital NHS Trusts nationally.
3. A total of 295 new clinical research studies received approval from R&D to start recruiting during 2023-24. Of these, 110 (37%) were commercial and 185 (63%) non-commercial, and 243 (82%) were on the NIHR portfolio (100% of the commercial studies and 72% of the non-commercial studies).
4. A total of 25,094 study participants were recruited at OUH in 2023-24. Of these, 1,054 (4%) were recruited to commercial studies and 24,040 (96%) to non-commercial studies.
5. There are over 370 clinical research delivery staff working across 38 teams supporting the delivery of these studies and are employed by either by the OUH or Oxford University, to deliver clinical studies to time and target.
6. The grant awarded by OUH to Oxford Brookes University in 2022, has achieved significant progress in its aims of developing research capability and capacity in the Health Care Professionals workforce, and providing research education and training across the two organisations.
7. The NIHR Oxford Clinical Research Facility (CRF), now in its second year of operation, is supporting an increasing volume and variety of early phase clinical research studies, primarily at the Experimental Medicine CRF.
8. In addition to their ongoing collaboration with colleagues in the Oxford JRO partner organisations, members of the OUH R&D teams have contributed to several high-profile national activities during the last year.

Recommendation

The Trust Board is asked to receive this report for information.

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Research & Development Governance and Performance Report 2023-24

1. Introduction

Structure and Organisation

- 1.1. Research and Development (R&D) is part of the Corporate Division of Oxford University Hospitals NHS Foundation Trust (OUH), reporting via the Director of R&D to the Trust’s Chief Medical Officer, who is an Executive member of the OUH Board.
- 1.2. Within R&D there are specialist teams responsible for Governance, IP and contracts, Finance and BRC management (Figure 1).
- 1.3. During 2023-24, the Lead for Nursing, Midwifery and Allied Healthcare Professionals (NMAHP) Clinical Research Delivery was formally brought into the R&D team.

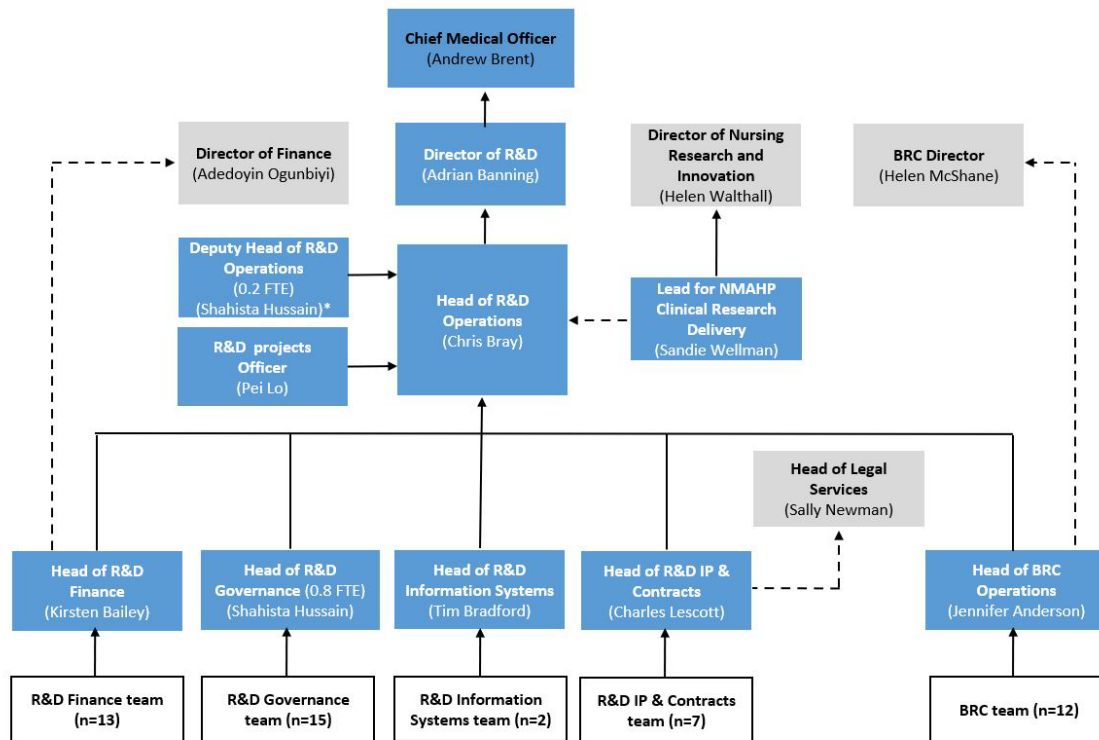


Figure 1. OUH R&D Organogram

- 1.4. In addition to this annual report to the Trust Board, R&D provides formal reports to the following committees:

- Joint R&D Committee (JRDC) 4 times/year

- Trust Management Executive (TME) 3 times/year
- 1.5. The JRDC was established in 2011 under the Joint Working Agreement between OUH and the University of Oxford (OU). The Trust's longstanding partnership with the University is fundamental to the delivery of high-quality research at the Trust. The University benefits from access to the Trust's patients, data and other resources to further its research, meanwhile the Trust's patients and staff benefit from the contributions of world-leading clinical academics and the advances in diagnosis and treatment that stem from their research. However, the organisations' different priorities, processes and systems mean that maintaining and developing these opportunities requires careful and active management.

The Joint Research Office

- 1.6. The OUH R&D teams are part of the Joint Research Office (JRO), a partnership originally established with the University of Oxford in 2011 to help deliver medical research in Oxford by improving communication and streamlining processes through shared knowledge and expertise between the University and the Trust. The JRO is overseen by the JRDC and the combined efforts of its teams have played a critical role in underpinning the continued success of the National Institute for Health and Care Research (NIHR) Oxford Biomedical Research Centre (see [Section 4](#)), as well as the NIHR Oxford Health Biomedical Research Centre, which focuses on brain health.
- 1.7. Further information about the activities of the JRO, which [expanded](#) in 2022 to become 'The Oxford JRO', by incorporating research support teams from Oxford Health NHS Foundation Trust and Oxford Brookes University, is provided in [Section 10](#) of this report.

NMAHPs

- 1.8. In line with [NIHR strategy](#), the number of NMAHP Chief Investigators (CIs) and PIs at OUH has increased. There are currently eight NMAHP Chief Investigators (CIs) leading 24 studies; and 41 NMAHPs working as PIs, leading 56 studies. The number from each professional group taking on PI responsibilities is detailed in Figure 2: 75% are nurses or physiotherapists.

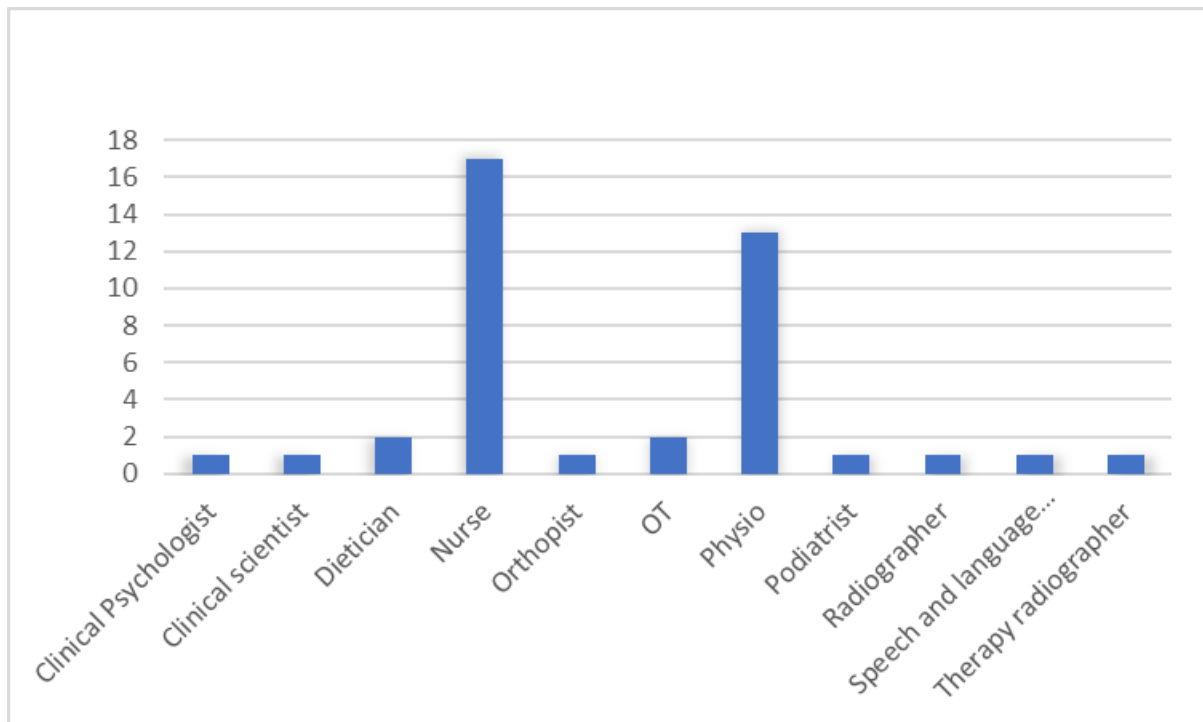


Figure 2. OUH NMAHP Chief Investigators, by professional group

- 1.9. Senior OUH NMAHPs Lizzie Stafford, Melanie Westmoreland and Govind Soni have completed the first year of the NIHR-AoMRC Clinician Researcher Credentialing Framework. This has been developed jointly by the NIHR, working with the Academy of Medical Royal Colleges, led by the Royal College of Physicians, and four higher education institutions. It is aimed at experienced healthcare practitioners from all professional backgrounds who aspire to take on leadership roles in clinical research delivery, such as Co-Investigator or Principal Investigator. Several research nurses have applied for the NIHR Principal Investigator Pipeline Programme which was launched in 2023, with the outcome pending.
- 1.10. The [grant](#) awarded by OUH to Oxford Brookes University (OBU) in 2022 to develop NMAHP research capability and capacity and to provide research education and training across the two organisations is now complete. During 2023-24, the four clinical academic research leads employed by OBU under this grant have increased research capacity and capability in each of the clinical and corporate divisions, under the leadership of Professor Paul Carding (OxInAHR, OBU) and Professor Helen Walthall (OUH). The investment has seen an increase in external fellowship and grant applications, an increase in QI and service evaluation activity that has led to significant service improvement impacting on patient outcomes. The capability activity includes the development of sharepoint site, webinar series, writing retreats leading to publications and conference presentations, doctorate applications

and conferment, newsletters and library bulletins, education resources, drop-in sessions and a research impact repository on Ulysses for NMAHP staff.

2. Clinical Research Activity

Background

- 2.1. OUH is one of the largest research-active university hospital trusts nationally, by any measure. Clinical research expands opportunities for the development of OUH's staff, as well as empowering and engaging the patients we care for and there is increasing evidence that it should improve outcomes, even for those who do not participate directly in research.
- 2.2. Research is included in [OUH's strategy for 2020-25](#), along with the related activities of education and innovation, in the World-Class Impact strategic theme, through which OUH can continue its global impact in improving health and care. Members of the JRO – from OU as well as OUH – were actively engaged in discussions during the development of the strategy.
- 2.3. Research also features prominently in OUH's [NMAHPs strategy \(2021-26\)](#) and in [Our Clinical Strategy \(2023-28\)](#).
- 2.4. Since April 2022 all requests to set-up new studies have been subject to the same delegated review and prioritisation process which is based on the model originally introduced for non-COVID studies wanting either to start, or to resume, during the early stages of the pandemic.
- 2.5. This process involves each request being reviewed by one of 10 Local Research Oversight Groups (LROGs), first to approve in principle the study taking place at OUH, and then to prioritise it relative to other studies approved by the LROG, subject to an allocation provided by R&D. Each LROG's allocation represents a proportionate share of OUH's overall set-up capacity, which is set on a rolling monthly basis by R&D, in consultation with key service Directorates, particularly pharmacy. The LROGs cover different groups of related clinical areas across OUH. Each LROG is chaired by a Principal Investigator (PI) from that area and its members include other PIs, representatives from OU and from the LCRN. All but two of the LROGs were set-up from scratch at the start of the pandemic. They are overseen by the Assessment & Prioritisation Panel (APP), which is chaired by the OUH Director of R&D and now meets monthly.
- 2.6. The model of approval and prioritisation by LROGs, whilst not perfect, is widely recognised as being a significant improvement on the more

informal and less transparent processes that guided study set-up processes across different parts of OUH prior to the COVID-19 pandemic. LROGs are now an established part of the R&D structure at OUH and proposals are being developed to recognise this more formally, as well as to expand their responsibilities, recognition and resources.

- 2.7. The APP, which brings together representatives from all the LROGs, R&D and other key stakeholders such as service Directorates and research delivery leads, has also proven to be a valuable and effective forum for working together to understand and address each other's perspectives and limitations in relation to study set-up. It has also become the obvious place to discuss and disseminate other important issues of relevance to all those involved in conducting research at OUH on a more *ad hoc* basis and there is clear potential for the APP's remit to be extended to realise this.
- 2.8. OUH has been actively engaged in supporting all relevant aspects of the UK Clinical [Research Recovery Resilience and Growth \(RRG\)](#) programme, led by DHSC and NHSE to ensure the restoration and delivery of a full portfolio of clinical research and maximise opportunities to build back better and deliver on the commitment to make the UK the leading global hub for life sciences.
- 2.9. The main focus of RRG in 2022 has been [Research Reset](#). This has required Sponsors to review their portfolio of studies which are not progressing, with the aim of giving as many as possible the chance of completing and yielding results, to generate the evidence needed to improve care and sustain our health and care system. This activity has been updated and maintained monthly by the R&D governance team for studies which are sponsored by OUH.
- 2.10. The [O'Shaughnessy review](#) was commissioned by the government in 2022 to offer recommendations on how commercial clinical trials can help the life sciences sector unlock UK health, growth and investment opportunities. OUH is one of a small number of NHS Trusts who were engaged during the review process. Published in May 2023, the O'Shaughnessy review includes eight 'problem statements', many of which are familiar to those involved in research at OUH, along with 27 recommendations to address these.
- 2.11. An assessment of the [full government response](#) to the O'Shaughnessy review (published in November 2023) has been conducted by R&D and shared with both the Oxford BRC Steering Committee and the Joint Research & Development Committee. This document set out a gap

analysis and identified actions that will be taken to ensure OUH is aligned with the government response.

Current research activity

- 2.12. A total of 1579 OUH-hosted clinical research studies were active (i.e. open to recruitment, recruiting or in follow-up) during 2023-24. This is a small increase compared to 2022-23 (1495). 84% were on the NIHR portfolio, 520 of which reported recruitment in 2023-24, more than any other NHS Trust in England, recruiting a total of 21,390 participants (the 7th highest for any NHS Trust in England). The number of portfolio studies open to recruitment or recruiting in 2023-24 was 727; the other 599 had completed recruitment and were in the follow-up phase.
- 2.13. The high volume and variety of clinical research hosted by OUH has important benefits for our patients, and major reputational and other benefits for the Trust. OUH-OU clinical research has had major impacts on patient care in the Oxford region, the NHS nationally, and internationally, in areas as diverse as infection control and treatment, vaccines, genomics, imaging, digital health and artificial intelligence, cancer, respiratory, diabetes, surgical innovations and many others. These advances have established new diagnostics and treatments, changed clinical guidelines for many conditions and have led to multiple spin-out companies. Examples of research studies supported by the Oxford BRC, which have depended on the expertise of the specialist teams in the Joint Research Office, are included in [Section 5](#).
- 2.14. These studies must all be conducted in accordance with international and national regulations, as well as Trust frameworks (see [Section 6](#)).

Hosted and sponsored active clinical research studies

- 2.15. The number of studies that are **Hosted** (i.e. OUH is the NHS organisation providing the clinical environment, capabilities and patient care) and **Sponsored** (i.e. OUH takes legal responsibility for the conduct of the study, as well as hosting it) by the Trust are shown in Table 1.

Table 1. Breakdown of hosted and sponsored active research studies

Study type		Hosted	Sponsored	Total
Interventional	Clinical trial of an investigational medicinal product (CTIMP)	559	3	562
	Clinical investigation or other study of a medical device	76	7	83
	Other clinical trial	211	9	220
Sub-total		846	19	865
Non-interventional	Other study	654	60	714
Total		1500	79	1579

2.16. The vast majority of OUH active clinical research studies are hosted for external Sponsors, of which OU is the largest, responsible for 391 (25% of the total).

2.17. Although the number of OUH-sponsored studies (79) is relatively small, compared to hosted studies they each require considerably more resource from the R&D teams to ensure the Trust's legal responsibilities as sponsor are met. This is an important part of the support provided by R&D for OUH staff, including an increasing number of NMAHPs, as they take their first steps as Chief Investigators, leading their own studies. During 2023-24, 22 new studies were allocated for OUH sponsorship review. Of these, nine have been approved to start recruiting, nine are still in the review process and the other four were abandoned prior to being approved to start recruiting; one was transferred to OU for sponsorship and three were withdrawn by the researcher (one of which had been rejected by the Research Ethics Committee (REC)).

2.18. The split of interventional:non-interventional active studies at OUH is roughly 55:45.

Research activity by OUH Division

2.19. Figure 3 presents a breakdown of the 1579 active studies of all types hosted by the Trust in 2023-24, according to the Divisions that are actively involved. Many studies involve more than one Division, with the Clinical Support Services Division (CSS) being involved in the largest number – usually providing pharmacy, radiology and imaging, or pathology and laboratory services to studies recruiting patients under the care of one of the other Divisions.

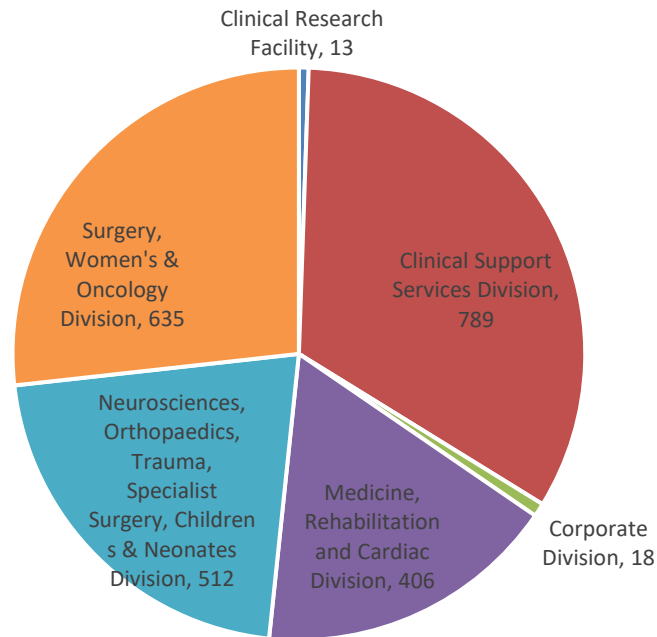


Figure 3. Active research studies at OUH in 2023-24, by Division

Studies opened to recruitment during 2023-24

- 2.20. A total of 295 new clinical research studies received approval from R&D to start recruiting during 2023-24. Of these, 110 (37%) were commercial and 185 (63%) non-commercial. This is an increase in approved commercial studies compared to 2022-23, when 91 (30%) of the new studies approved were commercial. The number of approvals/month during 2023-24 is shown in Figure 4.
- 2.21. The mean number of approvals was 25/month, which is comparable to the number of approvals before the pandemic and the same as in 2022-23. The total number of studies approved for set-up by LROGs and awaiting R&D approval to begin recruitment has remained stable over the last year, at around 150. Around half of these were prioritised for set-up at any point in time, with most of the remainder not yet being ready for set-up activities to begin.

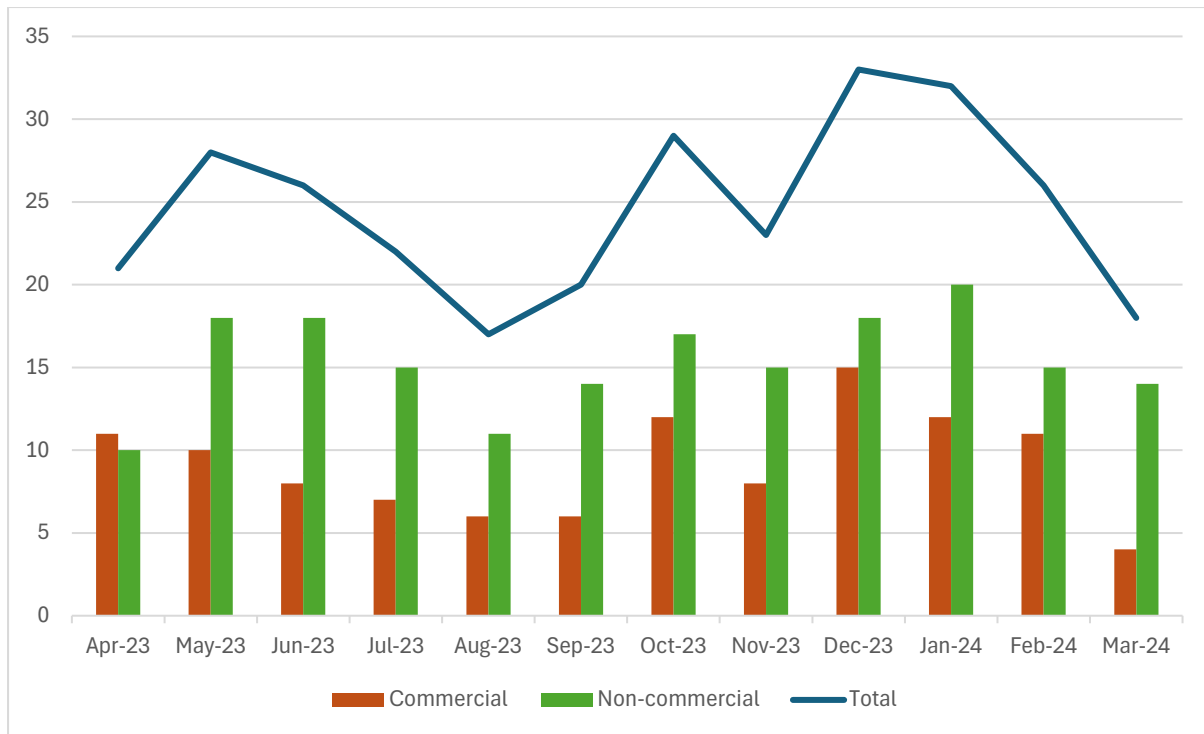


Figure 4. Studies approved to start recruitment during 2023-24

- 2.22. OUH is a recruiting site for the vast majority (87%) of the 295 studies approved in 2023-24, but 2% were Participant Identification Centres (PICs), where OUH identifies potential research participants to be recruited at a separate research site, usually one of the other Oxford Academic Health Partner (OAHF) organisations (OU, Oxford Health NHS Foundation Trust, or Oxford Brookes University). 3% were service sites where OUH provides services such as laboratory analysis or imaging, again usually for another OAHF organisation, but also to support an increasing number of studies which are recruiting in primary care.
- 2.23. 243 (82%) of the studies approved to start at OUH in 2023-24 were on the NIHR portfolio (100% of the commercial studies and 72% of the non-commercial studies).
- 2.24. There are many potential causes of delay in study set-up, which can reduce the approval rate by adversely impacting set-up activities. To gain a better understanding of these issues, new functionality has been added to the Studyline research portfolio management system which enables members of the R&D teams responsible for progressing set-up activities (contracts, costing and local capacity & capability) to capture the time spent waiting for input from others. Sufficient data has now been collected to conduct quantitative analyses of the main causes of delay, which are being used to identify opportunities for improvements to be made at OUH. The same tools will also allow study set-up

performance to be tracked over time, to monitor the effects of changes designed to minimise delays.

Substantial and non-substantial amendments

- 2.25. In addition to setting-up new studies, processing the high volume of amendments to active studies requires significant effort from OUH's R&D teams. This is an essential activity to maintain the Trust's large portfolio of research studies. All amendments are reviewed by the R&D Governance team, who will reassess capacity and capability, passing them to the R&D Finance and/or Contracts teams as appropriate. A total of 1815 amendments were processed during 2023-22, of which 966 were substantial and 849 non-substantial amendments.

3. Clinical Research Performance

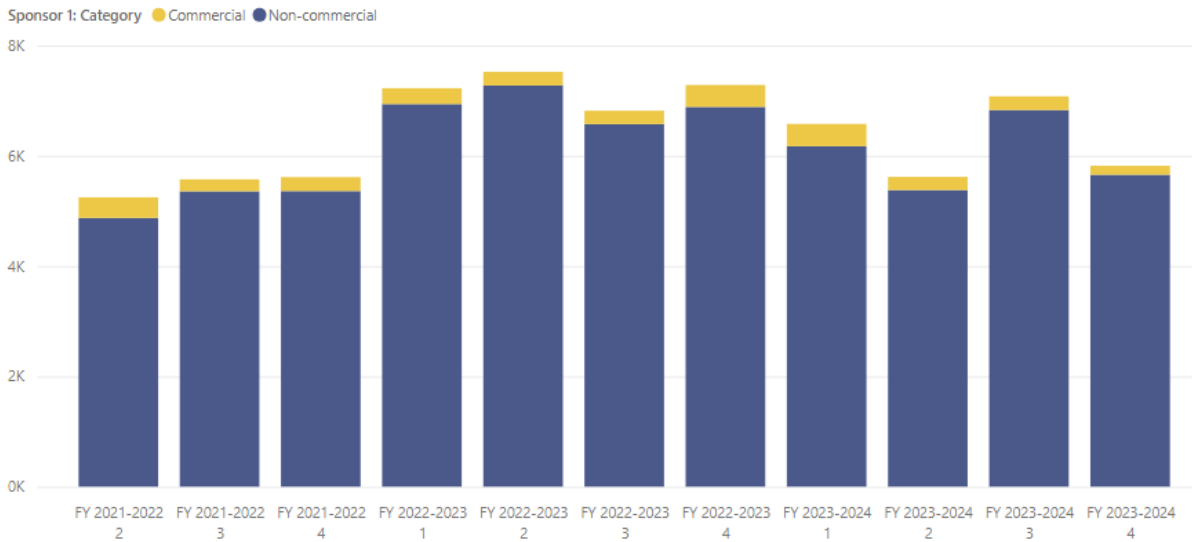
Background

- 3.1. The requirement for Trusts to measure and publish performance in initiating and delivering clinical research has been specified in the NHS standard contract since 1 October 2018.
- 3.2. Following a temporary suspension introduced at the start of the COVID pandemic, in December 2022 Trusts were informed that the national Performance in Initiating and Delivering (PID) clinical research exercise will be paused until further notice.
- 3.3. The DHSC/NHSE subsequently announced in the [Reset Bulletin](#) (April 2023) that PID reporting has been discontinued and that the routine provision of data to the Clinical Research Network (CRN) will replace PID to fulfil the requirements of the NHS standard contract. The rationale is that *“Removing this additional reporting and focusing on the data we have identified as necessary to manage the portfolio will reduce the burden on site staff and free up resource for other activity.”*
- 3.4. At a presentation to the national NHS R&D Forum meeting in May 2023, the DHSC outlined the scope of a successor to the PID metrics, but no clear timeline has been provided for when this will take effect and this remains the case.
- 3.5. It is therefore no longer possible to use PID metrics, so for the purposes of this report, alternative performance measures are presented which have been developed in-house for the quarterly updates provided by R&D to the Trust Management Executive.

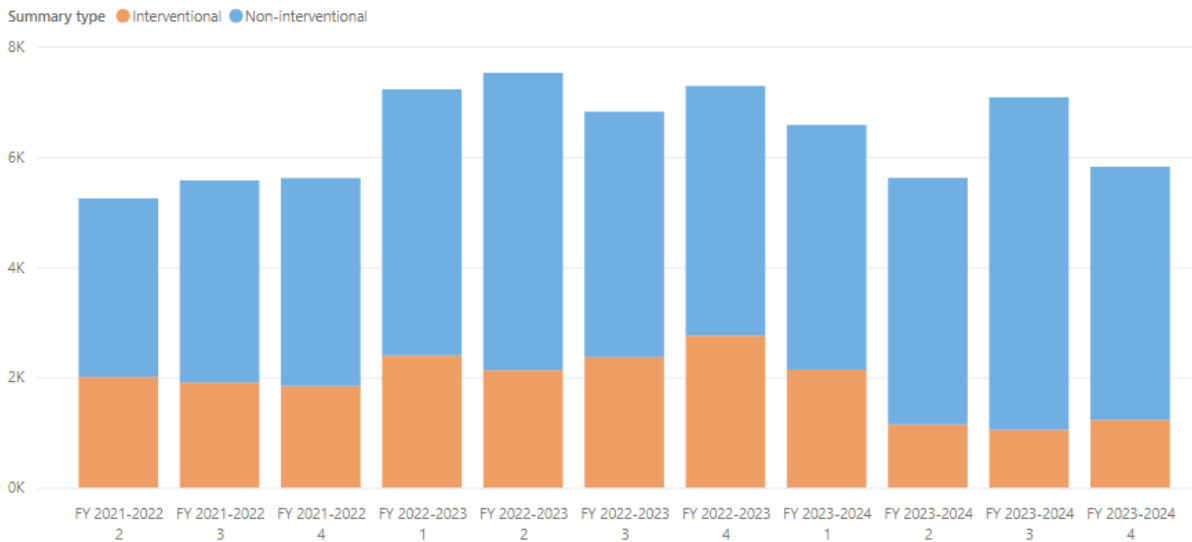
Participants recruited

3.6. Figure 5 shows the number of participants recruited to research studies each quarter since Q2 2021-22, immediately after a major review of OUH's research portfolio was completed, marking the end of the restrictions on research activity introduced during the COVID-19 pandemic.

Participants recruited to research studies trend



Participants recruited to research studies trend



Data sourced from Studyline 16-Jun-2024

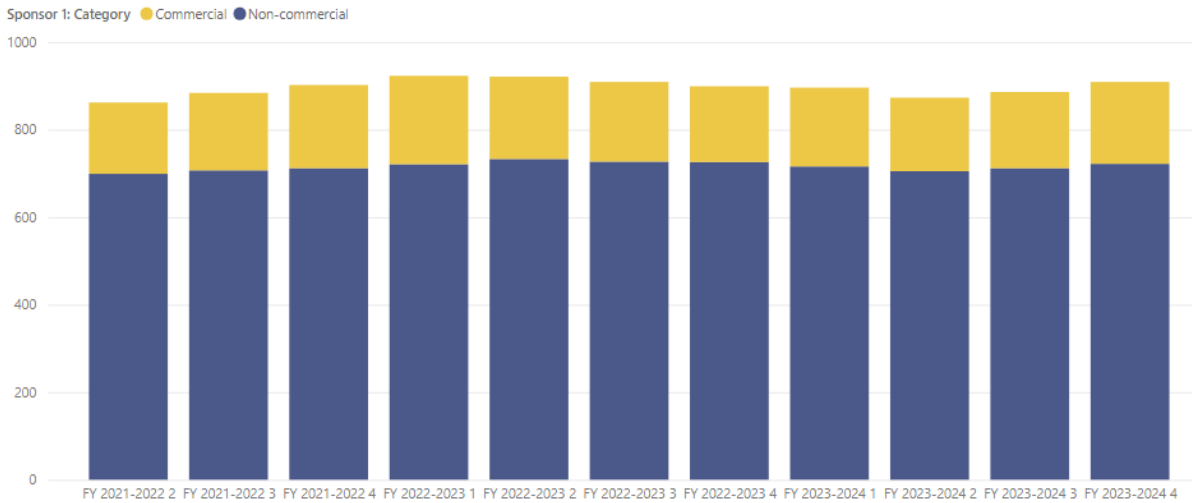
Figure 5. Participants recruited, by quarter

- 3.7. A total of 25,094 study participants were recruited at OUH in 2023-24. Of these:
- 1054 (4%) were recruited to commercial studies and 24040 (96%) to non-commercial studies.
 - 5560 (22%) were recruited to interventional studies and 19534 (78%) to non-interventional studies.
 - 22,712 (91%) were recruited to studies on the NIHR (National Institute of Health and Care Research) portfolio and 2382 (9%) to non-portfolio studies.
- 3.8. Overall recruitment in 2023-24 was 13% lower than in 2022-23 (28,851), with a similar reduction for both commercial and non-commercial studies.
- 3.9. Recruitment is affected by multiple factors. These include the number of studies open to recruitment and their recruitment targets (the number of participants to be recruited by an agreed date), as well as the number of eligible patients who are approached by the study team and consent to participate. Recruitment can also be skewed by individual studies which have very high targets (these are usually low-intensity, non-commercial studies). The decrease in recruitment compared to 2022-23 can be attributed primarily to five studies with high targets which completed recruitment last year, and another which was slowing down as it neared its target.
- 3.10. It should be noted that recruitment during the last quarter is often an underestimate for several months because of lag times in study teams reporting recruitment to OUH.

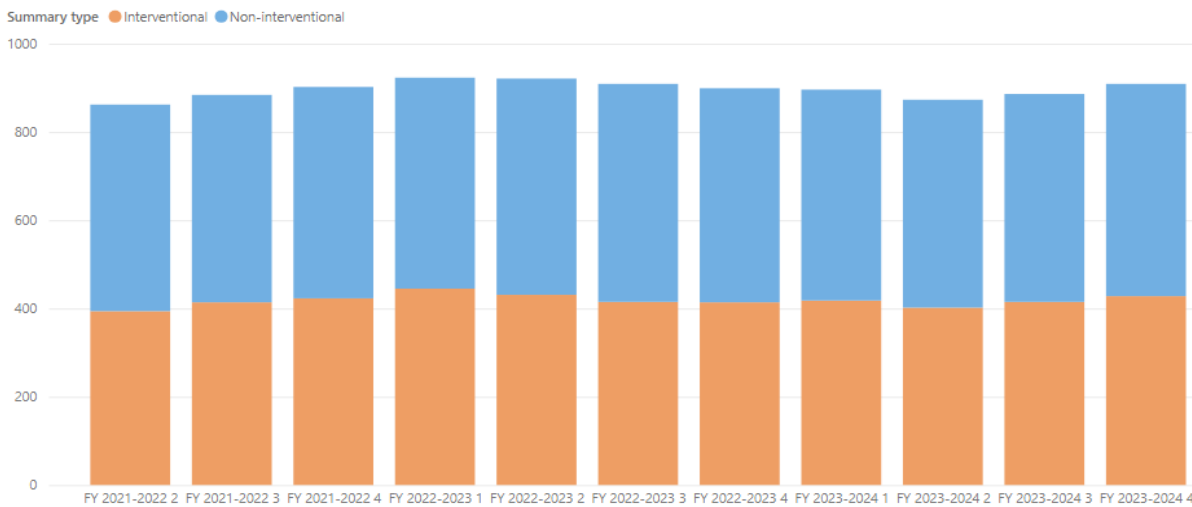
Studies open to recruitment

3.11. Figure 6 shows the number of studies open to recruitment each quarter since Q2 2021-22.

Studies RECRUITING trend



Studies RECRUITING trend



Data sourced from Studyline 16-Jun-2024

Figure 6. Studies open to recruitment, by quarter

3.12. A total of 921 research studies were open to recruitment at OUH during Q4 2023-24. Of these:

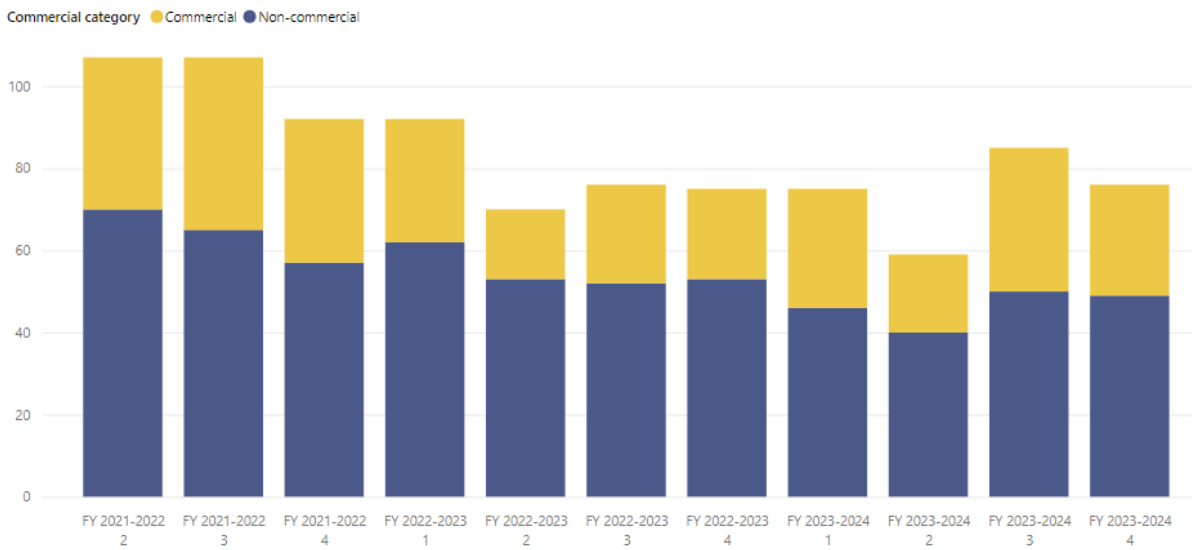
- 192 (21%) were commercial and 729 (79%) non-commercial.
- 439 (48%) were interventional and 482 (52%) non-interventional.
- 727 (79%) were on the NIHR portfolio and 194 (21%) were non-portfolio.

3.13. The number of studies open to recruitment each quarter has remained fairly steady, at around 900±25 over the last 2 years. The proportion of studies open to recruitment which are commercial vs. non-commercial and interventional vs. non-interventional has remained stable too.

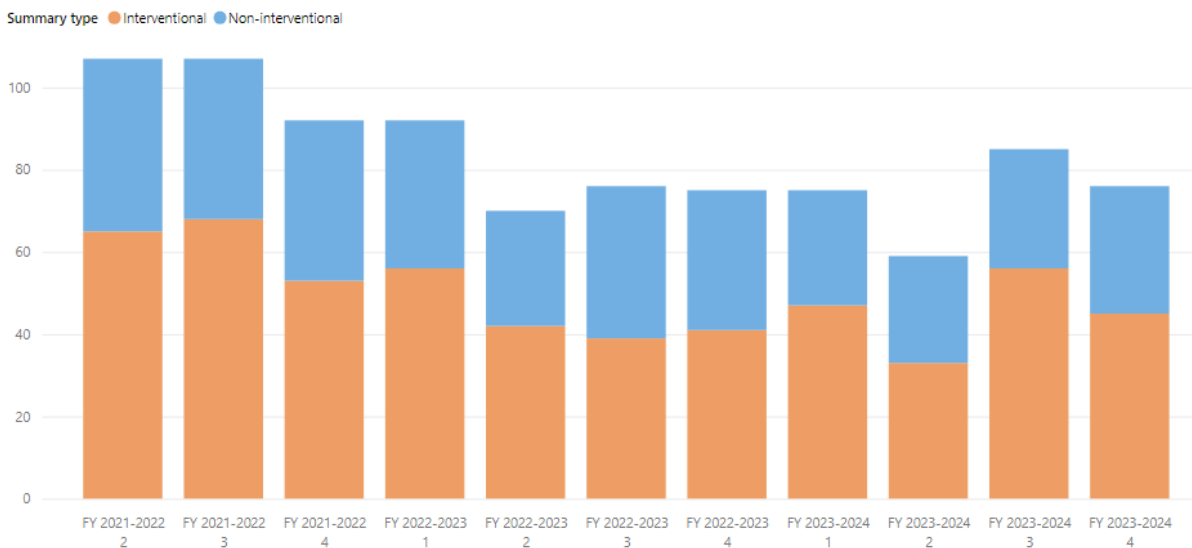
New studies approved to start recruitment

3.14. Figure 7 below shows the number of new studies approved to start recruitment at OUH each quarter since Q2 2021-22

Studies APPROVED to start recruitment trend



Studies APPROVED to start recruitment trend



Data sourced from Studyline 16-Jun-2024

Figure 7. Studies open to recruitment, by quarter

- 3.15. 295 new studies were approved to start recruitment in 2023-24. Of these:
- 110 (37%) were commercial and 185 (63%) non-commercial.
 - 181 (61%) were interventional and 114 (39%) non-interventional.
 - 243 (82%) were on the NIHR portfolio and 52 (18%) were non-portfolio.
- 3.16. The total number of studies approved to start recruitment each quarter has been fairly steady over the last two years, at around 76±16. This is lower than during Q2-Q4 2021-22, when 92-107 studies were approved each quarter, and addressing the pent-up demand to set up new studies was a top priority as COVID restrictions were relaxed.
- 3.17. The total number of studies approved to start recruitment in 2023-24 was 6% lower than in 2022-23 (313). However, the number of commercial studies approved increased by 18% (from 93 to 110), whilst the number of non-commercial studies decreased by 16% (from 220 to 185).
- 3.18. There is no Trust policy regarding the balance of commercial/non-commercial studies hosted by OUH, so the overall balance reflects the studies that were ready to be set-up and had been prioritised by the relevant OUH Local Research Oversight Group (LROG).

4. Clinical Research Delivery Workforce

- 4.1. Central to the delivery of the Trust's research portfolio is the clinical research delivery workforce. There are 38 teams employing over 370 individual staff members covering most clinical areas across the OUH. The teams work across all four hospital sites, although only three research delivery staff are based at the Horton General Hospital, resulting in fewer opportunities for patients attending the Horton to participate in research.
- 4.2. Approximately 70% of the clinical research delivery workforce are substantive employees of OUH, and around 100 are employed by the University of Oxford and have honorary contracts with OUH.
- 4.3. The majority of clinical research delivery posts are filled by registered nurses, followed by administrators, AHP & midwives and an increasing number of Clinical Research Practitioners (CRPs) - see Figure 8.

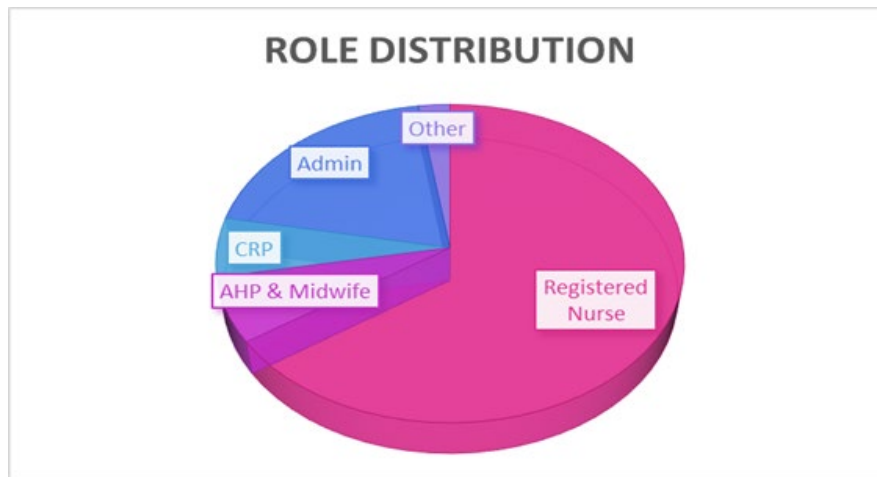


Figure 8. Clinical Research Delivery roles

- 4.4. Significant work has been undertaken to identify the Clinical Research Practitioner (CRP) workforce at OUH. This relatively new role already represents 25% of the NIHR workforce nationally, but less than 10% at OUH. A need to strengthen governance around these roles has been identified due to their *ad hoc* introduction. An appropriate governance structure is being developed, including a standard uniform for CRPs, an induction pathway and better management of recruitment processes to ensure there is clear distinction between CRP and research nurse roles. Generic job descriptions, role specific competencies and a career pathway for CRPs are also being developed.
- 4.5. Funding of OUH research delivery posts comes from a variety of sources, the biggest of which is the annual award from the Thames Valley and South Midlands Local Clinical Research Network (CRN) – see Figure 9. Changes in the NIHR clinical research delivery infrastructure – specifically the transition from the CRN to the Research Delivery Network (RDN) in October 2024 – may result in changes to the budget, but not until 2025-26.

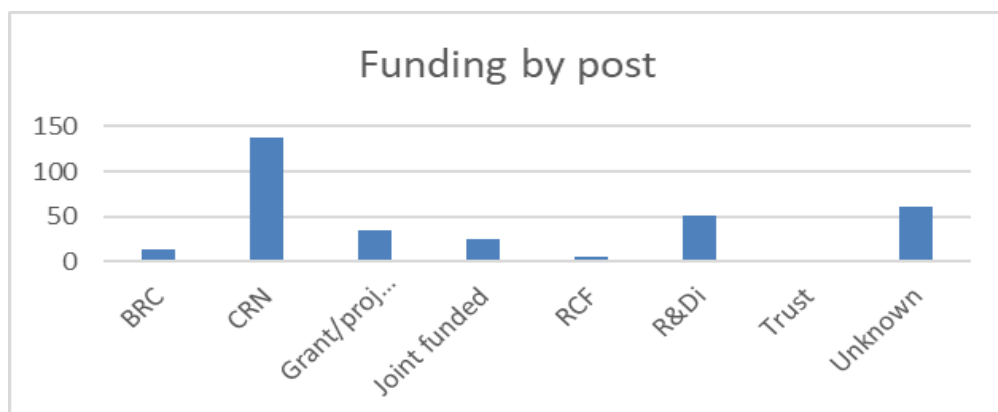


Figure 9. Sources of funding for OUH Clinical Research Delivery posts

- 4.6. We continue to develop the career pathway for clinical research delivery staff, which is essential to deliver our research agenda. In line with this, generic job descriptions have now been implemented to ensure consistency and appropriate capabilities within each role.
- 4.7. Engagement with the clinical research delivery workforce across OUH is achieved through two key regular meetings:
- The Lead NMAHPs Clinical Research Delivery (CRD) Forum. This well-established forum offers team leaders (band/grade 7 and above) the opportunity to come together to share information from the Trust/NIHR/University, best practice, identify issues (and solutions), agree trust wide processes for delivery, provide peer support and share information relevant to the professional group. Ongoing workstreams include introduction of a study intensity tool to measure capacity, a link NMAHP role for research and extension of placements for pre-registration students.
 - NMAHPs CRD network group offers the opportunity for more junior staff (band/grade 6 and below) to come together, share ideas, gain peer support.

5. NIHR Oxford Biomedical Research Centre (Oxford BRC)

- 5.1. The NIHR Oxford Biomedical Research Centre (BRC) is one of 20 BRCs across England. It supports high-quality early translational and experimental research across 15 research themes:
- Cancer
 - Cardiovascular Medicine
 - Digital Health from Hospital to Home
 - Gene and Cell Therapy
 - Genomic Medicine
 - Imaging
 - Inflammation Across Tissues
 - Life-saving Vaccines
 - Metabolic Experimental Medicine
 - Modernising Medical Microbiology and Big Infection Diagnostics
 - Musculoskeletal
 - Preventive Neurology

- Respiratory Medicine
- Surgical Innovation, Technology and Evaluation
- Translational Data Science

5.2. In addition, the Oxford BRC supports six 'enabling hubs':

- Academic Career Development
- Business Development
- Ethics
- Health Economics
- Medical Statistics
- Public and Patient Involvement and Engagement

5.3. The original award for the Oxford BRC was £86.6m for the period of 1st December 2022 – 30th November 2027 but in June 2023, BRCs were informed that NIHR would apply an uplift of 2.39% to each of the remaining years of the BRC. This is recognition of the impact of inflation on the costs of delivering research.

5.4. The majority of BRC funding (86%) is used for staff costs and in 2023-24 the BRC supported 430 posts (248 WTE).

5.5. The Oxford BRC, supported by teams in OUH R&D and the wider JRO, has continued to deliver a broad range of high impact translational research. In 2023-24 it supported 679 projects (e.g., through salary support for investigators associated with the project, use of the BRC facilities or direct project funding). A small number of examples of this research are provided below:

- Oxford researchers have [designed and developed a malaria vaccine](#), which has been recommended for use by the World Health Organisation (WHO). It has been licensed for use in Ghana, Nigeria and Burkina Faso.
- The Oxford-led Symplify study is the first large-scale evaluation of a multi-cancer early detection test, which involves a new blood test for more than 50 types of cancer. [It correctly revealed two-thirds of all cancers in people who had visited their GP with suspected symptoms](#). Some of these abnormalities have been shown through previous work to be evidence of tissue damage.
- Using primary care electronic health records from the UK, Spain, and Estonia, a research team from Oxford has found that [vaccination against COVID-19 consistently reduced the risk of long COVID symptoms](#).

- [National guidelines have been developed for clinicians on the use of genomics to diagnose and care for patients with monogenic inflammatory bowel disease](#) (IBD). These are already having a direct impact on patient care, having been adopted in clinical pathways by the NHS Genomic Medicine Service.
 - An [AI tool has been developed that can predict 10-year risk of deadly heart attacks](#). It was found to improve treatment for 45 percent of patients. AI technology required to power the tool has already commissioned by NHS England for a pilot programme in five NHS hospitals.
 - In the largest trial of its kind, an Oxford research team have found that [taking daily blood pressure readings at home and personalising medication doses in the weeks after giving birth improves blood pressure control for the first year after a hypertensive pregnancy](#). This could help to cut new mothers' risk of future heart disease and strokes.
 - The University of Oxford have entered into a partnership with Danaher Corporation to develop a [new test to enable precision medicine care for sepsis](#). The ultimate aim is to develop a PCR-type point-of-care test.
- 5.6. As part of the Research Reset Programme, NIHR/DHSC have decided that for future NIHR infrastructure competitions, applying NHS Trusts and their University partners will need to demonstrate that they are actively managing their portfolio as sponsors, specifically that 80% of open studies on the NIHR CRN portfolio are delivering to time and target. NHS Trusts and Universities that sponsor studies but do not meet the 80% target or cannot demonstrate significant progress by the time they apply for the infrastructure award, will remain eligible to apply for NIHR Infrastructure awards, but the level of funding may be limited to a percentage of the current award value. Going forward, close attention will therefore need to be paid to studies where OU or OUH are sponsors.

Training and Career Development

- 5.7. The Oxford BRC continues to provide a range of training and career development opportunities. In 2023-24 ~£350k was spent supporting writing retreats, research training bursaries, internships, pre-doctoral awards, post-doctoral fellowships and senior research fellowships. All of these opportunities are open to staff employed by either OUH or the OU, with priority given to NMAHPs.
- 5.8. One example of the impact of this funding is Joanna Snowball who was awarded a BRC internship in 2020 and then a pre-doctoral award in

2021 to continue her research. In July 2022 she became [the first OUH dietitian to be accepted onto the NIHR's Pre-doctoral Clinical and Practitioner Academic Fellowship](#). Joanna's research focuses on how to support people with cystic fibrosis who are experiencing rapid weight-gain as a result of new medications. Another is Lucy Dove who was awarded a BRC pre-doctoral award in 2022 and was awarded an [NIHR Doctoral Clinical and Practitioner Academic Fellowship](#) in December 2023. Lucy's research focusses on developing new treatments for patients with sciatica.

Patient and Public Involvement and Engagement in Research

- 5.9. The Oxford BRC held a joint Open Day with the Oxford Health BRC at Oxford Town Hall on 10 May 2023, building on the success of the inaugural joint Open Day in July 2022. The BRC Open Days are an opportunity to showcase the broad range of research that takes place in Oxford, how it benefits NHS patients and how members of the public can get involved in clinical trials.

The Oxford BRC holds regular public talks, aimed at engaging the public in its research, recordings of which are available on the [BRC's YouTube channel](#). Three talks were held in 2023-24, with a total of 120 in person attendees and ~850 YouTube views to date.

6. NIHR Oxford Clinical Research Facility (Oxford CRF)

- 6.1. Now in its second year of operation, the main focus of the Oxford CRF has been to expand the scope and volume of activity in line with its strategic objectives.
- 6.2. Within the federated Oxford CRF model, the Experimental Medicine CRF (EMCRF) is working as planned, with established studies, processes and infrastructure. The Children's CRF began operating in January 2024 and is also progressing well. Work is still underway to make the NOC CRF and the OCDEM CRU readily available and accessible to researchers across the Trust and University.
- 6.3. A CRF nursing team has been established to deliver a wide range of studies and a corresponding range of clinical activities. This has specifically enabled the conduct of new trials with commercial sponsors. An extensive programme of training for research nurses is being undertaken to support endoscopy, bronchoscopy and bone marrow biopsy procedures.
- 6.4. With funding from the Oxford BRC, the Oxford CRF also hosted an Applied Pharmacology study day for research nurses from across the UK working in early phase and experimental research. This provided an

opportunity for networking as well as for consolidating practical experience with theory.

- 6.5. The Oxford CRF's focus has been to expand capacity for more complex studies, especially those where complex tissue collection is a key feature, e.g. gastric mucosa; bronchus; lymph node; synovium; skin.
- 6.6. A successful outpatient clinic has been established within the Oxford CRF. This facilitates the identification of patients who are eligible for a large Inflammatory Bowel cohort and who can participate in tissue collection studies. The Oxford CRF is also working with Sexual Health and Dermatology as well as Haematology partners to support similar additional clinics, which will enable research whilst also managing routine patient care.
- 6.7. The EMCRF has recently supported an early phase dosing study for Hepatitis B patients, enabling OUH to be the first study site in the world to dose a patient at a new dose escalation level. The Trust provided the clinical oversight and support for emergency planning in the event of an adverse event, whilst OU supported the intensive sample processing required for such a study visit. This and all the other achievements of the EMCRF have only been possible because of the arrangements set out in the CRF Collaboration Agreement between OUH and OU (May 2022).
- 6.8. Over 20 studies are currently supported within the Oxford CRF. These involve both OUH patients and healthy volunteers. They range from vaccine trials to single-cell body mapping involving the complex interventions discussed above. Six of these are commercially sponsored, with another five studies for commercial sponsors due to start in Q2 2024-25.

7. Research Governance

Background

- 7.1. Research governance refers to the framework to manage the research process from end to end, to ensure that research is undertaken in a safe, appropriate and ethical manner, in accordance with national guidance and applicable laws to ensure that maximum benefit is derived from research for public and patients. Compliance with the legislation is overseen nationally by the Health Research Authority. This includes:
- 7.2. UK Policy Framework for Health and Social Care 2017 - The UK policy framework sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards.

- 7.3. Good Clinical Practice (GCP) – GCP is a set of internationally recognised ethical and scientific quality requirements for designing, conducting, recording and reporting research that involves human participation. Compliance provides public assurance that the rights, safety and wellbeing of participants are respected and protected, and that the data generated are credible and accurate.
- 7.4. EU Directives - The EU Clinical Trials Directive (EUCTD – 2001/20/EC) sets out how clinical trials investigating the safety or efficacy of a medicinal product in humans must be conducted. It includes medicinal trials with healthy volunteers and small scale or pilot studies. The Good Clinical Practice (GCP) Directive (2005/28/EC) supplements the EUCTD, strengthening the legal basis for requiring member states to comply with the principles and guidelines of good clinical practice. After leaving the EU the UK implemented the EUCTD (which become an EU Regulation on 31 January 2022), into domestic legislation. This is still the case, although the UK government has recently carried out a consultation for [legislative changes for clinical trials](#), the outcome of which was published in March 2023.
- 7.5. Medicines for Human Use (Clinical Trials) Regulations - The EUCTD was implemented into UK law in May 2004, as the Medicines for Human Use (Clinical Trials) Regulations 2004, and has since been amended (2006a, 2006b, 2008).
- 7.6. Human Tissue Act - The Human Tissue Act 2004 repealed and replaced the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they related to England and Wales, and the corresponding orders in Northern Ireland. The Human Tissue Authority regulates the removal, storage, use and disposal of human bodies, organs and tissue.
- 7.7. Declaration of Helsinki - The Declaration of Helsinki was developed by the World Medical Association as 'a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data' (Para 1, Declaration of Helsinki).
- 7.8. General Data Protection Regulation (GDPR) - Most clinical research requires the processing and/or storage of personal and sensitive information. The General Data Protection Regulation (GDPR) legislates for the control and protection of personal information relating to living individuals including both facts and opinions about the individual.
- 7.9. Mental Capacity Act - Research studies involving adults aged 16 or over who lack capacity must comply with the Mental Capacity Act 2005. This includes persons with dementia, learning disabilities, mental health problems, stroke or head injuries who may lack capacity to make certain

decisions, including consenting to participate in a research study. The act does not apply to studies falling under the Clinical Trials Regulations (CTIMPs).

7.10. OUH Frameworks for R&D Governance, Training and Monitoring – Locally, clinical research is governed by a number of OUH policies:

- Safety Reporting in Clinical Research
- Sponsorship of Clinical Research Studies
- Trust Management Approval for Clinical Research
- Monitoring and Audit of Research Studies
- Research Passports, Honorary Research Contracts and Letters of Access
- Management of Intellectual Property
- Integrity in Research
- Consent for use of clinical samples and data in research.

These policies are underpinned by a suite of Standard Operating Procedures (SOPs) within R&D governance. Policies and SOPs are updated in response to national and local developments. The OUH R&D Governance team conducts a wide variety of activities, which are summarised below. As indicated, many of these involve working in close collaboration with their JRO colleagues in OU's Research Governance, Ethics and Assurance (RGEA) team.

Oversight of Compliance and Safety

7.11. GCP Monitoring. The purpose of monitoring is to ensure that the safety of participants is assured; that the trial results will be credible and accurate and that the trial is conducted in accordance with the protocol and regulatory frameworks. The R&D Governance team undertakes monitoring visits for each OUH-sponsored regulated trial.

7.12. Formal auditing of compliance. An audit is part of implementing quality assurance. It is independent and separate from routine monitoring or quality control functions. The purpose of an audit is to evaluate a system(s) or trial conduct and compliance with the protocol, SOPs, Good Clinical Practice (GCP), and the applicable regulatory requirements. Where OUH is hosting research with an external Sponsor, such trials may be audited by the R&D Governance team. These trials are selected through a risk-based approach. Three compliance audits have been completed and closed during 2023-24.

- 7.13. Compliance checks. The R&D Governance team also routinely undertakes assessment of compliance with various aspects of clinical research; primarily focussing on informed consent and safety reporting. These brief checks are of great value for oversight of compliance as they are less resource intensive than formal audit and so a greater number of studies can be covered. During 2023-2024 42 informed consent and 10 safety compliance checks have been completed.
- 7.14. To support investigators and research teams, the R&D Governance team and Lead for NMAHP Clinical Research Delivery formally facilitate regulatory inspections of research conduct at OUH. This allows trends and best practice to be highlighted and communicated to improve standards across the Trust. During 2023-24 one FDA (US Food and Drug Administration) inspection and three MHRA (Medicines and Healthcare Products Regulatory Agency) site inspections were supported.
- 7.15. Safety Reporting. As Sponsor, the OUH is responsible for regulatory assessment of Serious Adverse Events (SAEs). As host organisation, the Trust has a responsibility for ensuring that safety reporting processes are appropriate and complaint. The appropriate level of oversight is established by a risk assessment prior to the granting of Trust Management Approval, for both sponsored and hosted trials. All SAEs reported are reviewed by the OUH/OU Joint Trials Safety Group (TSG). The aims of this review are: to pick up any trends, such as increases in un/expected events, and take appropriate action; to identify whether additional advice or information is required from investigators; to evaluate the risk of the trial continuing and take appropriate action where necessary, including requests for specific audits. During 2023-24 OUH has reviewed 98 SAEs which have also been presented at the quarterly Trial Safety Group meetings.
- 7.16. Consent. As part of the actions identified by the HTA's inspection of the OU's HTA Licence 12217 in 2018, the Trust recognised the need for improved consent processes to ensure that consent given by patients for the use of clinical samples and clinical data in future research studies is clearly recorded and can be retrieved, audited and modified in accordance with their wishes. The new electronic consent form (Concentric) being rolled out across the Trust includes options relating to medical imaging and tissue for research.
- 7.17. Incident reporting. The oversight of incidents relating to clinical research delivery across the whole of OUH has been strengthened since April 2023. The Lead NMAHP CRD and Head of R&D Governance meet to review all such incidents reported on Ulysses and ensure investigations are appropriately conducted and outcomes are relevant and

commensurate. The Lead for NMAHP CRD also reports to the APP and Lead NMAHPs' CRD forum on number of incidents reported on a quarterly basis, highlighting key themes and any shared learning. 188 incidents relating to clinical research delivery were reported in Ulysses in 2023-24.

Training

- 7.18. In collaboration with the OU Research Governance, Ethics and Assurance (RGEA) team, the R&D Governance team prepares and delivers a range of training to both Trust and OU staff. This covers all research related legislation and GCP, with separate courses designed for staff new to trials and to provide an update/refresh for experienced researchers.
- 7.19. Face-to-face training, which was stopped in March 2020 due to the start of the COVID pandemic has now moved online.
- 7.20. HRA and Ethics Submissions training is delivered live online, via MS-Teams. It has been attended by 130 people. The Introduction to Good Clinical Research Practice (GCRP) training has been delivered live online to 46 people during 2023-24.
- 7.21. The third-party hosting arrangement for the online platform which has been shared by both OU and OUH to offer their self-directed GCP training package to staff is no longer available. Each organisation decided to migrate this to their in-house learning platforms instead. The training material has been shared with the MyLearningHub team and should be made available to OUH staff in July 2024.

Letters of Access, Honorary Research Contracts and Research Passports

- 7.22. The R&D Governance team processed and authorised 133 applications for Letters of Access and 6 Honorary Research Contracts during 2023-24, to enable research activity to take place at OUH. The team also validated research passports for Oxford-based researchers planning to perform research activities in other NHS Trusts.

Classification Group

- 7.23. There are times when it is not clear if a project should be classified as a research study, audit or service evaluation. In order to establish an authoritative and collective opinion on such projects, OUH's R&D Governance team and the RGEA team in OU have established the Classification Group to review project outlines and give a considered opinion. This group, which meets at least monthly, or more often where there is high demand, classified a total of 88 projects during 2023-24.

8. Research and Development Finance

- 8.1. The R&D Finance team provides management accounting, costing, and pre- and post-award financial support to researchers undertaking or seeking to undertake research activity within OUH. The team's major responsibilities during 2023-24 included managing the finances for the Oxford BRC and the Thames Valley & South Midlands Local Clinical Research Network (LCRN) which are both hosted by OUH; costing commercial and non-commercial studies, providing and paying invoices for studies once they are active, and managing research funds for future research using income generated from commercial studies.
- 8.2. The finances are managed for individual studies from pre-award through to post-award to ensure all costs are considered, reimbursed and accounted for in line with funders' guidelines and the Trust's agreed procedures. The pre-award team also work closely with researchers and the LCRN to review the costs and activities included on grant applications to various funding bodies. This activity represents an important area which helps to secure funding opportunities for research projects across all clinical areas of OUH.

Financial Position and Current Activities to 31 March 2024

- 8.3. For the 2023-24 financial year, the annual income and expenditure budget for R&D was set at £51 million, as shown below. This included income and expenditure of £39 million from major NIHR grants for hosting the Oxford BRC and the LCRN, as well as other smaller NIHR grants and the Oxford CRF. £12 million of income and expenditure was budgeted for commercial and non-commercial (non NIHR) research projects.

High level breakdown of 2023-24 R&D budget

Research Funding by area	2023-24 Expenditure (£m)
NIHR Oxford Biomedical Research Centre (BRC)	18
NIHR Local Clinical Research Network (LCRN)	19
NIHR Research Capability Funding (RCF)	1
Other income (commercial & non-commercial, incl. NIHR grants)	13
	51
	51

- 8.4. At the end of the financial year (31 March 2024) all the major NIHR programme and smaller grants achieved a breakeven position as planned, and income exceeded expenditure by £1 million from the individual study accounts for all the commercial and other non-commercial trials and other research activities.

Research Capability Funding (RCF)

- 8.5. The NIHR sets out that the purpose of RCF is to help research-active NHS organisations to act flexibly and strategically to maintain research capacity and capability; support the appointment, development and retention of key staff undertaking people and patient-based research, and contribute towards the costs of hosting NIHR-funded or 'adopted' research that are not currently fully covered across NIHR's programmes, and that are not met in other ways. As a result of this flexibility, RCF is a very important funding stream for research at the Trust.
- 8.6. The RCF award received by OUH in 2023-24 was £873k (compared to £1.2 million in 2022-23). The reduction in the amount received was a result of a change in the basis for allocation of RCF to all Trusts. However, the award was boosted by an additional £100k part way through the year as a result of a one-off payment made to Trusts judged to be recruiting to time and target for the commercial studies they hosted.
- 8.7. Researchers at OUH and OU were invited to apply for RCF funding to help develop competitive grant applications for NIHR funding. RCF was also used to contribute towards research overhead costs and the costs of managing NIHR grants. The RCF panel also made a number of individual awards in support of NIHR funded research to cover absences as a result of parental and long-term sick leave. This enabled NIHR grant funded research to continue while key research staff have been on leave from the organisation.

National Contract Value Review (NCVR) for commercial studies

- 8.8. The NCVR process for the costing of commercial studies was implemented in October 22 following a delay of more than two years due to the COVID-19 pandemic. The aim of NCVR is to standardise and streamline the costing of commercial contract research, in particular to minimise duplication of effort at each site, so that commercial trials can be set-up more quickly in the UK. OUH R&D has been actively involved in this process, and by March 2024 had received just under 50 studies to cost where OUH is the lead site (an average of 3 per month).
- 8.9. A Senior Costing Officer from the OUH R&D Finance team has been seconded to a part-time role as NCVR Champion for all the Trusts in the Thames Valley & South Midlands CRN.

Financial Planning 2024-25

8.10. The following budget has been set for 2024-25:

	2024-25
Research Funding by area	Expenditure budget (£m)
NIHR Oxford Biomedical Research Centre (BRC)	19
NIHR Local Clinical Research Network (LCRN)	14
NIHR Research Capability Funding (RCF)	1
Other income (commercial & non-commercial, incl. NIHR grants)	17
	51
	51

8.11. The latest BRC award started in December 2022 and is currently due to end in November 2027. The core budgets for each of the 15 individual research Themes, and the management team, have all been confirmed for the next year.

8.12. The NIHR Clinical Research Network is ending (nationally) on 30 September 2024 and will be replaced by the Research Delivery Network (RDN) from 1 October 2024. OUH will therefore cease hosting the Thames Valley & South Midlands LCRN from 30 September, when University Hospital Southampton NHS Foundation Trust will begin hosting the new South Central Regional Research Delivery Network, which will include OUH. The R&D budget for 2023-24 has been adjusted to take account of this.

8.13. As in previous years the BRC and LCRN budgets forecast a break-even position for 2024-25.

8.14. The NIHR has confirmed that OUH will receive £1.3m of Research Capability Funding (RCF) during 2024-25. This increase of >£400k compared to 2023-24 is due to higher levels of payments made to OUH for NIHR grants during the 2023 calendar year.

8.15. The budget for income (and expenditure) from commercial and other non-commercial studies, including other NIHR grants, has been set at £17 million which is based on the average income over the last 2 years. This includes the reduction in income because of the NIHR's decision to close the UK Cochrane Centre, which OUH had hosted, on 31 March 2024.

9. Research Contracts and IP

9.1. During the year to 31 March 2024, 1121 research and IP related cases were finalised on behalf of OUH. This is 17% down compared to last year (1345), which is against a trend of steadily increasing output over previous years. This can partly be explained by the departure of two members of the team during the year which has reduced capacity whilst

replacements were sought. There were significant drops in confidentiality agreements, clinical trial agreements and amendments but there was a jump in the number of collaboration agreements. Data transfers, grants and service agreements were at a similar level.

Table 1. Cases completed by the Research Contracts and IP team in 2023-24

Case type	Number
Confidentiality Agreement	252
Amendment	217
Clinical Trial Site Agreement	216
Collaboration Agreement	121
Grant Application	116
Oxford Health	91
Service Agreement	57
Data Transfer Agreement	22
Other	15
Assignment/Revenue Share	11
MTA Donor Academic	3
Total	1121

- 9.1. The team also continued its contracting service to Oxford Health NHS Foundation Trust, closing 91 cases, a similar level to last year.
- 9.2. The team continues to use DocuSign to initiate and manage efficient paperless execution of agreements, including signatures for Oxford Health contracts and the LCRN where necessary. Use of electronic signatures during 2023 resulted in an estimated 2,897 lb reduction in carbon emissions, 3,634 gal of water conserved, 1,234 lb of wood saved, and 200 lb of waste eliminated.

10. Other Local, JRO, Regional and National updates

Local (OUH)

- 10.1. The R&D Information Systems team has developed a new [‘Find a study’](#) tool on the OUH website. Launched in June 2023, this uses information being maintained in the Studyline research portfolio management system to help our patients and staff identify studies which are currently open to recruitment at OUH, along with a lay summary and an email address to contact if they would like further information. Users are able to generate a customised list of studies based on free-text search terms they have entered and/or by selecting from a list of study categories (e.g. Cardiovascular or Respiratory).
- 10.2. The R&D Information Systems team has also developed a ‘Study status’ PowerBI report which gives OUH PIs and study team members access

to key information held in the Studyline system, including the current status of studies in set-up. Launched in February 2024, with the support of the APP and LROGs, this report is now being actively promoted across the Trust. PIs and their teams should benefit from being able to access real-time information on-demand, reducing the need to contact members of the R&D teams for general updates but enabling them to take appropriate action to progress set-up activities.

Oxford JRO

- 10.3. A JRO Away Day on 18 October was attended by ~120 members of the JRO, from all four partner organisations, who gave very positive feedback. The main purpose was to improve understanding and to identify and opportunities to work more efficiently together to support research activities across all four JRO partner organisations. This is an ongoing process, and these themes will again be the main focus of attention at the next JRO Away Day, on 11 July 2024.
- 10.4. A new JRO Booklet – the first since the JRO expanded to include Oxford Health NHS Foundation Trust and Oxford Brookes Universities as new partners in 2022 – was released in October 2023, to coincide with the last Away Day. This can be found in the JRO section of the Oxford Academic Health Partners' website [here](#).
- 10.5. Following the success of a 'taster' session at the last Away Day, the JRO supported two joint workshops on personal time management in February 2024 – one in-person and the other online. These customised workshops had the added benefits of strengthening the JRO by allowing a cohort from the JRO partners to learn together.
- 10.6. Following discussion at the BRC Steering Committee, OUH is meeting with OU to review to review joint working specifically in relation to setting-up OU-sponsored studies at OUH; to identify any opportunities for further streamlining which will be of benefit to both organisations and to our patients. The updated process-mapping of study set-up activities at OUH will be a key input to this exercise, alongside corresponding process-mapping of OU sponsorship.

Regional

- 10.7. The transition from the national Clinical Research Network (CRN) to the Research Delivery Network (RDN) will take effect on 1 October 2024. OUH is actively engaged at a senior level with University Hospital Southampton (UHS), which will host the new South Central Regional Research Delivery Network (RRDN), including around Transfer of Undertakings (Protection of Employment) Regulations (TUPE) arrangements for staff currently employed by OUH as the host of the Thames Valley and South Midlands LCRN, which will no longer exist

after 30 September 2024. Wider discussions about how the RRDN will operate will follow, once the Hosting Implementation Plan submitted by UHS has been approved by DHSC/NIHR (expected to be in late May).

- 10.8. A high-level summary of the activities of the TVSM CRN during 2023-24 is included in the [Appendix](#) to this report.

National

- 10.9. The Head of R&D Operations led the small team of volunteers which was responsible for preparing and delivering the national UKRD (R&D Leaders in the NHS) [Summit](#) at Leamington Spa in March 2024. This was attended by over 100 R&D Leaders in the NHS from around the UK (who report to the Board of their organisations), as well as senior representatives from DHSC, NIHR, NHSE and the HRA, including Prof Lucy Chappell, Chief Scientific advisor to the DHSC and CEO of the NIHR.

- 10.10. At the invitation of the Shelford Group, the Head of R&D Operations accepted an invitation to take part in a series of workshops organised by the Association of the British Pharmaceutical Industry (ABPI) with representatives of commercial sponsors, selected Trusts and DHSC/NIHR to prepare a site-sponsor [best practice guide](#) for commercial research. This was published by the ABPI in December 2023 and has been received positively, including by Lord O'Shaughnessy, who [described it on LinkedIn](#) as "...excellent, a great example of industry-academia-NHS collaboration to promote clinical trials."

- 10.11. Members of the R&D teams have had a total of eight abstracts accepted for the NHS R&D Forum meeting in May 2024; seven posters and one oral presentation, with the lead authors all attending. This annual event is attended by ~800 R&D staff from around the UK.

11. Acknowledgements

- 11.1. The lead authors would like to thank their colleagues for drafting relevant sections of this report and all the members of the teams they lead, whose work it describes:

Jennifer Anderson (Head of BRC Operations)

Kirsten Bailey (Head of R&D Finance)

Tim Bradford (Head of R&D Information Systems)

Cushla Cooper (Clinical Operational Lead, Oxford CRF)

Shahista Hussain (Head of R&D Governance; Deputy Head of R&D Operations)

Charles Lescott (Head of IP and Research Contracts)

Helen Walthall (Director of Nursing Research and Innovation)

Sandie Wellman (Lead for NMAHP Clinical Research Delivery)

12. Recommendation

12.1. The Trust Board is asked to receive this report for information.

APPENDIX. TVSM CRN Annual Report 2023-24

In lieu of a separate report to the OUH Board, this is a copy of the report submitted to the CRN National Coordinating Centre by the Chief Operating Officer for the Thames Valley and South Midlands CRN.



2023/24 LCRN Highlight Reports: Purpose, Guidance, Supplementary requests, and Template

Version 1.0 04/04/2024

LCRN Highlight Report purpose

The LCRN Highlight Report (“Report”) will be used as follows:

1. As part of the 2023/24 CRN Annual Report to DHSC (subject to editing by the RDNCC for consistency across reports etc, as in previous years).
2. Shared for information with the RDN Board and RDNCC Heads of Service.
3. As part of a publicly available Google site (see [example](#) from 2022/23).
4. Where examples of impact are provided, these may be considered to be developed, with the respective LCRN Leadership Team, as a Case Study shared with DHSC.

CRN Thames Valley and South Midlands Highlight Report

Part 1: Social value (including under-served)

Strategic funding. TVSM has now supported over 30 projects, with an emphasis on regions/topics that have historically received less attention. Work with non-NHS organisations has included support for the Wokingham Borough Council's Inequalities Project which ran a series of community-facing workers' and residents' workshops to describe how the building blocks of health and wellbeing differ between the most and least deprived communities, and which fed into a recent Inequalities Conference at University of Reading. We allocated funds for Slough Borough Council's research into the risks of vaping, prevalence, and drivers among young people. We worked with the Relationships in Good Hands Trial (CPMS 47989) and provided ring-fenced funding for the local authority fostering/adoption team to train members of our agile workforce to support consent and trial activities which had a major impact on study recruitment.

Primary Care. Our team also worked on the Genes and Health study (CPMS 18124), working with the Oxford University Centre for Research Equity, and engaging with Pakistani and Bangladeshi communities, faith and other stakeholders, to create effective recruitment strategies. All local trusts in the region have agreed to take part, alongside 30 GPs - acting as PICs, sites or hubs - especially in areas such as Aylesbury, Milton Keynes and Slough where we have had limited traction previously. Funding to Reading PCN has also led to the establishment of a new multi-disciplinary research team operating across all 4 local practices, which has delivered 14 site based studies and 8 PICs in its first year, and facilitated numerous outreach engagement events with local communities.

Under-represented Specialties. Targeted support from our Fellowship and Greenshoots programmes has significantly increased research opportunities for older adults during the year, and we continue to champion the ENRICH programme. 16 new homes signed up in 2023/24, bringing the total to 110 homes. These programmes also enabled us to grow a local Dentistry portfolio with support from our agile teams.

Other highlights. Examples include Berkshire Healthcare NHS FT (BHFT) which was the first site to open, and top recruiter to, the Black Arts study (CPMS 56977) exploring the insights of Black racial minority young people with psychiatric disorders and the

potential for creative arts therapies to improve mental well-being. Buckinghamshire Healthcare NHS Trust (BHT) delivered LOLIPOP (CPMS 44841), in partnership with local Muslim Community Champions as part of the Research Ready Programme. An additional 1,500 individuals signed up to the study, bringing the total to nearly 5,000. The Ophthalmology team at Oxford University Hospitals NHS FT (OUH), raised awareness of research opportunities by reaching out to GPs, charities, support groups and optometrists, using materials that were better suited to those with visual impairments, resulting in increased registrations to their consent to contact register. Royal Berkshire NHS FT (RBFT) are working with University of Reading on using Artificial Intelligence to help address health inequalities by reducing missed hospital appointments. The Milton Keynes University FT (MKUFT) research team worked with the Sensory Advice Resource Centre, the Disability Advisory Group, Diabetes UK, and a local scout group, to raise the profile and highlight the importance of inclusion in research across the trust. The Making Participation Work (MPW) project in BHFT sought to engage young people with SEND so that the trust could prioritise themes for research that better met their needs.

Part 2: Local initiatives/projects/programmes that have resulted in a national difference

Study Support Service. TVSM continued to play a lead role in the set up and delivery of large scale, multi-centre studies, that are led from Oxford. Major studies supported during the year included ASCEND PLUS (CPMS 51088), My Melanoma (CPMS 50634), RESPOND WP4 (CPMS 54654), DART (CPMS 51308), and SCOOT (CPMS 52228). PANORAMIC (CPMS 51313), also continued throughout the year, culminating in the successful recruitment of 29,295 participants at 72 different sites across 4 UK nations using a mix of recruitment strategies, including our peripatetic staff. The region also had the highest GP recruitment as a result of our GP hub and spoke models. Our work on both PANORAMIC and PRINCIPLE (CPMS 45457) was recognised at the recent Prix Galien UK 2024 Awards Ceremony, and production of a national report to highlight effective working practices is currently in progress with input from the region.

Capacity and Capability. Trusts continue to develop their capacity and capability to undertake portfolio research and to lead on new initiatives. For example, MKUFT is currently collaborating with the local council and Loughborough University on

ACTIVATE (CPMS 57291), which is a portfolio adopted, Digital Incentives Initiative aimed at getting patients with Type 2 diabetes to be more active, and has strong interest from local GP practices. Primary care has also remained strong, with c.35% of all recruitment for the region during the year generated by GP practices. In particular, the appointment of an engagement officer in primary care, has enabled us to engage more effectively with previously research naïve practices, such that we now have 50 practices signed up to our RSI scheme.

Workforce Development. Both our Deputy Chief Operating Officer and our Workforce Development Lead were seconded into national roles, and our lead CRP, based in BHFT, was involved in national CRP campaigns promoting the role and career development. Our joint Chief Nurses have undertaken a major piece of work to map local assets and build relationships for future work. We also co-led on the publication of the GCP recommendations paper, led the national pilot, and subsequently rolled out the new face-to-face and virtual consolidated sessions.

Greenshoots. Our programme continued into 2023/24, with a further 23 participants from 15 different Specialty areas, each of whom received 0.1 wte (1PA) funding per week for 6 months. Open to clinicians, nurses, AHPs and social/public health professionals, the initiative provided valuable protected time for learning, training, public engagement activities, and hands-on experience. The cohort recruited to 37 different portfolio studies, including OPTIMISE 2 (CPMS 56390), where a total of 31 additional patients were recruited at one site, and GASTRIC-PICU (CPMS 54988), where one site became one of the top recruiting sites nationally.

Fellowship Programme. This is now in its 7th year, and we have undertaken an exercise to evaluate its impact. Respondents felt strongly that programme had helped to embed a research culture and help them to develop both leadership and research skills. Several alumni have gone on to study further degrees or have secured research posts, and 9 have subsequently had papers published in major journals.

Ask the Experts. We also continued to champion this webinar programme which has now been rolled out nationally across all 15 regions. We hosted a 4 further webinars during the year (age related macular degeneration, asthma, depression, paediatric neuromuscular diseases), which have received over 1,000 views.

Part 3: Local initiatives/projects/programmes to grow the commercial portfolio

Joint Expression of Interest. TVSM has been investigating the potential of submitting a single expression of interest for all or several of the sites in the region in order to grow the commercial portfolio across our secondary care sites and increase the attractiveness for commercial companies to deliver their studies. Each trust would have their own target with an overall target for the region. A successful example of this is a recent GSK study for herpes (CPMS 61432) where 3 secondary care sites in the region have been selected.

Single Contract. Ongoing discussions have taken place with trusts, and with representatives from primary care, to evaluate the potential for adoption of a single contract initiative initially for commercial studies within the region. The intention would be to streamline processes for commercial partners increasing the attractiveness to run studies across the region, and then to subsequently link in with joint expressions of interest. Potential avenues would be to adopt the Southampton single contract model or to utilise the HRA's hub and spoke model. It is thought that this could be particularly beneficial for high recruiting vaccine studies and rare disease studies where accessing a higher patient base would be advantageous.

Global Clinical Site Accreditation (GCSA) award. The Research and Innovation team at RBFT were awarded full [GCSA](#) (Global Clinical Site Accreditation) Certification - The Global Quality Standard for Clinical Research Sites, ratified by The International Accrediting Organisation for Clinical Research (IAOCR).

NCVR. During 2023/24 TVSM has rolled the NCVR process out initially to the secondary care trusts and encouraged all commercially active GP practices to voluntarily sign up to the NCVR process. 10 training sessions for secondary care and 4 for primary care have been undertaken with 12 GP practices now voluntarily signed up to NCVR. Reciprocity between primary care and OUH has enabled improved completion when the sites undertaking the commercial studies are from a mixture of settings. With new and existing Chief investigators in primary care this has enabled NCVRs to be completed by GP practices as lead sites. An example is FLU SV MRNA-020 (CPMS 57656), an open-label multi-centre enabling study to evaluate Influenza-Like Illnesses and Severe Influenza Disease in adults aged 65 years and above which successfully recruited to target within an 8 day period.

Global First. BHT achieved a global first for the trial ChloroSolv03 (CPMS 54980).

Phase 1 Studies. Building on the success of the pandemic running phase 2 studies outside of Oxford, MKUFT is now running its first commercial Phase 1 on weight loss, SIRONA (CPMS 51908).

Industry Workshops. In order to increase the number of active Principal Investigators for commercial studies, 3 industry workshops were held in sites across the region with a mixture of stakeholders. Stakeholders included industry partners advising on Expressions of Interest, CRN staff discussing NIHR processes and R&D staff describing trust processes and expectations. In 2023/24 over 50 delegates attended these workshops.
