Oxford University Hospitals
NHS Foundation Trust

Cover Sheet

Trust Board Meeting in Public: Wednesday 9 July 2025

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Title:	**Research & Development Governance and Performance Report 2024-25**

Status:	**For Information**
History:	**Annual reporting**

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 2024-25.
2. The benefits of research in the NHS – for patients, staff, the NHS, and the UK economy – are recognised by the Care Quality Commission (CQC), professional bodies, NHSE and industry.
3. OUH is one of the most research-active university hospital NHS trusts nationally, with a portfolio of over 1,600 active clinical research studies supported by the National Institute for Health and Care Research (NIHR) through infrastructure awards (Biomedical Research Centre (BRC) and Clinical Research Facility (CRF)) and the Research Delivery Network (RDN), as well as industry.
4. Clinical research performance – especially for commercial studies – is the focus of a new cross-sector UK Clinical Research Delivery (UKCRD) Programme co-led by the Department of Health and Social Care (DHSC) and NHS England (NHSE). New metrics have been introduced for NHS trusts in 2025-26 and significant improvements will be needed to meet national targets.
5. Trusts failing to meet targets are at risk of reduced income from the NIHR and industry. OUH's performance in terms of studies recruiting to time and target demonstrates the need for action to be taken: of the 131 studies closed to recruitment in 2024-25, 54 (41%) had recruited to time and target. The national target is for 80% of open studies delivering to time and target.
6. A series of local improvement initiatives are underway, to complement the national study set-up plan workstreams led by the UKCRD programme. These focus on better information gathering and sharing, streamlining administrative processes, and maintaining the workforce needed to deliver OUH's research portfolio.
7. Proposals to strengthen R&D governance, performance and support at OUH have are in a late stage of development with wide stakeholder input and will be presented to the Trust Management Executive for approval. Key elements include establishing an R&D Committee and developing an R&D Strategy.

Recommendation

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

Contents

1. Introduction

1.1. Oxford University Hospitals NHS Foundation Trust (OUH) is one of the most research-active university hospital trusts nationally, by any measure.

1.2. The Care Quality Commission (CQC) has included research in its well-led inspection framework since 2018 because research-active healthcare organizations tend to deliver better patient outcomes and higher-quality care. This is also recognised by professional bodies such as the Royal College of Physicians, biomedical charities like the Wellcome Trust) and NHS England, alongside other benefits of embedding clinical research within the NHS, including staff morale, recruitment and retention, and economic prosperity. The value of industry clinical trials to the UK economy, the NHS and the UK's research and development base is presented in a recent report for the Association of the British Pharmaceutical Industry (ABPI).

1.3. 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 Oxford Joint Research Office (JRO) were actively engaged in discussions during the development of the strategy.

1.4. Research also features prominently in OUH's NMAHPs strategy (2021-26) and in Our Clinical Strategy (2023-28).

2. Structure and Organisation

2.1. An organogram summarising the structure and organisation of OUH Research and Development (R&D) is shown below (Figure 1).

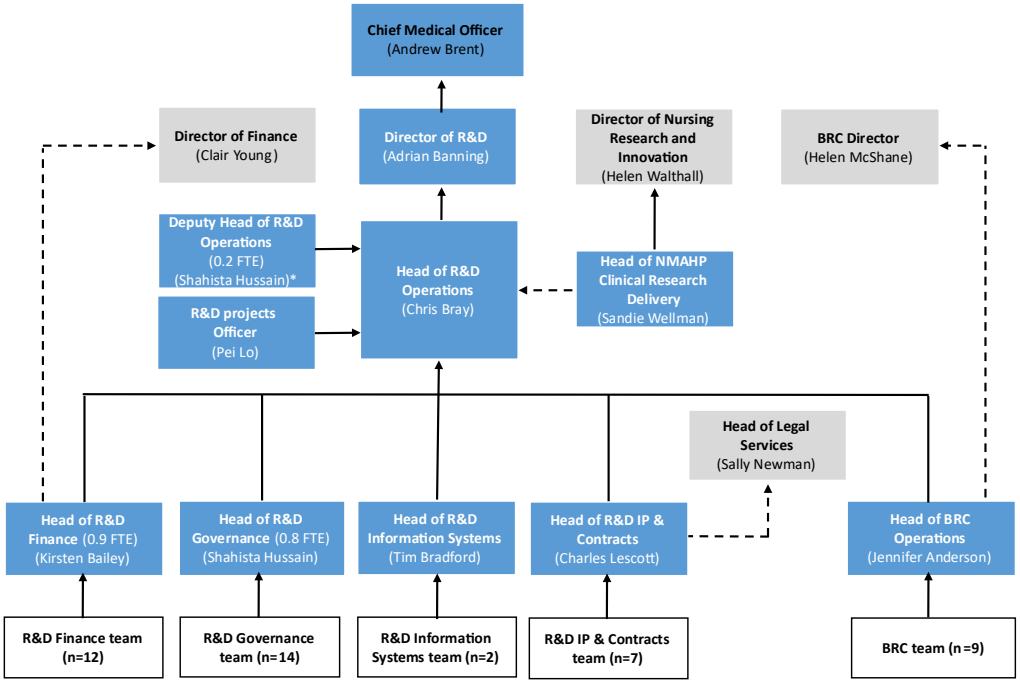


Figure 1. OUH R&D Organogram

2.2. In addition to this annual report to the Trust Board, R&D provides reports quarterly to the Joint R&D Committee (JRDC) and the Trust Management Executive (TME).

2.3. 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.

2.4. The OUH R&D teams are part of the Joint Research Office (JRO), a partnership with the University of Oxford, Oxford Health NHS Foundation Trust and Oxford Brookes University. The JRO is overseen by the JRDC.

2.5. The potential to further integrate and strengthen the JRO has been recognised by both OUH and the Oxford Academic Health Partners (OAHP) which has as one of its short-term goals to "create an integrated Oxford Joint Research Office across all OAHP partners to promote operational collaboration".

NMAHPs (Nurses, Midwives and Allied Health Professionals)

2.6. In line with National Institute of Health and Care Research (NIHR) priorities the overall number and activity of NMAHP Chief Investigators (CIs) and Principal Investigators (PIs) leading studies at OUH has increased significantly during 2024-25 (Table 1).

Table 1. Numbers of NMAHP CIs and PIs, and studies led

2023-24	2024-25
8 CIs leading 24 studies	28 CIs leading 50 studies
41 PIs leading 56 studies	38 PIs leading 47 studies
49 CIs or PIs leading 80 studies;	65 CIs or PIs leading 97 studies;

2.7. The number from each professional group taking on CI or PI responsibilities is detailed in Table 2.

Table 2. OUH NMAHP Investigators, by professional group

NMAHP Professional group	CIs	PIs
Clinical psychologist	6	5
Dietician	1	1
Health care scientist (physical sciences and clinical engineering)	2	1
Health care scientist (physiological sciences)	2	0
Midwife	0	1
Nurse	3	8
Occupational therapist	0	1
Other	4	3
Pharmacist	0	1
Physiotherapist	9	12
Radiographer	0	3
Speech and language therapist	1	2
Grand Total	**28**	**38**

2.8. Senior OUH NMAHPs are undertaking the NIHR-AoMRC Clinician Researcher Credentialing Framework.[1]

2.9. 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. Building on its success, a business case was approved to develop senior OUH NMAHP roles. There are three full

[1] 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.

time clinical academic research leads in post. Recruitment to a fourth role is in progress. They are externally funded through a combination of OU, OBU, NIHR Oxford Biomedical Research Centre (BRC) and R&D income.

3. Clinical Research Activity

3.1. A total of 1647 OUH-hosted clinical research studies were active (i.e. open to recruitment, recruiting or in follow-up) during 2024-25. This is a small increase (4%) compared to 2024-25 (1579). 84% were on the NIHR portfolio[2] (the same as last year), 499 of which reported recruitment in 2024-25, the second highest of all NHS Trusts in England, recruiting a total of 15,776 participants. The number of portfolio studies currently open to recruitment or recruiting was 767; the other 616 had completed recruitment and were in the follow-up phase.

3.2. Examples of recent high-impact research studies supported by the Oxford BRC are included in the Appendix.

Hosted and sponsored active clinical research studies

3.3. 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 3.

Table 3. Breakdown of hosted and sponsored active research studies

Study type		Hosted	Sponsored	Total
Interventional	Clinical trial of an investigational medicinal product (CTIMP)	605(99.9%)	1 (0.1%)	606
	Clinical investigation or other study of a medical device	74 (93%)	6 (7%)	80
	Other clinical trial	220 (96%)	9 (4%)	229
Sub-total		899 (98%)	16 (2%)	915
Non-interventional	Other study	670 (92%)	62 (8%)	732
Total		1569 (95%)	78 (5%)	1647

3.4. The vast majority (95%) of OUH active clinical research studies are hosted for external Sponsors, of which OU is the largest, responsible

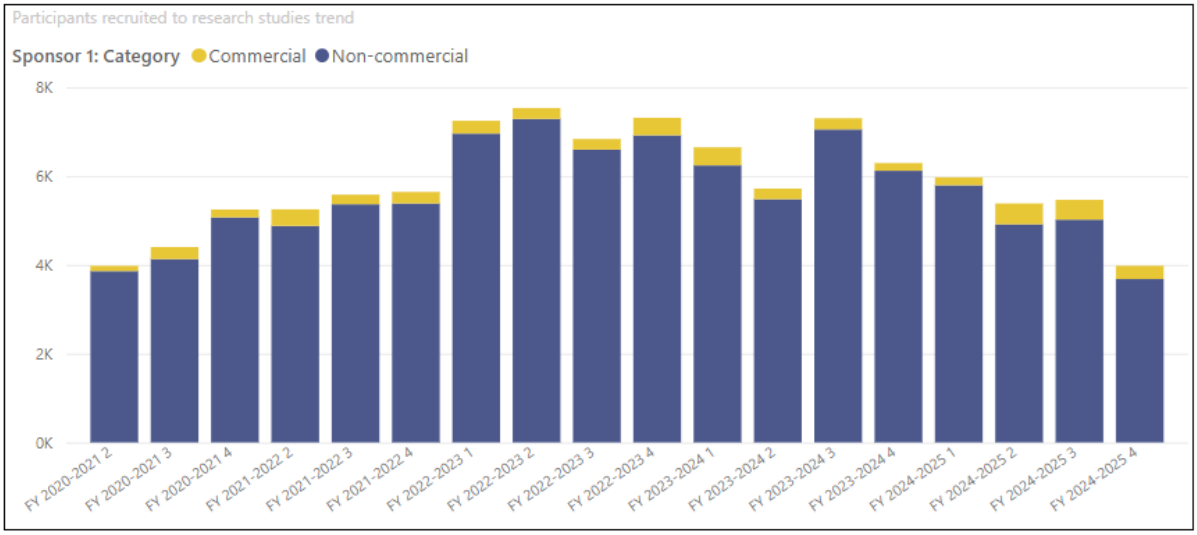
[2] Portfolio studies meet specific criteria set by the NIHR and are eligible for financial and other support provided or funded by the Research Delivery Network (RDN)

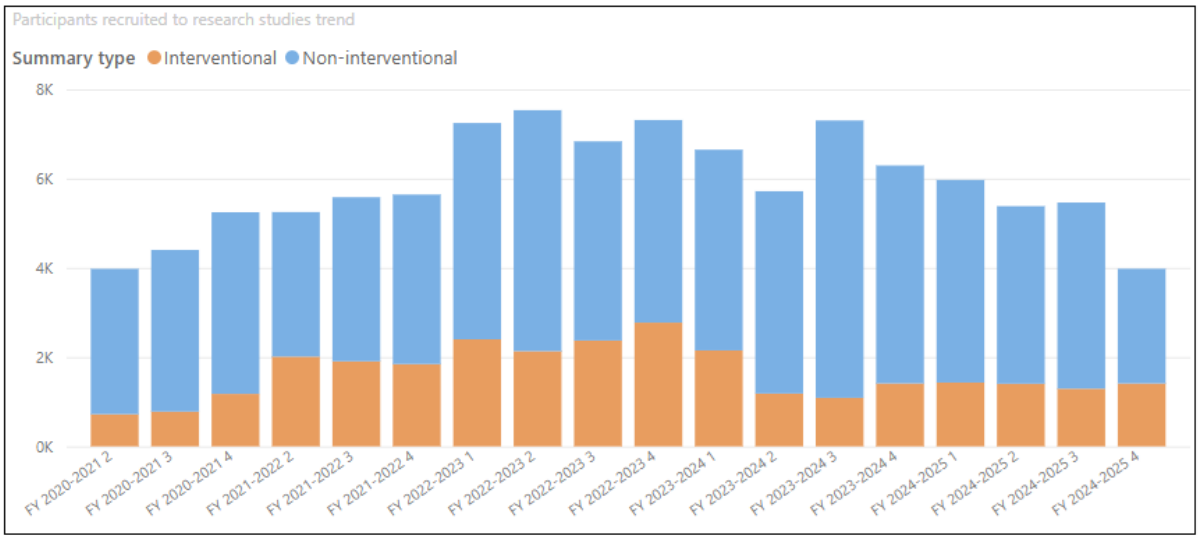
for 404 (25% of the total). 915/1647 (56%) of OUH active research studies are interventional.

3.5. A breakdown of OUH active research by Division is available in the Appendix.

Participants Recruited (trends)

3.6. Figure 2 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.





Data sourced from Studyline 16-May-2025

Figure 2. Participants recruited, by quarter

3.7. Recruitment to commercial studies increased by 32% compared to 2023-24, but there was a greater reduction (19%) in recruitment to non-

commercial studies. As a result, overall recruitment in 2024-25 was 17% lower than in 2023-24.

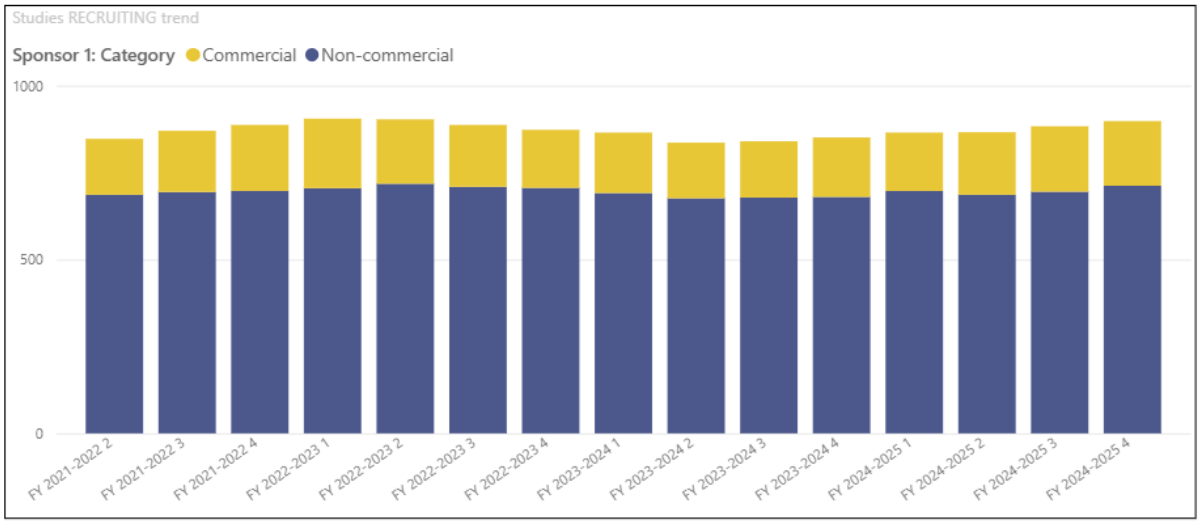
3.8. Recruitment is affected by multiple factors. These include the number of studies open to recruitment, how quickly they were opened to recruitment (especially for multicentre commercial trials with competitive recruitment models), their recruitment targets, and the number of eligible patients who are approached by the study team and who consent to participate.

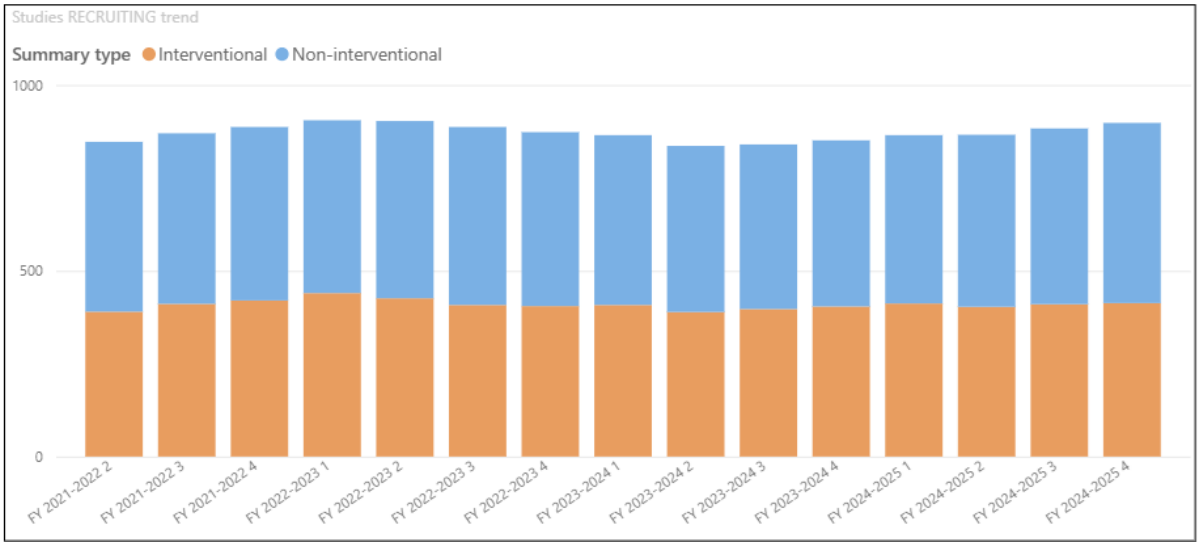
3.9. Recruitment can also be skewed by individual studies which have very high targets (these are usually low-intensity, non-interventional, non-commercial studies). Six very large studies completed recruitment at OUH during 2024-25, which had a disproportionate effect on overall recruitment.

3.10. It should be noted that recruitment during the last quarter is likely to be an underestimate of ~20% because of lag times in study teams reporting recruitment to OUH.

Studies open to recruitment

3.11. Figure 3 shows the number of studies open to recruitment each quarter since Q2 2021-22.



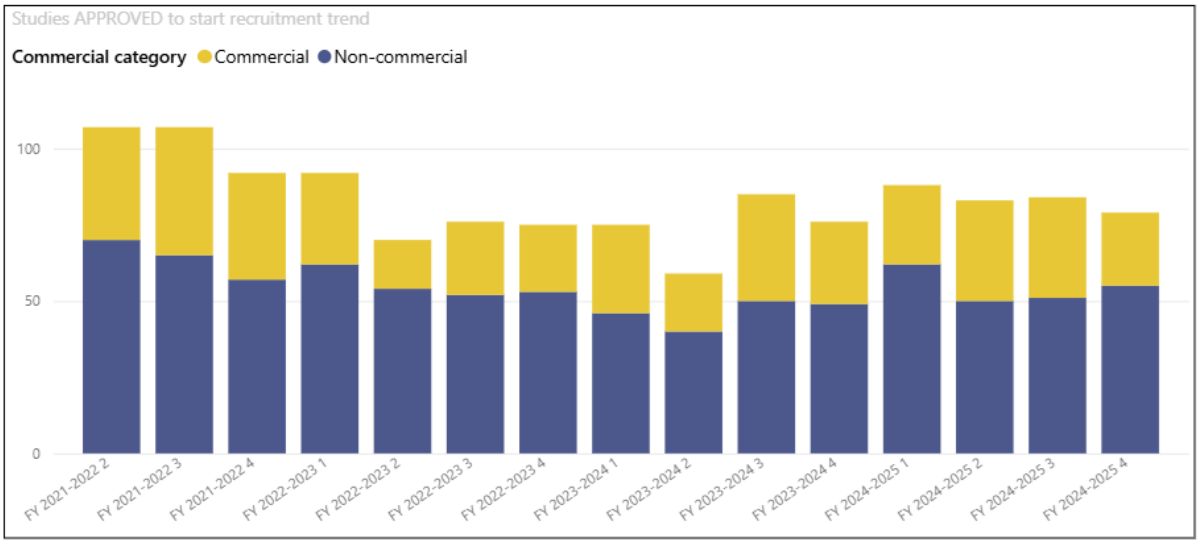


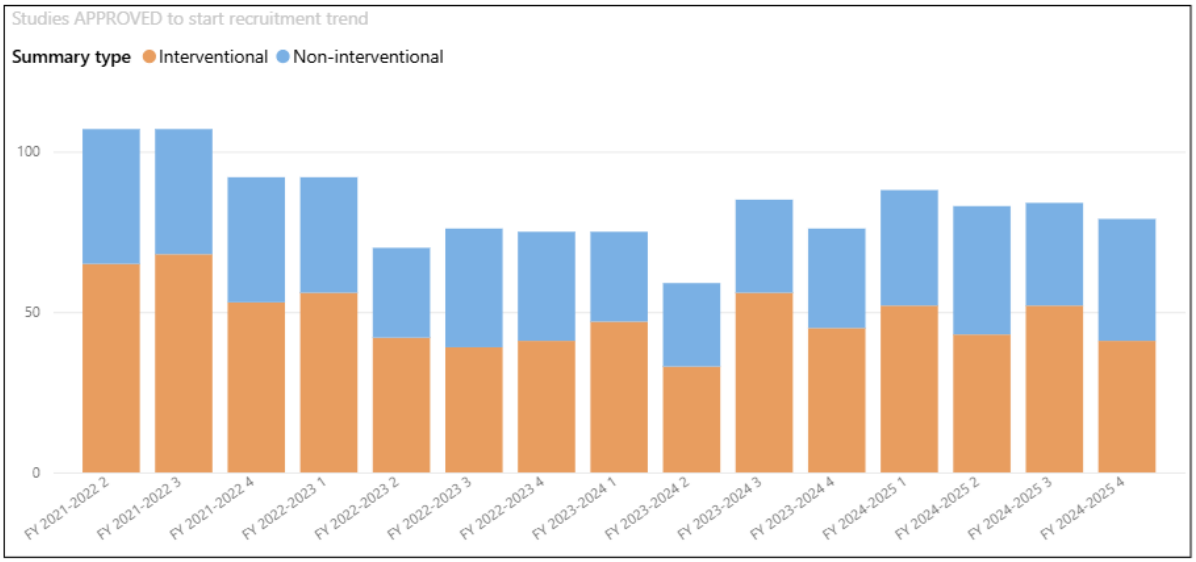
Data sourced from Studyline 16-May-2025

Figure 3. Studies open to recruitment, by quarter

New studies approved to start recruitment

3.12. Figure 4 below shows the number of <u>new</u> studies approved to start recruitment at OUH each quarter since Q2 2021-22





Data sourced from Studyline 16-May-2025

Figure 4. New studies opened to start recruitment, by quarter

3.13. OUH is a recruiting site for 274/334 (82%) of the studies approved to start recruitment in 2024-25 For a further 5% OUH was a Participant Identification Centres (PIC), identifying potential research participants to be recruited at a separate research site, usually one of the other Oxford Academic Health Partner (OAHP) organisations. For an additional 3% OUH was a service site, providing services such as laboratory analysis or imaging. Over time, in line with Government 'shift' for the NHS to move from hospital-centric care to integrated, community-based care, a greater proportion of research studies will be taking place outside of acute Trusts, which is expected to increase demand for OUH to provide services to these studies.

Table 4. Summary of activity in 2024-25

	Participants recruited	Studies open to recruitment	New studies approved to recruit
Commercial	1393 (7%)	186 (21%)	116 (35%)
Non-Commercial	19,406 (93%)	712 (79%)	218 (65%)
Interventional	5537 (26%)	413 (48%)	188 (56%)
Non-interventional	15,262 (73%)	485 (52%)	146 (44%)
NIHR portfolio	15,776 (76%)	708 (79%)	268 (80%)
Non-portfolio	5023 (24%)	190 (21%)	66 (20%)
Totals	20,799	898	334

4. Clinical Research Performance – R&D metrics

4.1. There are currently seven national UK Clinical Research Delivery Performance Indicators, each with its own target, four of which relate specifically to commercial contract studies. These high-level Indicators

all relate to the performance of studies, rather than to the individual study sites/Trusts recruiting to these studies. The DHSC has published monthly updates since January 2024.

4.2. Perhaps the most important Performance Indicator for OUH, and for OU, is the proportion of open studies they sponsor that are on track, delivering to time and target. This is because the NIHR has stated that NHS trusts and their primary university partner will be assessed on their ability to actively manage their research portfolios, with funding for infrastructure competitions (including for BRCs) limited for trusts and universities that don't meet the target of 80% of NIHR portfolio studies delivering to time and target.

4.3. As part of the UKCRD programme, a new Study Set-up Plan co-led by the DHSC and NHSE was published on 1 April 2025. This includes – for the first time – the collection and publication of the site-level study set-up data behind the two key performance indicators (KPIs) currently published for commercial clinical study set-up. Specifically:

- Proportion of commercial studies open to recruitment within 60 days of HRA approval letter
- Proportion of commercial studies recruiting first participant within 30 days of sites opening to recruitment

4.4. These new KPIs are being rolled-out across the UK from April 2025. There are no specific site-level targets, but these KPIs are obviously crucial to achieve the 90% targets for studies that have been set at national level. The results for all Trusts will be published online.

4.5. It is not yet possible to report OUH's performance in relation to these KPIs for 2024-25 in this report, but they will be an important addition to the quarterly reports to the TME from August 2025 and help focus our collective efforts to drive improvements. They will also be included in the next R&D Annual Report for 2025-26.

OUH performance

4.6. However, even without the benefit of official site-level performance indicators, it has been recognised for some time that significant improvements in site set-up speed and in study recruitment are necessary at OUH. This is demonstrated by the robust data available on the proportion of OUH-hosted studies that have recruited to time and target at the close of recruitment. Table 5 shows the overall performance for studies closed to recruitment in 2024-45 was 41%, much lower than the closely related target in the UK Clinical Research Delivery Performance Indicators, which is 80% of open studies recruiting to time and target.

Table 5. OUH hosted studies closed to recruitment in 2024-25

Study Type	Number closed to recruitment in 2024-25	Recruitment completed to time and target (%)	
		Recruitment time AND target met (%)	Recruitment target met or exceeded (%)
Commercial	51	25 (49%)	32 (63%)
Non-commercial	80	29 (36%)	50 (63%)
Interventional	93	40 (43%)	54 (58%)
Non-interventional	38	14 (37%)	28 (74%)
NIHR portfolio	119	51 (43%)	77 (65%)
Non-portfolio	12	3 (25%)	5 (42%)
All	131	54 (41%)	82 (63%)

4.7. The proportion of studies at OUH which recruit to time and target needs to be increased substantially. Current levels of recruitment performance present a reputational risk, poor use of resources, missed opportunities for patients and – for commercial studies – a failure to leverage the initial investment in study set-up to generate surplus funds. This is one of the key areas to be addressed in the proposed R&D strategy, in order to align all those involved in OUH research delivery.

4.8. The percentage of studies which recruited to (or exceeded) their target, including those that took longer than agreed to meet/exceed their target, is significantly higher. An analysis of all 92 studies that completed recruitment since January 2021 and had met (or exceeded) their recruitment target but missed their recruitment window demonstrates that 47 (51%) over-ran their recruitment window by ≤10% (see Figure 5 below). This suggests that improvements which bring forward recruitment by only a small margin – including faster set-up times – should have a significant impact on the Trust's overall recruitment to time and target.

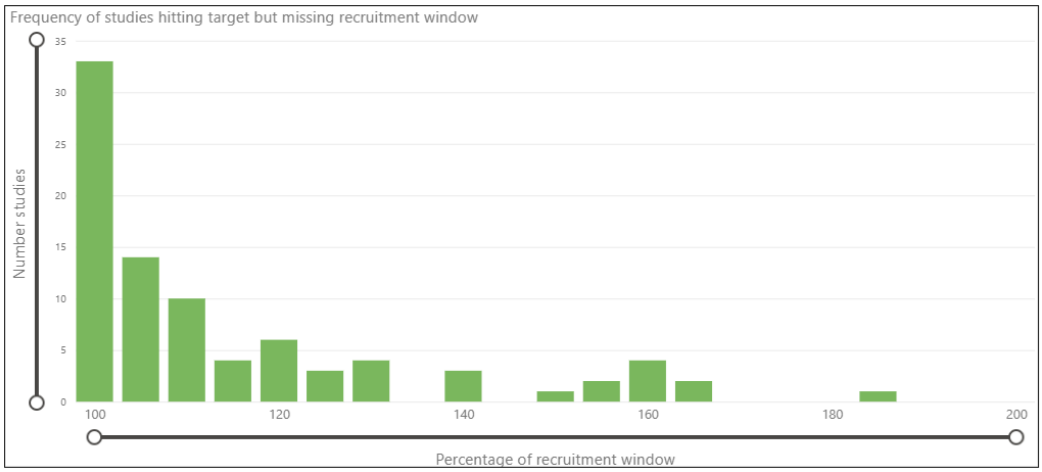


Figure 5. Studies which met recruitment target but overshot the target date

Initiatives to improve site set-up and recruitment performance

4.9. A wide range of local initiatives are underway, which will complement the national study set-up plan workstreams led by the new UKCRD programme. These include the following:

4.10. The Studyline research portfolio management system now 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. In addition to helping manage each study whilst it is being set-up, this granular information is being analysed to understand better the main causes of delay, to identify opportunities to make improvements and to monitor their impact.

4.11. The Director of R&D and Head of R&D Operations have worked with the Clinical Directors of CSSD, Radiology and Pharmacy to streamline and shorten study set-up and increase capacity.

4.12. Recognising the particular importance of being able to support OU-led studies, an end-to-end review of study set-up processes for OU sponsored, OUH hosted CTIMPs (drug trials) has been initiated, with the support of the OUH Quality Improvement (QI) team. OUH sets-up studies sponsored by OU 30% faster than other sponsors' studies, but mapping these processes in detail should reveal any opportunities to improve the overall efficiency and speed of study set-up, leveraging the JRO partnership to work in a more integrated manner. No obvious opportunities have been identified in relation to the first two studies considered, but having established the approach, the aim is now to analyse additional studies where significant issues and delays were experienced during set-up, to see how these could have been averted.

4.13. Another potential source of valuable information identified recently is studies that were opened to recruitment but then closed without having recruited a single participant. This applied to 25 of the studies close to recruitment during 2024-25, representing ~7% of the annual set-up capacity being wasted. All such studies will be reviewed immediately in future to identify any lessons that can be learned. If 'risk factors' can be identified, these can be fed back into the initial decision to set-up a study and revisited during the site-up process, especially if this is delayed.

4.14. Agility in recruitment to externally funded (and honorary) R&D posts will be essential to support the improvements that are required. This has been challenging since the introduction of OUH's Vacancy Control Process in February, following on from the recruitment pause in January. Discussions have been held at Executive Director level and progress is being made.

4.15. Under the proposed changes to strengthen R&D governance, performance and support (see paragraph 7.2), these and other initiatives, will be overseen by a Trust R&D Committee and aligned with a Trust R&D Strategy which recognises and builds on OUH's strengths and partnerships.

5. Clinical Research Delivery Workforce

5.1. Central to the delivery of the Trust's research portfolio is the clinical research delivery workforce. There are over 370 individuals working in 35 research delivery teams 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.

5.2. Approximately 60% of the clinical research delivery workforce are employees of OUH, and around 40% (140) are employed by the University of Oxford and have honorary contracts with OUH.

5.3. Following changes in the Research Delivery Network, the direct delivery team (now called the Agile team) are employed by University Hospitals Southampton, but it has continued to provide support to a portfolio of OUH studies, under Honorary Contracts with OUH.

5.4. The majority of clinical research delivery posts are registered nurses, followed by administrators, AHP & midwives and an increasing number of Clinical Research Practitioners (CRPs) - see Figure 6.

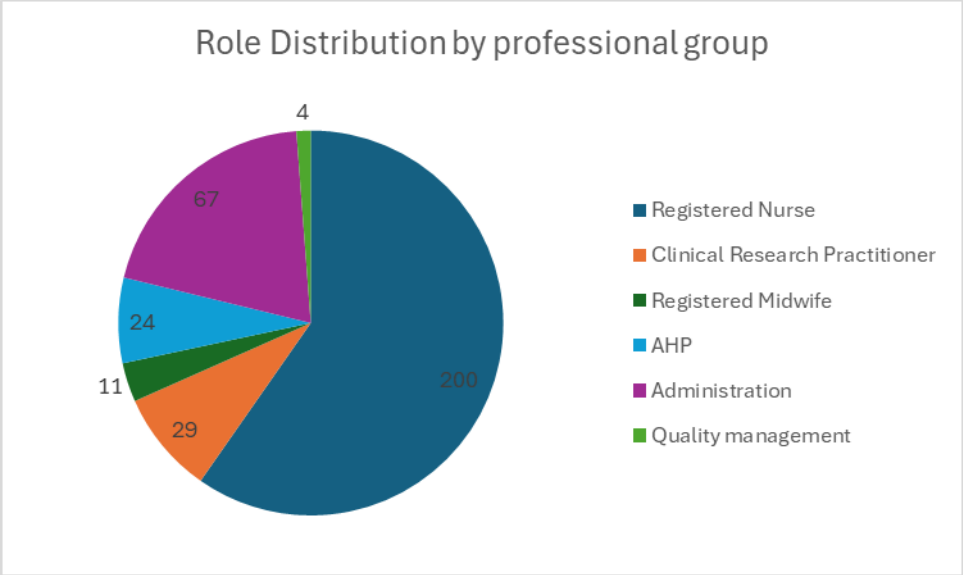


Figure 6. Clinical Research Delivery roles

5.5. The Clinical Research Practitioner (CRP) role is a relatively new role. Governance, generic job descriptions, role specific competencies and a career pathway for CRPs are being strengthened.

5.6. Funding of OUH research delivery posts comes from a variety of sources (see Figure 7). The biggest of these is the annual award from the NIHR, via the South Central Regional Research Delivery Network (RRDN), which replaced the Thames Valley and South Midlands Local Clinical Research Network (CRN) in October 2024. The annual funding award for 2025-26 to OUH from the RRDN has remained stable. From 2026-27 RDN funding to OUH is expected to be performance related, although no details have provided yet.

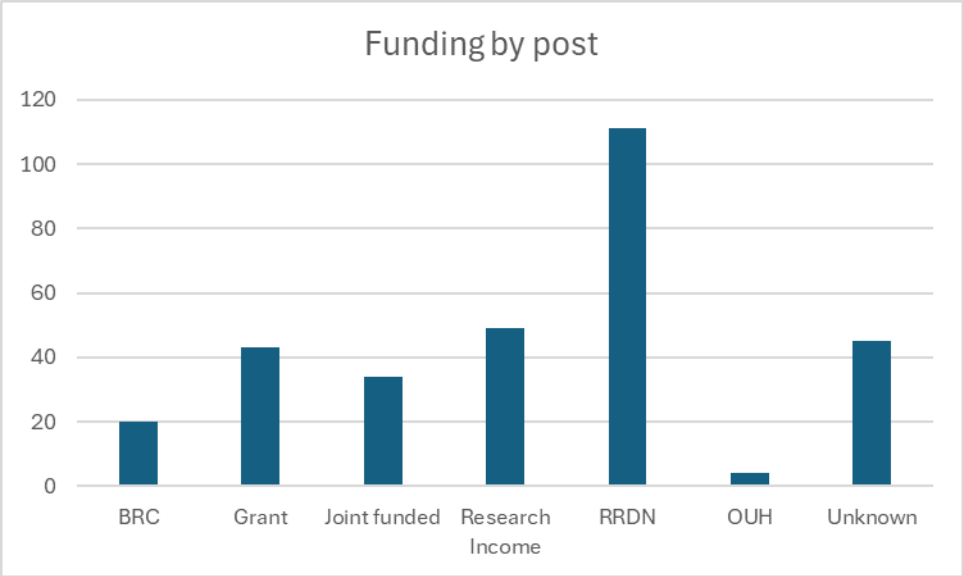


Figure 7. Sources of funding for OUH Clinical Research Delivery posts

5.7. We are developing a career pathway for clinical research delivery staff, implementing generic job descriptions for consistency and capabilities. Engagement with the workforce is achieved through the Lead NMAHPs Clinical Research Delivery (CRD) Forum for senior staff and the NMAHPs CRD network group for more junior staff. Ongoing workstreams include creating SOPs with an electronic system to track compliance, developing a bi-monthly induction programme and short modules on My Learning Hub, and enhancing advanced practice roles in clinical research delivery. Further details are available in the Appendix.

6. NIHR Oxford Biomedical Research Centre (Oxford BRC)

6.1. The Oxford BRC is one of 20 BRCs across England. It supports high-quality early translational and experimental research across 15 research themes and six 'enabling hubs'.

6.2. The original award for the Oxford BRC was £86.6m for the period of 1 December 2022 – 30 November 2027 but in March 2024, BRCs were informed that NIHR would extend the award by four months until 31 March 2028.

6.3. In 2024-25 the BRC supported 403 projects including through salary support for investigators associated with the project, use of the BRC facilities or direct project funding. A small number of examples of recent high-impact research enabled by the BRC are provided in the Appendix.

6.4. The Oxford BRC successfully applied to NIHR for £180k of additional funding to support NMAHP research careers. Led by Prof Helen Walthall, the funding has enabled us to support an additional 13 researchers with career development support. As with our other funding opportunities, awardees were supported with 1-2-1 mentoring and an education programme.

Patient and Public Involvement and Engagement in Research

6.5. The Oxford BRC held a joint Open Day with the Oxford Health BRC at Oxford Town Hall on 30 May 2024 and another is scheduled for 29 May 2025. 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.

6.6. 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.

7. NIHR Oxford Clinical Research Facility (Oxford CRF)

7.1. Now in its third year of operation, the Oxford CRF has continued to expand the scope and volume of activity in line with its strategic objectives.

7.2. A Variation to Contract (VTC) with the DHSC provides an extension of the current CRF agreement to 31 March 2029.

7.3. The Oxford CRF comprises the Experimental Medicine CRF (EMCRF), Children's CRF, Nuffield Orthopaedic Centre (NOC) CRF and the OCDEM Clinical Research Unit.

7.4. A CRF nursing team has been established to deliver a wide range of studies and a corresponding range of clinical activities. This has enabled the conduct of new trials with commercial sponsors. An programme of training for research nurses is being undertaken to support endoscopy, bronchoscopy and bone marrow biopsy procedures.

7.5. 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.

7.6. The successful outpatient clinic established within the Oxford CRF continue to function. 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, Dermatology, Colorectal surgery and Respiratory to support similar additional clinics, which will enable research whilst also managing routine patient care.

7.7. Over 30 studies are currently supported within the Oxford CRF. This is a 50% increase compared to 2023-24. These studies involve both OUH patients and healthy volunteers. They range from vaccine trials to single-cell body mapping involving the complex interventions discussed above. 19 are commercially sponsored.

8. Research Governance

8.1. An internal audit of R&D by BDO was conducted in Q2 2024-25. The report was approved by TME on 12 September 2024 and reviewed by the Audit Committee on 30 October 2024. The main recommendation was the creation of a Trust R&D committee, to bring OUH in line with most other research active acute trusts in England. The audit also identified there is no OUH R&D Strategy and the Trust R&D

Department provides a service that is entirely led by, and responsive to, the studies that Investigators want to initiate.

8.2. Proposals to strengthen R&D governance, performance and support at OUH have been developed with the CMO. Key elements include establishing an R&D Committee and developing an R&D Strategy, in line with the recommendations of the BDO audit of R&D in 2024. These proposals are being updated in the light of feedback received from stakeholders and will be presented to the Trust Management Executive for approval.

8.3. A summary of the governance frameworks governing research is available in the Appendix.

9. Research and Development Finance

9.1. The R&D Finance team provides management accounting, costing, and pre- and post-award financial support to researchers and infrastructure grants. This includes managing finances for the Oxford BRC, Thames Valley & South Midlands Local Clinical Research Network (prior to transition to the new Regional Research Delivery Network hosted by University Hospitals Southampton), and NIHR CRF; acting as lead site costers for National Contract Value Reviews (NCVR) when the CI is based at OUH; reviewing and costing study budgets and amendments; and managing commercial study income to support R&D activities.

Financial Position and Current Activities to 31 March 2025

9.2. For the 2024-25 financial year, the annual income and expenditure budget for R&D was set at £52 million, as shown below. This included £35 million from major NIHR grants for hosting the Oxford BRC and the LCRN.

9.3. High level breakdown of 2024-25 R&D budget:

Research Funding by area	2024-25 Expenditure (£m)
NIHR Oxford Biomedical Research Centre (BRC)	19
NIHR Local Clinical Research Network (LCRN); Apr-Sept	10
NIHR Regional Research Delivery Network (RRDN); Oct-Mar	5
NIHR Research Capability Funding (RCF)	1
Other income (commercial & non-commercial, incl. NIHR grants)	17
Total	**52**

9.4. At financial year end all major NIHR programme and smaller grants achieved a breakeven position and individual study income exceeded expenditure by £2.7 million.

Research Capability Funding (RCF)

9.5. NIHR RCF is awarded 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.

9.6. OUH received £1.3m of RCF in 2024-25 (compared to £873k in 2023-24). This is due to increased NIHR grant income during the previous calendar year, which is the main basis on which RCF awards are calculated.

9.7. The panel that oversees RCF at OUH made a number of individual awards in support of NIHR funded research in OUH and OU to cover absences as a result of parental or long-term sick leave. This provided essential support to ensure NIHR funded research could continue. RCF also made a significant contribution towards research overhead costs and the costs of managing NIHR grants. A local scheme also enabled researchers at OUH and OU to apply for RCF funding to help develop competitive grant applications for NIHR funding.

National Contract Value Review (NCVR) for commercial studies

9.8. The NCVR process standardises and streamlines the costing of commercial contract research, minimising duplication of effort at each site so that commercial trials can be set-up more quickly.

9.9. Since the system was established in October 2022, OUH has acted as the lead site for over 80 studies, negotiating the cost with the sponsor on behalf of all sites in the UK.

9.10. There have been considerable challenges with the NCVR process, with significant variability in the quality of costings OUH receives for commercial studies when it is not the lead site. This has improved over time but the expected benefits in terms of time-saving have yet to be realised.

Financial Planning 2025-26

9.11. The following budget has been set for 2025-26:

Research Funding by area	2025-26 Expenditure budget (£m)
NIHR Oxford Biomedical Research Centre (BRC)	18
NIHR Regional Research Delivery Network (RRDN)	9
NIHR Research Capability Funding (RCF)	1
Other income (commercial & non-commercial, incl. NIHR grants)	17
Total	**45**

9.12. As in previous years the BRC and RRDN budgets forecast a break-even position for 2025-26.

9.13. For budget setting purposes it had been assumed that OUH would receive a similar level of funding to last year (£1.3m). However, on 22 May 2025) the NIHR confirmed that the award to OUH for 2025-26 will be £580k. This will require some adjustments to be made, not least to ensure the R&D teams can be funded at an appropriate level.

9.14. 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.

10. Research Contracts and IP

10.1. During 2024-25, 1,360 research and IP related cases were finalised. Further details are provided the Appendix.

11. Other Local, Regional and National updates

11.1. A summary of local, regional and national updates is provided in the Appendix.

12. Acknowledgements

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

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- 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)
- Sandie Wellman (Head of NMAHP Clinical Research Delivery)

13. Recommendation

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

Appendix 1

14. Research activity by OUH Division

14.1. Figure 8 presents a breakdown of the 1647 active studies of all types hosted by the Trust in 2024-25, according to the Divisions that are actively involved in their delivery. 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.

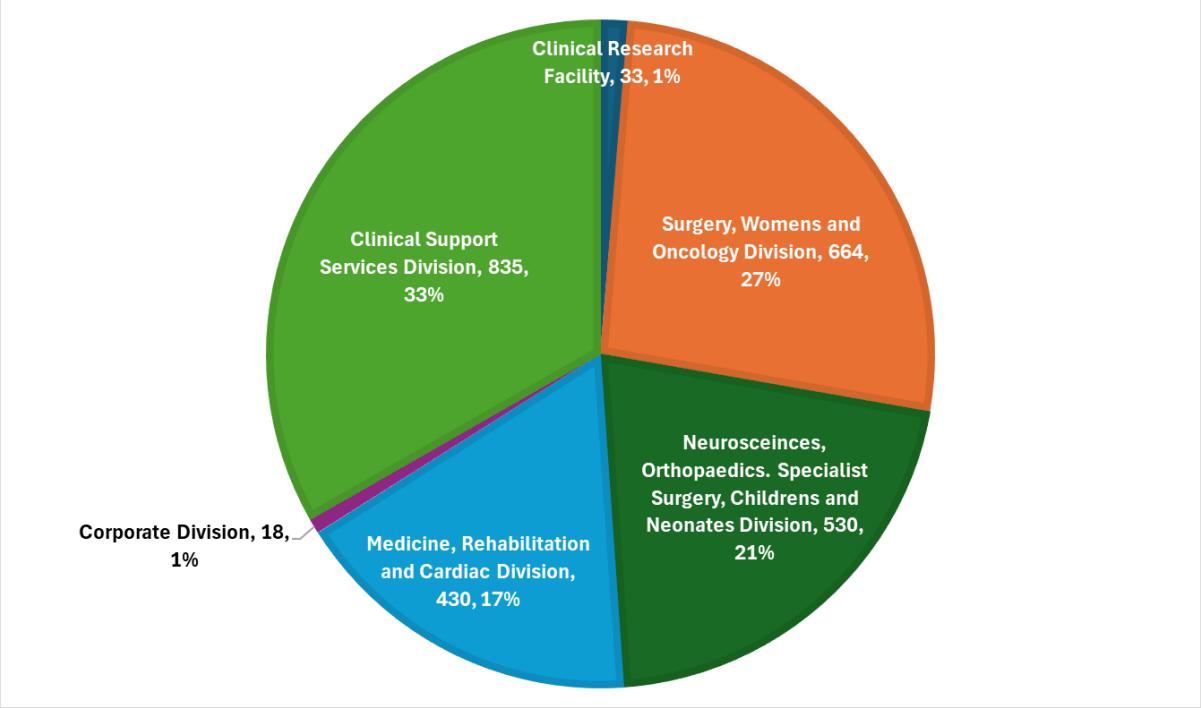

Figure 8. Active research studies at OUH in 2024-25, by Division

15. Clinical Research Delivery Workforce

15.1. 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.

15.2. 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.
- The NMAHPs CRD network group. This offers the opportunity for more junior staff (band/grade 6 and below) to come together, share ideas, gain peer support.

Several ongoing workstreams are being undertaken by these groups:

15.3. Developing a suite of SOPs which will be applicable to all research delivery staff and will introduce a clear governance structure. An electronic system for issuing SOPs with the ability to track receipt and acknowledgement is being developed and will be introduced during 2025-26. This will enable the Trust to evidence distribution and compliance with best practice across the research delivery workforce.

15.4. Developing an induction programme for all research delivery staff. This will be delivered bi-monthly and will ensure all research delivery staff receive the same initial training. There is also a plan to make five short modules available on My Learning Hub for all OUH staff as an introduction to clinical research, to raise awareness of research and how staff can be involved. This is in line with the CQC well-led inspection framework which emphasizes the importance of research awareness in NHS Trusts as part of its well-led framework, and encourages trusts to actively facilitate and promote research, ensuring that staff have opportunities to engage with research and innovation.

15.5. Developing enhanced and advanced practice in clinical research delivery. Several research delivery staff have completed training for enhanced practice including non-medical prescribing and advanced history taking, and there is one advanced clinical practitioner in post. A

pathway to support Advance Practice roles is being developed with the Trust lead for advanced practice.

16. Study impact

16.1. 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.

16.2. Recent examples of high-impact research carried out at OUH include:

- The RECOVERY Trial team have won a National Institute of Health and Care Research (NIHR) Impact Prize in the 'established investigator' category. The RECOVERY Trial, which has just recruited its 50,000th participant, was set up with support from the Oxford BRC in March 2020 during the early days of the COVID-19 pandemic to identify drug therapies to treat people hospitalised with severe COVID-19. Their work uncovered four treatments that reduce the risk of death from COVID-19, one of which was dexamethasone, which was estimated to have saved around one million lives worldwide by March 2021
- A new maternity early warning score that is derived from patient data is being rolled out across the English NHS. It will help healthcare providers identify and respond to signs of deterioration in pregnant women.
- The first new treatment for asthma attacks in 50 years has been developed, which is more effective than the current treatment of steroid tablets, reducing the need for further treatment by 30 percent.
- A glowing marker dye that sticks to prostate cancer cells could help surgeons to remove them in real-time. The marker dye found areas of cancerous tissue not picked up by the naked eye or other clinical methods. The dye allowed the surgeons to remove all cancerous tissues whilst preserving healthy tissues.
- University of Oxford researchers have for the first time established a controlled human infection model for tuberculosis (TB) that infects

people via the lungs – the way TB enters the body. The clinical trial, which used the BCG vaccine delivered via aerosol into participants' lungs, is a first step towards establishing a challenge model that can be used to test new TB vaccines.

17. Research Governance

Background

17.1. 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:

17.2. 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.

17.3. 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.

17.4. 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.

17.5. 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).

17.6. Following the completion of a consultation for legislative changes for clinical trials, published in March 2023, new UK clinical trial regulations

were signed into law on 11 April 2025. The new regulations are set to take full effect on 28 April 2026, after a 1-year implementation period. They aim to streamline approvals, enhance patient safety, and accelerate access to innovative treatments.

17.7. 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.

17.8. 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).

17.9. 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.

17.10. 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).

17.11. OUH Frameworks for R&D Governance, Training and Monitoring – Locally, clinical research is governed by the following 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

17.12. 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.

17.13. 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, which now has three lead auditors. These trials are selected through a risk-based approach. Five audits have been completed and closed by the R&D Governance team during 2024-25.

17.14. 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 and as they are less resource intensive than formal audit, a greater number of studies can be covered. During 2024-2025 17 informed consent and 2 safety compliance checks have been completed. The findings were fed back to the relevant teams and – in an anonymised format – with all the research delivery teams working across OUH, to help improve quality and promote best practice.

17.15. To support investigators and research teams, the R&D Governance team and Head of 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 2024-25 one pharmacovigilance MHRA (Medicines and Healthcare Products Regulatory Agency) site inspection was supported.

17.16. 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 compliant. 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; identify whether additional advice or information is required from investigators; evaluate the risk of the trial continuing and take appropriate action where necessary, including requests for specific audits. During 2024-25 OUH has reviewed 95 SAEs which have also been presented at the quarterly Trial Safety Group meetings.

17.17. Organisational Information Document (OID). When specified by the Sponsor, an OID can be used as the contractual agreement for non-commercial studies that are not clinical trials or clinical investigations. Unlike other site agreements with Sponsors, which are managed by the R&D Contracts team, the review; approval and completion of OIDs is managed by the R&D governance team. During 2024-25 100 OIDs were processed.

17.18. Incident reporting. The Head of NMAHP CRD reports the number of incidents to the APP and to the Lead NMAHPs' CRD forum on a quarterly basis, highlighting key themes and any shared learning. 154 incidents relating to clinical research delivery were reported in Ulysses in 2024. The breakdown by Division, shown in Figure 9, is at least in part a result of variation in reporting practice across Divisions.

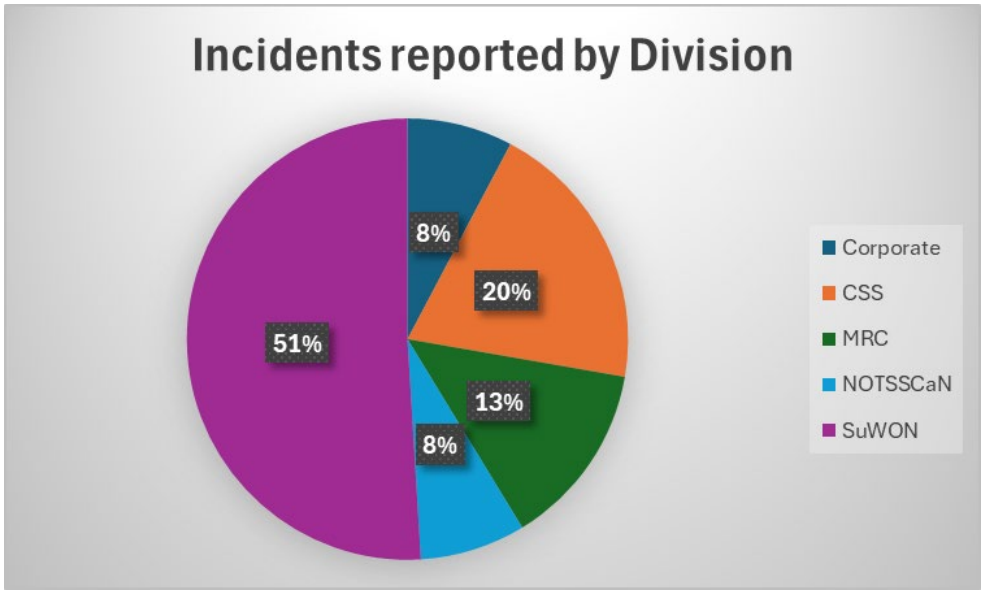

Figure 9. Incidents reported on Ulysses, by Division

Training

17.19. 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. All this training is now only delivered online.

Classification Group

17.20. 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 monthly, or more often where there is high demand, classified a total of 133 projects during 2024-25. 115 were reviewed at meeting and 16 were reviewed and approved by email.

18. Research Contracts and IP

18.1. The number of research and IP related cases finalised in 2024-25 (1360) is 21% higher than 2023-24 (1121) and a return to a similar level to 2022-23 (1345). The breakdown of contract types in Table 6 shows increases in most categories from the previous year, particularly site agreements and amendments.

18.2. Compared to 2023-24, there has been a 74% increase in the number of cases completed for Oxford Health, for whom we provide a research contract service. This has led to a renegotiation of the service provision which will be reported on next year.

Table 6. Cases completed by the Research Contracts and IP team in 2024-25

Case type	Number
Clinical Trial Site Agreement	276
Confidentiality Agreement	274
Amendment	266
Oxford Health	158
Grant Application	146
Collaboration Agreement	123
Service Agreement	72
Data Transfer Agreement	19
Assignment/Revenue Share	13
Other	9

MTA Donor Academic	4
Total	1360

18.3. The team continues to use DocuSign to initiate and manage efficient paperless execution of agreements, including signatures for Oxford Health contracts. Use of electronic signatures during 2024 resulted in an estimated 2,347 lb reduction in carbon emissions, 2,945 gal of water conserved, 1,000 lb of wood saved, and 162 lb of waste eliminated.

19. Local, Regional and National updates

Local (OUH)

19.1. Half day 'Team Consolidation Meetings' for all members of the R&D teams were held in July and December. These in-person events were attended by over 90% of the R&D members. The main sessions included the Staff Survey 2023 (Time to Talk), a review of the Annual R&D Governance and Performance report for 2023-24, and an update on training and development for R&D staff. Feedback was very positive: 83% Agreed or Strongly Agree with the statement 'I found the R&D Teams Consolidation meeting useful'. The next Team Consolidation Meeting will take place in July 2025.

19.2. The R&D Finance team has worked closely with Corporate Finance colleagues on a project to review and follow-up invoices issued by OUH for research activities which have been unpaid for many months. This has helped ease pressure on the Trust's cash position. Improved business-as-usual internal processes have been identified to help ensure this is managed effectively.

19.3. The R&D section of the OUH intranet has been completely redesigned and updated by members of the R&D teams, providing extensive guidance and information for all colleagues involved in conducting or supporting clinical research at OUH.

19.4. Recognising the significant potential of AI tools to transform many of their teams' most time-consuming and/or repetitive activities, including those related to trial set-up, OUH R&D and pharmacy arranged a Microsoft Copilot workshop in January, with focussed follow-up sessions extending into May. Following this, team members will be supported to use Copilot and peer-to-peer support to drive adoption.

Oxford JRO

19.5. The annual JRO Away Day was held in July 2024. Around 100 members of the research support teams from all four partner organisations attended (in person). The programme included brief updates from the JRO co-leads, a session on the power of networking, several talks by researchers and concluded with a presentation from the UCLH/UCL Joint Research Office. It was well-received by JRO colleagues; 85% Agreed or Strongly Agreed with the statement 'I found the JRO Away Day useful'.

19.6. The JRO Brochure, which provides an overview of the JRO and its constituent teams in all four partner organisation, was updated in February 2025.

19.7. The JRO has relaunched occasional seminars, on topics of interest to Oxford clinical researchers and those supporting them. The first 'Oxford JRO Seminar', in February 2025, was on the Thames Valley and Surrey Secure Data Environment (SDE), with presentations from SDE leaders followed by a panel discussion and Q&A with the audience. This was a live in-person event, chaired by Prof Keith Channon, Director of the Oxford Academic Health Partners, with over 100 attendees, around half of whom joined virtually. A recording is available on the OAHP website and the next JRO Seminar (on the BOB Integrated Care Board, and its research priorities) is scheduled to take place in May 2025.

Regional

19.8. The NIHR Thames Valley and South Midlands Local Clinical Research Network (LCRN), hosted by OUH, was closed on 30 September 2024 due to a major national reorganisation. As of 1 October 2024, OUH has been one of the Trusts which come under the South Central Regional Research Delivery Network (RRDN), hosted by University Hospital Southampton (UHS).

19.9. Approximately 70 staff employed by OUH in LCRN roles were transferred to UHS under the Transfer of Undertakings (Protection of Employment) Regulations (TUPE) on 1 October 2024, following a thorough consultation process, led by OUH R&D and HR, working closely with their counterparts from UHS.

19.10. Following two successful small-scale meetings (one in Southampton and another in Oxford) towards the end of 2024, members of the OUH and UHS R&D teams attended a joint in-person workshop in March, supported by funds provided by the South Central RRDN. OUH and UHS are the two most research active organisations

in the South Central RRDN. This was valuable for both Trusts and opportunities were identified to share best practice, work jointly on solutions to common challenges and look at alignment of processes and joint working where appropriate. A further workshop is planned for September, and it is intended also to extend these discussions to OUH and UHS pharmacy.

19.11. The aim was to support ongoing collaboration of OUH and UHS, identifying opportunities to share best practice, work jointly on solutions to common challenges and look at alignment of processes and joint working where appropriate. This was valuable for both Trusts and will be repeated in September. These discussions will also be extended to OUH and UHS pharmacy.

National

19.12. OUH R&D was well-represented at the annual NHS R&D Forum meeting in May 2024, which attracted more than 800 R&D staff from around the UK. The eight members of the R&D teams who attended were responsible for a total of seven posters and one oral presentation between them. The lead authors for the posters subsequently shared this experience with colleagues at the R&D Teams Consolidation meeting. Abstracts submitted by R&D team members in December 2024 have resulted in another seven posters being accepted for the next NHS R&D Forum meeting in May 2025.

19.13. The Head of R&D Operations has been working with a small team from several JROs to run a survey to collect structured information about as many of the current UK JROs as possible, to understand similarities and differences in terms of their scale and scope, as well as how they are organised and managed. The preliminary results of this survey were shared during a workshop which the Head of R&D Operations is organised at the UKRD (R&D leaders in the NHS) Annual Summit in Birmingham in March. This has led to further discussions including with NHSE and the ambition to establish a national group of JROs, in which Oxford would play a leading role.