Oxford University Hospitals
NHS Foundation Trust

Cover Sheet

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Title:	**Research & Development Governance and Performance Report 2022-23**

Status:	**For Information**
History:	**This is an annual report to Trust Board**

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 2022-23.
2. With a portfolio of around 1500 active clinical research studies, OUH is one of the largest and most productive research-active university hospital NHS Trusts nationally.
3. The strength of the OUH partnership with the University of Oxford (OU), especially the NIHR Oxford Biomedical Research Centre (BRC) and the support of the Joint Research Office (JRO), underpinned the delivery of Oxford's world-leading achievements, at unprecedented speed, during the COVID-19 pandemic. They remain of crucial importance in providing OUH patients with new opportunities to benefit from research participation enabled, for example, by new facilities such as the refurbished Acute Multidisciplinary Imaging and Interventional Centre (AMIIC) and the NIHR Oxford CRF.
4. The recent expansion of the JRO to include research support teams from Oxford Health NHS Foundation Trust and Oxford Brookes University presents opportunities to further align and integrate research activities and processes across Oxford, for the benefit of a greater diversity of research participants, as well as researchers.
5. In common with other Trusts in England, the increased demand to set-up new studies as COVID-19-related restrictions have eased, and then to recruit to time and target, has been challenging. There is currently no formal process by which to compare OUH performance metrics with that of other comparable Trusts, but an analysis conducted using data held in the national Central Portfolio Management System (CPMS) suggests that OUH performance is well above average for set-up times and about average for delivery. The findings and recommendations in the recent O'Shaughnessy review are welcomed as a national focus on how to improve performance for commercial trials.

Recommendation

The Trust Board is asked to

- Receive this report and note the content.

Contents

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).

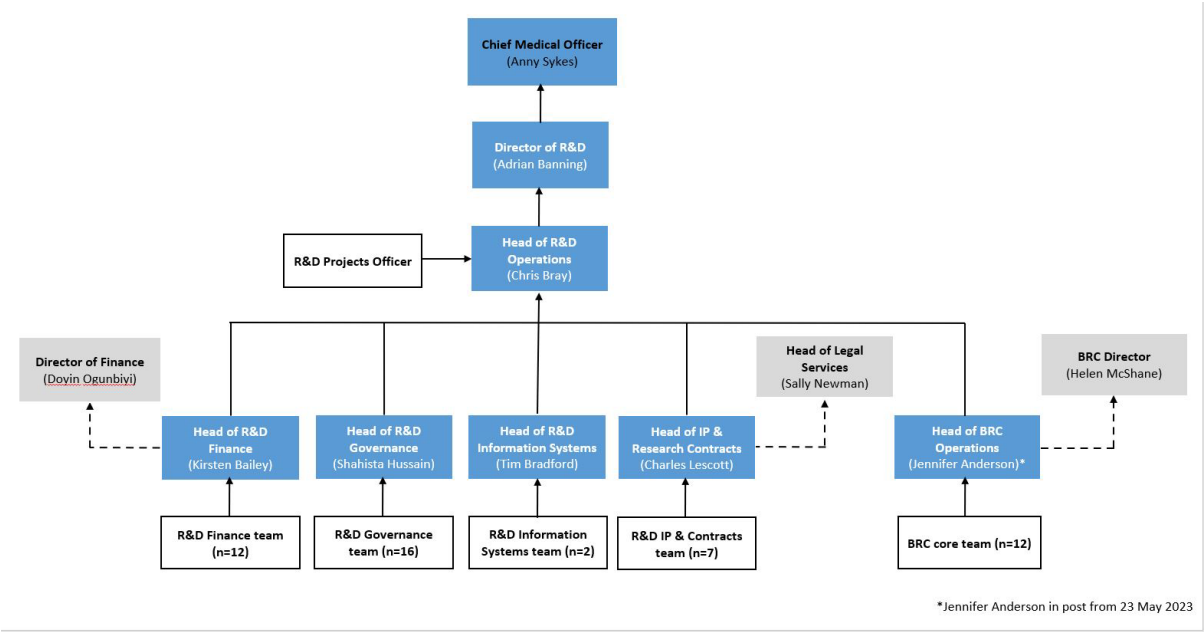

Figure 1. OUH R&D Organogram

1.3. 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

1.4. 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

1.5. The OUH R&D teams are part of the Joint Research Office (JRO), a partnership with the University of Oxford established 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 NIHR Oxford Biomedical Research Centre (see Section 4).

1.6. Further information about the activities of the JRO, including its expansion 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 9 of this report.

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 features prominently in OUH's strategy for 2020-25. It is included, 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. The incidence of COVID-19 and the need for wide-ranging measures to reduce the risks of its spread in all settings, including hospitals, had reduced significantly by the start of 2022-23. At the same time the number of COVID-19 studies had also declined significantly and these could no longer be assumed to be higher priority than other studies. For these reasons the OUH/OU COVID-19 Clinical Research Review Group, which played such an important role in overseeing and

coordinating COVID-19 studies, which had been automatically prioritised during the pandemic, was disbanded at the end March 2022.

2.4. Since April 2022 all requests to set-up new studies have therefore 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, activity 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 the 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 by 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 we are developing proposals 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. In recent months it has also been 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 the review of studies which are not progressing in the current context, with the aim of giving as many studies as possible the chance of completing and yielding results, to generate the evidence needed to improve care and sustain our health and care system. However, this has had relatively little impact on OUH hosted studies, thanks in part to the R&D-led comprehensive review of all paused OUH-hosted non-COVID-19 studies completed in Q3 2021, which resulted in the closure of around 500 of these studies because they were judged unlikely to be able to deliver.

2.10. The O'Shaughnessy review was commissioned by the government 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. The final report, which was published in May 2023, 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. In its response, the government has already accepted some of these recommendations and will be exploring the others over the coming months, ahead of a full implementation in autumn 2023. OUH R&D is already actively engaged with several recommendations, including full adoption of the National Contracts Value Review (NCVR) process, and measures to ensure that income generated by commercial sponsors is explicitly directed to those areas leading trials at OUH, to provide direct financial incentives to take part in commercial trials. Other recommendations will be implemented, as appropriate, once the government's position has been confirmed, and OUH R&D will take every opportunity to contribute to forthcoming discussions with relevant national bodies as part of this process.

Current levels of activity

2.12. A total of 1495 OUH-hosted clinical research studies were active (i.e. open to recruitment, recruiting or in follow-up) during 2022-23. This is virtually identical to 2021-22, when the figure was 1493. Of these studies, 82% were on the NIHR portfolio, and 499 reported recruitment in 2022-23, more than any other NHS Trust in England, recruiting a total of 23,769 participants (the second highest for any NHS Trust in England).

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, 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 the Appendix.

2.14. These studies all have to 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 total number of studies can be broken down into those that are **Hosted** (i.e. OUH is the NHS organisation providing the clinical environment, capabilities and patient care) or **Sponsored** (i.e. OUH takes legal responsibility for the conduct of the study, as well as hosting it) by the Trust (see 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	507	6	513
	Clinical investigation or other study of a medical device	64	8	72
	Other clinical trial	194	14	208
Sub-total		765	28	793
Non-interventional	Other study	645	57	702
Total		1410	85	1495

2.16. The majority of OUH active clinical research studies are hosted for external Sponsors, of which OU is the largest, responsible for 374 (25% of the total).

2.17. Although the number of OUH-sponsored studies (85) 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. However, this is an important part of the support provided by R&D especially for its staff, many of whom rely upon this

level of support from OUH as they take their first steps as Chief Investigators, leading their own studies.

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

Research activity by OUH Division

2.19. Figure 2 presents a breakdown of the 1495 studies of all types hosted by the Trust in 2022-23, 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.

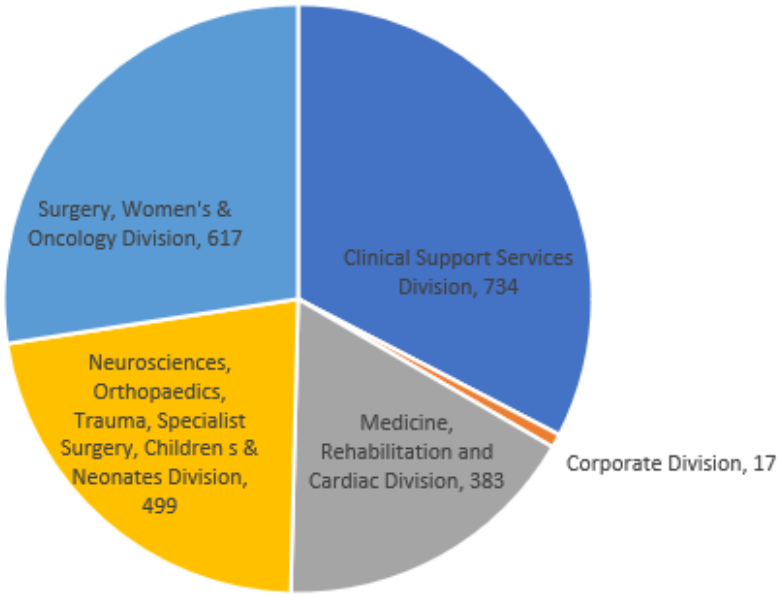

Figure 2. Active research studies at OUH in 2022-23, by Division

Studies opened to recruitment during 2022-23

2.20. A total of 303 new clinical research studies received approval from R&D to start recruiting during 2022-23. Of these, 91 (30%) were commercial and 212 (70%) non-commercial. The number of approvals/month is shown in Figure 3.

2.21. The mean number of approvals was 25/month, which is comparable to the number of approvals before the pandemic. This is significantly lower than the ~40/month achieved during 2021-22, when demand for set-up was at its peak as pandemic-related restrictions eased. However, the number of studies approved for set-up by LROGs and awaiting R&D approval 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.

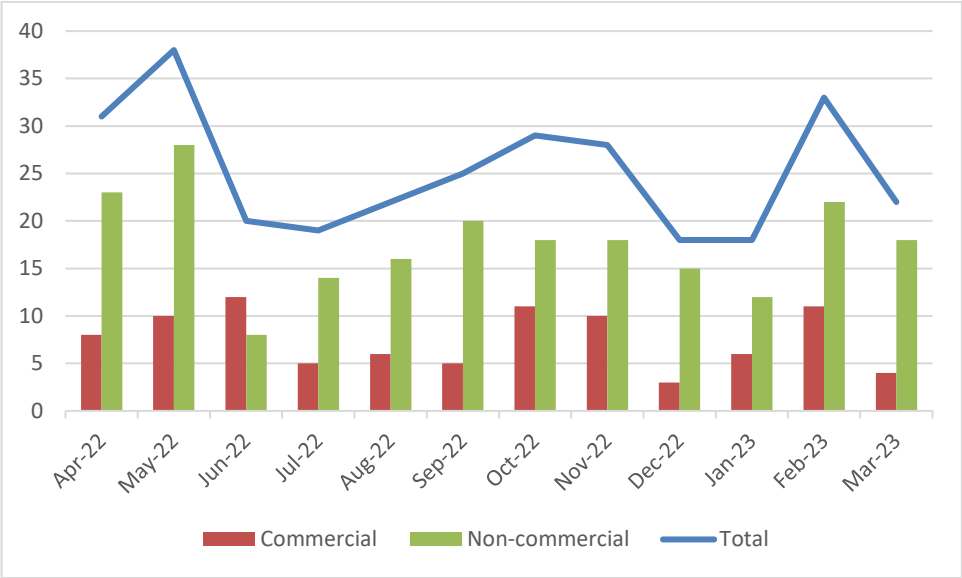

Figure 3. Studies approved to start recruitment during 2022-23

2.22. The vast majority (88%) of the 303 studies approved in 2022-23 were recruiting studies. 5% were PIC sites, where OUH identifies potential research participants to be recruited at a separate research site, usually one of the other Oxford Academic Health Partner (OAHP) organisations (OU, Oxford Health NHS Foundation Trust, or Oxford Brookes University). 4% were service sites where OUH provides services such as laboratory analysis or imaging, again usually for another OAHP organisation.

2.23. 252 (83%) of the studies approved to start at OUH in 2022-23 were on the NIHR portfolio (96% of the commercial studies and 76% 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 so that members of the R&D teams responsible for progressing set-up activities (contracts, costing and local capacity & capability) can now capture the time spent waiting for input from others. This system now been in use for several months. Sufficient data should soon have been collected to conduct quantitative analyses of the main causes of delay, which will be used to identify opportunities for improvements to be made at OUH. These may include streamlining the costing process, which is already underway as part of the National Contract Value Review (NCVR) process. Other known issues outside our control include delays with approvals from national regulators, especially the MHRA, which have

been acknowledged but we have been advised that it is likely to be several more months before any improvements will be apparent.

Substantial and non-substantial amendments

2.25. In addition to setting-up new studies, processing amendments to active studies represent a significant amount of activity for the Trust's R&D teams. 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. This represents a significant amount of activity, with a total of 1833 amendments processed during the past year, of which 999 were substantial and 834 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. In December 2022 Trusts were informed that that 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 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.

3.5. It is therefore not possible to use PID metrics for the purposes of this report, as they only cover the first half of 2022-23, and their successor is not yet available.

3.6. For the purposes of this report, the best alternative at this time is therefore to source performance data for OUH from the NIHR's national Central Portfolio Management System (CPMS), with the support of colleagues from the CRN. This allows historical comparisons to be made, as well as comparisons with the other largest teaching and research NHS hospital trusts in England. However, it should be noted

that these data use different definitions to PID metrics and may not always be complete and up to date – an issue identified in the O'Shaughnessy review into commercial clinical trials in the UK. The analyses in this report are therefore not directly comparable to the PID metrics which have been reported in previous years' R&D Governance and Performance reports.

Summary of performance for 2022-23

Performance in Initiating Research
(for all interventional portfolio trials opened – commercial and non-commercial)

3.7. 95 interventional trials initiated at OUH in 2022-23 have started recruitment (First Participant First Visit (FPFV)) and are included in this analysis. This figure is similar to 2019-20 (105), before the impact of the COVID-19 pandemic, but lower than 2021-22, when 148 trials were initiated and began recruitment, as part of a concerted effort to address the pent-up demand for new studies to be set-up as pandemic restrictions were eased. The figures for each quarter, from 2019-20 to 2022-23, inclusive, are shown in Figure 4.

3.8. Similar to the previous PID metrics, the key metric used here to monitor and to compare Trusts' performance in initiating research is the mean interval (in calendar days) between Date Site Selected (DSS) and FPFV. DSS is defined as the "*Date when the sponsor has provided the minimum defined documents to enable site to commence arrangement and/or confirmation of local capacity and capability as applicable representing that the site has been selected to take part in the study*".

3.9. As shown in Figure 4, the mean DSS-FPFV for OUH ranges from 90-123 days in each quarter in 2022-23. This is significantly lower (i.e. better) than the period before the pandemic, and there has been a clear progressive improvement over the last two years.

3.10. For the last three years the mean DSS-FPFV for OUH has been consistently lower (by around 30% in 2022-23) than that for the Shelford Group of Trusts[1], which has been identified as an appropriate comparator for the purposes of this report.

[1] The Shelford Group is a collaboration between ten of the largest teaching and research NHS hospital trusts in England https://shelfordgroup.org/members/

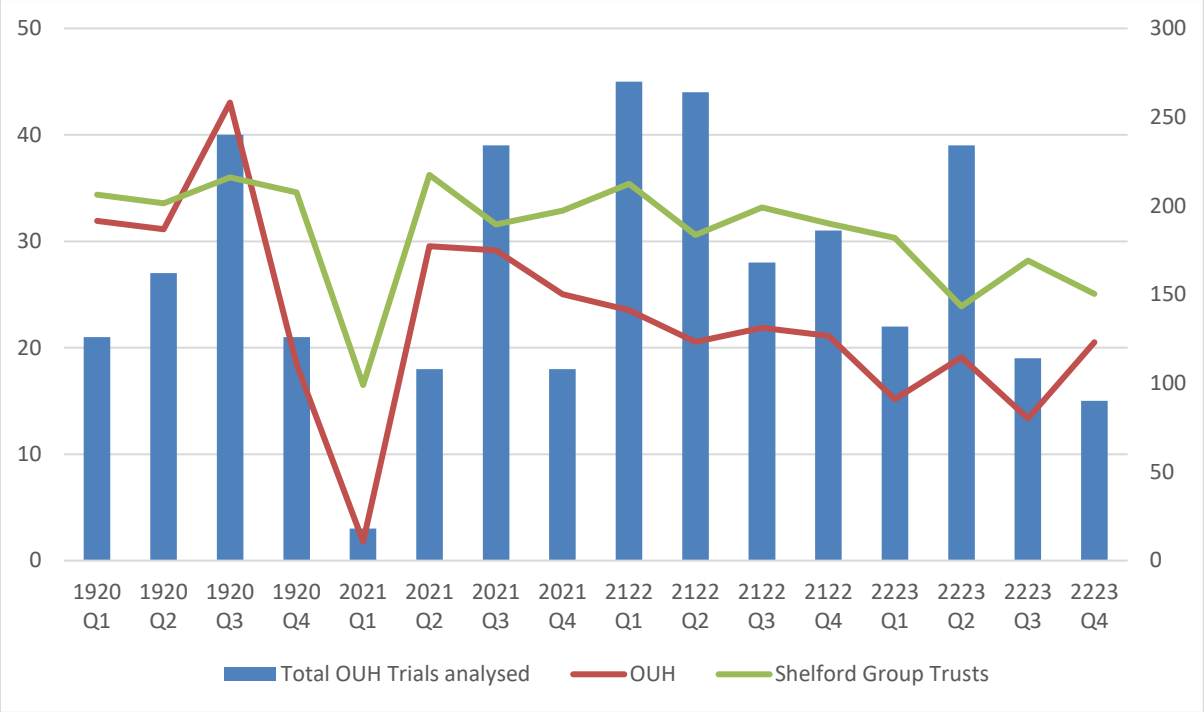

Figure 4: Mean Date Site Selected (DSS) - First Participant First Visit (FPFV) interval, for studies initiated each quarter

3.11. The discontinuation of PID metrics means it has not been necessary to collate and report to the NIHR the reason(s) why study set-up and first recruitment have been delayed – if applicable.

3.12. To get a better understanding of the nature, magnitude and causes of set-up delays, OUH R&D has recently enhanced the Studyline portfolio management system to allow set-up activities to be tracked at a much greater level of detail – in particular to capture the time R&D teams are waiting for input from others (especially the sponsor). Having collected these data for several months, it will soon be possible to analyse them to draw some conclusions and identify areas for improvement locally and also to contribute robust information about set-up delays – especially regarding commercial studies – to ongoing national discussions.

Performance in Delivering Research
(for all commercial interventional portfolio trials closed to recruitment)

3.13. This metric only applies to trials with a commercial sponsor and relates to recruitment numbers within the time period specified in the agreed contract with the host Trust. It should be noted, however, that the current processes by which the national records used for this analysis are updated if individual sites agree new targets with sponsors may not be reliable.

3.14. As shown in Figure 5, between 40-71% of these trials closed at OUH each quarter during 2022-23 recruited to time and target. This is lower (i.e. worse) than in 2019-20 (pre-pandemic) when at least 71% of trials closed each quarter had recruited to time and target.

3.15. OUH's performance in terms of recruiting to time and target is broadly comparable to that for the Shelford Group of Trusts.

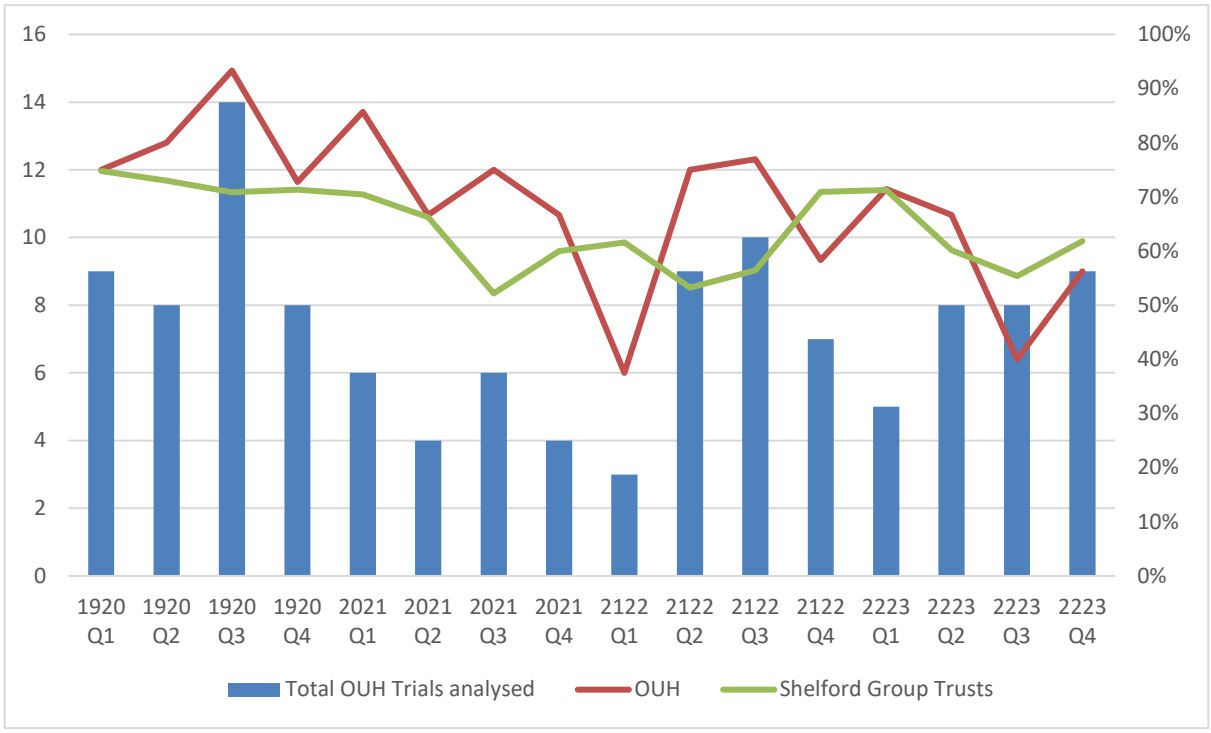

Figure 5: % recruited to time and target for studies closed each quarter

3.16. Recent statements made by the DHSC and NIHR, including at the national NHS R&D Forum meeting in May 2023, have made it clear that delivery to time and target – especially for commercial studies – will be the main focus of attention for improvements at a national level in the coming months. As part of the transition to the new national Research Delivery Network, which will replace the current Clinical Research Network from October 2024, it is expected that a new reporting process will be introduced to support this focus and there will be a greater emphasis on proactive engagement with sponsors to identify in a timely manner studies that are not progressing as planned, so that appropriate action can be taken. OUH R&D is also developing new tools in PowerBI which will help R&D, PIs and others to work together more effectively to improve the percentage of studies where OUH meet its target, as a recruiting site. This is likely to be part of an expanded remit for the Local Research Oversight Groups (LROGs), overseen by the Assessment & Prioritisation Panel (APP), in future.

4. NIHR Oxford Biomedical Research Centre (Oxford BRC)

4.1. The new NIHR Oxford Biomedical Research Centre was officially launched on 1 December 2022. The BRC was awarded £86.6m in government funding over the next five years to improve diagnosis, treatment and care for NHS patients. This fourth successive round of funding for the Oxford BRC will support translational research across 15 research themes:

- Digital Health from Hospital to Home
- Genomic Medicine
- Modernising Medical Microbiology and Big Infection Diagnostics
- Life-saving Vaccines
- Cancer
- Respiratory Medicine
- Cardiovascular Medicine
- Translational Data Science
- Surgical Innovation, Technology and Evaluation
- Musculoskeletal
- Inflammation Across Tissues
- Metabolic Experimental Medicine
- Preventive Neurology
- Imaging
- Gene and Cell Therapy

4.2. In total, the NIHR awarded nearly £800 million to 20 BRCs across England, following an open and competitive process judged by international experts and members of the public. This included £35m awarded to Oxford Health NHS Foundation Trusts for the Oxford Health BRC, bringing the total funding to both BRCs in Oxford to £122m over five years.

4.3. The Oxford BRC has been awarded the Freedom of the City of Oxford, the highest honour Oxford City Council can bestow. Councillor Louise Upton, who proposed the conferment, said the BRC's researchers had "saved more than six million lives by producing the Oxford-AstraZeneca Covid-19 vaccine, and their work across many other diseases has had and will continue to have a huge and beneficial impact on patients, both in Oxfordshire and nationally".

4.4. Following an external audit, the Oxford BRC was again successful in its ISO 9001 audit. Achieving this standard means an organisation has excellent quality management systems in place.

4.5. 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, examples of which are provided in the Appendix to this report.

People, Leaders and Awards

4.6. A team who developed a novel device to measure lung function were among several Oxford researchers to receive prestigious prizes from the Royal Society of Chemistry (RSC). The Molecular Flow Sensor Team – a multidisciplinary collaboration between chemists, physiologists, computer modellers and OUH clinicians – won the prize for the development a molecular flow sensor for non-invasive breath analysis to provide measurements of respiratory disease and cardiac output. The team includes Professor Peter Robbins from the Oxford BRC's Respiratory Theme.

4.7. Professor Fiona Powrie, who leads the Oxford BRC's Gastroenterology and Mucosal Immunity Theme, was made a Dame in the 2022 Queen's Birthday Honours List for services to Medical Science. She has made major contributions to our understanding of the immune system and has helped transform our understanding of how gut bacteria interact with the immune system.

4.8. Professor Marian Knight, the Oxford BRC's Co-Theme Lead for Cardiovascular Medicine, was awarded an MBE for services to Maternal and Public Health in the New Year's Honours.

4.9. OUH Director of Nursing and Midwifery Research and Innovation Professor Helen Walthall was appointed as a Senior Research Leader on the NIHR Nursing and Midwifery Programme, aimed at embedding a culture of research amongst nurses and midwives. Professor Walthall will spend the equivalent of two days a week working nationally while continuing her OUH role – and her role as Nursing, Midwifery and Allied Health Professionals Research Capacity Lead for the Oxford BRC – for the remainder of her time.

4.10. The Oxford BRC's Theme Lead for Cardiovascular Medicine, Professor Barbara Casadei, has been named an NIHR Senior Investigator in recognition of her outstanding leadership in research. Three other Oxford BRC researchers - Professor Matt Costa (musculoskeletal), Professor Richard McManus (primary care) and Professor Helen McShane (vaccines and BRC Director) – were reappointed to this prestigious position.

4.11. Joanna Snowball became the first OUH dietitian to be accepted onto the NIHR's Pre-doctoral Clinical and Practitioner Academic Fellowship (PCAF) scheme. Joanna, whose research focuses on how to support people with cystic fibrosis who are experiencing rapid weight-gain as a result of new medications, has received career support from the Oxford BRC.

4.12. OUH Clinical Academic Nurse Researcher Jody Ede was given an award by the British Federation of Women Graduates to continue her SUFFICE study, exploring how to improve the escalation of care for patients whose condition deteriorates in the hospital setting.

4.13. For International Nurses Day, the Oxford BRC produced a profile of clinical academic nurse researcher Dr Louise Strickland, who, with BRC support, is applying to be the first nurse at OUH to be awarded a postdoctoral research fellowship.

Training

4.14. Aspiring healthcare research leaders successfully completed the latest Oxford BRC Next Generation Leaders Programme, with course participants presenting the quality improvement projects they had been working on. Topics included health economics; equality, diversity and inclusion; research protocol writing; and patient and public involvement and engagement. This is the third edition of the six-month programme, commissioned and designed by the Oxford BRC to enable early- to mid-career researchers and health professionals to develop key skills in leadership and management capability.

4.15. Eight researchers supported by the NIHR attended the first dedicated training session on Equality, Diversity and Inclusion (EDI), run jointly with the Oxford Health BRC and the ARC Oxford & Thames Valley. It was one of a series of career development workshops for the BRC Senior Research Fellows, the others being leadership, change management and entrepreneurship.

Patient and Public Involvement and Engagement in Research

4.16. The BRC has created two videos highlighting the importance of involving people from diverse and under-served communities in the design and delivery of clinical trials and studies to ensure they benefit the people and communities who need it most. One video focuses on the participant perspective and the other shows researchers explaining how involving people from diverse communities added value to their research.

4.17. Members of the public involved in health research in Oxford attended a training workshop organised by the Oxford BRC and Oxford Health BRC

focused on the ways in which equality, diversity and inclusion (EDI) can help improve the quality of research.

4.18. The Oxford and Oxford Health BRCs have developed a survey to better understand the demographic make-up of members of their various patient and public involvement and engagement (PPIE) groups. The Tell Us About You survey was developed with vital input from their Diversity in Research Group. The aim of the survey – available for use across the BRCs' PPIE groups – is to capture demographic information, such as age, gender, race etc, to get a clearer picture of exactly who is involved in research, how representative they are of the general population and which sections of society are under-represented.

4.19. Patient and public contributors gathered with researchers in Oxford to discuss how patient and public involvement and engagement (PPIE) can be enhanced and play a bigger role in the Oxford and Oxford Health BRCs. The workshop at St Catherine's College, attended by representatives from a wide range of PPIE groups, was an opportunity to introduce the new research to be undertaken by the BRCs, but also to explore how to get more patient and public contributors – especially from under-served communities – involved.

4.20. Representatives of academia, the NHS, the non-profit sector and the healthcare industry attended a conference in Oxford on 30 May to explore how to tackle the current challenges in dementia research through improved collaboration. The 21st Century Translation Dementia Research conference was organised by the Oxford BRC and Dementia Research Oxford. A series of workshops and roundtable discussions sought to identify key challenges and opportunities for improved joint working with industry. There were also plenary sessions on the use of data science; how to use the RECOVERY Trial model for future dementia treatment trials; and new opportunities for biomarkers in precision medicine.

4.21. The Oxford BRC held a joint Open Day with the Oxford Health BRC at Oxford Town Hall on 5 July 2022. The Open Day, the first the BRC has been able to hold for over three years, was 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.

4.22. Senior Oxford BRC researcher and OUH Consultant Neurologist Professor Michele Hu took part in an NIHR public webinar about Parkinson's disease research on 19 July. The session was chaired by former BBC technology correspondent Rory Cellan-Jones, who was diagnosed with Parkinson's in 2019.

4.23. The BRC held the following virtual public talks, aimed at engaging the public in its research, recordings of which are available on the BRC's YouTube channel:

- Prof Kazem Rahimi, Professor of Cardiovascular Medicine and Population Health, spoke about his research into whether lowering blood pressure can help to prevent type 2 diabetes.
- Dr Luke Jostins-Dean, of the Kennedy Institute of Rheumatology, discussed his research into the possible genetic links between inflammatory bowel disease and anxiety.
- Professor Richard Bulbulia gave a talk on which treatment for carotid artery disease – stents or surgery – is more effective at reducing the risk of stroke.
- Professor Mark Middleton, Director of the Cancer Research UK Oxford Centre, and Sue Duncombe, a member of the Oxford Patient and Public Involvement (PPI) Group, discussed how using blood tests to detect cancer early might impact on cancer care in the NHS.

5. NIHR Oxford Clinical Research Facility (Oxford CRF)

5.1. OUH, in partnership with OU, bid successfully in the competition for NIHR Clinical Research Facility designation (2022-27). The Trust was awarded a £1 million grant over 5 years to establish a new NIHR Oxford CRF network. This seed funding, which started in September 2022, has been supplemented by an additional £2 million from other sources, and will be focussed on building research nursing capacity, developing patient and public involvement in clinical research, and supporting a core management team.

5.2. The Oxford CRF features a federated model which brings together the existing NOC CRF, the CRU at OCDEM and the new Experimental Medicine CRF set-up by OU on the Churchill site in summer 2021, as well as a new paediatric CRF in the Children's Hospital.

5.3. The expansion and reorganisation of the CRFs, which each have a different and complementary portfolio of research, will significantly increase and improve opportunities for OUH patients to benefit from new treatments.

5.4. Discussions between OUH and OU following refurbishment of the EMCRF in 2021 highlighted the need for a Collaboration Agreement to govern to operation of the CRFs, to ensure alignment with the regulatory, governance, estates and other requirements of both

organisations. The OUH Board approved the Collaboration Agreement for signature in May 2022.

5.5. 29 participants have been recruited to two studies in the Experimental Medicine CRF during 2022-23 and it is expected that many more will be recruited to studies across the CRF network in the future, with the Collaboration Agreement significantly streamlining and expediting the study set-up process.

6. Research Governance

Background

6.1. 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:

6.2. 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.

6.3. 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.

6.4. 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 is awaited.

6.5. 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).

6.6. 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.

6.7. 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).

6.8. 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.

6.9. 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).

6.10. 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. 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

6.11. 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 governance team undertakes monitoring visits for each OUH-sponsored regulated trial.

6.12. 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 governance team. These trials are selected through a risk-based approach.

6.13. Compliance checks. The governance team also routinely undertakes assessment of compliance with various aspects of clinical research; primarily focussing on informed consent and safety reporting. The 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. These checks were put on hold during the pandemic but since they restarted in January 2023, 26 studies have been selected across both programmes.

6.14. Safety Reporting. As Sponsor, the Trust 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 and 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 2022-23 OUH has reviewed 84 SAEs which have also been presented at the quarterly Trial safety group meetings.

6.15. 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. R&D contributed to a review of OUH's consent policy and processes, which has led to appropriate consent for clinical samples and clinical data to be used in future research studies being integrated with consent for clinical procedures.

Training

6.16. In collaboration with the OU Research Governance, Ethics and Assurance (RGEA) team, the OUH R&D Governance team prepares and delivers training to both Trust and University 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.

6.17. For CTIMPs (drug trials) there are both online and face-to face GCP courses available, with an online assessment to help experienced researchers assess their need for updating their knowledge. Both are recognised by industry sponsors due to their accreditation by Transcelerate, as well as the Royal College of Physicians.

6.18. An additional training course designed specifically for clinical researchers not engaged in the conduct of a CTIMP is also provided. Informal training is provided in the form of advice and support to researchers and their teams.

6.19. Face-to-face CTIMP training or non-CTIMP training, which was stopped at the start of the pandemic, had not resumed during 2022-23. However, 143 people attended training on Obtaining HRA and Ethics Approval which was delivered online and a further 487 applicants have been accepted onto the online GCP training course, which they work through in their own time.

6.20. Good Research Practice (GRP) training, which used to be delivered in-person, was suspended in March 2020 due to the of the COVID-19 pandemic. It has since resumed via MS-Teams and 97 people have attended since January 2022.

Letters of Access, Honorary Research Contracts and Research Passports

6.21. The Governance team processed and authorised 109 applications for Letters of Access and 14 Honorary Research Contracts to enable research activity to take place at OUH. Additionally, the team also

validated research passports for Oxford-based researchers planning to perform research activities in other NHS Trusts.

Classification Group

6.22. 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 80 projects during 2022-23.

7. Research and Development Finance

7.1. 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 include 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 and providing and paying invoices for studies once they are active.

7.2. 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 2023

7.3. For the 2022-23 financial year, the annual income and expenditure budget for R&D was set at £53 million, as shown in Table 2. This included income and expenditure of £42 million from major NIHR grants for hosting the Oxford BRC and the LCRN, as well as other smaller NIHR grants. £11 million of income and expenditure was budgeted for commercial and non-commercial (non NIHR) research projects.

Table 2. High level breakdown of 2022-23 R&D budget

Research Funding by area	2022-23 Expenditure (£m)
NIHR Biomedical Research Centre (BRC)	22
NIHR Local Clinical Research Networks (LCRN)	18
NIHR Research Capability Funding (RCF)	1
Other NIHR grants	1
Other income (commercial & non-commercial)	11
	53

7.4. At the end of the financial year (31 March 2023) all the major NIHR programme and smaller grants achieved a breakeven position as planned, and income exceeded expenditure by £1.8 million from the individual study accounts for all the commercial and other non-commercial trials and other research activities.

Research Capability Funding

7.5. 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 has been a very important funding stream for research at the Trust.

7.6. The RCF award received by OUH in 2022-23 was £1.2 million. This was 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 maternity and long term sick leave. This enabled NIHR grant funded research to continue while key research staff have been on leave from the organisation.

Financial Planning 2023-24

7.7. The following budget has been set for 2023-24:

Research Funding by area	2023-24 Expenditure budget (£m)
NIHR Biomedical Research Centre (BRC)	18
NIHR Local Clinical Research Networks (LCRN)	19
NIHR Research Capability Funding (RCF)	1
Other NIHR grants	1
Other income (commercial & non-commercial)	12
	51

7.8. The core budgets for each of the 15 individual research Themes, as well as the management team, in the new five-year BRC award have all been confirmed for the next year.

7.9. The current agreement with the NIHR to host the LCRN for the Thames Valley and South Midlands has been extended for 6 months until 30 September 2024. The total funding for the Thames Valley and South Midland for 2023-24 is £19 million.

7.10. The LCRN budget to support research at OUH for 2023-24 is £7.3 million. Final budgets to support research in each clinical area at OUH have been considered and awarded as the funding allocation allowed. The budget setting process was communicated in the usual way, with the network management team and the R&D finance team working closely with stakeholders to agree budgets before the start of the financial year.

7.11. As in previous years the BRC and LCRN budgets forecast a break-even position for 2023-24.

7.12. The Research Capability Funding (RCF) award to OUH for 2023-24 is £873k; 29% less than last year (£1.2 million). DHSC have been reducing the total national annual allocation of RCF for several years, and changed the weighting of how the awards are allocated for each NIHR income stream which calculates how much each Trust will receive. In comparison OUH received £5.5 million in 2016-17. OUH R&D has worked closely with senior Trust finance colleagues to agree how best to allocate this reduced RCF income in 2023-24 to support research activities in line with the NIHR guidance for this funding. However, he reduced RCF funding over the last few years has had a significant impact for OUH R&D funding to meet both OUH infrastructure costs and project-specific research capacity and pump-priming.

7.13. The budget for income (and expenditure) from commercial and other non-commercial studies has been set at £12 million in line with previous years.

7.14. The National Contract Value Review Process for the costing of commercial studies was implemented during 2022-23, following a delay of more than two years due to the COVID-19 pandemic. The aim of this new process is to standardise and streamline the costing of commercial contract research, in particular to minimise duplication of effort at each site, so these trials can be set-up more quickly in the UK. The OUH R&D finance team has been actively involved in this process, and had costed 11 studies to March 23 where OUH is the lead site.

8. Research Contracts and IP

8.1. During the year to 31 March 2023, 1,345 research and IP related cases were finalised on behalf of OUH, continuing the steady increase in output over several years. The team also continued its contracting service to Oxford Health NHS Foundation Trust, closing 94 cases. Clinical trial agreements and confidential disclosure agreements were the two most numerous contract types to be completed; 332 and 335 respectively. This was closely followed by study amendments (273). Each type of agreement had an increase on last year.

The remaining smaller categories include Material Transfer Agreements (MTAs), Service Agreements (SAs), Collaborations, Data Transfer Agreements (DTAs) and IP related agreements. A breakdown of the Research Contracts and IP team's main activities in 2022-23 is provided in Table 3.

Table 3. Research contract and IP cases completed 2022-23

Case type	Number
Confidentiality Agreement	335
Clinical Trial Site Agreement	332
Amendment	273
Grant Application	114
Oxford Health NHSFT	94
Collaboration Agreement	72
Service Agreement	58
Assignment/Revenue Share	24
Data Transfer Agreement	19
MTA Donor Academic	12
Other	12
Total	**1345**

8.2. The team was stable during 2022-23 with the two members recruited last year improving their output as their knowledge and experience grows.

8.3. Major projects undertaken this year include agreeing new BRC and CRF funding agreements. Work on putting in place the associated Partnership Agreements with the University of Oxford continues and should be completed soon.

8.4. Analysis of how revenue is shared from exploitation of BRC funded intellectual property was conducted along with the Commercial Team.

8.5. Since moving to hybrid working, contracts are signed electronically whenever possible and the team has an account with DocuSign to initiate electronic signatures with other parties. This significantly improves efficiency in collecting signatures and has added environmental benefits too; figures from DocuSign for the last three months alone show it has resulted in an estimated 2,328 lb of carbon emissions reduced, 2,920 gal of water conserved, 991 lb of wood saved, 161 lb of waste eliminated; a small but worthwhile contribution to OUH's environmental objectives.

9. The Oxford Joint Research Office

9.1. With the encouragement and support of the Oxford Academic Health Partners (OAHP) and the Joint R&D Committee (JRDC), the JRO Co-leads from the founder partners (OUH and OU) have been working with colleagues from the new partners, Oxford Brookes University (OBU) and Oxford Health NHS FT (OH), to identify and develop opportunities for closer working and coordination of research support activities across the NHS/academia interface in Oxford.

9.2. Over 100 members of the expanded Oxford JRO, from all four partners, along with senior executives from each of their organisations, took part in a face-to-face JRO Away Day (the first since September 2018) in Oxford on 7 June 2022. The programme included talks by researchers whose studies depend upon support from the JRO, and a panel discussion chaired by Prof Helen McShane (Oxford BRC Director) with panellists representing all four partners, including the OUH CMO and Director of R&D. There was also a breakout group session in which mixed groups of attendees worked together to help define and refine some of the major common objectives which will be the focus of the expanded JRO's activities in the short-medium term.

9.3. Prior to the recent expansion of the JRO there were nine specialist subgroups within the JRO, each of which provides a forum for

colleagues from the original partners (OUH and OU) who are responsible for a particular area or activity to work together on delivering better support for researchers for the benefit of patients, now and in the future. The JRO Heads of Teams have recently developed proposals to extend the membership of some of these subgroups to representatives from the two new partner organisations, and to establish another five new specialist subgroups.

9.4. Representatives from the JRO's two Trust partners (OH and OUH) hosted a valuable informal in-person meeting with visitors from the DHSC in August. The topics discussed included barriers to the speed and efficiency of clinical research delivery, and closer alignment and cooperation with regards to sponsorship and contracts.

9.5. The JRO supported a two-day in-person Research Contracts training session in March for 28 attendees representing all four JRO partner organisations. By joining forces, it was possible to arrange for the providers to deliver this specialist training in Oxford in March. This represented a significant saving in terms of both time and money. It also had the added benefits of enabling some tailoring of the course and strengthening the JRO by allowing a cohort from the JRO partners to learn together.

10. Recommendation

10.1. The Trust Board is asked to receive this report and note the content.

APPENDIX. Illustrative examples of research supported by the Oxford BRC

COVID-19 related studies

Vaccines

Researchers have found that the higher risk of blood clots in COVID-19 outpatients, was largely reduced after vaccination. The Oxford BRC-supported research team were studying the link between people diagnosed with COVID-19 as outpatients and the short-term risk of developing blood clots, and the clinical and genetic risk factors that predispose them to developing post–COVID-19 thrombosis.

A study found that while COVID-19 vaccination is effective in most cancer patients, the level of protection against COVID-19 infection, hospitalisation and death offered by the vaccine is less than in the general population and vaccine effectiveness wanes more quickly. The study by the UK Coronavirus Cancer Evaluation Project, was led by the University of Oxford's Dr Lennard Lee and supported by the Oxford BRC.

Long COVID

OUH and the medical imaging technology company, Polarean Imaging plc, entered into a research collaboration to study the long-term effects of COVID-19 in patients still experiencing breathlessness months after infection. Polarean produce an investigational drug device combination product using hyperpolarised xenon gas to enhance magnetic resonance imaging (MRI) in pulmonary medicine. This technology will enhance ongoing BRC-supported research at OUH, such as the EXPLAIN Study into the possible long-term impact on the lungs of long COVID.

Oxford researchers found that prior COVID-19 infection is associated with more uneven inflation of the lungs during normal breathing. There was also an association between hospitalisation with COVID-19 and smaller lung volumes, and admission to the intensive care unit was associated with an enlarged respiratory 'dead space'. The BRC-supported study, based on 178 participants, including OUH patients, used a novel computational approach to assess how COVID-19 may affect long-term lung function.

Oxford University researchers have found a new way of directly quantifying vascular inflammation in COVID-19 patients, in a study that could pave the way to more efficient trials of new treatments and identify patients who might be at risk of long-term complications. The study, supported by the Oxford BRC, developed a novel image analysis platform, which uses artificial intelligence to quantify cytokine-driven vascular inflammation from routine CT angiograms to derive 'virtual biopsies'.

Other (non-COVID-19) research studies and activities supported by the BRC

An injectable cure for potentially fatal inherited heart muscle conditions could be available in a few years after a team of researchers led by Prof Hugh Watkins, the Oxford BRC's then-Theme Lead for Genomic Medicine, was announced as the winners of a major award from the British Heart Foundation. At £30m, it is one of the largest non-commercial grants ever given. Prof Watkins's CureHeart team aim to develop the first cures for inherited heart muscle diseases by editing or silencing the faulty genes that cause them.

The NIHR launched five new Blood and Transplant Research Units (BTRUs), three of them based in Oxford. The £20m programme, co-funded by NHS Blood and Transplant, is aimed at providing new technologies, techniques or insights that will benefit donation, transfusion and transplantation, and that can be delivered at scale. The three units at the University of Oxford are Precision Cellular Therapeutics, Data Driven Transfusion Practice and Genomics to Enhance Microbiology Screening.

Around 15 percent of people aged between 40 and 75 may have a form of undiagnosed high blood pressure that occurs only at night-time. Because they do not know about this, and are therefore not being treated for it, they are at a higher risk of cardiovascular disease such as stroke, heart failure and even death, according to new Oxford BRC-funded research.

University of Oxford researchers and their partners have reported new findings from their Phase 2b trial which tested the effectiveness of a booster dose of their candidate malaria vaccine, which had previously demonstrated high-level efficacy 12 months after being administered in West African children in 2021. In their latest findings, they found that a vaccine booster dose one year after the primary three-dose regime continued to meet the WHO's goal of at least 75 percent efficacy.

Recruitment got under way for a phase I clinical trial of a tuberculosis vaccine in human volunteers to develop a new way to test the efficacy of future TB vaccines. The study is led by Oxford BRC Director Prof Helen McShane. Until now, it has not been possible to use a human challenge study, where people are intentionally infected with a disease, to test a new tuberculosis vaccine. In this new study, volunteers are 'challenged' with the BCG vaccine administered through aerosol inhalation, with the aim of mimicking how TB bacteria enter the lungs. If well tolerated by the participants, this method could be used to test new TB vaccines in the future.

Oxford BRC-supported researchers launched the first UK study in the general population to test for early markers of type 1 diabetes before children develop symptoms or need insulin. This feasibility study will initially involve 60 children being screened in two GP practices in the Thames Valley when they attend their pre-school booster vaccination.

Oxford BRC clinical academics are leading a £2.2 million project aimed at giving more people newly diagnosed with type 2 diabetes the chance of going into remission. Professors Susan Jebb and Paul Aveyard joined forces with Diabetes UK on the five-year NewDAWN project, which is also being funded by the NIHR. They aim to create a new NHS support service for people newly diagnosed with type 2 diabetes who are overweight or living with obesity, so they can try different weight loss programmes and find the one that's right for them.

A new NIHR BioResource aimed at investigating inflammatory bowel disease (IBD) in children, led from Oxford by Professor Holm Uhlig, the Oxford BRC's Co-theme Lead for Inflammation, has opened. The new Paediatric Inflammatory Bowel Disease (PIBD) BioResource, with a national panel of volunteers who have consented to participate in health studies, will drive research into Crohn's disease and ulcerative colitis in children. The first participant was recruited at the Oxford Children's Hospital.

Professor Uhlig was one of the key researchers who coordinated new national guidelines for clinicians on the use of genomics to diagnose and care for patients with monogenic inflammatory bowel disease (IBD). The new guidelines, developed with several patient groups, have been endorsed by national gastroenterology bodies and adopted in clinical pathways by the NHS Genomic Medicine Service.

University of Oxford researchers were awarded a grant from the NIHR to investigate whether anti-tumour necrosis factor (TNF) therapy can reduce or prevent post-operative delirium, the most common surgical complication in older adults. Oxford scientist have already found that the trauma associated with surgery leads to the release of proinflammatory mediators, especially TNF, which in turn leads to inflammation of the part of the brain involved in memory. The new trial is led by Oxford BRC Co-theme Lead Professor Matt Costa.

Researchers supported by the Oxford BRC found that the anti-TNF treatment adalimumab is likely to be a cost-effective treatment for people affected by early-stage Dupuytren's disease. Anti-TNF treatments are commonly used to treat conditions such as rheumatoid arthritis and psoriasis. There is currently no approved treatment for early-stage

Dupuytren's disease, which causes the fingers to irreversibly curl into the palm due to nodules of tissue forming cords under the skin.

There is no added benefit of using citrate-based drugs in the treatment of acute kidney disease in intensive care, when compared to the anticoagulation drug heparin, despite their extra cost, new research has found. The study, which was supported by the Oxford BRC and involved OUH patients, was based on routinely collected data from a national audit of ICUs.

Researchers and clinicians in Oxford have begun an evaluation of artificial intelligence software that could help pathologists diagnose prostate cancer. Testing of the technology in a busy clinical setting, now under way at OUH is a key milestone in the University of Oxford-led ARTICULATE PRO study. The two-year project aims to help pathologists detect, grade and measure tumours in prostate biopsies as part of their routine work. The project forms part of the BRC's Surgical Innovation, Technology and Evaluation Theme, which is looking to combine Oxford's expertise in digital pathology with big data analysis to enhance surgical decision-making.

New research identified a genetic marker that could be used to predict a patient's risk of developing serious side-effects when undergoing immunotherapy treatment for skin cancer. The study, supported by the Oxford BRC, analysed genetic information from more than 200 patients undergoing treatment for melanoma, to find stretches of DNA that correlated with whether the patient developed severe side-effects from the treatment.

A new type of genetic variant has been discovered that can be responsible for two skeletal disorders. Whereas many genetic conditions are caused by structural variations that involve deletions, insertions or duplications of segments of DNA, an Oxford BRC-supported team found that the genes were partially inverted – the DNA sequence was in the correct place, but flipped upside down. Using data from the 100,000 Genomes Project, the researchers looked at 43 genes known to be connected to Greig syndrome and Marfan syndrome. Ten people from three different families were found to have genetic inversions.

Two studies by Oxford BRC-supported researchers showed that studying lymph nodes reveals details of the mechanisms of autoimmunity and are very different to those revealed by blood. Lymph node sampling was more accurate in identifying the mechanisms by which the autoantibodies were produced and better correlated with the clinical efficacy of treatments administered to the patients.

A study involving Oxford researchers has outlined a way to find the crucial peptides (protein fragments) that drive autoimmunity, as well as the immune cells that respond to it. The BRC-supported researchers identified peptides presented by the HLA B27 gene, the strongest genetic risk factor contributing to the arthritic disease ankylosing spondylitis (AS) and the inflammatory eye condition acute anterior uveitis (AAU).

A University of Oxford team received a grant from the national charity Asthma + Lung UK to study why women are more likely to have asthma and why they are twice as likely to die from it. The team, supported by the Oxford BRC, is analysing data from 12 previous studies to look at how inflammation of the airways might relate to hormone levels; which genes cause female forms of asthma; and how inflammation in women with asthma responds to steroid treatment. It is hoped that a better understanding of these factors might lead to new treatments and a more personalised approach.

An Oxford researcher was awarded Medical Research Council funding to expand her cutting-edge research into the genetic mechanisms of rare and severe forms of asthma. Dr Anastasia Fries's project, which is supported by the Oxford BRC, entails conducting whole genome sequencing on 500 patients with severe asthma in Oxfordshire. To work out how novel genetic findings drive asthma, the team will use an innovative approach using stem cells to grow lung tissue in the lab. The project arose from a single patient in the Oxford severe asthma clinic, who had an unusual form of severe asthma that had not responded to standard treatments.

A research team in Oxford launched a new project involving members of the public that is aimed at developing diagnostics for infection and antibiotic resistance. The team of physicists, microbiologists, data scientists and doctors, who are supported by the NIHR Oxford Biomedical Research Centre (BRC), have launched the 'Infection Inspection' citizen science project, hosted on the Zooniverse platform. Using a similar model to the successful 'Bash the Bug' project, 'Infection Inspection' asks members of the public to help classify images of E. coli that are either resistant or sensitive to an antibiotic.

The only project of its kind anywhere that studies patients with all types of acute vascular events – including strokes, heart attacks, aneurysms – in order to develop better diagnostic tests and treatments celebrated its 20th anniversary in April 2022. The Oxford Vascular Study (OxVasc) began in 2002 and involves University of Oxford staff at the John Radcliffe Hospital providing clinical care, carrying out scans and other investigations, and collecting detailed research data and blood samples.

It has recruited nearly 13,000 Oxfordshire participants and has then followed their progress for at least 10 years. A collaboration with about 100 Oxfordshire GPs, it is the first study in the world to assess and follow up all vascular conditions at the same time in the same population.

New research from an Oxford BRC-backed team revealed that treatment for the most common fracture in children can be simplified, reducing NHS costs. The study found there was no difference in pain or function between children with a torus fracture of the wrist who had a rigid splint and outpatient follow-up, and those who received a bandage and no planned follow-up.

A study by University of Oxford researchers found a genetic variant that increases the risk of both carpal tunnel syndrome and trigger finger, opening the door for potential new therapies. Trigger finger and carpal tunnel syndrome – two of the commonest hand conditions worldwide – frequently co-exist in patients. Now, for the first time, it has been shown that this co-occurrence can partly be explained by genetics.

Liposomal bupivacaine, a post-operative pain treatment widely used in the USA and recently licensed in the UK has no effect on post-operative knee replacement recovery or pain, compared to the current treatment when administered at the site of surgery, a study has found. The SPAARK (Study of Peri-Articular Anaesthetic for Replacement of the Knee) Trial, involved the University of Oxford's Surgical Intervention Trials Unit (SITU), which is supported by the Oxford BRC.

Consumption of seven or more units of alcohol per week is associated with higher levels of iron in the brain, according to a new study supported by the Oxford BRC. Accumulation of iron in the brain has been linked with Alzheimer's and Parkinson's diseases and is a potential mechanism for alcohol-related cognitive decline.

The first participants in a clinical trial of a bioelectrical therapy to treat incontinence received their 'smart' bioelectronic implants, developed by Oxford spin-out company Amber Therapeutics. This is the latest use of the Picostim-DyNeuMo research platform, first implanted in Oxford in 2022 for the treatment of Parkinson's-like multiple system atrophy. This neuromodulation research is supported through the Oxford BRC's new Surgical Innovation, Technology and Evaluation Theme.

The NIHR awarded an Advanced Fellowship to OUH emergency medicine doctor David Metcalfe to study the diagnosis of the spinal condition cauda equina syndrome, which is caused when the nerves at the end of the spinal cord are compressed. There is currently no particular pattern of symptoms that can rule out a diagnosis without an

MRI scan, but with no MRI scanning available at night some patients end up waiting too long before getting a diagnosis.

A new Acute Multidisciplinary Imaging and Interventional Centre (AMIIC) was officially opened at the John Radcliffe Hospital in January 2023. The refurbished centre, previously the Acute Vascular Imaging Centre, is a purpose-designed research facility embedded in a clinical hospital environment, specifically adjacent to the Emergency Department and Heart Centre. It is the first facility in the world to host a hybrid photon-counting CT scanner with an interventional suite, supported by an artificial intelligence facility. AMIIC is the location for several Oxford BRC imaging and cardiovascular studies.

A new building at the University of Oxford's Botnar Institute for Musculoskeletal Sciences was opened by the then Duchess of Cornwall (now Queen Camilla). The institute, on the site of the Nuffield Orthopaedic Centre (NOC), carries out research, much of it supported by the Oxford BRC, into improving the treatment of arthritis, osteoporosis and other bone and joint diseases. The new Marcella Botnar wing will focus on bioengineering, with researchers working on developing new technologies, materials, and interventions to treat patients with musculoskeletal conditions.

A study by NIHR Oxford BRC researchers revealed that a lack of time, work and clinical commitments, and family and childcare responsibilities are common barriers to training and development for doctors, dentists and nurses. The aim of the study was to understand what the training and development needs are of our translational researchers and research support staff and, just as importantly, what are the barriers that make attending training more difficult.
