Oxford University Hospitals
NHS Foundation Trust

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Title	**Research and Development Governance and Performance Report**

Status	For information
History	This is an Annual Report

Board Lead	**Professor Meghana Pandit, Chief Medical Officer**			
Key purpose	Strategy	**Assurance**	Policy	**Performance**

Executive Summary

1. This paper presents the OUH Research and Development Governance and Performance Report for 2018-19.

2. The NIHR Oxford BRC – now in year 3 of its third 5 year cycle – has continued to be highly productive, with more than 1000 papers published and £187m of external funding attracted, representing a leverage ratio of almost eightfold. Prof Helen McShane succeeded Prof Keith Channon as the BRC Director in September 2018. The BRC currently includes 18 NIHR Senior Investigators, four of whom were new awards this year. A patient representative now sits on the BRC Steering Committee. The BRC hosted visits by the Health Minister, Lord O'Shaughnessy, and the DHSC's Chief Scientific Advisor, Prof Chris Whitty. In addition to the annual Technology Showcase event, this year with the theme of Therapeutics, Small Molecules and Biologics, the BRC organised an Academic Industry Meeting Day and several other high profile events. BRC-supported research featured in 377 media stories in 2018/19, with approximately 74 national stories. The BRC marked the NHS's 70th birthday with a public talk on the significance of Oxford in the history of medical research and how medical breakthroughs in Oxford have benefitted the NHS. This, and other BRC public talks given throughout the year, were live-streamed, and recordings are available online.

3. OUH retains its position as one of the largest research-active University Hospital Trusts nationally. During 2018-19 the Trust hosted more than 1900 active research studies, a three-fold increase in the last 10 years. Of these studies, 534 are on the NIHR CRN portfolio – placing OUH second in the national league table for the number of portfolio studies. More than 32,000 OUH patients were recruited to these portfolio studies in 2018-19, the second highest figure for any Trust in England. OUH recruited 4600 participants to commercial contract studies in 2018-19, representing 10% of the national total and more than any other single Trust in England. Over 90% of the research studies hosted by the OUH have external sponsors, but the Trust itself sponsors over 100 studies, including some drug and device clinical trials. These research activities are supported by annual revenues of £55m.

4. A number of OUH-hosted research studies are led by nurses and Allied Health Professionals (AHPs), notably physiotherapists and midwives. The Trust is supporting initiatives to increase the engagement of nurses and AHPs in the conduct and leadership of research.

5. The NIHR replaced the '70 day' metric for initiating clinical trial recruitment with new local study-specific metrics, introduced at OUH from Q2 18/19, in order to identify studies where recruitment was delayed. This new metric is more sophisticated but its recent introduction means no historical comparisons can be made with regards to the proportion of studies where recruitment was delayed. Of the 127 trials confirmed this year which received a study-specific recruitment target, 42% met their target. The main causes were sponsor delays (including investigational drug delivery issues, urgent safety measures or global recruitment reached earlier than expected), which are beyond the Trust's control, and pharmacy-related delays within the Trust. A working group has been set-up to oversee and monitor the introduction of a range of changes to improve processes and reduce delays with regards to adult cancer trials (which account for around 50% of all the clinical trials hosted by the Trust). The Trust's performance in commercial trials recruiting to time and target has improved during the year – from 41% in Q1 to 54% in Q4. From Q1 2019/20 research teams will be required to report recruitment updates directly and in a timely manner in the new *Siteline* system. This should make it easier for R&D staff to identify and remedy trials at risk of failing to meet their initiation and recruitment targets, within the study benchmarks.

6. The relocation of the Trust R&D teams from the Churchill Hospital to OUH Cowley in August 2017 continues to present a number of challenges. There are clear advantages for the OUH R&D teams to be co-located with Joint Research Office (JRO) colleagues from the University of Oxford, and in closer proximity to the clinical researchers they support.
7. OUH has led the development of the *Studyline* research portfolio management system that has become a key operational link between OUH and University clinical research. Further significant developments are planned for the year ahead. These include an interactive dashboard to give Trust staff access to real-time information about all OUH-hosted studies and the new complementary *Siteline* system for research teams to log recruitment to clinical studies and access other features to help them manage and integrate their activities more efficiently, with significant new features being developed to address the needs of additional stakeholders. A launch of the new *Studyline* system is anticipated in Q1 2019 to encourage wider use and awareness of the benefits.
8. The Trust has initiated a programme of work to update its policy on clinical consent, and to incorporate digital consent processes for clinical procedures. This will also address the need for improved 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 patients' wishes. The work for developing this capability, deployed within the OUH's EPR system, is now in progress.

9. Recommendation

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

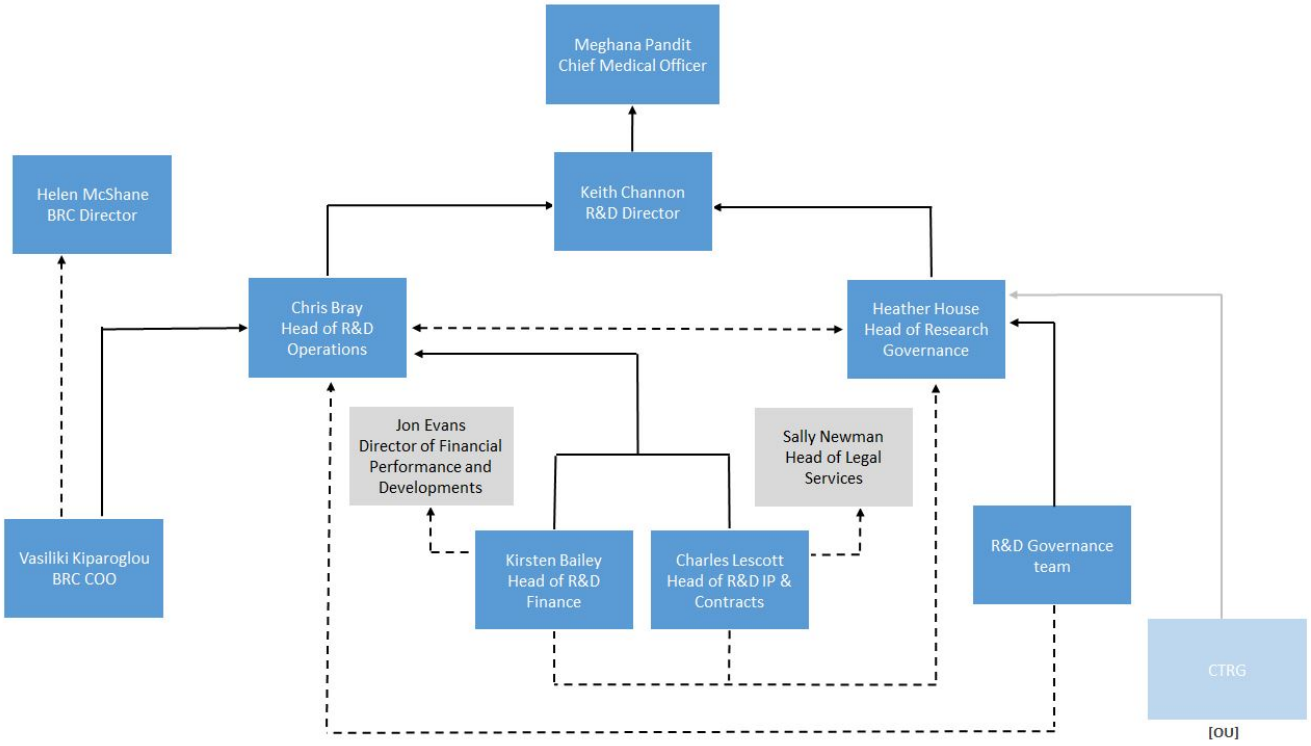
1. Introduction

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.

1.2. There are four specialist R&D teams, responsible for Governance, IP and contracts, Finance and BRC management. Reporting and accountability lines are presented in 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 and boards:

Committee/Board	Frequency
Joint R&D Committee (JR&DC)	4 times/year
Trust Management Executive (TME)	3 times/year
Strategic Partnership Board (SPB)	3 times/year

1.4. Two of these (the JR&DC and SPB) are joint committees/boards between OUH and the University of Oxford. The Trust's 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 and data to further its research, meanwhile the Trust – and its patients – benefit from the contributions of world-leading academic clinicians and the advances in diagnosis and treatment that stem from world-leading 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. There are currently over 100 staff in the JRO, divided roughly 60:40 between the Trust's R&D teams and University teams. The JRO's Co-leads (one for the Trust and one for the University) meet regularly with the Heads of the seven JRO teams to oversee and develop this important relationship. Around half of the interventional clinical trials sponsored by the University are hosted by the Trust and this same group represents around 20% of all the trials hosted by the Trust, making the University the largest single sponsor of studies being carried out in the Trust. The combined efforts of the JRO's teams also play a critical role in underpinning the success of the NIHR Oxford Biomedical Research Centre.

1.6. The JRO teams were co-located in shared office space at the Churchill Hospital until 2017/18, when a move became necessary due to the building being condemned, and because of continued JRO expansion. It was not possible to identify an alternative facility that could accommodate all the teams, so the Trust and University staff had to move to separate locations; the OUH teams to Unipart House, Cowley and the University teams to Boundary Brook House (BBH), adjacent to Old Road Campus in Headington. This physical separation has presented some challenges and a variety of initiatives have been put in place to maintain the close and effective working relationships, including various joint activities and intermittent social events, both organised and informal. There are important reciprocal arrangements to enable University teams to work alongside Trust colleagues at Unipart House and for OUH staff to work alongside their University colleagues and take advantage of meeting rooms at BBH. Access to facilities at BBH is especially valuable to the Trust teams because of its close proximity to OUH's Principal Investigators and their research teams. However, there are clear advantages for the Trust's R&D teams to return to a JRO base on the Hospital campus, alongside University colleagues and in close proximity to the clinical researchers they support.

1.7. Further information about the activities of the JRO is provided in Section 8 of this report.

2. NIHR Oxford Biomedical Research Centre

2.1. The Trust hosts the OUH-University of Oxford BRC, which has been awarded funding of £114m for the period 2017-22. Prof Helen McShane is the BRC Director, succeeding Prof Keith Channon in September 2018 after 9 years in the role. OUH also is a key partner, with the University of Oxford, in the Oxford Health NHS Foundation Trust BRC in cognitive and mental health, awarded £12m for 2017-2022.

NIHR Oxford BRC 2018-19 Annual Report highlights

2.2. In its Annual Report to the NIHR, the Oxford BRC reported that its 20 research themes published 1,008 papers acknowledging the BRC in peer-reviewed journals in 2018-19, including papers in Nature, Nature Genetics, The Lancet, BMJ and New England Journal of Medicine.

2.3. Four Oxford BRC-funded academics were named National Institute of Health Research Senior Investigators. They are:

- Prof Helen McShane, Director of the NIHR Oxford Biomedical Research Centre; Professor of Vaccinology, Nuffield Department of Medicine
- Prof Sarah Walker, Professor of Medical Statistics and Epidemiology, Nuffield Department of Medicine
- Prof Matthew Costa, Professor of Orthopaedic Trauma, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
- Prof Richard McManus, Professor of Primary Care, Nuffield Department of Primary Care Health Sciences

2.4. There were also two new NIHR Emeritus Senior Investigators from the Oxford BRC:

- Prof Alastair Buchan, Professor of Stroke Medicine, Radcliffe Department of Medicine (RDM)
- Prof Ian Pavord, Professor of Respiratory Medicine, Nuffield Department of Medicine

2.5. Each Senior Investigator is awarded a discretionary fund of £15k per year, while the NHS institutions with whom Senior Investigators are associated and which are eligible for Research

Capability Funding (RCF) attract an additional amount for each of their Senior Investigators. Further information about RCF is provided in Section 6.3 of this report.

2.6. The BRC currently includes a total of 18 NIHR Senior Investigators, 14 NIHR Emeritus Senior Investigators, 246 NIHR Investigators supported by the BRC, 350 NIHR Associates and 30 NIHR Academy Members with specific BRC funding.

2.7. During 2018/19 the BRC attracted £187.2m of external funding, representing a leverage ratio of almost eightfold. This funding includes £56.4m from research councils, £35.8m from research charities, £20.5m from DHSC/NIHR, £15.2m from other non-commercial sources, £53.1m from industry collaborations and £5.8m from industry contracts.

2.8. A BRC Steering Committee away day was held in November 2018 to assess the progress of the themes in meeting their stated objectives. An external Scientific Advisory Board attended and undertook a review of the themes. This board will take part in the BRC's Mid-Term Review in November 2019.

2.9. A patient representative has been appointed to the BRC Steering Committee, reflecting a commitment to delivering meaningful PPI and for patients to have a real say in the BRC's governance.

2.10. Medical research teams in Oxford will benefit from £17.5 million in new funding, thanks to a government initiative to boost new artificial intelligence (AI) healthcare projects. The funding, to benefit patients with a range of conditions, will be provided through the Government's Industrial Strategy Challenge Fund as part of a £50m investment to establish a network of digital pathology, imaging and AI centres. The University of Oxford will lead the National Consortium of Intelligent Medical Imaging (NCIMI), which as well as £10 million in government funding, will receive £5 million from commercial partners. Oxford is also a partner in the centre focusing on digital pathology, Project PathLAKE, and will receive £2.7m.

2.11. Business Secretary Greg Clark also announced the UK's first-ever dedicated Vaccines Manufacturing Innovation Centre, to be built in Oxford with an investment of £66m through UK Research and Innovation.

2.12. Prof McShane and Prof Walker, along with Prof Alison Simmons from the MRC Human Immunology Unit, were among eight University of Oxford scientists elected to join the prestigious Fellowship of the Academy of Medical Sciences.

2.13. The Oxford BRC appointed seven new Senior Research Fellows who have demonstrated high quality, high-impact research, as well as leadership, independence and collaboration with other research groups. The aim of the fellowships is to support individuals to advance an independent research area which will enhance BRC research in Oxford and strengthen future BRC funding applications. The fellows will receive an award of £10,000 per year for a period of two years that can be used flexibly to facilitate their translational research programme and career development.

2.14. A new project, led by Prof Martin Landray, the Oxford BRC's Theme Lead for Clinical Informatics and Big Data, will use NHS data to accelerate recruitment into clinical trials and increase the opportunities for NHS patients to participate in research. The project is one of ten 'Sprint Exemplar Innovation Projects', innovative data-based solutions to healthcare challenges that have been funded by the Government.

2.15. A BRC-supported researcher, Dr Tim Hinks, received a Wellcome Trust Clinical Research Career Development Fellowship and a £1m grant to expand his research into the immunology of lung diseases, including asthma and COPD. The funding allows him to establish his own research group and purchase the necessary equipment and research reagents. Dr Hinks was later awarded the £25,000 Wellcome-Beit Prize for his research.

2.16. A BRC study found that government investment in healthcare research is good for the wider economy, with a return on investment in the Oxford BRC of 46% in terms of income and job creation alone. The paper, 'A macroeconomic assessment of the impact of medical research expenditure: A case study of NIHR Biomedical Research Centres', was published in the Plos One

journal.

2.17. Following an external audit, the Oxford BRC was again successfully certified to the internationally recognised ISO 9001:2015 standard. Oxford is the only NIHR BRC in the country to have designated ISO 9001 certification.

DHSC visits

2.18. The Health Minister, Lord O'Shaughnessy, visited the NIHR Oxford BRC on 30 May to take a look at the ground-breaking research that is taking place in the fields of cancer and genomics. He visited the Early Phase Clinical Trials Unit at the Churchill Hospital's Cancer Centre, before visiting the Wellcome Centre for Human Genetics.

2.19. The Department of Health and Social Care's Chief Scientific Adviser, Prof Chris Whitty, visited Oxford in July. He met several senior investigators from the BRC's 20 research themes, who outlined their latest research in areas such as anti-microbial resistance, vaccines, genomics, imaging and big data. Prof Whitty then held a question-and-answer session with a group of early career researchers.

BRC Research Successes and Media

2.20. Oxford BRC has been at the forefront of attempts to treat sight-loss conditions using gene therapy. A trial, led by Prof Robert MacLaren, to tackle choroideremia, a rare genetic cause of blindness, showed positive results, with a sustained gain in vision across the group of patients as a whole. The trial, which began in 2011, involved 14 patients at the Oxford Eye Hospital receiving a single injection into the back of the eye of a virus containing the missing gene. Prof MacLaren is conducting a similar trial with patients who have a more common form of blindness, retinitis pigmentosa.

2.21. The success of the choroideremia trial has led to a much larger international gene therapy trial involving more than 100 patients in nine countries, led by Nightstar Therapeutics, a spin-out company established by the University of Oxford and Syncona, to develop the treatment further. It was announced in March 2019 that Nightstar had agreed to be acquired by Biogen for around $877m. The deal is expected to be completed in the middle of 2019.

2.22. Gene therapy is also being deployed against the UK's most common cause of sight loss, age-related macular degeneration. Prof MacLaren carried out the first procedure designed to correct the underlying gene defect in a new Phase 1 trial in January 2019. Rather than 'curing' the condition, it is hoped the gene therapy will halt the progress of the disease, meaning that in future, early intervention might prevent significant vision loss. As a result of a national BBC TV news report and accompanying press release, this story got a large amount of national and international media coverage.

2.23. A second person has experienced sustained remission from HIV-1 after ceasing treatment, ten years after the first such case, known as the 'Berlin Patient'. Like this first occasion, the second patient was treated with stem cell transplants from donors carrying a genetic mutation that prevents expression of the HIV receptor CCR5. The study involved Oxford researchers as part of the CHERUB collaboration, involving five leading NIHR Biomedical Research Centres. The story received widespread national and international media coverage.

2.24. University of Oxford researchers, supported by the Oxford BRC, have developed a new technology based on analysis of computed tomography (CT) coronary angiograms that can identify patients at risk of heart attacks years before they occur. Working with colleagues from the US and Germany, they found that the plaques that cause blockages in the coronary artery release chemical messengers which modify the surrounding fat. The new technology detects the inflamed plaques that are prone to cause heart attacks by analysing CT images of the fat surrounding the arteries. Their new biomarker, the Fat Attenuation Index, was reported in The Lancet and presented at the European Society of Cardiology congress in Munich.

2.25. Clinical and research teams at the John Radcliffe Hospital, supported by the Oxford BRC, used whole genome sequencing and electronic patient data, along with infection prevention and control best practice, to halt an outbreak of *Candida auris*, after detecting that multi-use patient

equipment was responsible. Many hospitals in the UK and around the world have been unable to halt their outbreaks; this was the first time an outbreak of the potentially deadly fungal pathogen was completely ended with a clear understanding of the cause. A paper on how the OUH outbreak was tackled was published in the New England Journal of Medicine (NEJM). How Oxford dealt with the outbreak has featured regularly in media reports about *C.auris*.

2.26. Oxford researchers and their international colleagues have shown how our understanding of the genetic code of tuberculosis is now so detailed that we can predict which commonly used anti-TB drugs are best for treating a patient's infection and which are not. The study, led by the international CRyPTIC consortium, based at the University of Oxford and facilitated by the 100,000 Genomes Project in partnership with Public Health England, was published in the NEJM and announced at the UN General Assembly high-level meeting on tuberculosis. It revealed a much greater accuracy in predicting the susceptibility of the bacterium to anti-TB drugs than had been expected, and should herald a quicker, more tailored treatment for the millions of people around the world living with TB.

2.27. For the first time an online support programme to improve sleep is being offered free to people living in the Thames Valley. Sleepio, a web-based programme based on cognitive behavioural therapy, is a proven alternative to sleeping pills, and the first ever NHS roll-out of direct-access digital medicine. It came after the largest ever research trial into the impact of digital cognitive behavioural therapy on adults with insomnia demonstrated the link between better sleep and improved overall health. The study, published in JAMA Psychiatry, was carried out by researchers from the University of Oxford's Nuffield Department of Clinical Neurosciences, supported by the Oxford BRC.

2.28. Deaths from stroke in England halved between 2001 and 2010, thanks to improved treatment, a study by Oxford BRC-funded researchers has found. The study by the University of Oxford's Nuffield Department of Population Health, published in the BMJ, looked at the hospital and mortality records of almost 800,000 people and found that stroke mortality rates decreased by 55 per cent, while the overall number of strokes fell by 20 per cent, and the number of people who died from stroke decreased by 40 per cent. However, the researchers warned that there had been an increase in the number of people under the age of 55 who had had strokes, an increase they attributed to higher obesity and diabetes rates in younger people. The study was well covered by national media outlets.

2.29. Researchers led by the Oxford BRC's Stroke Theme Lead, Professor Peter Rothwell, showed that a 'one-dose-fits-all' use of aspirin to prevent heart attacks, stroke or cancer, is ineffective or harmful in most people, and that a more tailored strategy is required. Writing in The Lancet, Prof Rothwell said that the dosage of aspirin needed to take account of the patient's weight to be effective.

2.30. New national guidelines are recommending that all babies born with Down's syndrome should have a new genetic test to detect signs of a condition that can lead to leukaemia. The new British Society for Haematology (BSH) guidelines, published in the British Journal of Haematology, follow 12 years of research and clinical studies by a University of Oxford group led by NIHR Oxford BRC-supported researchers Prof Irene Roberts (Department of Paediatrics) and Prof Paresh Vyas, the Oxford BRC's Co-theme Lead for Haematology. Early intervention will greatly increase the chances of survival for children who develop symptoms.

2.31. A team from the MRC-WIMM has developed a new technique – named TARGET-seq - that allows scientists to reliably track genetic errors in individual cancer cells, and find out how these might lead to uncontrollable growth. The research, supported by the Oxford BRC and published in the journal Molecular Cell, could be a significant step towards a more personalised cancer treatment. It is the first time researchers have been able to reliably track DNA errors in thousands of individual cancer cells, while also measuring how these mutations lead to disruption in how DNA is read within the individual cells of a tumour.

2.32. In a breakthrough that allows more precise targeting of drugs at cancers, a University of Oxford team, supported by the Oxford BRC, used ultrasound and lipid drug carriers to remotely trigger

and enhance the delivery of a cancer drug in humans for the first time. The study, published in Lancet Oncology journal, was conducted by a multi-disciplinary team of biomedical engineers, oncologists, radiologists and anaesthetists at the Churchill Hospital. It used focused ultrasound from outside the body to selectively heat liver tumours and trigger drug release from heat-sensitive carriers, known as thermosensitive liposomes.

2.33. The risks associated with shoulder replacement surgery for arthritic conditions are higher than previously estimated, according to a study by BRC-supported researchers from the University of Oxford's Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS). The findings, published by the BMJ, show that one in four men aged 55-59 years is at risk of needing further revision surgery, especially during the first five years after surgery, while the risks of serious adverse events (heart attacks, major blood clots and chest infections) within 90 days of surgery are much higher than previously estimated, particularly in those over 85 years.

2.34. Using routinely collected data from the National Joint Registry, NDORMS researchers, supported by the BRC, found that many more patients could be given a partial knee replacement instead of a total knee replacement, which would result in improvements in their quality of life and lower costs for the NHS. Unicompartmental replacements were found to be better for patients who have only part of their knee affected by arthritis. The procedure is less invasive, allows for a faster recovery, carries less post-operative risks and provides better function. It is also a cheaper intervention for the NHS, in both the short and long term.

2.35. Replacing food with a low-calorie diet of soups, shakes and bars, alongside regular sessions with a counsellor, is a safe and clinically effective way to treat obesity in primary care, a study supported by the Oxford BRC found. The authors of the study, published in the BMJ, suggest there is now enough evidence for total diet replacement programmes to be a recommended NHS treatment for people who are obese. A follow-up study, published the journal Obesity, demonstrated that the total diet replacement approach would be cost-effective as a routine treatment for obesity. The original study - led by the BRC's Obesity, Diet and Lifestyle Theme, Prof Susan Jebb – garnered a great deal of national media coverage.

2.36. An online tool that allows people with ulcerative colitis, a form of inflammatory bowel disease, to manage their own condition and reduce unnecessary hospital visits has been rolled out to more patients in Oxford. The decision to expand the use of the True Colours platform to around 370 patients at the John Radcliffe followed a successful six-month trial, supported by the Oxford BRC. The tool, which could be used for other chronic conditions, allows clinical teams to identify in real time when a patient's condition is deteriorating and use their resources more efficiently.

Industry Engagement

2.37. The BRC organised an Academic Industry Meeting (AIM) Day in April 2018 on the topic of Biomedical Imaging. AIM days, which focus on small group discussions based around a question from industry, bring together academic researchers, industrial representatives and clinicians to identify areas of common interest and potentially joint collaboration. A similar event is planned in July 2019 on the subject of antimicrobial resistance.

2.38. The BRC's annual Technology Showcase took place on 13 June 2018 at Oxford's Saïd Business School, with the theme of Therapeutics, Small Molecules and Biologics. The event, jointly organised with the Oxford Academic Health Science Network and Oxford University Innovation, was attended by around 200 leading academics, clinicians and investors, who discussed the most exciting commercial opportunities and projects in fields such as small molecule discovery, vaccines, experimental medicine and novel modalities. Industry representatives ranged from small spin-outs and start-ups to large multinational pharmaceuticals companies such as Johnson & Johnson and Pfizer.

2.39. A smartphone application for women with gestational diabetes, developed by Oxford BRC-supported researchers, was launched commercially, following a two-year clinical evaluation. Launched by Sensyne Health, after being developed as part of a five-year agreement with OUH and the University of Oxford to commercialise digital health products, GDm-Health is already being used in five NHS Trusts. So far, four products have been licensed by Sensyne as part of

the agreement.

Public Engagement

2.40. The NHS's 70th birthday celebrations provided an opportunity for the Oxford BRC to highlight the research that takes place at OUH and central role it has at the Trust. During the week of the anniversary, the BRC hosted six behind-the-scenes tours of research facilities and organised a public talk by the then BRC Director, Prof Keith Channon, on the significance of Oxford in the history of medical research and how medical breakthroughs in Oxford have benefited the NHS.

2.41. Other free public talks organised by the BRC included talks on tuberculosis – including how the study of TB genetics is changing the way we diagnose and treat the disease - and on the links between high blood pressure and stroke. These talks, which were live-streamed, are available on the BRC website.

2.42. Scientists backed by NIHR Biomedical Research Centres teamed up with designers and young people living with HIV to create a show garden at the 2018 RHS Chelsea Flower Show. The garden, whose theme was 'HIV: stigma and cure', highlighted the successes and challenges still faced by young people living with HIV. The garden was conceived by Prof John Frater, who is supported by the Oxford BRC, and who jointly leads the NIHR's CHERUB collaboration (Collaborative HIV Eradication of Reservoirs UK BRC).

2.43. With BRC support, a group of A-level students from schools across Oxfordshire spent time getting valuable work experience at the Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM) at the Churchill Hospital as part of the in2science scheme, which aims to help students from disadvantaged backgrounds to progress to careers in science and research careers through high quality work placements.

2.44. Beyond routine news articles, highlights included:

- BBC news report (and subsequent widespread media coverage) on gene therapy for age-related macular degeneration; Prof Robert MacLaren and one of his retinitis pigmentosa patients were the subject of a feature in The Guardian.
- Primetime BBC series The Big Crash Diet Experiment, featuring Profs Susan Jebb and Paul Aveyard, on BRC-supported research into total diet replacement programmes
- BBC Horizon documentary, and in-depth features in the Guardian and New Statesman, featuring Prof Andy Carr's research into placebo surgery

Other events

2.45. A one-day meeting involving clinicians, academics and patients took place in Oxford on 28 February 2018, Rare Diseases Day, to celebrate the successes of the 100,000 Genomes Project and explore how genomic medicine becomes a routine part of NHS care in future. Among the speakers was Prof Dame Sue Hill, Chief Scientific Officer for NHS England, who praised the "significant contribution" Oxford made nationally, including crucial support given by the Oxford BRC and the NIHR's Clinical Research Network. During the 100,000 Genomes project, Oxford recruited over 6,000 patients, helping to drive new diagnoses for patients, deliver a massive research agenda and lay the groundwork for the new national Genomic Medicine Service.

2.46. In June 2018, the NIHR Oxford BRC and the UK Cochrane Collaboration organised the Oxford Impact 2018 workshop to "think differently about research impact". The event sought to tackle the disparity between what healthcare research delivers and what patients need. The upcoming challenges of the 'impact agenda' were outlined in a blog by Prof Trish Greenhalgh, the Oxford BRC Theme Lead for Partnerships for Health, Wealth and Innovation.

2.47. In November, the BRC organised an international symposium to discuss how to maximise the impact of medical research, including the concept of 'value co-creation', where multiple stakeholders combine their efforts to devise products and services to increase their value for everyone.

2.48. The challenges and opportunities thrown up by the move to more personalised medicine were the focus of an event at St Anne's College in Oxford, the first of a series of workshops and seminars

on this topic, jointly organised by the Oxford BRC's Partnership for Health, Wealth and Innovation theme and the Centre for Personalised Medicine (CPM).

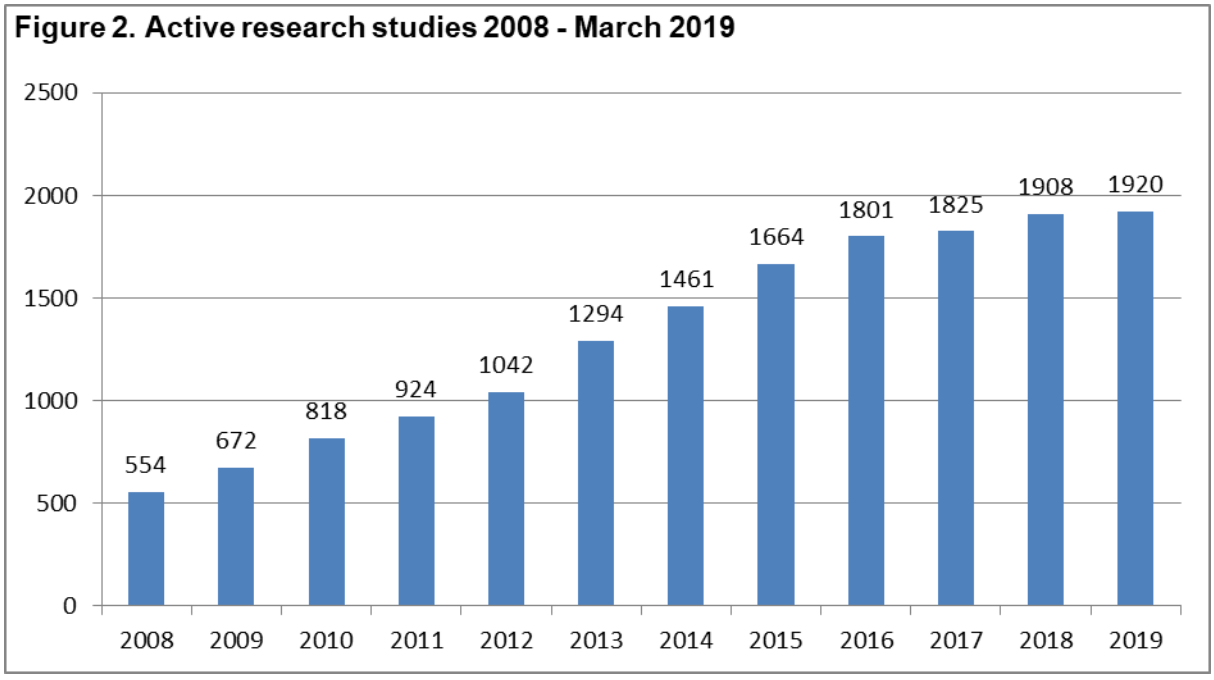
2.49. The BRC and University are key partners in the EU's Starbios2 (Structural Transformation to Attain Responsible BIOSciences) project, which aims to implement a Responsible Research and Innovation (RRI) approach in research institutions. BRC staff, along with colleagues from the Radcliffe Department of Medicine involved in the Starbios2 project attended a two-day workshop at the UNESCO headquarters in Paris in March 2019, providing input on draft guidelines and model of RRI in Biosciences, and presenting their latest research on the various Starbios2 research themes (Public Engagement, Gender, Education, Open Access and Ethics). The project continues until 30 April 2020.

3. OUH Research Activity

Overall activity

3.1. OUH is one of the largest research-active university hospital trusts nationally. During 2018-19 the Trust hosted more than 1900 active research studies, three times more than 10 years ago (see Figure 2). Of these studies, 534 are on the NIHR CRN portfolio – placing OUH second in the national league table for the number of portfolio studies. More than 32,000 OUH patients were recruited to these portfolio studies in 2018-19, the second highest figure for any Trust in England. OUH recruited 4600 participants to commercial contract studies in 2018-19, representing 10% of the national total and more than any other single Trust in England.

Figure 2. Active research studies 2008 - March 2019



3.2. This growth has important benefits for OUH patients both locally and across the region, and major reputational and other benefits for the Trust. OUH-UoO clinical research has had major impacts on patient care in the Oxford region, the NHS nationally, and internationally, in areas in including 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.

3.3. Clinical research is a key component of the Trust's strategic objectives. It expands opportunities for the development of its 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. These studies all have to be conducted

in accordance with international and national regulations, as well as Trust frameworks (see Section 5).

Hosted and Sponsored active research studies

3.4. 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
Inteventional	Clinical trial of an investigational medicinal product	523	5	528
	Clinical investigation or other study of a medical device	79	11	90
	Other clinical trial	235	16	251
Sub-total		837	32	869
Non-interventional	Other study	970	81	1051
Total		1807	113	1920

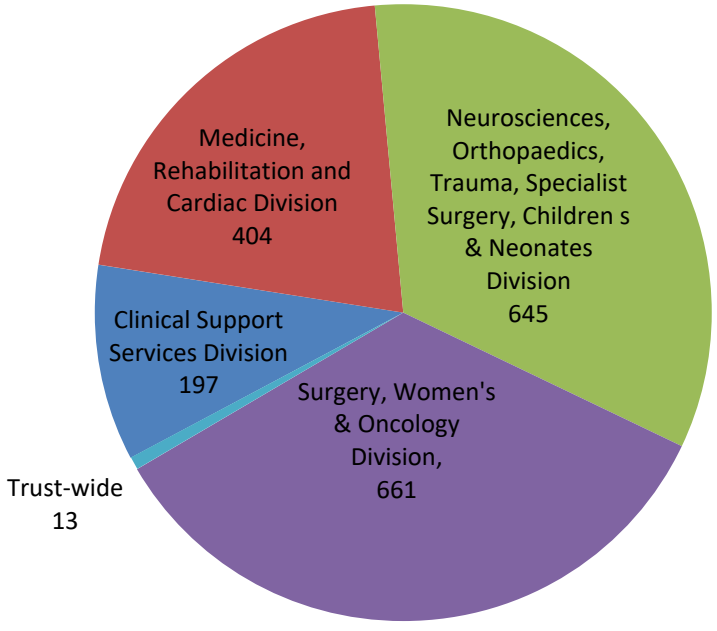
3.5. The vast majority of active studies are hosted for external Sponsors. Although the number of OUH-sponsored studies is relatively small, the R&D teams have to commit a significant amount of resource to ensure the Trust's obligations as sponsor are met.

3.6. The split of interventional:non-interventional active studies at OUH is roughly 50:50.

Research activity by OUH Division

3.7. Figure 3 presents a breakdown of the 1920 studies hosted by the Trust in 2018-19, according to Principal Investigators' (PIs') clinical Division. Two Divisions are particularly active, each accounting for approximately one third of the total number of studies hosted by the Trust.

Figure 3. Active research studies by Division



Substantial and non-substantial amendments

3.8. In addition to setting-up new studies, 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 2062 substantial and non-substantial amendments and urgent safety measures reviewed during the past year (see Table 2).

Table 2. Amendment activity

	Apr-Jun 2018	Jul-Sep 2018	Oct-Dec 2018	Jan-Mar 2019	Total
Substantial amendments	359	296	303	351	1309
Non-substantial amendments	238	162	178	175	753
Urgent safety measures					
Total	597	458	481	526	2062

Care Quality Commission (CQC) well-lead inspection January 2019

3.9. The CQC carried out a Trust-wide Well-led Inspection of OUH, 8-10 January 2019. This is the first such inspection of OUH since research was added as an additional element to the inspection framework in October 2018. The inspection included a discussion dedicated to research with the Trust's Director of R&D, Head of Research Governance and Head of R&D Operations. Research was also raised during the inspectors' meetings with other staff from across the Trust. The CQC inspection was very helpful in raising the profile and priority of clinical research across the OUH, and gave both OUH staff and the CQC inspection team a useful opportunity to understand the importance of clinical research to the OUHs mission and the impact on high-quality clinical care for patients.

Opportunities and new developments for non-medical research staff

3.10. The majority of the clinical research studies hosted by OUH are led by medically-qualified staff. However, a number of important studies are led by nurses and Allied Health Professionals (AHPs), notably physiotherapists and midwives. OUH's ambition is to increase research capacity and capability in all clinical service areas, at all sites and among all staff groups and professions – especially nurses and AHPs – and to enhance recruitment and retention through promotion of research and innovation as a career pathway.

3.11. Recent initiatives to encourage professional development amongst non-medical research staff, include 19 awards made by the Oxford BRC in 2018/19 to research nurses, postdoctoral researchers, clinical governance managers, pharmacists and clinical trial managers.

3.12. Through close working with Oxford Brookes University's Institute of Nursing, Midwifery and Allied Health Research (OxINMAHR), OUH supports and guides the training of these staff. OUH will continue to strengthen these relationships and to invest in the necessary infrastructure to develop its research capability to deliver patient benefit in Oxford, and beyond.

3.13. OUH's commitment to developing opportunities for research nursing in the coming years is demonstrated by the plans, which are at an advanced stage, to appoint a Head of Research Nursing who will report to the Chief Nurse. This post will work across the Trust and Oxford

Brookes University, linking in with a new Professor of Research Nursing post at Oxford Brookes University via the BRC's Training and education subtheme.

4. Clinical Research Performance

Background

4.1. The Government's Plan for Growth, published in March 2011, aimed to increase efficiency in initiation and delivery of clinical research, focusing on recruitment of the first patient to clinical trials within 70 days of receiving a valid protocol; and delivery of commercial clinical trials to time and target. It was stated that from 2013 there would be funding implications for underachieving Trusts.

4.2. The NIHR continues to place emphasis on reporting metrics for the approvals and initiation of clinical studies, which are used for monitoring the R&D performance of NHS Trusts. Attainment of key metrics is a requirement for NIHR funding, including BRCs, and performance metrics are published for each NHS Trust receiving NIHR funding.

4.3. Information regarding its performance to these metrics is published by the Trust in a readily accessible page on its website (http://www.ouh.nhs.uk/about/publications/default.aspx#research), as required by the NIHR.

4.4. Although the '70 day' benchmark has bnow een replaced, the NIHR is continuing to collate and publish national performance metrics for initiating research. The reasons for delay submitted by Trusts are only reported in aggregate, but the minimum, mean and maximum numbers of days between the date of site selection and the date of first patient recruited are reported for each Trust. However, no allowance is made for factors such as the prevalence of studies with strict eligibility criteria, or relating to rare diseases, in a Trust's portfolio of trials, so reliable direct comparisons between Trusts cannot be made using these data.

Summary of performance for 2018/19 submitted to the NIHR

Data Completion

4.5. Full sets of data were obtained, submitted to the NIHR and published on the Trust's website within the specified timelines.

Metric 1: Performance in Initiating Research (for all interventional trials confirmed during the previous 12 months)

4.6. On 1st June 2018 the NIHR announced that performance in initiating clinical research will no longer be assessed with a 70 day benchmark for the interval between Date Site Selected and date of First Patient Recruitment. A renewed focus will be placed on transparency, accuracy, and meeting sponsor expectations. Any and all delays which have affected or may affect agreed study timelines are still required to be reported, although there was no guidance for Trusts on how they should determine what constitutes a delay.

4.7. OUH R&D therefore developed a new approach, which calculates study-specific target dates for first patient recruitment, based on the target total recruitment number and the time available in which to complete recruitment. Using this as a benchmark allows studies where delays have been experienced to be identified and commented upon in a more sophisticated and relevant manner.

4.8. OUH R&D received confirmation from the NIHR that this new approach is 'sensible' and has therefore adopted it for OUH interventional trials with effect from Quarter 2 2018-19. The study-specific target date is added to the Trust letter of authorisation issued to the PI. This approach may be amended, should more specific requirements be articulated by the NIHR.

4.9. Of the 158 trials submitted to the NIHR in Q4, i.e. were confirmed during the year 2018/19, 127 received a study-specific target for the recruitment of the first participant using the new approach. This is the last quarter in which some of the trials submitted will not have used the new approach. The performance of these 127 trials is summarised in Table 1, together with the corresponding trials that were submitted in the previous two quarters which also had their own study-specific recruitment targets set. It will, however, be difficult to make any meaningful comparison between

each of the quarterly submissions until they are all based on a full years' data using the new approach, i.e. Q2 2019/20. The change in methodology for identifying delayed in recruitment also means it is not possible to make any direct comparison with the performance in previous years.

Table 1. Study-specific target for recruitment of first participant

	Submission to NIHR		
	Q2 2018/19	Q2 2018/19	**Q4 2018/19**
Trials which met target date	10 (26%)	18 (20%)	**35 (28%)**
Trials which did not meet target date	3 (8%)	37 (42%)	**47 (37%)**
Trials with target date in the future	*26 (67%)*	*34 (38%)*	***45 (35%)***
Total	39 (100%)	89 (100%)	**127 (100%)**

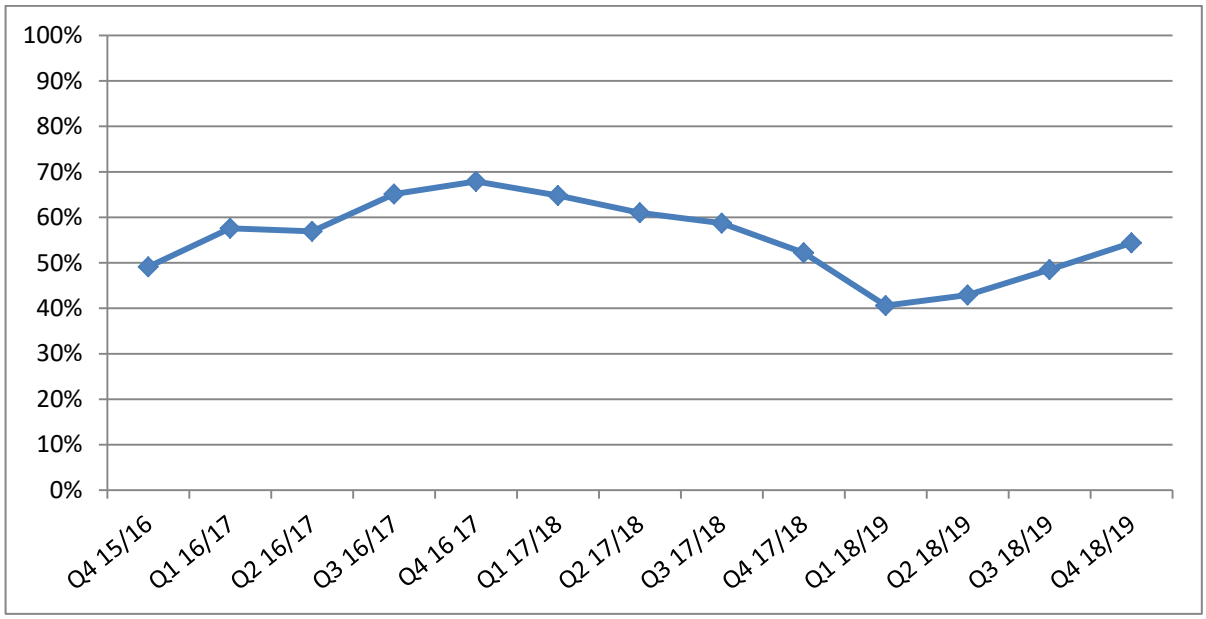
4.10. Of the 82 trials submitted in Q4 that had passed their target date, 35 (42%) had met this target by recruiting their first participant by this date and 47 (58%) had not. All the studies that failed to meet their recruitment target have been reviewed individually. The main causes were sponsor delays (including IMP delivery issues, halt due to urgent safety measures or global recruitment reached earlier than expected), which are beyond the Trust's control, and pharmacy-related delays within the Trust.

4.11. A small working group, chaired by the Director of R&D (Prof Keith Channon) and including senior representatives from Pharmacy, Haematology & Oncology and R&D, was set-up in Q3 2018/19. This group has continued to meet regularly to Significant progress has been made in several key areas, including a doubling (from two to four) of the number of trained pharmacist approvers, but it may be some time before this is reflected in improved performance to the NIHR metrics because of the significant lag time that is inherent in their design (based on the previous 12 months' data).

Metric 2: Performance in Delivering Research (for all commercial trials closed to recruitment during the previous 12 months)

4.12. This metric applies to trials with a commercial sponsor and relates to recruitment numbers within the time period specified in the agreed contract with OUH. NIHR evaluation of this metric is limited to trials that have closed to recruitment in the previous year. OUH's performance is shown in Figure 4.

Figure 4. Percentage of trials meeting the recruitment target



4.13. As this metric is limited to trials closed to recruitment during the last 12 months, changes in R&D processes will take time to translate to performance. It is not clear whether any penalties will be imposed, in the future, for showing little or no improvement in this metric.

4.14. There is an opportunity for the R&D teams to monitor trials more closely, to identify those at risk of missing their recruitment target whilst there is still time for this to be addressed. This will be facilitated by the introduction of the new Siteline system from Q1 2019/20, for research teams to report recruitment updates in a timely manner. However, sufficient R&D staff will also be required to ensure trials identified as being 'at risk' of missing their targets can be followed-up in a timely manner, in addition to R&D's highest priority activities which will continue to be the oversight of quality and safety.

5. Research Governance

Background

5.1. Research governance refers to the framework in OUH 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:

UK Policy Framework for Health and Social Care 2017

5.2. 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.

Good Clinical Practice (GCP)

5.3. 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.

EU directives

5.4. 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.

5.5. 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.

Medicines for Human Use (Clinical Trials) Regulations

5.6. 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). For details see the full document.

Human Tissue Act

5.7. 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.

Declaration of Helsinki

5.8. 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).

General Data Protection Regulation (GDPR)

5.9. 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.

Mental Capacity Act

5.10. 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).

OUH Frameworks for R&D Governance, Training and Monitoring

5.11. Locally, clinical research is governed by a number of OUH Trust polices:

- 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

5.12. These policies are underpinned by a suite of Standard Operating Procedures (SOP) within R&D. Policies and SOPs are updated in response to national and local developments.

5.13. The Governance team conducts a wide variety of activities, which are summarised in Sections 5.2 – 5.6. As indicated, many of these involve working in close collaboration with their University colleagues in the JRO's Clinical Trials Research Governance team.

Oversight of compliance and safety

GCP Monitoring

5.14. 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 to each OUH-sponsored trial

Formal auditing of compliance

5.15. 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.

5.16. 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..

Compliance checks

5.17. The governance team 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.

Safety Reporting

5.18. 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.

5.19. All SAEs reported are reviewed by the Trust and University 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.

Consent

5.20. As part of the actions identified by the HTA's inspection of the University of Oxford's HTA Licence 12217 in 2018, the Trust has identified the need for improved consent processed 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 patients' wishes.

5.21. The OUH has undertaken a review of its consent policy and is committed to implementing a digital consent process that integrates consent for both clinical procedures and for use of clinical samples and clinical data in research studies. The work for developing this capability, deployed within the OUH's EPR system, is in progress.

Training

5.22. Through collaboration with the University Clinical Trials and Research Governance team (CTRG), training is provided to both Trust and University staff to cover all research related legislation and GCP; courses being designed for both staff new to trials and an update for experienced researchers.

5.23. For CTIMPs there are both online and face-to face 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.

5.24. 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.

5.25. For the period covered by this report there have been 128 attendees of the CTIMP training and 69 of the non-CTIMP training. A further 956 applicants have been accepted onto the online GCP training course.

Research Passports

5.26. The Governance team processed and authorised 125 applications for Letters of Access and nine 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

5.27. There are times when the classification of a project is unclear; i.e. whether it is a research study, audit or service evaluation. In order to establish an authoritative and collective opinion on such projects, the Governance team and the Clinical Trials and Research Governance team in the University have an established group which meets to review project outlines and give a considered opinion. The group meets at least monthly, or more often where there is high demand, and classified a total of 108 projects during the period covered by this report.

6. Research and Development Finance

6.1. The R&D Finance team is responsible for costing of research studies to be hosted by OUH, with timely and accurate invoicing for those studies, once they are active. The team also manages the finances for the NIHR Oxford BRC and the Thames Valley & South Midland LCRN, which is hosted by OUH.

Year Ended 31st March 2019

6.2. For the year ending 31st March 2019, in total OUH R&D spent £55 million on research activities in support of the OUH Trust (including joint studies with the University).

6.3. The grants received from the major NIHR infrastructure programmes for the year were spent as planned, resulting in a breakeven position with no underspend.

Research Funding by area	**2018/19 Expenditure (£m)**
NIHR Biomedical Research Centre (BRC)	23
NIHR Local Clinical Research Networks (LCRN)	15
NIHR Research Capability Funding (RCF)	4
Other NIHR grants	2
Other income (commercial & non-commercial)	11
	55

6.4. Activity for commercial and non-commercial studies has increased year on year for a number of years (as reflected in the steady growth of active studies currently held at the OUH) and the R&D finance team actively manage the finances for individual studies from pre-award through to post-award, to ensure all finances are in place and are accounted for in line with the Trust's agreed procedures.

6.5. The pre-award team work closely with researchers and the Local Clinical Research Network 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 the Trust.

6.6. The R&D Costing team are currently involved in the pilot of the NIHR single contract review

process for commercial studies using nationally defined standards. The OUH was identified as one of 36 NHS organisations with a high volume of commercial contract research (and therefore a high level of experience in costing such research), and as a result was invited to participate in a pilot for this new process. This pilot is currently in phase 1 of the testing period which is set to continue in 2019/20.

Financial Planning 2019-20

6.7. For the 2019-20 financial year, the Trust has set an annual budget of £55 million for Research and Development. The plan represents:

- £45 million from the major NIHR funded schemes which have been awarded to the Trust
- £10 million from other commercial and non-commercial R&D activities

6.8. The budgets for 2019-20 have been set and agreed for all income streams. For the major NIHR funded programmes, the Biomedical Research Centre (BRC) 2019-20 represents the third year of the five year funding award for 'BRC 3'. Total income and expenditure for the year has been set at £23.8 million. As this is a similar amount to 2018/19, the core budgets for the 20 Research Themes and the management team are in line with the previous year.

6.9. For the Local Clinical Research Network (LCRN), the annual funding award has been confirmed, and the budgets have been set at £15.5 million to break even. Although the OUH Trust received an overall increase in CRN funding of 2% for 2019/20 compared to the previous year, this represents a cut in real terms due to the additional pay costs under the second year of the NHS three year pay deal for 2019/20. However, research support costs will continue to be supported at a similar level to 2018/19 by reallocating some of the strategic and unplanned costs, and continuing to manage other costs effectively.

Research Capability Funding

6.10. Research Capability Funding (RCF) is awarded to research-active NHS organisations in proportion to the varying amounts of other NIHR income received, and the number of NIHR Senior Investigators associated with the organisation.

6.11. The purpose 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 or supporting people and patient-based research.
- 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.

6.12. The amount of RCF funding allocated to the OUH Trust in 2018/19 was the maximum amount that can be awarded to any NHS Trust, which is capped at £4 million. After making an allocation in support of Trust overheads for research, the remaining balance was awarded through a combination of larger strategic awards overseen by the BRC Steering Committee, and many smaller operational awards to support staff working on Trust and University of Oxford projects.

6.13. In 2018/19 the Department of Health and Social Care (DHSC) concluded a national review to identify the degree to which Research Capability Funding (RCF) is meeting its current aims, and whether changes are required to ensure that RCF policy, and its implementation, remain fit for the future of the National Institute for Health Research (NIHR). It was concluded that RCF plays an effective role in helping to ensure that the health and care system can act flexibly and strategically to maintain research capability and capacity. The use of these funds by OUH reflect the aims of the NIHR.

6.14. Although the level of funding for RCF over the next four years will significantly reduce, the DHSC has confirmed that it will be retaining RCF as a funding stream for the foreseeable future. The RCF funding awarded to the OUH for 2019/20 is £3.958 million. Although this is less than the £4 million awarded in 2018/19, OUH will receive the highest amount of RCF funding of all NHS Trusts in 2019/20. This is due to the high level of NIHR research activity and number of senior investigators across the organisation.

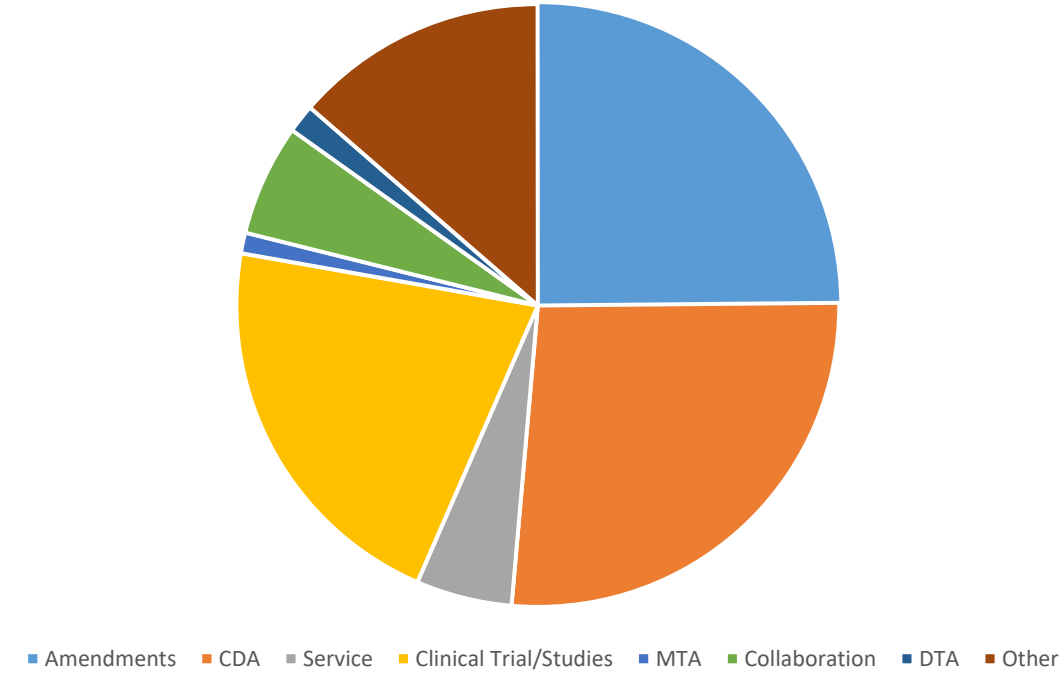
7. Research Contracts and IP

7.1. During year to 31 March 2019, 737 research and IP related cases were finalised on behalf of OUH. The team also continued its contracting service to Oxford Health NHS Foundation Trust. As in previous years, Confidentiality Disclosure Agreements (CDAs) and Amendments provided the bulk of the activity (191 and 179, respectively). Amendments increased in part due to the introduction of GDPR.

7.2. During the same period a total of 153 clinical trial agreements were finalised, which was a drop from last year although this doesn't represent a drop in research activity.

7.3. 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 2018-19 is provided in Figure 5.

Figure 5. Breakdown of contract-related activity



7.4. The R&D report for 2017-18 referred to a Strategic Research Agreement (SRA) with Sensyne Health (formally Drayson Technology Limited). In the last year, this relationship has developed and a further SRA and data sharing arrangement has been agreed with a further allocation of equity secured.

7.5. Other activity includes OUH successfully registering to be a participant in EU-funded research and receiving its first grant. We have also registered projects with the Government to secure funding in case the UK leaves the EU without a deal.

7.6. The team participated in the Oxford BRC open day and attended the NHS R&D Forum where a poster about clinical research contracts was presented.

7.7. A lot of time has been committed strengthening our working relationship with the University of Oxford by agreeing an Overarching Clinical Trial Agreement (OCTA), designed to streamline the financial and contractual processes for trials hosted by the Trust which are dependent on the provision of services and/or staff by the University.

8. Joint Research Office

Joint working

8.1. A JRO awayday workshop was held at the University's Examination Schools in September 2018. This was especially important as it was the first since the separation of the Trust's and the University's teams.

8.2. There are many other well-established collaborations between the JRO's Trust and University teams. These include the joint activities involving the Trust's Research Governance team and the University's CTRG team detailed in Section 5. Another development has been the initiation of joint working groups, led by relevant HoTs and involving other staff from outside the JRO when appropriate, to focus on making improvements to complex areas of joint activity. One such group has been tasked with reviewing and streamlining the contractual and financial arrangements for projects involving OUH patients and University staff or other resources.

8.3. As usual, members of the JRO's OUH teams attended the Annual NHS R&D Forum Meeting (in May 2018). However, this year – for the first time – they submitted and had accepted three abstracts – one for an oral presentation and two for posters. This was a valuable opportunity to share some of the work the Trust's staff have been doing locally, in collaboration with University colleagues, to underpin OUH's research performance and to prompt interesting discussion with colleagues from other Trusts across the country.

8.4. The Co-leads of the JRO are planning to host an initial meeting of all the established JROs across the UK. The main aim will be to better understand their similarities and differences, to help inform each JRO's decisions about how it should develop in the future. It is hoped this may lead to closer involvement and cooperation with other JROs, for mutual benefit.

8.5. JRO staff have worked with Oxford Medical Illustration to produce two videos. The first is a seven minute video to raise awareness amongst all staff of the benefits to patients of the research taking place across the Trust and will be included in the induction program for OUH staff from April 2019. The second is twenty minute video for use in the inductions for JRO staff. It features representatives from each of the JRO teams who talk about the work they do, in particular with regards to a study led by a leading University/Trust researcher (Prof Robert MacLaren), who describes the study and the support he received from the JRO in setting it up.

8.6. During 2018/19 the JRO organised two seminars for Trust and Universty staff on topical issues. These were chaired by the OUH Director of R&D (Prof Keith Channon) and featured presentations from several recognised experts who then took part in a panel discussion, with Q&A from the audience. The first seminar was on the General Data Protection Regulation and its relevance to clinical research. The second was on Research with adults who lack mental capacity. Both seminars were well attended and generated positive feedback. The JRO intends to organise more of these seminars in the future.

Studyline (project and portfolio management system)

8.7. Detailed information relating to all of the clinical research studies hosted or sponsored by OUH and/or the University of Oxford, is held in the Studyline project and portfolio management system. Studyline has been developed by OUH R&D, in close collaboration with University colleagues, and is a prime example of joint working. From its initial focus on supporting the activities of the Trust's governance team and the University's CTRG (critically, eliminating the need for them to maintain separate records pertaining to the same studies), the Studyline system is now also being used by the other five Trusts across covered by the Thames Valley & South Midlands LCRN as their Local Portfolio Management System.

8.8. Studyline has already had a profound impact on the management of research at OUH and its partners. The rollout of the complementary Siteline system in Q1 2019/20 will streamline significantly the reporting of recruitment information by research teams to the Trust and to the NIHR CRN in a timely manner. This will help OUH R&D to identify studies at risk of failing to meet their targets for initiating and completing recruitment, so that efforts can be focussed on working with the appropriate research teams before it is too late. Further enhancements to Siteline are planned, to provide additional features that should help research teams to manage and integrate their activities more efficiently.

8.9. Other developments planned for Studyline in 2019/20 include making available to all OUH staff 'real-time' information on all research studies hosted by the Trust, through a highly informative and interactive visual dashboard. Additional features are also to support and integrate the activities of other key stakeholders, in particular pharmacy, who will be able to manage their activities as well as view and update information about studies in a common central location, minimising the need for inefficient 'offline' communication with OUH R&D and the potential for risk and uncertainty resulting from inconsistent information.

9. Recommendation

The Trust Board is asked to note this report.

Professor Meghana Pandit
Chief Medical Officer

Report prepared by: Professor Keith Channon
Director of Research and Development