

Research Impact Evaluation Report 2022/2023



Contents

Executive Summary.....	3
Executive conclusion.....	7
Background	8
Research Governance	9
Research Strategy 2020-2025	10
Goal 1	10
Goal 2	14
Goal 3	22
Goal 4	26
In conclusion	32

Executive Summary

Research is a key part of Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) 'Caring with PRIDE' Corporate Strategy. This report covers Year 3 of implementation of NNUH's dedicated Research Strategy 2020-2025¹.

Advancing Strategic Goal 1 *'Embed a culture of research throughout NNUH creating an inspirational environment that is recognised nationally and internationally, which inspires future leaders of clinical research'*

- The National Institute for Health and Social Care Research allocates Research Capability Funding (NIHR RCF) to NNUH on annual basis. In 2022/23 NNUH received £221,828 which was used to support key roles (such as R&D finance and governance) and to pump prime new research projects which have a realistic prospect of generating competitive, new NIHR grant applications. Researchers were invited to submit a proposal and following competitive review, 5 pump priming awards were granted: epilepsy biomarkers in adults, seizure detection in neonates, smoking cessation, informatics support for an arthritis database, genomic factors in high-risk pregnancies.
- NNUH was successful, in partnership with University of East Anglia (UEA), in securing new research funding from public bodies such as NIHR and Medical Research Council and research charities – 24 grants and £8.1m in total (note funding will be passed through from the 'lead' organisation to research partners).

Advancing Strategic Goal 2: *'Consolidate and deepen the special partnership with the University of East Anglia and Quadram Institute Bioscience'*

- The first ever Clinical Associate Professors in Clinical and Translational Medicine were appointed in October 2022. These joint appointments are supported by the Norwich Medical School and NNUH to foster clinical academic leadership and expand growing research themes in collaboration with our partners on the Norwich Research Park. Eight appointments were made and the post holders are expected to develop and lead a programme of clinical research in their specialist area, secure research funding through commercial research and successful grant applications.

¹ Note due to clinical pressures, not all Research Leads were able to return reports therefore this report is an under representation of our research outputs.

- The purpose-built Clinical Research Facility (CRF) housed in the Quadram Institute continued to be jointly supported by NNUH, QIB and the UEA. A business development plan was implemented to optimise the use of the facility including building new capabilities and capacity through workforce development.
- For the Norwich Research Park (NRP) Biorepository (part of the NNUH, QIB, UEA partnership) a Biorepository Access Committee was established (reporting to the Research Oversight Board) to provide ethical review of applications from NRP researchers to access tissue and Biorepository services (note the Biorepository has ethical approval from the Health Research Authority). This committee replaced the human tissue sub-committee of the UEA's Faculty of Medicine and Health Sciences Ethics Committee thereby strengthening NNUH governance and oversight.
- NNUH sponsors (i.e. takes responsibility and liability for) clinical research studies. At the end of this reporting period NNUH sponsored 25 studies including one Clinical Trial of an Investigational Medicinal Product (CTIMP), with a further 7 and 24 sponsored by Quadram Institute Bioscience and UEA respectively. The Norwich Clinical Trials Unit (NCTU) manages 9 of NNUH's sponsored research studies, the majority of which are multicentre Randomized Controlled Trials (RCTs) funded by NIHR with a total grant value in excess of £10m. This includes four large NNUH sponsored Clinical Trials of an Investigational Medicinal Product (CTIMPs, with funding in excess of £5.5m).
- 94 new grant submissions (with either NNUH or UEA as the lead applicant) were submitted, with 24 successes resulting in £7.7m in new grant funding with 3 grants each in excess of £1.5m and 6 grants each in excess of £200,000.

Advancing Strategic Goal 3 *'Develop sustainable strategic partnerships critical to the region and wider NHS'*

- A successful grant application has meant that NNUH has received the prestigious



award and status of 'NIHR CRF Norfolk' which, from October 2022, will support early phase research in the Quadram CRF, CRF-Central (in the Education Centre) and the CRF-Neonatal Intensive Care Unit. This places NNUH within the network of 28 NIHR supported CRFs in the UK.

- NNUH continues to host the core NIHR Clinical

Research Network East of England team (managing a £20m budget covering Cambridgeshire, Norfolk, Suffolk and parts of Bedfordshire, Essex and Hertfordshire). NNUH's own CRN funding 2022/23 allocation was £2,143,568. This included in-year funding to address staffing 'Capacity and Constraints' coming out of the pandemic and resuming business as usual and also Greenshoots awards for individuals to have protected time to gain experience as Principal Investigators leading research studies (e.g. award to Samuel Hodgson, Physiotherapist).

- Overall NNUH had 255 studies open (including studies actively recruiting new participants and also studies in follow-up and closed to recruitment) which are heavily biased towards non-commercial studies. All divisions contributed. The number of new participants recruited into research studies was 3679 which was in line with the predicted number although overall decreased relative to previous years.
- Development of relationships across the NRP has continued and with strategic participation of senior NNUH staff in Boards (such as Anglia Innovation Partnership, NRP Knowledge Exchange Group, Norwich Institute of Healthy Ageing) developing NNUH's role as an influential partner.

Advancing Strategic Goal 4: 'Be recognised as a leading NHS Trust in applying research and adopting innovation to deliver the best patient care and to benefit the wider NHS'

- NNUH generated and disseminated a large body of new research knowledge. In 2022, more than 250 new research papers were published covering a wide range of specialities and reflecting the quality of NNUH research (although this represents an underestimate as not all Research Leads were able to return reports). Published papers included articles in the highest impact, widely read influential medical journals

- The British Medical Journal, The Lancet, Journal of the American Medical Association, Nature and speciality journals.
- NNUH researchers were invited as expert speakers and chairpersons at regional, national and international conferences of professional and learned bodies and contributed as: peer reviewer; editors for peer reviewed journals; educational and training workshops.
- NNUH researchers also act as Chairs, research committee members, clinical advisors to learned bodies and commercial organisations and have contributed to the introduction of new evidence-based changes in clinical guidelines such as in dermatology, dietetics, endocrinology and diabetes and radiology.

Executive conclusion:

Progress against the Research Strategy 2020-2025 has been sustained amid the challenges faced in recovery from the pandemic position, in particular clinical pressures. There have been challenges which are not unique to NNUH and have in part been recognised in Lord O'Shaughnessy's review of 'Commercial Clinical Trials in the UK', 2023². We can report good overall NNUH performance in terms of contributions to the NIHR CRN, new research publications and in high impact journals, grant submissions (and successful awards), levels of professional development (such as post graduate qualifications) and involvement in external organisations. Of note is the prestigious NIHR grant award for a NIHR Norfolk Clinical Research Facility.

² Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report - GOV.UK (www.gov.uk)

Scope

This report summarises research activity carried out by the Norfolk and Norwich University Hospitals NHS Foundation Trust (NNUH) and evaluates its impact during the 2022/2023 financial year. This report was presented initially to the Research Leads Group and the Research Oversight Board for review prior to wider circulation³.

Background

Research active hospitals have better outcomes for patients^{4,5}. NNUH's commitment to research is embedded within NNUH's new Corporate Strategy 'Caring with PRIDE'⁶ (launched April 2022) with aspirations to 'Drive world class research' by extending partnerships with our key stakeholders such the University of East Anglia (UEA) and Quadram Institute Bioscience (QIB) on the Norwich Research Park (NRP) and to 'Embed world class research' across our hospitals and to increase research capability and activity.

NNUH research is supported by public funds and income generated from research grants and contractually based studies with non-commercial and commercial organisations. For all research undertaken, we aim to carry out clinical research of the highest quality and, through that research, expect to achieve demonstrable benefits for our patients, our staff, the wider economy and society.

During the period covered by this report (April 2022 to March 2023), similar to other trusts, NNUH research activities were influenced and impacted by recovery of the post pandemic research portfolio and the continuing impact on the workforce and NHS clinical pressures. To address the challenges at national level, the Department of Health and Social Care introduced the Research Reset programme. RESET superseded the Restart and Managed Recovery post Covid initiatives and was aimed at focusing available capacity on studies likely to meet their endpoints in the post-pandemic environment. This required sponsors of research, NNUH included, to review and confirm deliverability of their own studies. Through RESET there was a shift in focus to

³ Note due to clinical pressures, not all Research Leads were able to return departmental reports therefore this report is an under representation of our research outputs.

⁴ Ozdemir BA, Karthikesalingam A, Sinha S et al., Research Activity and the Association with Mortality. PLoS ONE 10(2) e0118253

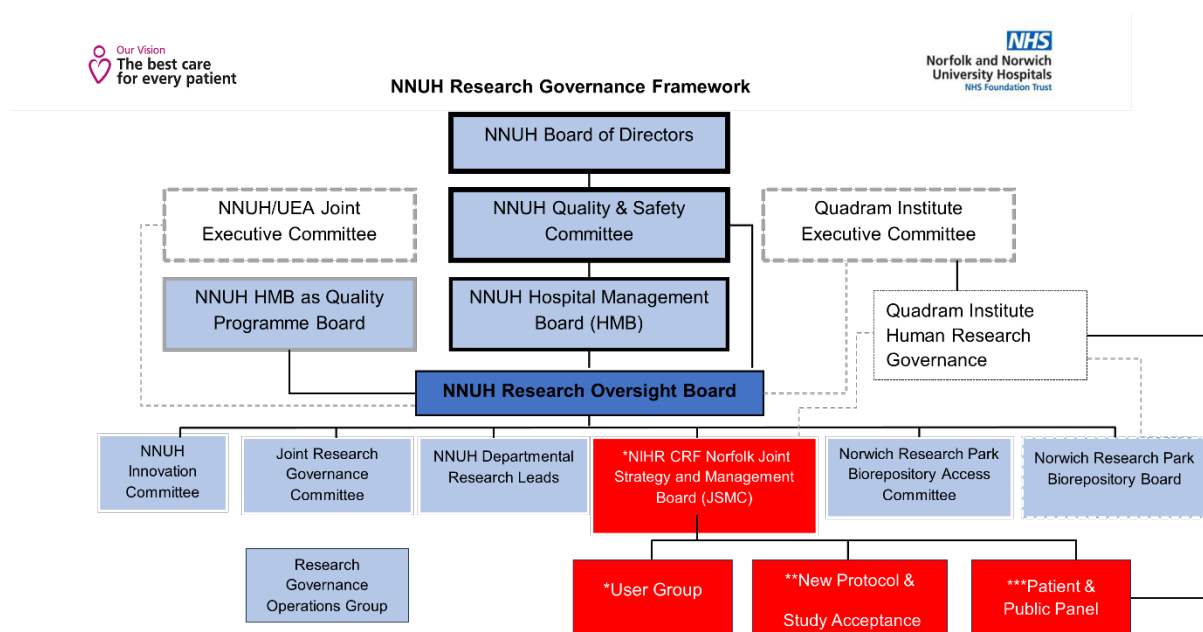
⁵ Jonker L, Fisher SJ, Dagnan D. Patients admitted to more research-active hospitals have more confidence in staff and are better informed about their condition and medication: Results from a retrospective cross-sectional study J Eval Clin Pract 2020 26(1):203-208.

⁶ [Caring with PRIDE: Our plan for the next five years by NNUHinformation - Issuu](#)

commercial studies with increasing importance and metrics around delivery of studies to time and target.

Research Governance

There is a hierarchy of research governance (see figure below) with the Research Oversight Board being pivotal in NNUH's research governance framework and overseeing other research governance committees.



The Research Oversight Board functions to advance the Trust's research capability, provide assurance to the Hospital Management Board and Board of Trustees of a solid and sustainable foundation on which to carry out research and continue to build. During 2022/23, the Board received and reviewed key areas:

- Progress on implementation of the Research Strategy 2020-2025.
- Applications and outcomes of proposals submitted to National Institute of Health and Social Care Research (NIHR) for infrastructure funding including Clinical Research Facility (CRF), and Biomedical Research Centre (BRC).
- The financial position, with reports from the dedicated R&D Finance Manager, on research income derived from grants (including NIHR CRN annual allocation and Research Capability Funding) and commercial research contracts.
- Outputs derived from utilisation of the funding received from the NIHR Clinical Research Network upon which NNUH currently relies as a source of research income to support research delivery services.

- The Quadram Institute Clinical Research Facility and the Norwich Research Park Biorepository (part of the partnership with University of East Anglia and the Quadram Institute Bioscience).
- Oversight of the new Biorepository Access Committee.

Research Strategy 2020-2025

NNUH's Research Strategy 2020-2025 provides a focus and clarity of direction for the organisation, our patients and stakeholders and is intended to position NNUH in a leading role in driving research locally, nationally and internationally. The Research Strategy was published in August 2020.

The present report aligns NNUH's research outputs to progress towards Year 2 implementation of the Research Strategy 2020-2025 and against the following strategic goals i.e. to:

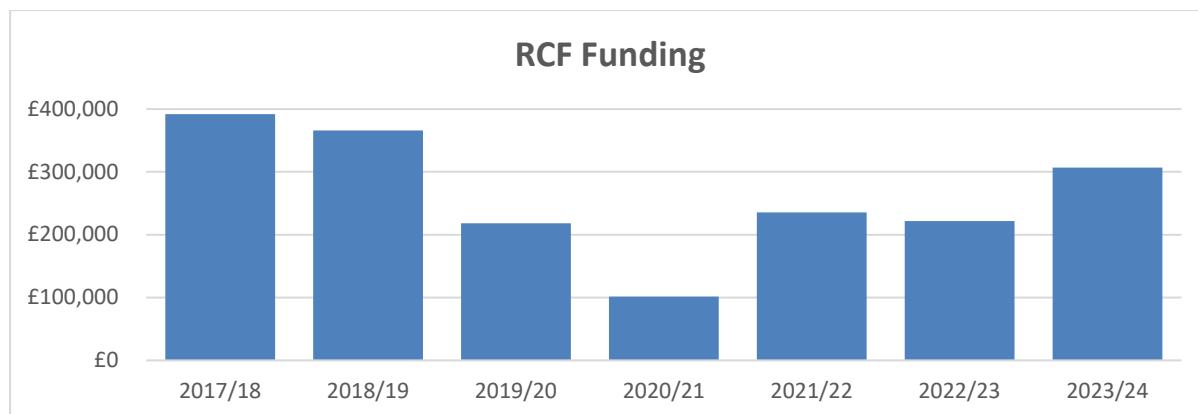
- Embed a culture of research throughout the NNUH creating an inspirational environment that is recognised nationally and internationally, which inspires future leaders of clinical research.
- Consolidate and deepen the special partnership with the University of East Anglia (UEA) and the Quadram Institute Bioscience (QIB).
- Develop sustainable strategic partnerships critical to the region and the wider NHS.
- Be recognised as a leading NHS Trust in applying research and adopting innovation to deliver the best patient care and to benefit the wider NHS.

Goal 1 Embed a culture of research throughout NNUH creating an inspirational environment that is recognised nationally and internationally, which inspires future leaders of clinical research

Enhancing Research Capability

NIHR Research Capability Funding (RCF) is allocated to NHS organisations that undertake research supported by NIHR grants. The designated purpose of RCF is to support or pump prime new research ideas (by generating data to strengthen future NIHR grant applications), providing bridge funding for NIHR faculty members falling between grants and helping to maintain research capacity and capability. The amount of RCF allocated per year to NNUH is proportional to NNUH's NIHR grant funding in the previous year and in relation to the overall level of funding available to NIHR. The graph

below shows NNUH's RCF funding allocation has reduced over previous years with the lowest recorded £101,345 in 2020-21. 2021/22 reversed this trend with £235,652 awarded for 2021-22, £221,828 awarded in 2022-23 and £307,000 awarded in 2023-24.



NNUH's RCF is used in a targeted way to support key research services posts (such as finance, research governance, long term absence of staff critical to the progress of existing NIHR funded projects) and, importantly, to pump prime new research projects to generate pilot data to strengthen future grant applications. On an annual basis, the availability of NNUH RCF is advertised widely and researchers submit proposals. The eligibility criteria are provided in the guidance and applications can be received from researchers from institutions on the NRP provided there is a connection to NNUH (such as an Honorary contract or a bona fide collaboration with an NNUH member of staff), with the expectation that NNUH leads any future proposal resulting from an RCF award. Proposals for RCF are competitively reviewed by a panel and scored against criteria which include alignment with the Research Strategy 2020-2025. Successful applicants are expected to submit a progress report and use RCF to support research of no longer than one year duration that will lead to a successful NIHR grant application.

RCF Recipients 2022-23

Awardee	Amount	Project/Aims(s)	Progress
Dr Ekkehart Staufenberg (Consultant, Neurology)	£8,353	To carry out a retrospective clinical case note review to identify pre versus post vagus nerve stimulation implantation for changes in seizure characteristics and neuro-behaviour parameters. With an aim to determine whether ictal tachycardia could be a biomarker for seizure occurrence	Data will be shown at next year's International League against Epilepsy (ILAE) conference and published in Epilepsia. The team have applied to the Medical Research Council Impact Accelerator Award funding call for the next stage of the work.
Dr Ian Pope (Specialty Doctor, Emergency Medicine)	£15,855	To develop an NIHR HTA application for an RCT of a smoking cessation intervention in the pre-operative period. To develop the application team, undertake PPI work, undertake a literature review of the field and write the application. Also undertake an audit to establish smoking prevalence amongst patients on surgical waiting lists to support the application.	A NIHR Health Technology Assessment (HTA) application was submitted and got through to stage 2 with very positive peer-review comments, sadly it was unsuccessful at committee stage. Planning to make the suggested changes and resubmit to HTA given the positive feedback.
Max Yates Honorary Consultant Rheumatologist)	£19,948	Developing an Integrated Care Research Resource by linking NOAR (Norfolk Arthritis Database) and its bioresource to the Norfolk PMS and Cogstack, providing a truly unique resource for the global research community.	Have employed a data scientist to create the platform to link the data
Samuel Fountain (Professor, School of Biological Sciences, UEA)	£19,583	Validating novel therapeutic interventions for the treatment of early onset severe fetal IUGR: assessing the vasodilatory action of P2X/ P2Y agonists, NO donors and PDE inhibitors in human placental arterioles from normal and growth restricted donors.	A protocol was developed to functionally characterise human placental vessels using wire myography. They pharmacologically characterised the tissue response to purinergic agonists and PDE inhibitors. The pilot data generated from this study will be used for a future British Heart Foundation project grant and a PhD studentship.
Vivek Kalra (Consultant Paediatrician)	£14,407	Cerebral function monitoring (CFM) uses a bedside monitor to record continuously electro-cortical activity in NICU. In general Paeds patients have 4 hourly obs, we anticipate that this approach doesn't accurately detect seizures. So want to investigate CFM in this setting	Gathering PPI support, meetings with other team members and getting the application and research protocol ready. Have been interviewing various parents of children who are admitted and potential candidates to be enrolled in future. Plan to apply to NIHR Research for Patient Benefit

New Research Grants – developing world class research and research important to our community

New research grants

NNUH (and in partnership with the UEA) has been successful in securing research funding from the grant making bodies listed below. We are delighted by the breadth of the awards and the success of our Chief Investigators in leading these research grant applications, bringing together complex research teams with diverse areas of expertise to develop a successful proposal. These funding bodies include local charities that support research of high and direct importance to NNUH's patients and our communities and also major grant giving bodies such as NIHR which can award funding anywhere in the UK and internationally. Therefore, competition in these national funding schemes is very strong and funding success is an indicator of the quality and importance of the proposed research.

Brainomix

British Otorhinolaryngology & Allied Sciences Research Society

British Skin Foundation

Cancer Research UK

Chartered Society of Physiotherapy

Cordis

Health Education England

Medical Research Council

Melanoma Focus

3Million

National Institute of Health and Social Care Research (i4i; DRF: HTA; RCF; Greenshoots)

Primary Sclerosing Cholangitis Support

QIB Seedcorn to support clinician scientists

Royal College of Surgeons

UEA Health & Social Care Partners

New Research Fellowships

The following Fellowship awards (to support individuals with potential to develop future clinical academic careers) were granted:

- 2 Cardiology Advanced Clinical Fellowships
- NICU Advanced Clinical Fellowship
- Urology Advanced Clinical Fellowship
- Cardiology Development and Skills Enhancement Fellowship
- Hepatology Post Doctoral Fellowship

Completed Research Grants

The table below shows grants from prior years that were completed.

Chief Investigator	Project	Funder
Prof Bill Fraser	RETURN	MoD
Prof Bill Fraser	PHAB	MoD
Mr John Philips	Meniere's Disease Registry	Meniere's Society
Prof Iain McNamara	Capability	Smith & Nephew

Goal 2 Consolidate and deepen the special partnership with the University of East Anglia and Quadram Institute Bioscience

Collaboration through supporting clinical academic research leadership

Clinical Associate Professors in Clinical and Translation Medicine

The Norwich Medical School at the UEA and NNUH agreed to establish a number of posts for Clinical Associate Professor in Translational and Clinical Medicine - these joint appointments intended to benefit both partners by working towards the shared goal of expanding the collaborative relationship between the Medical School and NNUH through strengthening the clinical-academic base, collaborative research themes and contributions to undergraduate and postgraduate education.

Both NNUH and Norwich Medical School recognise that sustainable research funding is important in developing a stable successful research environment. The programme was aimed at early career researchers and to provide NNUH Consultants appointed as

Clinical Associate Professors with programmed activities over a four-year fixed term for the equivalent of one day (2PAs) per week.

Recruitment to these posts opened in February 2022 through a competitive process with successful candidates taking up their posts in October 2022. Eight appointments were made in dermatology, gastroenterology, obstetrics, older people's medicine, palliative medicine, respiratory medicine (2) and vascular surgery.

Collaboration through supporting strategic research infrastructure

Quadram Institute

The Quadram Institute (QI) is a unique partnership between Quadram Institute Bioscience (QIB), UEA and NNUH. The Quadram Institute houses the NNUH Endoscopy unit and state of the art clinical research facilities (see below) and Quadram Institute Bioscience to foster intradisciplinary translational research. There has been support from a large grant from the Biotechnology and Biological Sciences Research Council (BBSRC) which provided core funding for two key infrastructure resources of national importance i.e., Clinical Research Facility (CRF) - Quadram Institute and the NRP Biorepository located in the Bob Champion Research and Education Building (BCRE).

Clinical Research Facility (CRF)- Quadram Institute

The CRF-QI is a NHS facility which provides high quality outpatient facilities for research. This includes research studies led by NNUH and, reflecting the partnership, studies led by QIB and UEA and delivered by NNUH on behalf of the QI partners. This is reflected in shared finances for some of the core costs (including estates, utilities and core staffing to minimally support the functioning of the facility).



The partners have also shown their support of the CRF through their contributions to the successful CRF bid to NIHR to become the NIHR Norfolk Clinical Research Facility. This NIHR funding stream provides infrastructure support with £1m (over 5 years being awarded in September 2022). This NIHR infrastructure funding is prestigious as it positions NNUH

alongside 27 other NIHR supported CRFs in the UK. The award was celebrated to the

delight of our workforce, the NNUH Trust and Hospital Management Boards as well as QI Partners Executive Board.

The NIHR Norfolk CRF status allowed opportunity to bid for further NIHR capital equipment funding (ie for items of equipment valued at more than £5,000) from NIHR in January 2023 to support the planned research that the NIHR Norfolk CRF will deliver over the 5 year term of the grant. This was successful and resulted in a capital equipment award of £420k to NNUH to add to our capability to carry out research in neonatal intensive care, maternal health and to establish research facilities at Cromer Hospital. It also includes £100k for an olfactory e-nose breath analyser that will enable extension of collaborative research between QIB and NNUH and drive the generation of new studies in this field.

As part of the NIHR Norfolk CRF award, the CRF-QI Steering Committee was reconfigured and extended to create a NIHR Norfolk CRF Joint Strategic Management Committee (JSMC) (reporting into Research Oversight Board) to specifically oversee the NIHR CRF award. This includes research studies that take place outside the CRF-QI in the other sub-units of the NIHR Norfolk CRF i.e. CRF-Central (in the education Centre in the main hospital building) and CRF-Neonatal Intensive Care. As NIHR CRFs focus on early phase research, translational research and experimental medicine, the JSMC committee ensures that later phase research or studies led by QIB or UEA that may lie outside the primary NIHR CRF focus, are supported and contribute to the strategic development of the CRF-QI. Therefore, the membership of JSMC and its sub-group, the Patient and Public Involvement and Engagement (PPIE) Working Group is 'integrated' including the NIHR Norfolk CRF Directors and representatives from NNUH, QIB, UEA and the NRP who together play a significant role in setting direction and priorities of research as well as monitoring performance.

In 2022/23 there has been strategic and operational focus on increasing the occupancy of the CRF-QI. The JSMC has approved an action plan for business development activities, workforce development and training to allow new areas of research to be carried out in the CRF-QI such as paediatric and early phase clinical trials.

Achievements to date resulting from these business development activities to expand capability are:

- Transfer of some research clinics to the CRF-QI with new specialties starting research clinics: Oncology, Vascular, Orthopaedics, Respiratory
- Planning the creation of a safe and child friendly environment in readiness for new Paediatric research clinics and enhancing the professional competencies of CRF delivery staff through paediatric life-saving skills training.

- Initiation of new risk assessments and development of mitigation plans to ensure safe conduct of early phase clinical research within the CRF-QI. This has included all resident CRF-QI clinical staff trained in Intensive Life Saving skills and Trust support to maintain the deteriorating patient/crash ext 2222 service.
- Over 10 promotional CRF tours offered to commercial pharmaceutical companies, NNUH and UEA board members, overseas scientists.

Norwich Research Park (NRP) Biorepository

The NRP Biorepository hosted and governed by NNUH has continued to expand its portfolio of support for human tissue research projects across the NRP (and beyond). NRP Biorepository staff are embedded in the NNUH endoscopy unit to consent patients and collect tissue samples. NRP Biorepository staff typically work with 4-5 clinicians, attending clinics throughout the week to provide bespoke fresh and frozen tissue samples to researchers.



The NRP Biorepository supported more than 30 projects led by either NNUH, QIB and UEA with 9 new projects approved by the Biorepository Access Committee. BR staff consented more than 630 participants for the use of tissue samples and data, accumulating in more than 3800 tissue samples collected for research use. Of these, 182 were patients attending appointments at the NNUH

Endoscopy department in QI, resulting in the collection of over 1000 gastrointestinal biopsies (and associated participant data).

A Biorepository Access Committee was established to review and approve requests from researchers to access human tissue through the NRP Biorepository. Membership of the committee consists of a wide range of staff from across NRP institutes, including those with governance, clinical, statistical and human tissue research expertise. This committee takes over from the UEA Faculty of Medicine and Health Sciences Human Tissue Ethics Sub-committee that had previously undertaken this function.

Other developments include:

- Implementation of a cost recovery model (developed with NRP Biorepository stakeholders) for projects requiring BR support (including ethical approval, admin, storage) to help support sustainability.
- Substantial amendments to the overarching ethical permissions for i) improvements of participant consent and patient information sheets; ii) changes in process to reflect the new Biorepository Access Committee (see above); iii) approval for the use of CogStack (a digital health informatics tool) for Proof-of-Concept in the applicability of application with Biorepository data.
- The Laboratory Information Management system (Achiever Medical) in operational use, including the upload of historical participants' information, consent forms and samples information from 2020 and 2021.
- Development for online consent portal through the Biorepository website, giving the general public as well as patients the opportunity to be a part of research.
- There has been full operational implementation of the Standard Operating Procedures, and Q-Pulse, a quality assurance and management system.
- Charitable funding from Breast Cancer Now continues to support a member of the NRP Biorepository staff meaning that NNUH is a collection site that contributes to the national Breast Cancer Now tissue bank.
- The Biorepository is governed by NNUH's Human Tissue Licence and was inspected by the Human Tissue Authority in September 2022. There were no major findings although the HTA recommended that the Biorepository seeks a licence independent of the existing NNUH licence.
- NNUH senior research managers continue as members of the NRP Biorepository Strategy Board.

Digitising the NRP Biorepository: research governance and operational changes

<p>The NRP Biorepository has an informative website (biorepository.org.uk) which has been developed as a platform to allow for participants to consent into the NRP Biorepository for the collection of surplus tissue and/or data for research. Substantial amendments to the ethical permissions have been approved for the online consent of potential donors and user testing of the signing up process has been completed. A small-scale launch of the online facility is planned through a clinic at the NNUH by the end of 2023, with a view to role out more widely in 2024.</p>
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Norwich Clinical Trials Unit

The Norwich Clinical Trials Unit (NCTU) is part of the UEA and was established in 2013 to provide an effective platform for the conduct of high-quality clinical trials. NNUH works with NCTU to develop funding applications and on trial design, management, quality assurance, analysis and reporting. NCTU has grown steadily since 2013 and is now established as one of the leading clinical trials units in the UK in terms of its support for NIHR research.

NCTU is fully registered with the UK Clinical Research Collaboration (UKCRC) and has expertise in core research competencies such as medical statistics, health economics, data management, trial project management and delivery, quality control systems across a wide range of drug, device and complex intervention trials.

The close working relationship between NNUH and UEA is underpinned by the Joint Research Governance Committee and joint Standard Operating Procedures (SOPs) applicable to all health care research. Senior NNUH research staff are members of the NCTU Executive Committee and NCTU management staff are members of NNUH's Research Oversight Board.

NCTU is currently conducting 9 NNUH sponsored trials with a total grant value in excess of £10m.

Strategic Collaboration

NNUH is embedded on the NRP through participation in key institutes and representation on research boards:

- The Norwich Institute of Healthy Ageing (NIHA) launched in 2020 is based at the UEA and focuses on the impact of lifestyle factors (e.g. nutrition, physical activity, smoking, alcohol, sleep) on health outcomes. NIHA is a consortium of NRP organisations together with Norwich City Council and Norfolk County Council and as a founding member NNUH is represented on the NIHA Executive Group by Dr Martyn Patel (Consultant Geriatrician) and Professor Jeremy Turner (Consultant in Diabetes and Endocrinology) with Dr Ketan Dhatariya (Consultant in Diabetes, Endocrinology and General Medicine) as deputy lead on the Cardiometabolic Health and Brain Ageing theme.
- Norwich Cancer Research Network showcases the breadth and depth of cancer research taking place on the Norwich Research Park, improving links between scientists, clinicians and research bodies and driving high quality research and open communication.
- NNUH is represented on the Norwich Clinical Trials Unit (NCTU) Executive Committee by Prof Kris Bowles (Consultant Haematologist, Associate Medical

Director of Research), Dr Jenny Longmore (Director of Research Operations), Prof Erika Denton (Medical Director) and Mr James Hernon (Consultant General and Colorectal Surgeon). Prof Andrew Wilson (Consultant in Respiratory Medicine) is also Clinical Associate Director of the Norwich Clinical Trials Unit.

- QI Executive Committee which is a strategic body overseeing the Quadram Institute. NNUH participates actively in the quarterly meetings with permanent membership represented by Mrs Felicia Rowe (CRF Operations Manager), Mr John Paul Garside (Head of Legal Services) and Dr Simon Rushbrook (Consultant Hepatologist);
- NRP Enterprise Committee which is a park-wide enterprise advisory body, and expert panel to share knowledge and consider enterprise activity and funding opportunities that add value to the individual members. The Enterprise Committee advises the CEO of the Anglia Innovation Partnership on proposed recommendations on the NRP Enterprise Strategy and operational activity for the Anglia Innovation Partner LLP Board. NNUH is represented by Director of Research Operations (Dr Jenny Longmore).
- NRP Knowledge Exchange Group a forum which facilitates protection and exploitation of novel intellectual property. NNUH is represented by Dr Jenny Longmore (Director of Research Operations).
- NNUH is one of the 11 Associate Partners of the NRP Doctoral Training Programme (UKRI-BBSR) which supports the provision of high-quality PhD research training.

Collaboration through research sponsorship

NNUH plays an important role in facilitating collaborative research. As a large acute teaching hospital, robust clinical and research governance mechanisms are in place and NNUH is able to sponsor research studies (meaning to take responsibility and liability for running all aspects of the research study under the UK Policy Framework for Health and Social Care Research). Collaborative arrangements allow NNUH to sponsor QIB / UEA led research for studies when the Quadram partner is not able to sponsor e.g. clinical trials regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). Currently NNUH acts as sponsor for 25 studies with a further 7 and 24 sponsored by Quadram Institute Bioscience and University of East Anglia respectively. These arrangements are reflected in a Joint Research Governance Committee with membership from all Quadram partners and the Norwich Clinical Trials Unit, in addition to joint governance arrangements for the CRF and NRP Biorepository.

Collaboration through research grants

Grants are a way of securing funding for research. The importance of being a grant holder is that it reflects that the research is conceived and driven by the grant holder, although there may be collaborations and distribution of the grant funding to other organisations. With support from the Research Services Office, NNUH researchers and UEA and/or QIB researchers regularly collaborate to submit joint grant applications taking into account the most appropriate organisation to lead on the grant application and be the 'holder'.

94 new grant submissions were made either with NNUH, UEA or the QIB as the lead applicant and the successful awards are shown in the table below, totalling £8.1m in new grant funding.

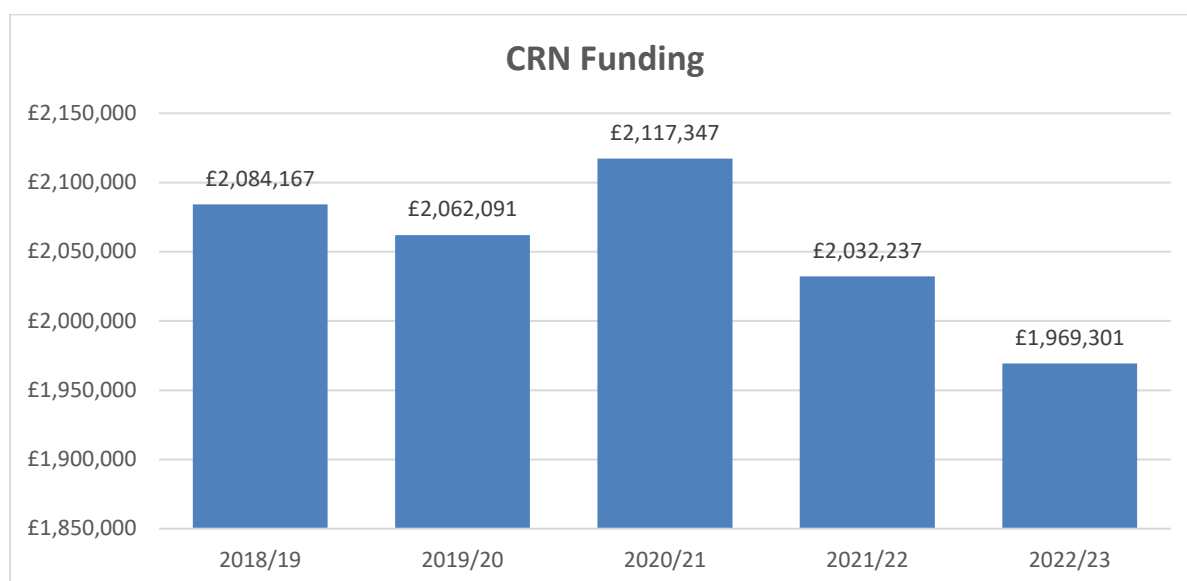
New Grants Awarded 2022/23 *Total award forecasted			
Applicant (NNUH)	Project	Funder	Award*
Dr Leo Alexandre	PREDICT-GI-IRON	N&W ICB RCF	£7k
Prof Nail Broomfield	EASE	NIHR HTA	£1.9m
Dr Natasha Corballis	Coronary Bifurcation PCI	NIHR DRF	£389k
Heather Dinar	Diabetic foot	HEE	£7.5k
Mr Andrew Douds	Mucosodom	QI Seedcorn	£58k
Dr Amara Elzuiber	SABR-PSC	NIHR DRF	£749k
Dr Mairenn Garden	Smell Test	Boars	£1k
Dr Catherin Gooday	DFU-REFORM	NIHR HTA	£200k
Dr Sadiyah Hand	Obese female asthma phenotype	N&W ICB RCF	£7k
Dr Francois Kwong	Machine learning to standardise the quantification of Tertiary Lymphoid Structures within cancer	NIHR i4i	£33k
Dr Eleanor Mishra	Bacteriology and mechanisms of infection and colonisation of indwelling pleural catheters	QI Seedcorn	£34k
Prof Helen Murphy	PROTECT	NIHR HTA	£1.5m
Dr Alagaratriam Niruban	Identification of Parkinson's-Specific Microbiota (ParMic study)	QI Seedcorn	£58.5k
Prof Sheng Qi	Adopting digital 3D technology to improve breast cancer management	UEAHSCP	£20k
Mr Mark Rochester	PREMIS	NIHR HTA	£1.8m

Dr Stephanie Smith	Urine Biomarkers	NIHR DRF	£400k
Mr Phil Stather	Walk-a-Cise	UEAHSCP	£14k
Dr Vasiliki Tsampasian	SGLT2i	NIHR DRF	£475k
Dr Zoe Venables	Molecular genetics of Melanoma	CRUK	£25k
Dr Zoe Venables	UKMCC	BSF	£300k
Dr Emma Webb	TOSCA	UEAHSCP	£20k
Dr Emma Webb	The interaction of diet, gut microbiome and pharmacotherapy in young people with severe obesity.	QI Seedcorn	£56k
Prof Ailsa Welch	EAMIT	N&W ICB RCF	£13k
Prof Andrew Wilson	Brainomix	Brainomix	£76k

Goal 3 Develop sustainable strategic partnerships critical to the region and wider NHS

National Institute for Health Research (NIHR): Clinical Research Network (CRN)

NNUH hosts the core NIHR CRN East of England team (covering Cambridgeshire, Norfolk, Suffolk and parts of Bedfordshire, Essex and Hertfordshire). CRN East of England are responsible for allocating approximately a £20m annual budget across partner organisations in the East of England intended to support delivery of studies adopted onto the CRN portfolio. The total funding received by NNUH from the NIHR CRN for the 2022/23 financial year was £1,969,301 (2021/22: £2,032,237) and is summarised in the chart below along with past years.

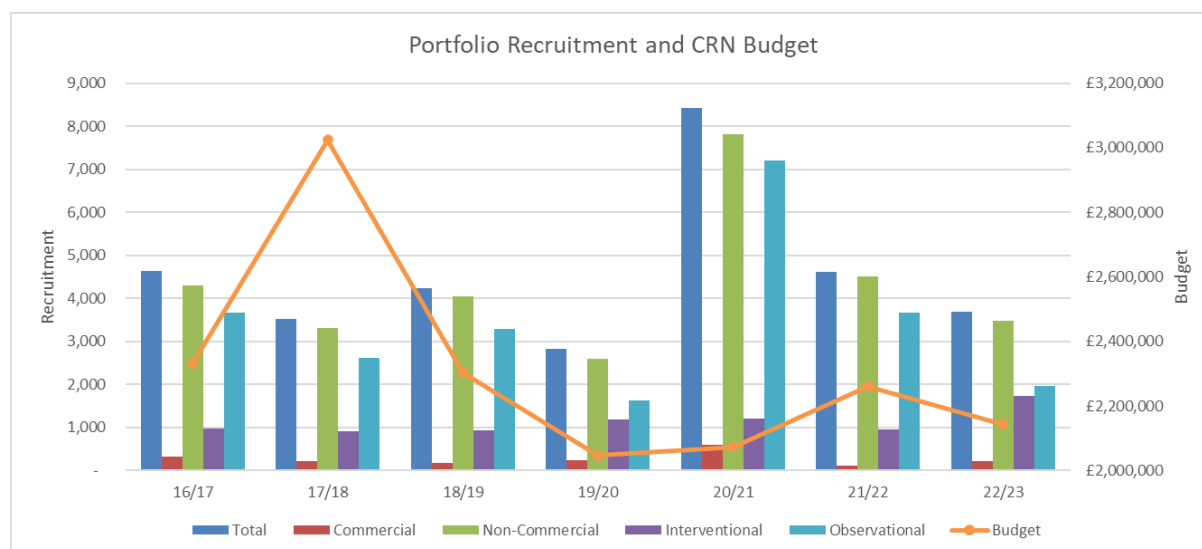


The majority of the allocation supported a dedicated research delivery team (Nurses, Midwives, Corporate services staff, Clinical Trial Practitioners, non-clinical staff and medical staff). In addition, the following in year funding was also awarded:

£147,744 Capacity and Constraints - to assist in facilitating the success of the Managed Recovery Programme by boosting the staffing establishment.

£24,395 (2021/22: £25,000) Greenshoots – competitive awards to individuals either making or with potential to make significant contribution to the conduct and delivery of a study by taking on the role of Principal Investigator (PI).

New Greenshoots awarded 2022/23	
Applicant (NNUH)	Specialty
Parivakkam Suriyaprakasam Arunakumari	Reproductive Health and Childbirth
Philip Christopher Bennett	Surgery
Raducu Costel Clapuci	Children
Samuel Hodgson	Stroke
Vrinda Arora	Reproductive Health and Childbirth



Studies adopted onto the CRN portfolio are multi-centre studies and at the end of the 2022/23 reporting period (31st March 2023) NNUH had **255 studies** open (this includes studies actively recruiting participants and studies which have completed the recruitment phase and are in follow-up). The aim is to increase NNUH's income derived from research with commercial companies. In 2022/23, 29 studies are sponsored by

commercial organisations with a range of pharmaceutical, biopharmaceutical, biotechnology and medical devices based in the UK and internationally.

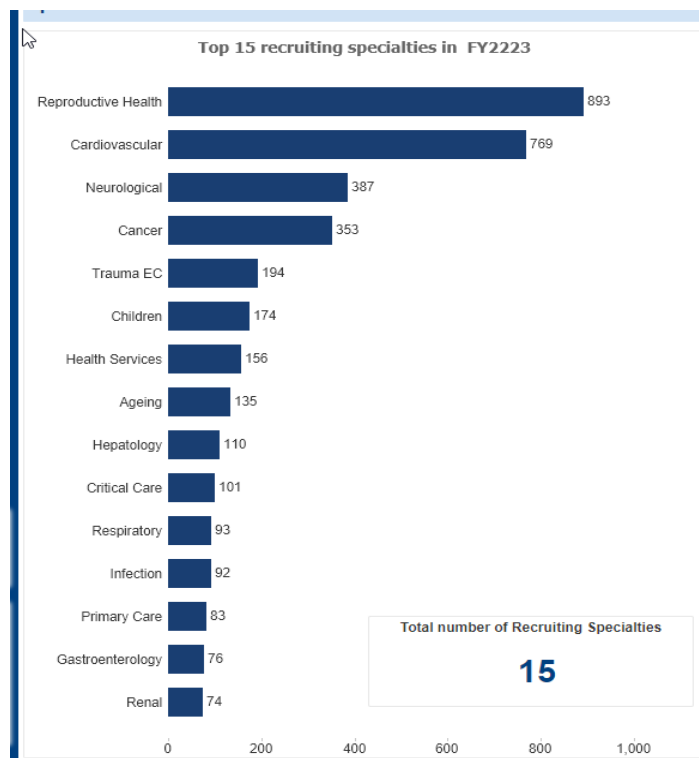
Below are some of the highlights in relation to research hosted by NNUH:

- NNUH is one of the four national sites delivering the Baby Breathe study (prevention of return to smoking in post-natal period, devised by Dr Caitlin Notley, UEA) with the Midwifery Research team consistently recruiting the most women to the study since it opened in July 2021.
- Patients attending Cromer hospital were provided with the first opportunities to participate in research through into a rheumatology study designed to monitor inflammatory conditions and also as tissue donors for the NRP Biorepository.
- High level of efficiency in delivering the CLEAR study (minimally invasive procedures in benign prostatic hyperplasia) recruiting the UK participant in the UK to this commercial study and the highest international recruitment.
- Achieved second highest worldwide recruitment for ADJUST trial (juvenile arthritis).
- Inflatable neonatal incubators previously used on the mOm study (looking at a severe form of spina bifida in neonates) were sent to Ukraine to assist in the conflict.

Overall, the number of participants recruited was 3679 in 2022/23 (representing 5.1% of the total in the CRN East of England region) and recruitment is heavily biased towards non-commercial studies. The Critical Care research team were recognised as the 8th highest recruiter of 143 sites in the UK to the REMAP-CAP clinical trial (Randomised, Embedded, Multi-factorial, Adaptive Platform Trial for Community-Acquired Pneumonia).

	Recruitment onto CRN portfolio studies* (% participants n = 3617)
Non-commercial sponsor	94.5%
Commercial sponsor	5.5 %
Observational type	49.0%
Interventional type	51.0 %
Observational & interventional	0.0%
*Note: in addition 335 participants recruited into non-CRN portfolio studies	

The top recruiting specialties (as determined by the NIHR CRN categorisation of the study) are shown below:



Contributions to the wider NHS benefits: Highlights

Occupational Therapy

Successful award of Research Scholarship programme funded by Norfolk Institute of Coastal and Rural Equality (NICHE) and led by JPUH.

Rebecca Winter, Occupational Therapist led a 'craft' group for acute inpatients on the neurosciences ward at the NNUH. Our stroke patients should be meeting forty-five minutes of therapy daily as per SSNAAP (Stroke Sentinel Audit Programme) national targets.

Reproductive Health

Reproductive Health is an area that continually achieves high accrual rates with studies successfully recruiting pregnant women into many different areas of interest. There are currently seven open NIHR CRN portfolio studies that are all meeting time and target with some going beyond this. There are several pipeline studies chosen for beneficial outcomes and potentially optimal changes in practice for the women cared for. The team

have formed professional relationships with academic researchers from the UEA, Biorepository and the QI where they have successfully delivered their studies and are awaiting dissemination of findings to change practice.

Goal 4 Be recognised as a leading NHS Trust in applying research and adopting innovation to deliver the best patient care and to benefit the wider NHS

Generating and disseminating new research knowledge

Publications

Publication of new research findings contributes to the global body of knowledge. Research should be carried out to the standards required for the findings to be published in peer reviewed medical journals which have international readership and influence.

Bibliometric analysis

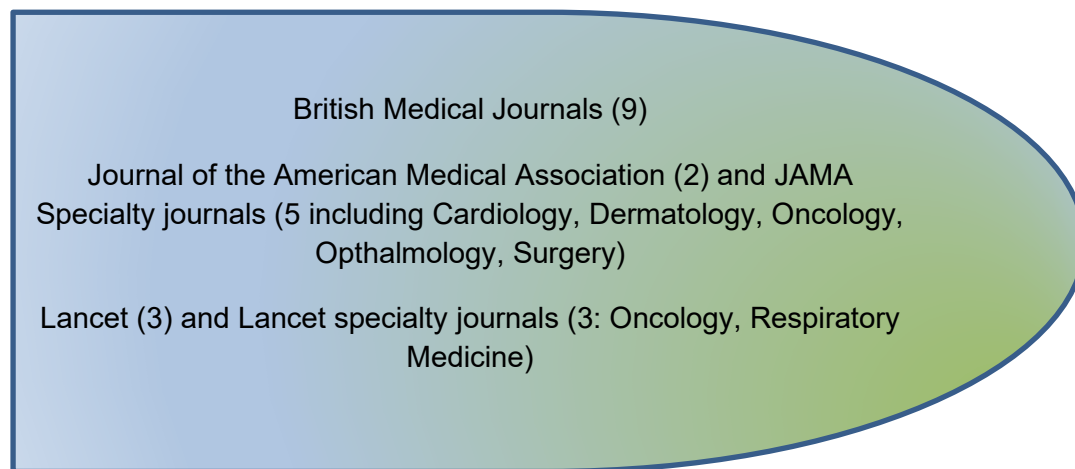
A literature search was conducted by the NNUH librarian using the search terms 'research', 'Norfolk and Norwich University Hospitals' and the year of publication as '2022', this included searching for:

- peer reviewed original articles
- clinical care guidelines
- scientific / research reviews

The following were excluded or removed from the resultant search:

- Case studies / reports
- Service evaluation and audits
- Editorials
- Letters/ comment/notes
- Erratum
- Conference abstracts / proceedings

The list was cross checked with the publications provided in the individual reports from the Research Leads resulting in 283 publications. This is likely an under representation as not all Research Leads returned reports and there is a continued issue that when authors hold joint appointments between and NNUH and the UEA, listing of both institutions in the address field of the publications does not always occur.



These papers reflect the quality of NNUH research. The publications cover a wide range of specialities for example cardiology, endocrinology, infectious diseases, obstetrics, oncology, orthopaedics, rheumatology, respiratory medicine and surgery. They represent collaborative projects with UEA colleagues and also national and international partnerships. There were publications in the world's highest impact and most widely read medical journals including British Medical Journal, Journal of the American Medical Association (and JAMA specialty journals), Lancet (and Lancet specialty journals) and Nature (and Nature specialty journals) and also in high impact specialty journals such as British Journal of Cancer, Circulation, Clinical Oncology and Hepatology.

Multi-centre research studies are part of the modus operandi of the NIHR's CRN, contributing to the CRN a highly valued strategic resource of national importance. NNUH researchers who act Principal Investigators for multi-site studies are not always cited as authors on peer review publications but are named in acknowledgements. Since acknowledgements are not accessed by standard bibliometric search tools these contributions are not reflected in the list of published research papers.

Wider influence: research leadership and supporting excellence

A substantial portion of NNUH's researchers are research leaders and contributors to their specialist fields and hold prestigious positions which influence and promote research excellence regionally, nationally and internationally. This includes specialty areas of dermatology, palliative medicine, rheumatology, urology, hepatology and gastroenterology, histopathology, radiology, reproductive health.

The positions and roles include:

- Editor in Chief / co-editor / associate editor and members of Editorial boards for peer reviewed journals
- Expert reviewers for new national clinical guidelines
- Expert reviewers for grant funding bodies such NIHR and local charities
- Regional and national Specialty Leads / Mentor with the NIHR CRN
- Chair / deputy chair / board / honorary treasurer / research committee members / working party members and advisors of national and international professional bodies, charitable organisations, patient-focused organisations and disease registries, eg Caroline Barry is Clinical Advisor (Palliative and End of Life Care) for Norfolk and Waveney ICB and in 2022 Caroline Barry was also regional clinical advisor (East of England) for Macmillan and Professor Andrew Wilson is co-module lead of the Asthma UK Centre for Applied Research Committee.
- Membership of global clinical trials management groups including trials supported by commercial organisations and also disease specific Clinical Trials Networks
- Expert advisory panel member for grant funded projects
- External examiner for MSc course
- External referee for grants programmes

Research that benefits patients and the wider NHS

It is accepted that research active hospitals have better health outcomes for patients and patients have more confidence in staff and are better informed about their condition and medication (for example see Jonker et al 2020).

NNUH researchers are motivated by their research making a real difference to patients and the wider public. An important part of evaluating the impact of research is to determine the value and benefit to patients. This is often less tangible to measure than the quantification of research income, number of studies and number of publications. Nevertheless, NNUH is a teaching hospital and research excellence benefits our patients by changing clinical practice and improving patient experience. Below are examples of how research has influenced clinical practice at NNUH and how NNUH researchers and clinicians have contributed to the introduction of new clinical guidelines at national level.

Cardiology

NNUH's cardiology research is included in a Scientific Statement by European Association in Preventive Cardiology 'Promotion of healthy nutrition in primary and

secondary cardiovascular disease prevention: a clinical consensus statement from the European Association of Preventive Cardiology' referencing the publication by Vassiliou VS, Tsampasian V, Abreu A, Kurpas D, Cavarretta E, O'Flaherty M, Colombet Z, Siegrist M, De Smedt D, Marques-Vidal P. Eur J Prev Cardiol. 2023 Jun 1;30(8):696-706. doi: 10.1093/eurjpc/zwad057

Dermatology

The British Association of Dermatologists published a guideline for the management of people with vitiligo (a condition which has an increased impact on people with richly pigmented skin) which incorporated research from the HI Light Vitiligo NIHR clinical study for which NNUH participated as a recruiting centre with Nick Levell as the local Principal Investigator. Nick Levell was also a named collaborator in this guideline as Chair of guidelines committee)⁷.

Neonatal Medicine

The results of ARCTIC antiseptic randomised controlled trial have informed the development of the chlorhexidine position statement published by NPPG (Neonatal and Paediatric Pharmacists Group)/endorsed by BAPM (British Association for Perinatal Medicine).

Results of vitamin K observational study in preterm babies⁸ indicate routine post-discharge vitamin K should be given to breastfeeding preterm infants. Application to introduce this service improvement was made to D&TC, 2022. New vitamin K supplementation policy is being introduced November-December 2023.

Nutrition and Dietetics

Members of the Endocrinology & Diabetes team (Dr Myint and research Dietitians Katherine Paterson & Rachel Ball) contributed to an international phase 3 double blind randomised multicentre controlled trial 'Effect and Safety of Semaglutide 2.4 mg Once-weekly in Subjects With Overweight or Obesity'. This was a major trial sponsored by NovoNordisk that evaluated the efficacy and safety of semaglutide as an adjunct to a

⁷ British Journal of Dermatology 186 (1), 18-29 Vitiligo British Association of Dermatologists guidelines for the management of people with vitiligo 2021*V Eleftheriadou, R Atkar, J Batchelor, B McDonald, L Novakovic, JV Patel, J Ravenscroft, E Rush, D Shah, R Shah, L Shaw, AR Thompson, M Hashme, LS Exton, MF Mohd Mustapa, L Manounah, British Association of Dermatologists' Clinical Standards Unit.

⁸ <https://doi.org/10.1111/jth.15874>

lifestyle intervention for body weight reduction which, overall, recruited 1961 participants in multiple research centres. It led to a publication in a high impact journal (Wilding et al 2021, New England Journal of Medicine 384: 989-1002)⁹. Research dietitians Hannah Bone and Katherine Paterson contributed to the preceding phase 2 trial to determine optimal dose of semaglutide for the above phase 3 trial.

The resultant evidence from this study (1) has contributed to this year's NICE Technology Appraisal 875; (2) recommendations for its use in specific weight management services in England 'Semaglutide for managing overweight and obesity' (March 2023)¹⁰.

Radiology

Cardiac MRI and 4D flow imaging research team and Dr Pankaj Garg's Cardiology patients at NNUH have become the first to benefit from ongoing research that uses MRI to create detailed images to diagnose heart valve disease. Dr Pankaj Garg, NNUH Honorary Consultant Cardiologist, Associate Professor at the UEA Norwich Medical School lecturer, and Wellcome Trust Clinical Research Career Development Fellow is putting his research into clinical practice for the first time, thanks to the latest MRI equipment installed as part of an £8m project to replace ageing CT and MRI scanners at the Trust and new 4D flow software. Dr Garg works closely with the Imaging Research team and our radiologist and radiographer staff to make these research developments successfully transition into the clinic.

A systematic literature review by Prof. Tom Turmezei and colleagues published in 2021 was pivotal in NICE re-evaluating their decision to not just restrict radiofrequency ablation in the treatment of spinal metastasis to research only, but also allowing it in selected clinical palliative cases. See <https://www.nice.org.uk/guidance/IPG758> (Murali N, Turmezei T, Bhatti S, Patel P, Marshall T, Smith T. What is the effectiveness of radiofrequency ablation in the management of patients with spinal metastases? A systematic review and meta-analysis. J Orthop Surg Res. 2021 Nov 6;16(1):659. doi: 10.1186/s13018-021-02775-x. PMID: 34742319; PMCID: PMC8571892).

⁹ <https://www.nejm.org/doi/full/10.1056/NEJMoa2032183> Once-Weekly Semaglutide in Adults with Overweight or Obesity | NEJM

¹⁰ www.nice.org.uk/guidance/ta875 guidance published March 2023

Respiratory

Contributed to European Society of Cardiology (ESC) and the European Respiratory Society (ERS) Guidelines for Pulmonary Hypertension specifically the importance of genetic testing and identify specific phenotypic features in patients with idiopathic pulmonary artery hypertension – with the guidelines referencing ‘Identification of rare sequence variation underlying heritable pulmonary arterial hypertension’ by Graf, Haimel, Bleda, Hadinnapola et al. Nat Commun. 2018 Apr 12;9(1):1416.

Rheumatology

Dr Chetan Mukhtyar’s editorial on “Getting it Right for PMR” in the journal ‘Rheumatology (Oxford)’ has given rise to a pan-European project to form recommendations for the early referral of patients with PMR. This has resulted in one systematic review of literature recently published (PMID 37639896) and draft recommendations which will be presented first at the American College of Rheumatology annual conference in November. Dr Mukhtyar was the methodologist for that project.

Dr Chetan Mukhtyar’s work as a co-methodologist has resulted in a European project on designing remote care and tele-health programmes.

Dr Chetan Mukhtyar’s expertise in vasculitis contributed to a European project on managing cardiovascular risk in patients with autoimmune rheumatic disorders.

An independent group called ‘Medics for rare diseases’ approached Dr Chetan Mukhtyar to help formulate an easily digestible package to revise the topic of large vessel vasculitis for medical students revising for final exams (link above).

Urology

An integrated app has been created to promote patients physical exercise preoperatively following the CADENCE clinical trial.

Websites

A number of websites have been developed for outreach to our communities including:

- www.biorepository.org.uk – a dedicated website for the NRP Biorepository
- www.Charmerstudy.org – a dedicated website for CHARMER a five year (2020-2025) England-wide research project to develop and test a hospital deprescribing behaviour change intervention

- www.chiefpd.blogs.bristol.ac.uk – a website to support recruitment to CHIEF PD study (Cholinesterase Inhibitors to Prevent Falls in Parkinson's Disease) of which NNUH was a recruiting site
- www.octa-research.org/index.html Computerised Tomography In Osteoarthritis research (OCT) – a group chaired by Prof Tom Turmezei.
- Social media videos were created by the research midwifery team to help promote the Baby Breathe study and Pearl study led by UEA and QIB respectively.

A new maternity research webpage was added to the NNUH intranet.

In conclusion:

Progress against the Research Strategy 2020-2025 has been sustained amid the challenges faced in the post pandemic environment. We can report good overall NNUH performance metrics for NNUH in terms of contributions to the NIHR CRN, new research publications, grant submissions (and successful awards), levels of professional development (such as postgraduate qualifications) and involvement in external organisations consistent with prior years. NNUH researchers continue to be involved in research that leads to evidence based changes in patient care.