

## Our Clinical Research Strategy 2021-2026





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Our context .... Key achievem Introduction .... Developing ou Our vision ..... Our goals and For our Patier For our Patier For our Partn To remain Pic To improve ou

Foreword .....

Please note: some photographs in this document were taken prior to the COVID-19 pandemic

# Contents

4
6
10
12
14

## Foreword

The unprecedented local and global research response to the COVID-19 pandemic has brought the importance of clinical research into sharp focus, and significantly increased awareness and interest in this important area.

It is well recognised that clinical research answers scientific questions to address health challenges. What can be less obvious to some is the positive impact of clinical research upon organisations and populations. Not only is clinical research known to improve science, it also improves clinical care and outcomes, patient experience, staff satisfaction and retention. It helps to build organisational reputation and it attracts investment. It supports the health, wealth and wellbeing of the population.

It follows then that if we collectively embrace and embed research in Newcastle Hospitals then we are creating a better future for our patients, our staff and the wider population.

That is why research and innovation is a vital component of our Trust strategy and why we have this more detailed supporting strategy that outlines our plan to achieve local excellence and global reach through our clinical research.

We are building upon a strong foundation in Newcastle. Our research excellence is recognised nationally and internationally in areas including but not limited to ageing, cancer, child health, diagnostics, robotic surgery, advanced therapeutics, microbiology, mitochondrial disease, immunology, transplantation, rare diseases, liver and musculoskeletal diseases.

Our strategy sets out how we will build on this legacy so that Newcastle cements its national and international reputation for excellence, whilst continuing to make a tangible difference to local people.

We want you to read our strategy and think about how you can support

or become more directly involved in an area of research. Clinical research should not be limited to those who are directly delivering research studies. We can all contribute in some way, whether it is informing research through clinical observations, signposting patients to research opportunities and information, promoting the fact that we are a research-active organisation or adapting clinical practices in line with research findings.

We then want everyone to share our ambition to deliver world-class research that not only advances science but enhances our services, promotes economic growth and ultimately, enhances the health, wealth and wellbeing of the Newcastle population and beyond.

## Our COVID-19 Response

One year on from when we first received patients with COVID-19 in Newcastle Hospitals, we have recruited over 4,000 participants (adults and children) to 44 different COVID-19 research studies – placing us in the top three Trusts in the country for the total number of COVID-19 studies opened and the total number of patients recruited.

These predominantly urgent public health studies have been opened in record time (in days rather than months) and included four separate COVID-19 vaccine studies.

One of the vaccines delivered as part of our research in Newcastle has since been approved for use in a number of countries with others expected to be approved in the near future. Other studies have helped to discover new medical treatments that significantly reduce mortality rates for patients with COVID-19 and shorten recovery time for those admitted to hospital.

We have also contributed to world-leading laboratory science with a recent Newcastle-led study increasing understanding of the immune response to COVID-19 at the 'single cell' level.

Then, in addition to the delivery of research, our clinicians have also been actively contributing to national and international discussions on the prioritisation of COVID-19 studies.



Dame Jackie Daniel Chief Executive Officer



Andy Welch Medical Director and Deputy Chief Executive Officer



## **Our Context:**

**Research at Newcastle Hospitals** 



#### We have much to be proud of in terms of our clinical research at Newcastle Hospitals.

In an average year, we recruit in excess of 10,000 individuals into hundreds of different research studies (or trials), ensuring that we are consistently one of the best performing organisations in national league tables pertaining to research activities.

With the support of over 350 members of staff employed specifically to support the set-up and delivery of clinical research, we offer a full range of research, from 'early phase' trials where medicines are tested in patients for the first time through to 'late phase' trials which are essential before a medicine finally receives approval for general use. In addition to testing medicines, we perform many other forms of research, from something as simple as completing a questionnaire through to 'discovery' research that may involve taking small pieces of tissue, for example from an area of inflammation, to understand more about disease.

Whilst most of our research participants live in the North East and North Cumbria, we are also seeing an

increasing number of participants from much further afield because of our reputation and our nationally leading work into the design and delivery of virtual clinical trials<sup>1</sup>

Our on-site trials operate across all our hospitals sites, often in dedicated stateof-the-art research facilities including:

- The National Institute for Health Research (NIHR) Newcastle Clinical Research Facility (CRF) based at the Royal Victoria Infirmary (RVI) incorporates the Dental Clinical Research Facility in the Dental Hospital and the Clinical Ageing Research Unit at the Campus for Ageing and Vitality (CAV).
- The Sir Bobby Robson Unit at the Freeman Hospital. > This is **1 of 14** NIHR Cancer Research UK Experimental Cancer Medicine Centres.
- The Newcastle Hospitals Clinical Research Vaccination Hub at the Freeman Hospital.

6



> This is **1 of 23** CRFs in England

• The NIHR Newcastle Patient Recruitment Centre (PRC) at CAV. > This is **1 of 5** centres in England.

Our Newcastle Joint Research Office (NJRO) and our research informatics team based at Regent Point have an enviable national reputation for their expertise, experience and innovation.

Our major and high quality research activities, which generate in excess of £35 million per year, have secured our reputation as an efficient, worldleading research organisation that has generated strong industry partnerships enabling us to have preferential access to new research opportunities.

Whilst we collaborate closely with various academic, healthcare, research and industry partners in formal and informal partnerships and networks, our partnership with Newcastle University is critical to our delivery of high calibre research. A large proportion of our research funding is awarded through collaboration with the University. There is no doubt that we benefit



from the University's ranking as one of the top medical schools in the UK, with almost all of its research being officially classified as world-leading or internationally excellent in terms of originality, significance and rigour. The strength of this relationship is evidenced by the Academic Health Science Centre (AHSC) status awarded to the partnership in April 2020 by the NIHR, NHS England and NHS Improvement.

In addition to having its own Clinical Trials Unit (CTU), the University hosts the NIHR North East and North Cumbria Research Design Service, 1 of 4 NIHR Blood and Transplant Research

Units and the only NIHR Innovation Observatory in England.

Our hosted NIHR infrastructure also extends beyond our own research delivery facilities to include the Local Clinical Research Network (LCRN) for the North East and North Cumbria.

We co-host the Northern Alliance Advanced Therapy Treatment Centre and work closely with regional NIHR infrastructure such as the NIHR Applied Research Collaborative, which focuses on health and social issues relevant to our regional population.

We receive NIHR infrastructure awards

for the Newcastle Biomedical Research Centre (1 of 20 in England and the only one focusing on ageing and long-term conditions) and the Newcastle Med-Tech in vitro Diagnostics Cooperative (1 of 11 centres in England).

Existing at the interface between the NHS, the University and industry, Newcastle then has Novopath - an innovation hub for tissue-based diagnostics which has emerged from the Newcastle Molecular Pathology Node (1 of 6 nodes in the UK funded by the Medical Research Council and the Engineering and Physical Sciences Research Council).

#### An Academic Health Science Centre: Newcastle Health Innovation Partners

The name of our AHSC is Newcastle Health Innovation Partners (NHIP)

It is one of just eight AHSCs in the UK, with core partners comprising:

- The Newcastle Upon Tyne Hospitals NHS Foundation Trust
- Newcastle University
- Newcastle City Council
- Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
- Academic Health Science Network for the North East and North Cumbria

The collective vision of NHIP is to become the most integrated and innovative Academic Health Science Centre in the world, working with innovators to discover, develop and deliver new solutions in healthcare to improve population health in the North East and North Cumbria.

The concept behind this and all the AHSCs is that they build upon the 'added value' of collaborative activities that institutions cannot do alone and where the whole is greater than the sum of the parts.

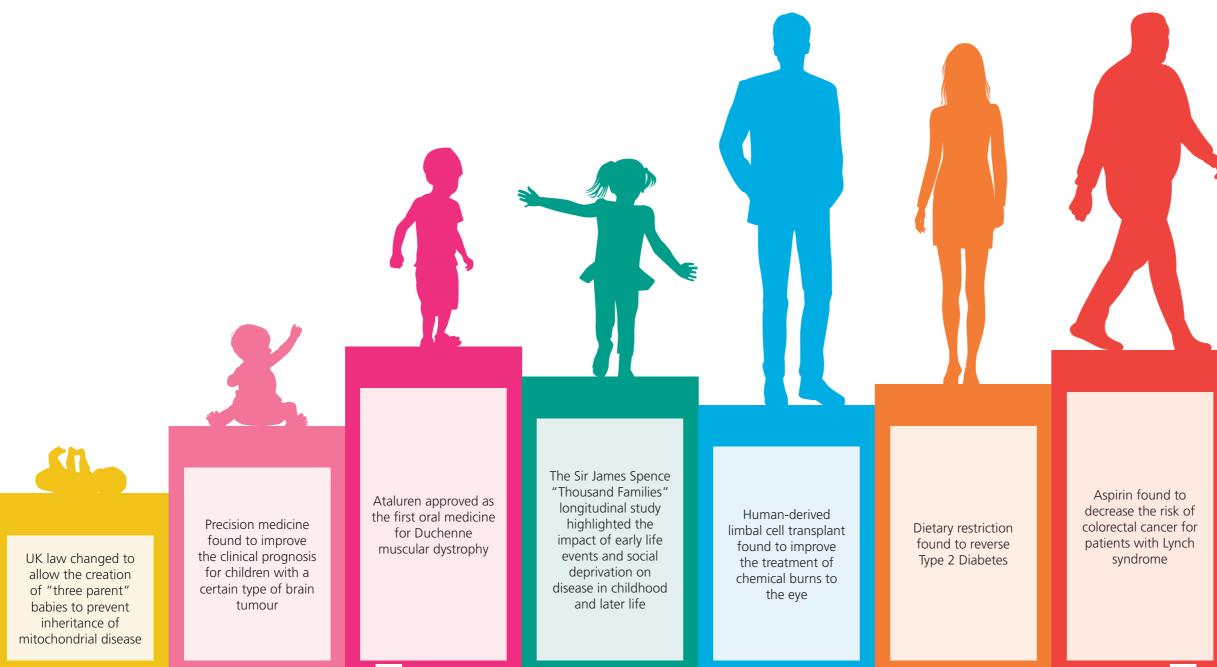
<sup>1</sup>Clinical trials that use technological solutions, such as video conferencing software and courier services, to avoid the need for participant attendance at a research facility.

Our major and high quality research activities, which generate in excess of £35 million per year, have secured our reputation as an efficient, world-leading research organisation that has generated strong industry partnerships enabling us to have preferential access to new research opportunities

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# Key Research Achievements

Some research achievements from across the lifespan of our patient population, realised through collaborative working with our partners.



Rubraca developed and licensed for use as a medicine in the treatment of ovarian cancer

A toolkit developed to improve the diagnosis and management of Lewy body dementia

## Introduction



12



Clinical research is the scientific study of health and the prevention, diagnosis and treatment of illness. Not only is it important for scientific advancement, experts around the world are coming to understand that clinical research is good for everyone involved with it. The collaborative clinical research already taking place within Newcastle Hospitals has shaped this new understanding, helping to show the world how a culture of embedded research can create a virtuous circle of improvement for patients, staff, organisations and ultimately, the wider population.

In Newcastle and our wider community, we have all the necessary ingredients to develop and deliver excellent clinical research: enthusiastic patients, passionate staff, state-of-the-art facilities and then several strong partnerships with organisations who share our ambition to improve the health, wealth and wellbeing of the community. Indeed, we already have an international reputation for the clinical research we are delivering in numerous areas.

This strategy sets out our vision and plans to take Newcastle Hospitals' clinical research activities to the next level by further embedding research into patient care in our organisation in new and exciting ways.

This strategy is specific to clinical research, however, the established culture of innovation and enterprise in Newcastle Hospitals will be vital in facilitating the accelerated adoption and implementation of relevant research ideas into everyday care within the organisation.

Whilst this strategy serves our organisation, our research activities are delivered through a multitude of collaborative arrangements and partnerships, most notably NHIP. Our research success depends upon and contributes to strong system leadership in the wider research landscape.

Furthermore, whilst we will be using the strategy to guide our priorities and decisions over the next five years, the research ecosystem is in a constant state of change requiring us to continually reflect, looking both backwards and forwards, to ensure agility in what we do.

#### The virtuous circle of research

We believe that clinical excellence and research excellence exist together, each enhancing the quality of the other.

Outstanding clinical care

Research excellence



#### In early 2020, the arrival of a new leadership team for clinical research presented a timely opportunity to take stock of our research activities and review the future direction of travel to ensure continued improvement.

Initial thoughts for future strategic priorities, shaped from meetings with key stakeholders and their representatives, were presented to the clinical research workforce and the Trust's clinical, corporate and operational leaders across a series of open-invitation engagement sessions. A recording of one session was then distributed to the clinical research workforce along with a survey that invited anonymised feedback. More detailed documents were shared with colleagues in the Local Clinical Research Network (LCRN) for the North East and North Cumbria<sup>2</sup> and also Newcastle University - a key research partner through history, geographical adjacency, a shared clinical workforce and the mutual relevance and interdependence of much of our research activity.

In addition, and of great importance, we sought patient and public feedback with a tailored video presentation and survey that was shared widely amongst our own engagement groups and those of partner organisations. To maximise reach and diversity of

#### **Staff Engagement - Survey Results**

- 98% of those who completed the survey agreed the strategic goals were the right ones
- 96% agreed the goals were inclusive of their views
- 95% agreed the goals included the key elements for research success
- 83% felt the goals were achievable while 14% were unsure

#### **Patient and Public Engagement - Frequent Findings**

- Research participants need regular, timely feedback
- We should integrate research into routine patient care
- Patients should support the development and selection of research topics
- Research results need to be disseminated to the public
- Newcastle Hospitals needs to be a collaborative partner with other organisations

<sup>2</sup> LCRNs help to increase the opportunities for participants to take part in clinical research, ensure that studies are carried out efficiently, and support the Government's Strategy for UK Life Sciences by improving the environment for commercial contract clinical research.

# Developing our Strategy



14

representation, our video presentation and accompanying survey were also promoted on several organisational social media accounts.

This bottom-up approach ran in parallel to discussions with Board members to ensure the emerging strategy was aligned with the overarching Trust strategy and objectives. To consolidate this alignment, we have themed our priorities under the Trust's five overall priorities – Patients, People, Partnerships, Pioneers and Performance.

# Our Newcastle Hospitals Vision:

Achieving **local excellence and global reach** through compassionate and innovative healthcare, education and **research**.



# Achieving Our Vision

18



All patients are aware of the value of clinical research and the potential personal benefits of research participation.

# Patients

## **Our patient-related goals**

#### By 2026 we will ensure:

- All patients are aware of the value of clinical research and the potential personal benefits of research participation. All patients will be routinely invited to participate in clinical research relevant to them.
- Patients will be involved in the development, design and planning of our research activities.
- All research participants will have the opportunity to share their experience of research and we will use that feedback to drive improvements.
- Information about research studies will be easily accessible to participants.

#### How we will achieve these goals:

- We will use a variety of media and events to ensure that patients and the public are informed about research, using examples of local successes to explain the importance and benefits of research participation.
- We will ensure that information pertaining to research is systematically included in patient correspondence and features prominently in our clinical environments, on our website and on the emerging electronic patient portal. Where appropriate, patient information will include an invitation to participate in research.
- We will educate all patient-facing staff to understand the importance of research and its linked benefits.
- We will ensure information on open studies can be easily located on the internet so that clinical teams can support recruitment and where appropriate, patients and the public can directly sign-up for research opportunities.
- We will review and build upon our model of patient and public involvement and engagement, introducing dedicated resource to improve what we do from development to the dissemination of findings, with a key focus on improving diversity, inclusivity and accessibility.
- We will offer the Participant in Research Experience Survey (PRES) to all participants involved in research and ensure that the relevant teams regularly review and act upon the findings.

#### Key indicators of success:

- An increased proportion of patients recruited to research studies.
- A consistently positive research participant experience, as measured by the PRES, reported by a large, representative sample of participants.

#### The Young Person's Advisory Group North England (YPAGne)

The Young Person's Advisory Group North England (YPAGne) comprises a group of young people (aged 12-18 years old) who meet monthly in Newcastle to increase the input and influence of young people in the development of clinical and public health research.

The group has supported the production of a large number of research projects on wide-ranging topics and has designed and delivered interactive training to junior doctors, providing their perspective on some of the challenges felt by young people whilst accessing health services.

The work of this group has attracted national award and international recognition.

#### **Our Participant in Research Experience Survey (PRES) Findings**

Every year, we ask people who have volunteered for clinical research to feedback on their experience so we can make improvements. To do this, we use the NIHR PRES.

In 2020/21, there were 689 PRES responses from or on behalf of research participants from Newcastle Hospitals:

- 96% of research participants felt the information received prior to taking part in a study prepared them for their experience
- 80% felt they had been kept updated about the research study they were participating in
- 82% reported knowing how they would receive the results of the research study
- 96% knew how to contact someone from the research team if they had any questions or concerns
- 94% felt our researchers valued them taking part in the research
- 98% felt they were treated with courtesy and respect by researchers
- 96% would consider taking part in research again

with people at our heart



# People

## **Our people-related goals**

#### By 2026 we will ensure:

- All staff understand the importance and far-reaching benefits of clinical research.
- Our organisational leaders have facilitated a research-positive culture, empowering colleagues to lead, support or become involved in research.
- All individuals with research aspirations can access the support and guidance required to fulfil their ambitions.
- All researchers are afforded time to progress their research.
- Our clinical research teams are highly engaged as evidenced by the national NHS Staff Satisfaction Survey and other local measures.

#### How we will achieve these goals:

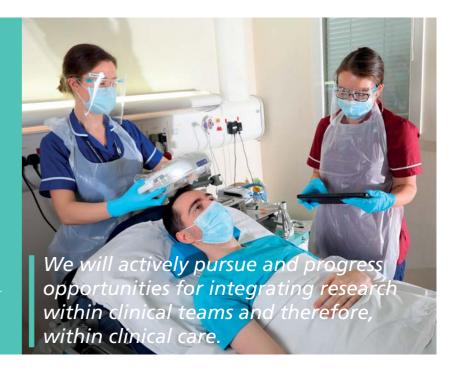
- We will actively pursue and progress opportunities for integrating research within clinical teams and therefore, within clinical care.
- Research will feature prominently in the induction for all new starters and the preceptorship programme and each Clinical Directorate will develop a bespoke plan for optimising their research engagement.
- We will improve the visibility of research across the organisation with impact and experience case studies being widely shared and with the establishment of inclusive 'Grand Rounds'.
- With our partners, we will build upon existing initiatives to de-mystify research and teach the fundamentals of how to develop and deliver research.
- We will design and deliver a comprehensive programme of engagement for our clinical research workforce to include career progression, education, training and mentorship.
- We will show our appreciation of the entire research workforce, celebrating successes, promoting diversity and raising the profile of achievements. We will educate all staff on the multiple mentorship, educational and funding opportunities available to them.
- We will reconfigure research finances to enable researchers to apply for funded time for research.
- We will enhance research leadership opportunities for all professions including nurses, midwives and allied health professionals, health care scientists and pharmacists.
- We will develop a framework for research fellowships for the most promising researchers across all healthcare professions.

#### **Key indicators of success:**

- An increased proportion of staff are research-active.
- Improved engagement of our research workforce as measured by the National NHS Staff Satisfaction Survey and local recruitment and retention rates.

#### **Integrating Research within Clinical Practice in Stroke**

research within clinical practice. Rather than having research and stroke nurses working alongside one another, nurses in this unit are dual trained in stroke and clinical research. This integrated model of staffing enables the team to recruit patients into research



lealthcare at its best with people at our heart





## **Partnerships**

## **Our partnership goals**

#### By 2026 we will ensure:

- We are a strong and valued NHIP partner, helping NHIP deliver on its research and innovation objectives.
- All our local and regional partnerships are working effectively to develop a seamlessly aligned and collaborative research framework that includes social care and primary care.
- We are the 'go to' partner for collaborative clinical research.
- Our contributions to national and international consortia and studies are prominent and highly valued.
- Our strong links with industrial partners are further developed to help our patients receive and test the most promising new therapies.

#### How we will achieve these goals:

- We will promote an outward facing and connected approach to research, fostering strong regional, national and international collaborations. Our researchers will provide strong leadership to these collaborations, demonstrating the highest levels of quality and integrity.
- We will contribute substantially to the development of NHIP, initiating and supporting creative partnerships that drive innovation and involve the breadth of our workforce.
- An increasing proportion of our researchers will be recognised as key opinion leaders internationally, increasing our number of Chief and Principal Investigators.
- We will continue to advise on, and contribute to, the important work of research funders and charities.
- We will support joint appointments with University partners to strengthen integration of research and clinical roles, ensuring that research addresses questions and ideas from the front line.

#### **Key indicators of success:**

- An increased number of Newcastle-based Chief and Principal Investigators overseeing national and international clinical trials.
- An increased number of investigator-initiated research studies with industrial partners.

#### The Newcastle Joint Research Office (NJRO)

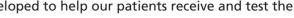
The NJRO was established in 2006 between Newcastle Hospitals and Newcastle University to support researchers and teams along the research pathway, from shaping an idea and processing funding applications through to study set-up and, ultimately, close-down. Through the partnership, Newcastle Hospitals acts as sponsor<sup>3</sup> for all University research involving patients, and a Quality Assurance team provides oversight of research activities, including the storage of biological samples used in research.

A dedicated industry-facing team within the NJRO has helped secure strong strategic partnerships with Pfizer and Syneos Health, whilst also helping foster excellent relationships with Sanofi, Medpace, Parexel, Novartis and Roche. The respective non-commercial team works to foster our relationships with other funders, including NIHR, UKRI<sup>4</sup> and charities, to help secure major research project funding across the partnership.

<sup>3</sup> A study sponsor is the organisation that takes responsibility for overseeing the research study. <sup>4</sup> UK Research and Innovation.











## Pioneering

## **Our pioneering goals**

#### By 2026 we will ensure:

- We continue to be recognised nationally and globally as a research and innovation centre of excellence, accelerating the journey from innovation discovery to implementation.
- Our research activities are underpinned by a state-of-the-art infrastructure including research-specific software within our electronic health record so that our research processes are 'Paperlite'.
- Our researchers are driving, and contributing to, national research policy and the national and international clinical guidelines that emerge from their work.
- Innovative trial designs are a prominent feature of our landscape, with a particular focus on virtual trials and electronic recruitment strategies.
- We co-create, with industry partners, a research-specific sustainability policy to reduce the environmental impact of our activities.

#### How we will achieve these goals:

- Through NHIP, we will support investment and expansion in areas of research strength including precision diagnostics, rare diseases, healthy ageing, advanced therapies and robotic surgery.
- We will ensure seamless integration between research and innovation, signposting a clear journey from discovery to evaluation and adoption of novel ideas.
- We will support creative ideas in novel research areas, such as artificial intelligence and medical imaging, exploiting synergies between NHIP partners.
- We will develop a 'Dragon's Den', where researchers can gain initial funding and support for their innovative research ideas.
- We will maximise opportunities for the ethical and transparent use of the electronic health data, capitalising on both local and regional resources, such as the Great North Care Record.
- We will deliver a comprehensive programme of digitisation for clinical research.
- We will encourage our researchers to apply for prestigious awards, such as the NIHR Senior Investigator Award, and celebrate their successes.

#### Key indicators of success:

- An increased number of fellowships, awards and international and national leadership positions presented to Newcastle researchers.
- An increased portfolio of research impacts, where our research has influenced clinical care, care pathways or guidance.

### **Pioneering Virtual Trials**

During the COVID-19 pandemic, our NIHR PRC: Newcastle used a pioneering virtual trial design to run the RELIEVE IBS-D study which aims to test a new treatment for patients with irritable bowel syndrome and diarrhoea. The study became the UK's first virtual interventional trial for this patient group and one of the UK's first virtual trials of any therapy.

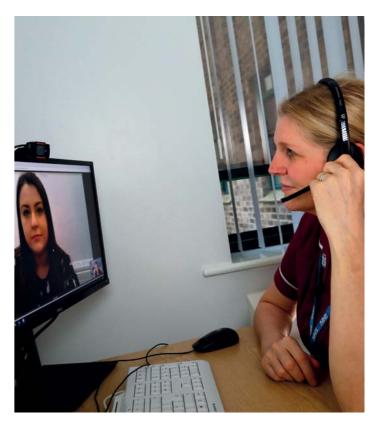
The virtual trial design means that patients from across the country are able to participate from the comfort of their own home as the interventional treatment is delivered straight to their door and digital technology has enabled electronic documentation and consultations.

The greater geographical reach of this trial and the ease of participation was likely to be responsible for participant recruitment in Newcastle being 67% faster than all other 28 sites using a traditional approach.

The approach has gained national acclaim for developing treatment at a faster pace and marks a significant stepchange in the way patients can participate in research, including traditionally 'difficult to reach' groups, and how digital technology can facilitate the recruitment to and delivery of clinical trials.

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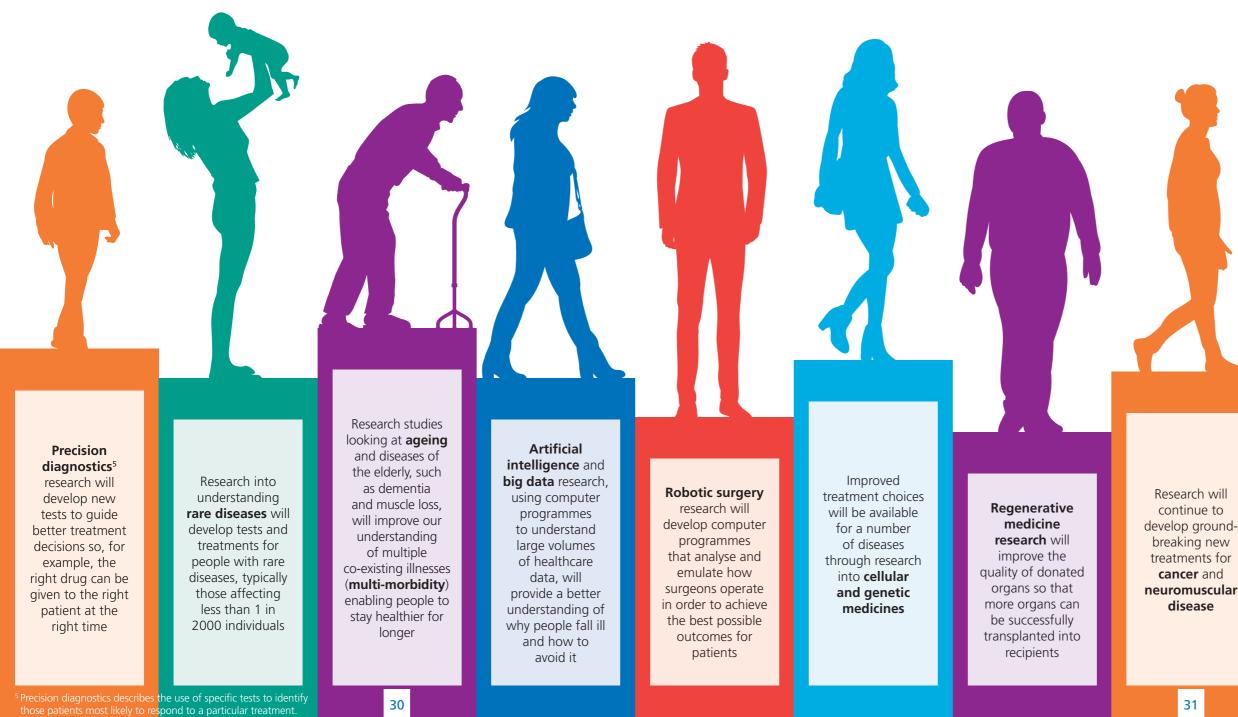




## **Looking Beyond 2021**

Some of our future research aspirations, to be realised through collaboration with partners.

We continue to be recognised nationally and globally as a research and innovation centre of excellence, accelerating the journey from innovation discovery to implementation.



New disease classifications (inflammation medicine) will be developed by studying diseased tissues leading to better treatments for patients

Research will identify disease risk factors, such as lifestyle and genetics, enabling disease prevention and interventions for healthier living



# Performance

## **Our performance goals**

#### By 2026 we will ensure:

- We have achieved accreditation from the Medicines and Healthcare products Regulatory Agency (MHRA) for our Phase I research.
- We are routinely and robustly assessing our research performance against a range of indicators, using interactive electronic dashboards.
- Our study set-up, approval and delivery processes provide consistently efficient performance, increasing our attractiveness to research partners and funders.
- We have a model of financial sustainability for clinical research that enables the delivery of our strategic goals.
- Our research workforce has sufficient and appropriate space to conduct its activities.

#### How we will achieve these goals:

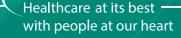
- We will ensure a balanced portfolio of research across its different phases, from early discovery to population testing and post-marketing surveillance.
- The research leadership team will undergo a quarterly performance review whilst also reporting regularly to the Trust Board and Quality Committee.
- An electronic tracking system will be introduced to provide real-time visibility of study set-up status, enabling rapid remedial action where required.
- We will establish interactive, electronic dashboards relating to activity, performance and financial management using Power BI and benchmark our performance against leading national research organisations.
- Our governance processes will ensure we make the best use of our finances, assets and estates and that our investment decisions are aligned to our strategic priorities.
- We will maximise our research income from commercial, charitable and other funding sources, and maximise the reinvestment of research income back into supporting research.

#### Key indicators of success:

- A UK-leading study set-up time, highlighting our efficiencies, organisation and determination.
- Sustainability of our research financial position, allowing year-on-year investment.

#### **Phases of Drug Research**

	Phase I	Phase II	Phase III	Phase IV
Aims	To test a new treatment in humans for the first time with a primary focus on safety.	To explore the safety and benefits of different doses of a new treatment.	To confirm that a new treatment works and is safe at selected doses.	To monitor long-term safety and effectiveness of a new treatment.
Sample	Small, typically healthy volunteers.	A larger group of patients, with a certain condition/disease.	A broader group of patients who have the condition/disease	A larger group of patients who are being treated with a new medicine in 'everyday' clinical practice.
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organisation and determination. on-year investment. We will ensure seamless integration between research and innovation, signposting a clear journey from discovery to evaluation and adoption of novel ideas.

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## Find out more

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- www.newcastlejro.com
- У www.twitter.com/NuTHResearch

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