NIHR | National Institute for Health Research

nhsa Northern Health Science Alliance

A Health Partnership for Northern England

NIHR Northern BRC Collective:
Innovating with Industry

Contents

Foreword

The North of England is home to some of the best scientific and clinical research organisations in the world.

Our universities and NHS Trusts train researchers and clinicians that are respected globally, and they work alongside patients and industry to innovate and solve globally important challenges. They do this for the benefit of our local communities and beyond.

The North of England is an ideal location to research, develop, evaluate and implement ground-breaking medical innovation. Crucial to the success of research in the region are our National Institute of Health Research (NIHR) Biomedical Research Centres (BRCs). The BRCs bring together our academic institutions and NHS trusts, with the objective of translating cutting edge biomedical research into tangible benefits for patients and the economy.

Our four BRCs in the North work on some of the most challenging and relevant health issues of our time. They are leading the way in: scientific discovery; developing therapeutics, diagnostics and medical technologies; running trials and working with industry.

The NHSA is proud to be working alongside the NIHR BRCs to stimulate collaboration and celebrate their impact. The NHSA networks across advanced therapies, diagnostics, data integration and other disciplines are connecting and mobilising excellence at scale throughout the North and beyond. Our publications, seminar series, industry engagement and networking programmes, in which the BRCs feature strongly, help connect and reinforce the position of the BRCs within the wider health and life science ecosystem. There has never been a more appropriate time to acknowledge the value of the UK research and innovation base to the national and global Life Sciences sector. The BRCs are a fundamental part of that science base and the four in the North are a vital part of our clinical academic infrastructure.

This brochure showcases the capabilities and impact of our four northern BRCs and highlights some examples of how the they work with industry partners to deliver the next generation of medicine. We are delighted to be supporting a collegiate and complementary approach that can take this work to another level.

Seamus O'Neill
CEO, Northern Health Science Alliance

Introduction

NIHR's 20 Biomedical Research Centres (BRCs) are collaborations between world-leading Universities and NHS organisations that bring together academics and clinicians to translate lab-based scientific breakthroughs into potential new treatments, diagnostics and medical technologies.

There are many steps in the development of a new treatment or technology; from basic science research often conducted in University departments looking for new targets and potential therapies through to clinical trials for safety and efficacy before a new treatment can be adopted into clinical practice.

Biomedical Research Centres help to bridge the gap in translating new discoveries into early phase experimental medicine or technologies. They do this by working with patients to understand true clinical need, and industry partners to accelerate the translation of new research.

The BRCs work with industry to:

- Accelerate the route to market
- Assist with scale up for clinical trials
- Translate research into clinical practice
- Generate the evidence needed to succeed
- Enable tailor made collaborations

The case studies presented in this brochure showcase the wide range of activity in which this takes place. From early phase clinical study design, biomarker identification, developing and engineering new imaging techniques, to gene sequencing, and creating cutting edge cell and gene therapies.

Additionally, working with any of the Northern BRCs gives you access to the entire biomedical research ecosystem and beyond in the region.

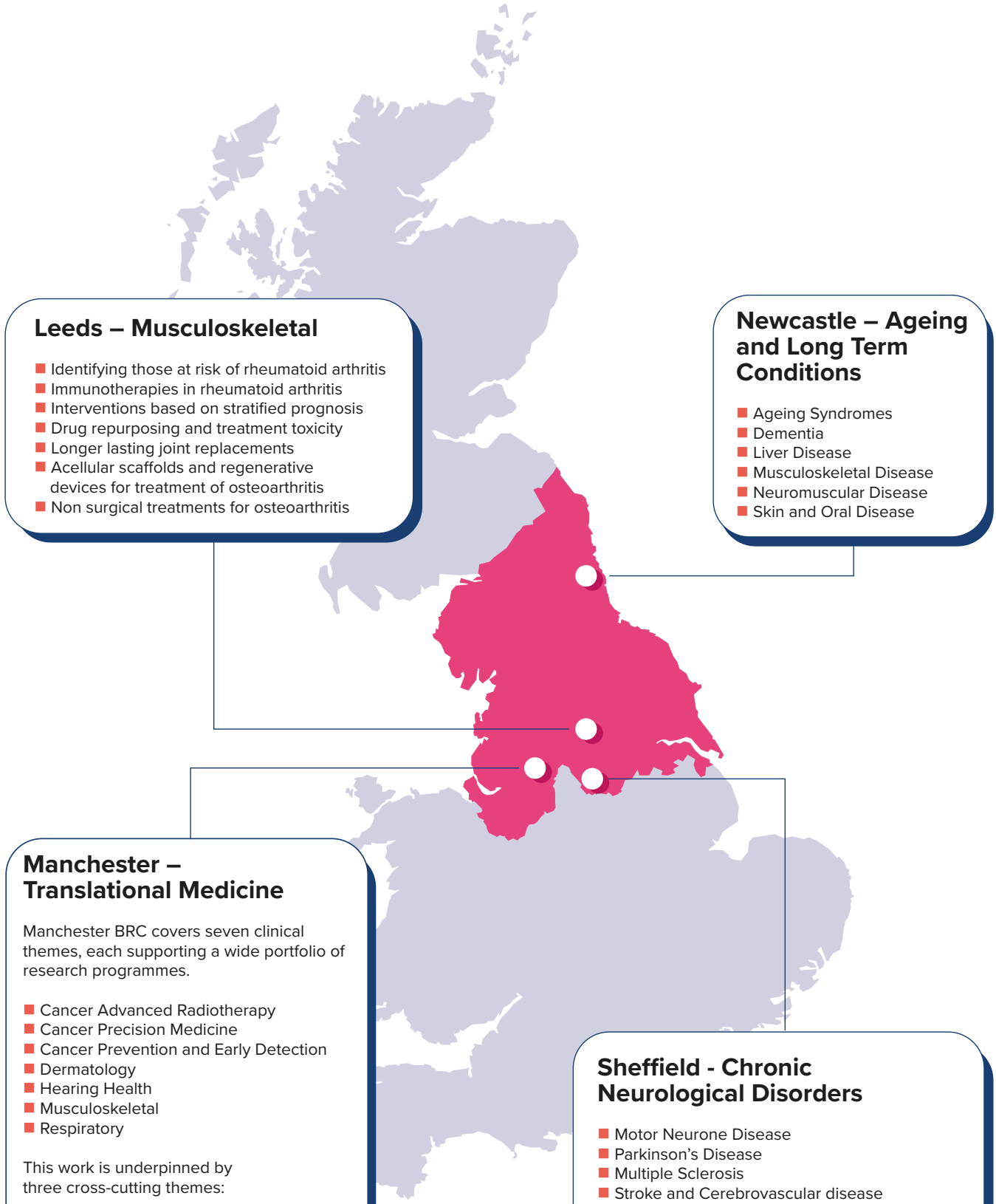
Each BRC works closely with local partners such as the NIHR Medtech and In-Vitro Diagnostic Co-operatives (MICs), the NIHR Clinical Research Networks (CRN), NIHR Clinical Research Facilities (CRF) and exemplar research institutes.

Furthermore, the Northern BRCs collectively work at the overlap and interface of their disciplines. Working with any one BRC automatically connects you to the wider network, as well as a national NIHR infrastructure.

Finally, the Northern BRCs work closely with the Northern Health Science Alliance (NHSA). The NHSA is a membership organisation comprised of world leading research intensive universities, NHS trusts and academic health science networks in the North of England.

Our mission is to unlock the combined potential of the North's health research and innovation assets for the benefit of the people and the economy.
The NHSA works with the Northern BRC collective to build a collaborative innovation ecosystem within the region, to benefit patients and drive economic growth.

Research Strengths



Leeds – Musculoskeletal

- Identifying those at risk of rheumatoid arthritis
- Immunotherapies in rheumatoid arthritis
- Interventions based on stratified prognosis
- Drug repurposing and treatment toxicity
- Longer lasting joint replacements
- Acellular scaffolds and regenerative devices for treatment of osteoarthritis
- Non surgical treatments for osteoarthritis

Newcastle – Ageing and Long Term Conditions

- Ageing Syndromes
- Dementia
- Liver Disease
- Musculoskeletal Disease
- Neuromuscular Disease
- Skin and Oral Disease

Manchester – Translational Medicine

Manchester BRC covers seven clinical themes, each supporting a wide portfolio of research programmes.

- Cancer Advanced Radiotherapy
- Cancer Precision Medicine
- Cancer Prevention and Early Detection
- Dermatology
- Hearing Health
- Musculoskeletal
- Respiratory

This work is underpinned by three cross-cutting themes:

- Biomarker Platforms
- Informatics and Data Science
- Rapid Translational Incubator

Sheffield - Chronic Neurological Disorders

- Motor Neurone Disease
- Parkinson's Disease
- Multiple Sclerosis
- Stroke and Cerebrovascular disease
- Dementia
- Gluten related neurological disorders and ataxia
- Advanced Medical Imaging
- In Silico (Predictive) Medicine
- Genomic Medicine and Bioinformatics

NIHR | Leeds Biomedical Research Centre

The NIHR Leeds Biomedical Research Centre opened in 2008 and in 2017 was upgraded to Biomedical Research Centre (BRC) status.
It exists to provide infrastructure to support translational research across musculoskeletal disease. In 2017, the Leeds Teaching Hospitals Trust (LTHT) was awarded a further £6.7 million for five years. Since 2008, this has meant £21.1 million of funding to the Leeds NIHR infrastructure.

The Leeds BRC is hosted at LTHT in partnership with the University of Leeds (UoL). The two institutions are brought together through a formal research framework agreement. Through this agreement, the Leeds BRC has developed an outstanding reputation for translating basic biomedical research into innovative clinical practice and improved patient care.

The Leeds Partnership is internationally recognised in MSK research which is a priority area for both organisations.
An analysis of highly cited publications as part of the NIHR BRC competition found the UoL was the most highly cited Higher Education Institution for MSK disease publications, with LTHT the most highly cited NHS Trust, ranking first and third respectively across all institutions.

Leeds BRC is led by Professor Paul Emery OBE and supported by two Deputy Directors, Professors Philip Conaghan and Anne-Maree Keenan OBE. Research is led across several workstreams by Professors John Fisher, Ann Morgan, Maya Buch, Dennis McGonagle, Eileen Ingham, Hemant Pandit and Assistant Prof Francesco del Galdo.

Research activities in the BRC are driven by the two musculoskeletal conditions that have the largest economic and personal burden; immune mediated inflammatory diseases (IMIDs) and osteoarthritis (OA).

IMIDs affect the immune response of the body and include a number of inflammatory arthritic conditions (such as rheumatoid arthritis, spondylarthropathies and polymyalgia rheumatica), inflammatory connective tissue conditions (such as scleroderma and systemic lupus erythematosus) and the vasculitides (such as giant cell arteritis and Behçet's Syndrome).
IMIDs affect over 5% of the population and result in joint damage, physical disability and reduced life expectancy. Effective treatments exist and some are expensive, as such, it is crucial that people with IMIDs receive the right treatment at the right time.

With its burden of pain and reduced participation, OA presents a greater challenge in terms of population health: worldwide estimates of OA indicate that one in ten men and one in five women aged over 60 have symptomatic OA and treatment options remain poor.
The prevalence of OA is rapidly increasing with ageing and obese populations, with increasing joint replacement surgery in younger people who will subsequently be living longer with their replacements.

Novel simulation methods in joint replacement surgery

Research led collaboration with implant manufactures leads to improved, longer lasting joint replacements.

Project Lead: Professor John Fisher

Before 2011, pre-clinical testing of hip and knee prostheses took place under one set of conditions - a standard walking cycle, with one surgical position. This didn't account for variation in surgical positioning or activities and conditions undertaken by different patients.

This meant the effect of various input variables was unknown. The UK hip register showed a four-fold difference in hip revision rates between surgical centres, with other studies showing a strong association of higher revision rates with variation in surgical positioning.

The Institute of Medical and Biological Engineering (iMBE) at Leeds BRC worked with Simulation Solutions and implant manufacturers to develop novel pre-clinical simulation methods.
Investigations supported by UKRI EPSRC and NIHR looked into the effect of surgical positioning and different patient activities.

This project started by understanding implant manufacturers needs and offered abilities to pre-clinically assess how prostheses functioned under wider sets of conditions. This enabled robust solutions to be created, aiming to reduce variability in clinical function and performance.

> "Simulation Solutions have worked with University of Leeds since 1997. Since 2013 we have worked with Professor Fisher and Dr Jennings on the advancement of novel simulation methods and systems and the development of simulation equipment."
> **Nick Eldred Managing Director of Simulation Solutions**

Through the iMBE, Leeds BRC developed and evaluated new advanced simulation methods.
This supported novel commercial test equipment to be created by Simulation Solutions. The simulation methods were validated through comparison with the variation found in retrieved implants.

The project demonstrated that variation in surgical positioning, and specifically, combinations of variations in rotational and translational positioning had a marked effect on function and performance of hip joint replacements.
Different implant designs and materials were affected to differing amounts by variations in clinical conditions.
Methods were developed and evidence was collected to enable a new international standard to be developed and approved.

This standard supported commercialisation of new advanced test equipment by Simulation Solutions across the globe. Work continues with implant manufacturers to apply advanced methods developed to create prostheses with improved function and performance.

Future partnership work will enable the widespread adoption of new methods and commercial sale of the simulation equipment across the globe.
Work continues with implant manufacturers to support the development of improved, more robust longer lasting hip and knee prostheses.

Early phase trial with Medivir

A feasible, short term trial to assess osteoarthritis structure modification.

Project Lead: Professor Philip Conaghan

Osteoarthritis (OA) is a significant worldwide problem resulting from ageing and increasingly overweight populations. The disease includes damage to joint-lining cartilage and bone underneath the cartilage. A major unmet need in the field is to develop a therapy that slows the slow structural joint deterioration in OA.

Trials of OA structural progression use x-rays and require several hundred patients per study arm, with patients needing to be followed up over two years. Even with existing more sensitive MRI outcomes, approximately 150 patients per arm is required for a minimum 12 month study.

This means structure modifying trials are very expensive, and prohibitively for pharmaceutical companies, an early phase study can take over five years to produce a result.

For many years, Prof Conaghan's team at Leeds BRC have collaborated with external company Imorphics (Manchester, UK). Through accurate machine learning-derived automated segmentation highly responsive imaging outcomes were produced including bone shape.

Medivir, a Sweden based pharmaceutical company, approached Prof Conaghan's team with a novel cathepsin-K inhibitor. This drug could potentially slow OA structural progression, but needed a study design and outcomes that could be done in a feasible timescale.

The Leeds BRC team supported the development of an early phase two randomised trial in people with knee OA. The trial consisted of 70 patients per arm, three arm (two doses of study drug, one matched placebo). In this multicentre trial, MRI scans were performed at baseline and six months.

The study demonstrated a reduction in bone deterioration rates for both doses of the study drug, it did not however, fully show a demonstrable benefit on people's pain. This was the first time any therapy was shown to reduce rates of bone pathology change in OA. The report results were published in a high impact factor International journal.

Importantly, this study demonstrated drug efficacy. It also demonstrated the feasibility of carrying out smaller and shorter duration structure modification trials in OA. Looking forward, Medivir seek partners to develop their therapy.

Prof Conaghan's BRC team continues to validate their quantitative 3D imaging biomarkers to improve clinical trial design, providing insights into key time points for targeting OA structural progression.

Leading the way in International COVID-19 trials

Testing the efficacy and safety of drugs to reduce the severe immune overreaction seen in COVID-19 patients.

Project Lead: Clinical Associate Professor Sinisa Savic

Leeds BRC together with Leeds CRF and Leeds Teaching Hospitals NHS Trust have been involved in several nationally prioritised, urgent public health research studies related to COVID-19. These included CANCOVID and RUXCOVID, which are both global phase three randomised, double-blind, placebo controlled multi-centre trials sponsored by Novartis. These studies aimed to test the efficacy and safety of the drugs ruxolitinib and canakinumab which are typically used for treatment of inflammatory disorders.

In this trial, they were utilised as a way to reduce the severe immune overreaction that was seen with COVID-19 infection which resulted in patients developing pneumonia, acute respiratory distress syndrome and needing intensive care support including breathing support by mechanical ventilators.

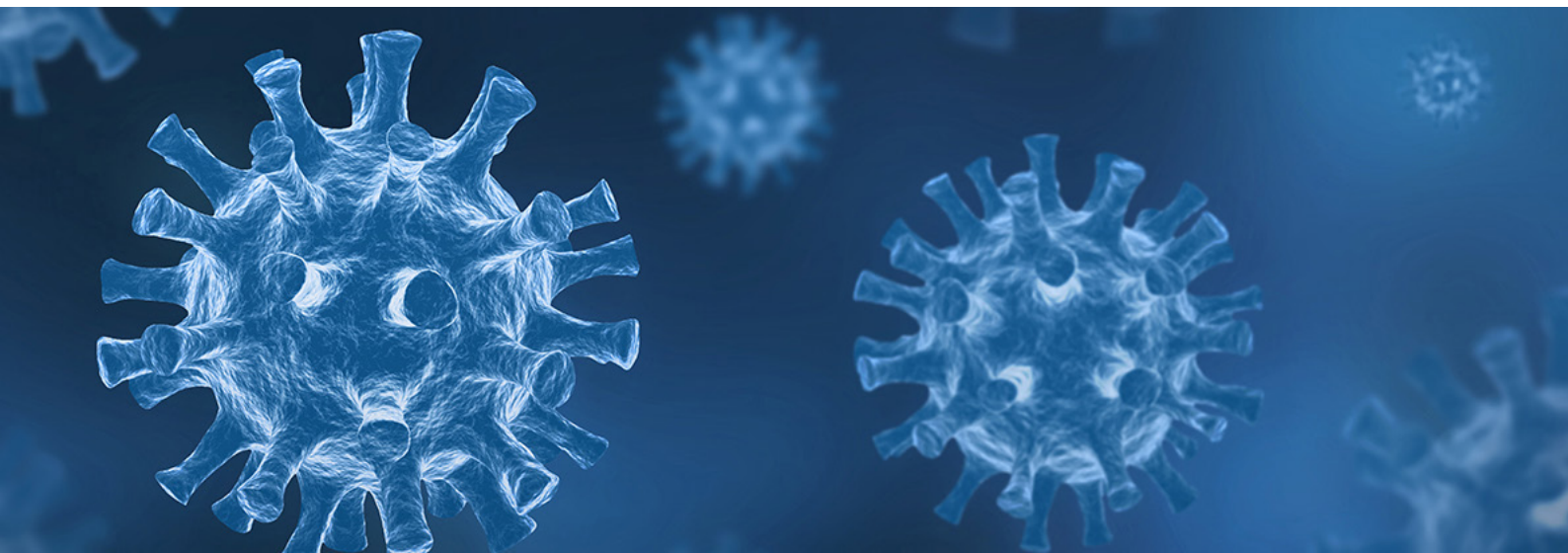
The COVID-19 research team in Leeds was able to recruit the first patients globally into the RUXCOVID study and the first UK participant for CANCOVID trial. This was achieved despite the team continuing to recruit into other COVID-19 trials, including the nationally mandated study RECOVERY and another commercial trial COVACTA.

> Leeds was able to recruit the first patients globally into the RUXCOVID study and the first UK participant for CANCOVID trial.

The COVID-19 research team was rapidly assembled using research staff with different specialist backgrounds. Together, they showed great agility and flexibility to quickly set up the studies and initiate the recruitment.

All commercial studies have now been successfully completed. The efforts by the Leeds team have been recognised, including the local PI, Dr Savic, as an author on two publications that have been produced following the trials.

The findings of COVACTA trial have been published in New England Journal of Medicine. Dr Savic has been invited to be a senior author on the manuscript describing findings of RUXCOVID study which will shortly be submitted to the Lancet.



NIHR | Manchester Biomedical Research Centre

The NIHR Manchester Biomedical Research Centre (BRC) is the beating heart of translational research across Greater Manchester (GM), transforming scientific breakthroughs into diagnostic tests and life-saving treatments for patients, and reducing health inequalities across our region.

Awarded £28.5million (2017-2022), Manchester BRC brings together world-leading researchers based at The University of Manchester and three of the country's foremost NHS trusts; with a vision to drive health improvements and lasting change for all through creative, inclusive and proactive research that identifies and bridges gaps between new discoveries and individualised care.

Manchester BRC is driving forward pioneering research in the areas of cancer (Prevention and Early Detection, Advanced Radiotherapy, Precision Medicine), inflammation (Musculoskeletal Disease, Respiratory Disease, Dermatology), and regenerative medicine (Hearing Health).

These research themes are underpinned by cross-cutting themes in Biomarkers and Informatics & Data Science, supported by a Rapid Translational Incubator that brings together key infrastructure essential to the design and delivery of clinical studies, as well as the commercialisation of new healthcare products.

Manchester BRC is committed to training and development, including the next generation of highly skilled scientists and clinical researchers working within a specialised infrastructure. We use an interdisciplinary Team Science model to enhance and maximise our research design, development and outputs. Working with Vocal, it also champions the voices of patients and the public, involving and engaging them to improve the quality of our research, tackle health inequalities, and ensure we focus on the needs of and what matters to our population.

Working with partners and local research and innovation infrastructure, including Heath Innovation Manchester (HInM), Manchester BRC is integrated within the Greater Manchester Health and Care Partnership, the country's only devolved health and social care system.
This allows the freedom and flexibility to focus on the areas that will benefit the people of Greater Manchester.

Manchester BRC has significant experience of delivering collaborative commercial work with large multi-nationals and SMEs, and prioritises this approach as a way of driving patient and population benefit. It works with local partners to provide companies access to infrastructure that supports and enables early phase commercial development and evaluation. Manchester BRC has worked with more than 60 SMEs, established nearly 50 strategic partnerships and generated more than £120 million since its inception in 2017.

MEDLD: Manchester Early Detection of Lung Disease

Piloting mobile screening units to improve detection and outcomes in lung cancer

Project Leads: Dr Phil Crosbie and Professor Caroline Dive

Manchester has the poorest premature death rate in under-75s in the country. A primary contributor of this is lung cancer, with the population having some of the highest levels of deprivation and smoking in the UK.

Researchers from Manchester BRC's Cancer Prevention and Early Detection (PED) and Cancer Precision Medicine themes developed a pioneering screening programme to improve this.

Led by Dr Phil Crosbie and Professor Caroline Dive, the project aimed to identify lung cancer at an earlier stage – when it is more treatable – by screening current or past smokers. Professor Dive's team are also working with biomarker companies to test the feasibility of blood-based 'liquid biopsy' biomarkers – collected from community pharmacies – for disease prediction and recurrence.

> "Cobalt is very excited to be part of the first commissioned lung screening service in the UK. As a medical charity, we have been supporting oncology services with the NHS for over 50 years using the latest technologies."
> **Peter Sharpe, CEO, Cobalt Health**

The team wanted to develop a model to identify potential lung cancer patients in the community, before presentation and diagnosis at later stages when treatment options are limited.

BRC researchers worked with colleagues at Cobalt Health and Siemens to deliver community-based 'Lung Health Checks' via mobile screening units in supermarket car parks and other convenient locations, targeting deprived areas of Greater Manchester with a high proportion of smokers.

With demand far exceeding expectation, more than half of invited participants qualified for a CT scan, with one in 33 scans detecting early stage lung cancer. Early detection meant potentially curative treatment was offered to nine out of ten people with the disease.

The pilot study has since expanded into a screening service across the city region, while Dr Crosbie has supported the roll out of this model in a Yorkshire pilot study. Professor Dive's team continues to work on the biomarker element of the study.

In 2019, NHS England launched 10 pilot sites across England – based on the Manchester model – which could form the basis of a national lung cancer screening programme and is expected to save up to 800 lives across two years.

PALOH: Pharmacogenetics to Avoid Loss Of Hearing

Preventing antibiotic-related hearing loss in newborns with the world's first emergency genetic test

Project Lead: Professor Bill Newman

"Approximately 14,000 babies worldwide born each year will carry a genetic variant which will lead to profound irreversible hearing loss if given gentamicin. Successful implementation of the gentamicin test will be a first in the integration of a rapid decision-making, genetic-based diagnostic in the UK NHS."
Professor Bill Newman, Manchester BRC Hearing Health Genomic Solutions Associate Lead.

Each year in the UK around 90,000 newborn babies in intensive care are given the antibiotic gentamicin to treat sepsis and other serious infections. However, one in 500 babies has a genetic predisposition to profound, irreversible hearing loss if given this antibiotic treatment.

The Pharmacogenetics to Avoid Loss Of Hearing (PALOH) study aims to prevent hearing loss in these newborns with the world's first emergency genetic test. Successful implementation of the test will be a first in the integration of a rapid decision-making, genetic-based diagnostic in the NHS.

Newborn babies admitted to intensive care units with an infection should be given antibiotics within the first hour to stand the best chance of survival. Gentamicin is usually the antibiotic given but, it can damage the sound detecting cells in the inner ear of babies with the genetic predisposition. Previous tests to identify those babies that would be affected by gentamicin took too long.

The challenge was to develop a rapid test to predict whether newborn babies receiving antibiotics in intensive care should be given an alternative treatment to gentamicin. Researchers from Manchester BRC's Hearing Health theme worked with Manchester-based SME Genedrive to develop a test using their point-of-care device, and evaluated through clinical trials at Saint Mary's Hospital, part of Manchester University NHS Foundation Trust, and Liverpool Women's Hospital. In excess of 750 babies were tested and 160 hospital staff were trained to provide rapid testing in this critical care setting. The test, which involves a simple cheek swab, can be conducted in 20 minutes at the beside.

Successful implementation of the technology across the UK could prevent an estimated 180 babies a year from profound hearing loss, and also save the NHS an estimated £5 million every year in cochlear implantations and other hospital costs. Following the initial trial, Manchester BRC researchers are continuing to work with Genedrive who hope to commercialise the test in the near future.

The research team is also working with the Health Innovation Manchester to roll out the test across the North West and the country.

"Despite the emergence of COVID-19, our clinical partners showed huge dedication in keeping this important project on-track, becoming the first in the world to generate valuable information on the utility of this approach in an emergency care setting. As we see updated guidance and greater awareness to the requirement for genetic testing, we only expect increased interest in our novel assay."
David Budd, Chief Executive Officer of Genedrive

RADicA: Rapid access diagnostics for asthma

Revolutionising asthma diagnosis

Project Lead: Dr Clare Murray

Asthma is an extremely common condition but, diagnosis can be challenging, with no single definitive test available. Getting an accurate early diagnosis of asthma is vital – it is often a lifelong condition and receiving the wrong diagnosis and treatment can have life-changing consequences.

> "The emergence of new devices that enable biomarkers to be detected in breath has the potential to revolutionise asthma diagnosis, and we are very pleased to be working with Owlstone Medical on this vital project."
> **Dr Clare Murray, NIHR Manchester BRC Asthma Programme Associate Lead**

Researchers from Manchester BRC's Respiratory theme are working alongside global medical device company Owlstone Medical as part of the RADicA study to test a novel breathalyser device which measures the small airways in the lungs and breath-based biomarkers to diagnose the condition quickly and guide patients to the correct treatments.

To address the difficulties of easily obtaining an accurate asthma diagnosis the RADicA study aims to provide clear diagnosis with a non-invasive approach offering a 'window' into overall lung health and reduce the number of people that are wrongly diagnosed resulting in them taking unnecessary medication.

Owlstone's novel Breath Biopsy platform is collecting breath samples from asthmatic patients and healthy controls, which are analyzed to identify breath-based biomarkers. Using these breath-based biomarkers and measures of small airway function, will allow the rapid, accurate and low-cost diagnosis and monitoring of asthma, along with better classification of different forms of asthma, their progression, and effect on airway inflammation. This will also allow the predication of a participant's likely response to inhaled corticosteroid (ICS) treatment.

The RADicA study is utilising the world-class facilities at the NIHR Manchester Clinical Research Facility, supported by a highly experienced team of research nurses for patient oversight and management.

The study has benefited from the Manchester BRC's expertise in recruiting participants from the hugely diverse populations near our hospitals, with recruitment rates exceeding expectations. Manchester BRC worked with local GPs to develop a pop-up system on patient systems which prompts them to discuss the study when their patients enter the term "wheeze".

> "We remain committed to deploying Breath Biopsy to help the 5.4 million people with asthma in the UK and estimated 339 million worldwide who could benefit from personalized healthcare."
> **Billy Boyle, co-founder and CEO at Owlstone Medical**

By using the data collected in the study, the project is comparing the performance and clinical use of these approaches to the existing large airway tests.

RADicA is now expanding to study novel diagnostic approaches in children, working with Exhalation Technologies and Revenio Research, to hopefully result in simpler diagnosis and appropriate treatment sooner.

The research is jointly funded by Asthma UK and Innovate UK.

NIHR | Newcastle Biomedical Research Centre

The NIHR Newcastle Biomedical Research Centre (Newcastle BRC) is a partnership between Newcastle upon Tyne Hospitals NHS Foundation Trust (Newcastle Hospitals) and Newcastle University, sitting at the heart of a city and region with a long track record in ageing research.

Awarded £16 million, it is the only BRC in the country to focus on the conversion of lab-based research in ageing and long-term conditions, into practical and meaningful benefits for patients, the public and the health and care system. With a focus on the delivery of advances in diagnosis, treatment, and prevention of conditions associated with ageing and poor health, the Newcastle BRC is improving lives in Newcastle, the North East and beyond.

The Newcastle BRC is able to harness world-leading experimental medicine expertise in its individual research themes of dementia, liver disease, musculoskeletal disease, neuromuscular disease, and skin and oral disease, in order to advance the diagnosis, treatment and prevention of ageing syndromes such as sarcopenia, frailty and multimorbidity. By understanding the underlying mechanisms of these diseases, the Newcastle BRC can help address the major challenges of an ageing population, including the complex issue of patients living with multiple long-term conditions in later life.

> Partnerships with the life sciences industry are vital to accelerating the translation of discoveries into patient benefit and economic growth, with companies attracted by access to experienced clinicians and scientists, extremely well-characterised patient cohorts, robust delivery infrastructure and track record of effective collaboration.

The Newcastle BRC is a key part of the world class research infrastructure within the region's clinical and academic landscape, helping to build research capacity, create and support a sustainable health care system and lead research design, delivery and policy. Its partnerships with the life sciences industry are vital to accelerating the translation of discoveries into patient benefit and economic growth, with companies attracted by access to experienced clinicians and scientists, extremely well-characterised patient cohorts, robust delivery infrastructure and a track record of effective collaboration.

The following case studies demonstrate the value of gaining knowledge in underlying mechanisms related to ageing syndromes, acknowledging that these characteristics can advance our knowledge in the biology of several different conditions, and therefore allow a broad scope for the development of potential treatments.

From the Neuromuscular Disease Theme, we look at how the Newcastle BRC has supported partner organisations to build clinical trial capacity across the UK for diseases affecting the muscles. From the Musculoskeletal Disease Theme, we share details of a project designed to carry out phase Ib/IIa studies to examine the potential for an experimental anti-cancer treatment to be used by people living with some of the most significant symptoms of Rheumatoid Arthritis (RA). Finally, in our pioneering digital health research, we show how a project with industry is examining whether wearable technology may be a valuable addition to monitoring some of the most debilitating symptoms of rheumatic illnesses.

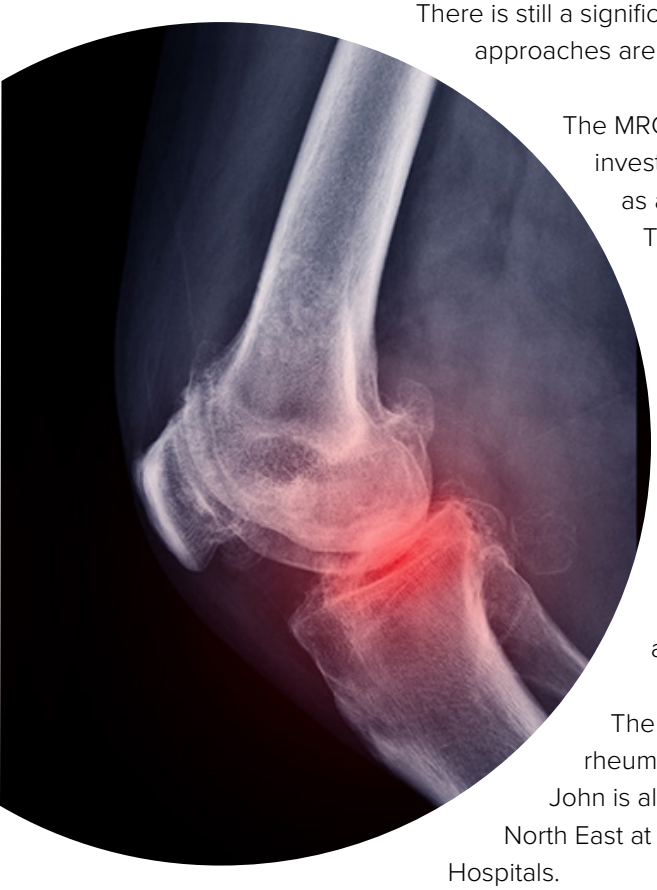
TRAFIC pioneering novel therapeutic approaches for Rheumatoid Arthritis

Investigating the safety, tolerability and potential efficacy of seliciclib as an addition to existing therapy in participants with Rheumatoid Arthritis.

Project Lead: Professor John Isaacs

Rheumatoid Arthritis (RA) affects 0.5-1.0% of adults, including 700,000 individuals in the UK alone. About one third of sufferers have stopped working within two years of onset and around a half by ten years. Annual NHS costs are estimated at £560 million, with additional costs to the economy of £1.8 billion in sick leave and work-related disability (source: National Audit Office 2009 report).

Advances in RA management and biologic therapies have each contributed to an improved prognosis for sufferers but, even now, only a minority achieve lasting remission, and 5-10% are refractory to all treatments. Sub-optimally controlled joint inflammation leads to damage and deformity, with consequent disability and impaired quality of life. Furthermore, chronic inflammation reduces life expectancy by increasing the risk of cardiovascular disease. There is still a significant unmet need in RA management, and novel therapeutic approaches are still required.



The MRC-funded TRAFIC study, in partnership with SME Cyclacel, seeks to investigate the possibility of repurposing a small molecule anti-cancer drug as an anti-fibroblast drug for RA, for the very first time.

The study, led by academics from Newcastle University, along with the industry partner and colleagues from Birmingham and Glasgow Universities, is a phase Ib/IIa clinical trial of seliciclib in patients with RA who have failed at least one biologic therapy.

The trial will initially study the tolerability of seliciclib in patients with RA. Eighteen patients living with RA will then participate in a 12-week trial designed to estimate potential therapeutic benefits of the treatment. Estimates of potential efficacy will be based on clinical measures as well as objective measures of synovitis, using magnetic resonance imaging and ultrasound-guided joint biopsies. The trial will also seek pharmacodynamic biomarkers within the blood and joints.

The Chief Investigator for the study is Professor John Isaacs, a rheumatologist who also leads the Newcastle BRC's Musculoskeletal Theme. John is also Deputy Director for the Newcastle BRC, Director of Therapeutics North East at Newcastle University and Director of Research for Newcastle Hospitals.

The Newcastle BRC supports this study through both academic expertise, as well as clinical research infrastructure, both key in providing the scientific basis, as well as development and facilitation of the study.

Our experience, track record and well-established clinical infrastructure provides our industry partners with confidence that we can ensure the safety and efficacy that are essential to carrying out such complex studies. Our integration with the Musculoskeletal

Unit at Newcastle Hospitals, as well as excellent public and patient involvement and engagement, will facilitate recruitment of participants who will take part in the trial through the NIHR Newcastle Clinical Research Facility (Newcastle CRF); a dedicated clinical research space supported by a highly experienced team of research nurses for patient oversight and management. The trial is sponsored by Newcastle Hospitals; hosts of the Newcastle BRC and the Newcastle CRF, and is also supported by the Newcastle Clinical Trials Unit.

At the end of the study, Cyclacel and Newcastle University will be able to make an informed go/no-go decision regarding progression of seliciclib into phase IIb/III trials in rheumatoid arthritis.

If the results are encouraging, we anticipate rapid progress, potentially culminating in a licensing application in 4-6 years. Success will also have important implications for other diseases, both rheumatological and non-rheumatological, where fibrosis plays a role.

Developing objective assessment tools for measuring fatigue in clinical studies

Using wearable devices to explore the potential benefits of technology in assessing fatigue symptoms in autoimmune conditions.

Project Lead: Professor Wan-Fai Ng

Fatigue is one of the most debilitating symptoms for patients living with many rheumatic and long-term conditions. As well having a major impact on quality of life, it is often a key factor affecting one's difficultly remaining in gainful employment. As a result, fatigue as a symptom of disease represents a huge health and economic challenge to the NHS and society.

There is currently no validated objective measure of fatigue; clinicians rely on a patient's self-assessment, something that can be difficult to reliably quantify due to the multiple factors involved for each individual. In addition, with the severity of fatigue subject to fluctuation, capturing subjective fatigue measures is challenging.

If a validated objective measure of fatigue were available, it could complement patient assessments of fatigue symptoms and allow a more accurate and sensitive measurement of changes, in response to therapeutic interventions.

In order to test the validity of wearable devices in collecting this data, the industry partner needed to work with a clinical service designed to deliver research, where engaged participants who live with a range of rheumatic symptoms were available.

In a project funded by the Newcastle BRC Professor Wan Fai Ng and colleagues, in collaboration with industry partner GSK, will evaluate the benefits of new therapies for autoimmune rheumatic diseases and ageing syndromes.

Using digital devices worn by participants, the study will capture physical and bio-behavioural activity with data. This has the potential to provide an indirect, objective assessment of fatigue, as well as an assessment of the "impact" of fatigue on the daily lives of those taking part in the study.. It will also allow assessment in patients' own environment, capturing the real-time fluctuation levels of fatigue.

The study's aim is to generate pilot data that can be analysed using advanced data analytic and statistical modelling methods, potentially identifying robust bio-behavioural markers of fatigue as well as different dimensions of fatigue such as "physical" and "mental".

Professor Wan-Fai Ng is Deputy lead for the Newcastle BRC's Musculoskeletal Theme. He is also Honorary Consultant Rheumatologist with Newcastle Hospitals and Professor of Rheumatology at Newcastle University.

> "We're very excited about the valuable pilot data that this study will provide which can provide the basis for further studies that will expand the dataset and allow us to validate the use of such tools as objective measures of fatigue in clinical studies"
> **Professor Ng, NIHR Newcastle BRC**

His dedication to clinical research is demonstrated by his role in establishing the UK Primary Sjorgen's Syndrome (PSS) patient registry, as well as leading the NIHR Bioresource Centre in PSS. More recently, he became Director of the NIHR Newcastle Clinical Research Facility (CRF); a space dedicated to patient participation in ongoing clinical research at Newcastle Hospitals. This commitment to including patients and the public in research studies makes his work well suited to industry projects where patient involvement is required.

Having more reliable data will bring huge advantages for the understanding of fatigue, for example:

- Data collection via wearable devices will remove the reliance on participant recollections, and therefore reduce the chance of errors.

- By identifying key activity and physiological response patterns associated with fatigue, a deeper understanding of the symptoms will be possible.

- For mental fatigue, based on the symptoms described by patients, neuropsychological tests that measure parameters such as short-term memory, concentration and alertness, have the potential to provide objective, quantifiable measurements.

- By creating reliable objective ways to measure fatigue, a key barrier to the pharmaceutical industry investing in new programmes to develop new treatments for fatigue, will be removed.

The interim analysis of this project has identified a potential digital biomarker of fatigue, which was presented at the prestigious International Symposium of Wearable Computers. This work has also enabled the team to win further European research funding of €42 million to extend work into other autoimmune diseases and neurodegenerative disorders (see www.idea-fast.eu for details).

Duchenne Muscular Dystrophy Hub

Working collaboratively to support the on-going delivery of trials into muscle diseases

Project Lead: Professor Volker Straub

Duchenne muscular dystrophy (DMD) is a muscle-wasting disease and one of the most common fatal genetic diseases diagnosed in childhood. The disease almost always affects boys, and they tend to be diagnosed before the age of five.

DMD is classified as a rare disease; with around 2,500 patients in the UK and an estimated 300,000 sufferers worldwide. There is no cure for DMD, which means that to achieve a better quality of life for children and adults living with the disease, effective drug treatments are essential.
Prior to the DMD Hub, an increasing number of trials were on the horizon for DMD, yet with only two experienced UK sites there was limited capacity to be able to take them all on. The goal was to increase experience and capacity beyond the Newcastle and London sites by providing more funding and training for other sites across the country.

> "The collaboration between NIHR Newcastle BRC, the JWMDRC and Duchenne UK has fundamentally changed the landscape for DMD clinical trials in the UK, offering hope to thousands of patients, and opening up expertise and talent in the UK to industry sponsors. We are grateful for the support of the BRC and look forward to continuing our collaboration with them in the future."
> **Emily Crossley and Alex Johnson, Founders, Duchenne UK**

Through support from the Newcastle BRC and similar partners, the DMD Hub was launched in 2016 by Duchenne UK, a parent-led charity. Duchenne UK has invested £3 million into the DMD Hub and is now funding 30 posts. This has enabled a network of sites throughout the UK; providing expert advice and enabling additional sites to begin running clinical trials. The DMD Hub has also pioneered a pump priming funding model to ensure sustainability of posts past the initial funding period.

The Newcastle BRC supports the work of Professor Volker Straub, Deputy Lead for the Newcastle BRC's Neuromuscular Theme and Director of the John Walton Muscular Dystrophy Centre (JWMDR); a main partner of the DMD Hub. In addition, the Newcastle BRC funds a clinical trial coordinator for the DMD Hub, who supports in the planning and development of trials within the JWMDR and is involved in the organisation of the network of DMD Hub coordinators, aimed at sharing best practice, knowledge and experience across sites in the UK.

By supporting the work of Professor Straub, via direct projects, or through the support of the Centres and Hubs that facilitate on-going trials in muscle diseases, the Newcastle BRC is helping to build links between research, patient care and industry, while also feeding knowledge back into the Neuromuscular Theme, which in turn, supports an understanding and progression of other conditions affected by muscle degeneration.
Photo: DMD Hub Steering committee (from left to right). Dr Michela Guglieri, Emily Crossley, Emma Heslop, Prof Francesco Muntoni, Prof Volker Straub, Alex Johnson.

Since the launch, the DMD Hub has achieved a clear expansion of the network across the UK. This has resulted in nine new DMD Hub trial sites, 25 additional trials, and more than 300 participants being recruited onto trials.
This means that not only can more UK patients access clinical trials, but industry can now work with a broader range of sites, patients and clinical partners, who can all draw from the world-class expertise of the London and Newcastle sites.

An example of this is when the DMD Hub supported the Essence 53 trial, delivered by Sarepta Therapeutics in 2020. The industry partner contacted the DMD Hub to assess site capacity for extra patients and paired them with eligible patients from other DMD Hub sites.

The DMD Hub is currently focused on preparing the field for the imminent arrival of gene therapy trials. They hosted a meeting in 2019 to identify and address the challenges, which included understanding patients' views around taking part in a gene therapy trial, fair and equitable trial recruitment, and assessing institutional readiness of the hospitals potentially able to run the trials.

The findings from the meeting have now been published in the journal Neuromuscular Disorders, "Gene Therapy in Duchenne muscular dystrophy: Identifying and preparing for the challenges ahead".

DMD Hub Steering committee (from left to right). Dr Michela Guglieri, Emily Crossley, Emma Heslop, Prof Francesco Muntoni, Prof Volker Straub, Alex Johnson

Heslop E, Turner C, Irvin A, Muntoni F, Straub V, Guglieri M. Gene Therapy in Duchenne muscular dystrophy: Identifying and preparing for the challenges ahead. Neuromuscular Disorders. Published: October 15, 2020 DOI: https://doi.org/10.1016/j.nmd.2020.10.001

NIHR | Sheffield Biomedical Research Centre

The NIHR Sheffield Biomedical Research Centre (BRC) was awarded £4.1million in 2017 to create a research partnership between the University of Sheffield and Sheffield Teaching Hospitals NHS Foundation Trust; to pull-through ground-breaking scientific discoveries into the clinic for the benefit of our patients.
We are the only BRC in the country dedicated to Neurology; our mission is to improve the treatment and care of people living with chronic neurological disorders. As the population ages, more people than ever before will be affected by a neurological disease of some kind, but few effective treatments currently exist.

In order to find new treatments, we first need to answer the following questions:

- Why do certain diseases develop in some people but not in others?
- Why do people with the same disease often progress at different rates from each other?
- And why do some treatments work in some people but not in others?

We routinely collaborate with industry to advance translation of new discoveries and breakthroughs; ensuring real-world benefits to patients, the wider public health community and the wealth of the life sciences sector.

Our three main areas of research are:

- Neurodegenerative diseases – such as Alzheimer's, dementia and brain ageing, Parkinson's disease (PD) and motor neuron disease (MND)
- Neuroinflammation – including multiple sclerosis (MS), Ataxias and Gluten Related Neurological Disorders (GRND)
- Cerebrovascular disease –Prevention, early diagnosis and improved rehabilitation and treatment of stroke

The 3 case studies highlighted demonstrate the federated approach we have in Sheffield to utilise the facilities and expertise across our cross-cutting research themes of: Advanced Medical Imaging, Genomics & Bioinformatics, Predictive in-silico Medicine (INSIGNEO) and the NIHR Sheffield Clinical Research Facility; to accelerate and strengthen our research programmes via collaborative partnerships across a breadth of industry representatives.

Developing an Advanced Therapies programme at Sheffield

Discovery, translation and clinical scale up of Cell and Gene therapies

Project Lead: Professor Dame Pamela Shaw and Professor Mimoun Azzouz

Motor neuron disease (MND) is a fatal, progressively paralysing neurodegenerative condition that urgently needs disease-modifying therapies. Riluzole, the only approved drug for MND, has only modest effects extending survival ≤3 months. Most patients die from respiratory failure within 3 years of diagnosis. In 2% of cases, a toxic gain of function mutation in copper-zinc superoxide dismutase-1 (SOD1), an antioxidant enzyme, causes MND.

Architect's impression of planned Gene Therapy Innovation and Manufacturing Centre (GTIMC)

> "Translational advances in gene therapy are progressing at a rapid pace. Advanced Therapy Treatment Centres have opened up to deliver 'world-first' stem cell and gene therapies; work to facilitate the entry of such treatments into the NHS is ramping up. In Sheffield, we are the first site in the UK to deliver both stem cell transplantation for multiple sclerosis and gene therapy for motor neuron disease clinical trials"
> **Professor Dame Pamela Shaw**

Research led by Professors Shaw and Azzouz at the Sheffield Institute for Translational Neuroscience (SITraN) provided the seminal, robust proof-of-concept that gene silencing using RNA interference knocks down the SOD1 protein, demonstrating the best improvement in survival to date in preclinical models of MND. This pioneering pre-clinical work gave confidence for pharma companies to adopt the SOD1 silencing approach for first-in-man studies.

Sheffield were the sole UK site invited to deliver the first genetic therapy trial for MND and they continue to lead the UK in translating genetic therapies for MND through experimental medicine trials as the UK Biogen ALS/MND Innovation Hub.

We were also the sole UK site to participate in the phase1/2 intrathecal antisense oligonucleotide (ASO- tofersen) trial for MND patients with SOD1 mutations sponsored by Biogen. The results recently published with an accompanying editorial in the New England Journal of Medicine showed that the ASO lowered the target SOD1 protein and biomarker neurofilament levels in the cerebrospinal fluid and blood.

This represents an exciting first identification of biomarkers of therapeutic efficacy anticipated to have a major impact on future trials in MND.

In 2020, The University of Sheffield and Pfizer launched a new consortium which aims to standardise and accelerate the development of Advanced Therapy Medicinal Products (ATMPs), allowing potentially transformative treatments to reach patients sooner.

The new, five-year consortium, Accelerating Research and Innovation for Advanced Therapies (ARDAT), is supported by the EU Innovative Medicines Initiative (IMI) and brings together the leading expertise of 34 academic, non-profit and private organisations from

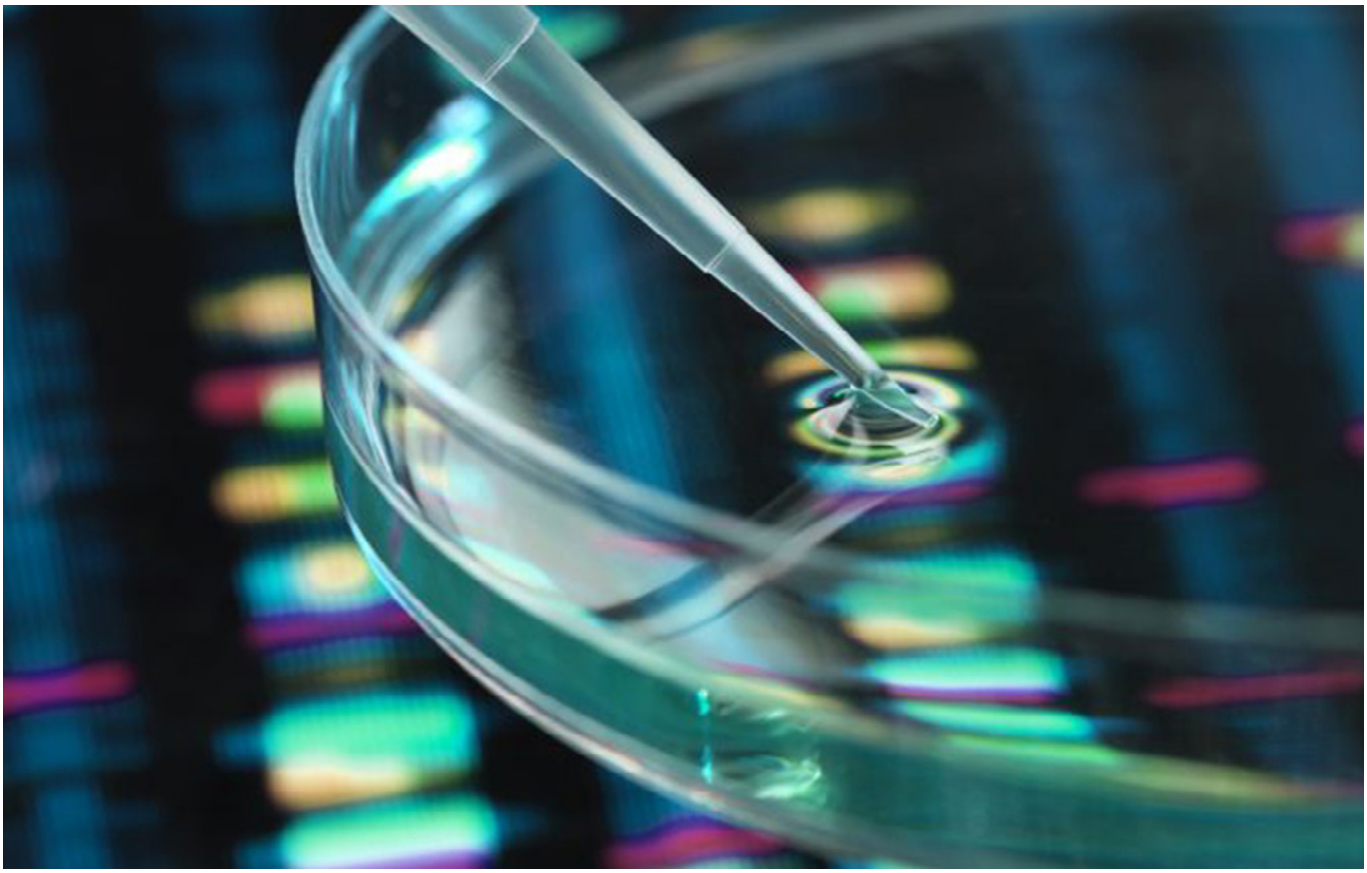
across Europe and the US to pioneer a €25.5 million project to accelerate the development of ATMPs which includes gene and cell therapies.

Current UK facilities for manufacturing viral vectors suitable for human treatment cannot meet demand, thus seriously hindering the translation stage of moving exciting gene therapies into clinical trials. The Gene Therapy Innovation and Manufacturing Centre (GTIMC), led by Professor Mimoun Azzouz, is one of three pioneering hubs announced on 18 March 2021 in a new £18 million network funded by LifeArc and the Medical Research Council (MRC), with support from the Biotechnology and Biological Sciences Research Council (BBSRC).

> "While still an emerging field, ATMP research has largely been fragmented and siloed within organisations with little opportunity to share best practices and information,"
> As gene and cell therapies research grows and more potential ATMPs move into later-stage clinical trials, it is in the interest of the industry and of patients to further our collective understanding of their mechanisms by sharing data and regulatory expertise."
> **Dr Greg LaRosa, Head of Scientific Research, Rare Disease Research Unit at Pfizer**

Gene therapy is a promising treatment option for more than 7,000 rare diseases that currently have no cure. It aims to treat these conditions, by engineering another gene to replace, silence or manipulate the faulty one.

The GTIMC will integrate multidisciplinary partners from the Midlands, Wales and North of England with the aim to bring complementary expertise that we have identified as essential components to unravel the existing knowledge gaps focused on adeno-associated virus (AAV) manufacturing, analytics, process innovation, safety, regulatory, clinical pathways, training and commercialisation. The GTIMC includes provision of a new build state-of-the-art GMP manufacturing facility (see model above).



Utilising Sequencing Technology for MND and COVID-19 Genotyping

Rapid Sequencing and Analysis of genomes for efficacy testing and longitudinal tracking

Project Leads: Dr. Matthew Parker and Professor Dame Pamela Shaw

Sheffield Bioinformatics Core

Inherited forms of motor neuron disease (MND) are often caused by a mutation in the C9orf72 gene. This change is a mistake where some letters of DNA are repeated from a few, to thousands of times. The length of this repeat determines whether a patient is likely to be affected by MND so is measured in NHS diagnostic laboratories.

The current test is limited to measuring ≤30 repeats, potentially missing individuals who could develop MND. The size of the repeat mutation, or other modifications to DNA could determine patient prognosis, and inform the efficacy of treatments available.

We developed an approach using new DNA sequencing technology, Oxford Nanopore GridION, which measures the exact repeat length and modifications to surrounding DNA. This could be crucial in therapeutic clinical trials for MND, and could affect the efficacy of new treatment approaches.

To explore further we partnered with Biogen, which is currently carrying out a genetic therapy trial for C9orf72-MND to see how well their drug treats the disease.

In future our assay could determine which patients will respond to new treatments – facilitating a "personalised medicine" approach.

> "The capabilities we have developed within SITraN are crucial for Sheffield to expand our sequencing of the virus and to continue to contribute timely, accessible data that will help in the global management of the current pandemic."
> **Matthew Parker, Clinical Bioinformatics Scientist at the NIHR Sheffield Biomedical Research Centre and the analyst for the study at Sheffield Institute for Translational Neuroscience**

The equipment and experience of the Nanopore sequencers meant that we were ideally placed to respond to the SARS-CoV-2 pandemic. We became a key centre in the UK consortium (COG-UK) which has successfully sequenced tens of thousands of COVID-19 samples and tracked changes in the virus longitudinally, reporting on a regular basis to Public Health England to inform the outbreak response. In an unprecedented scale-up of our sequencing capacity, supported by Oxford Nanopore, we have contributed >8,000 genomes to this effort of tracking the COVID-19 pandemic.

Our now extensive sequence and clinical dataset has yielded multiple pre-print and peer-reviewed articles and press coverage. As featured in mainstream media, collaboration with Los Alamos Laboratories and Duke University charted the rise of the D614G spike protein mutation predicted to lead to increased transmissibility.

The viral genomes we generated are shared in a public repository (gisaid.org) that allows comparisons with other viral genomes worldwide.

This accelerates international efforts to test vaccines and track changes to the virus. We have impacted on the quality of viral genomic data from worldwide centres by repurposing a computational tool, IncDB, developed by Sheffield, and previously used to assess clinical human genomes. IncDB was able to identify mutations in the SARS-CoV-2 genome that were sequencing errors and enabled a Belgian sequencing centre to correct their reported findings.

Development of the 'HeadUp' Collar

Delivering a new device for neck weakness to market

Project Lead: Professor Christopher McDermott

There are 35,000 patients who suffer from motor neuron disease (MND) in the UK and USA, with a further 5,500-6,000 patients with spinal muscular atrophy (SMA). Many of these patients experience severe neck muscle weakness, and associated problems with swallowing, breathing, mobility, communication and pain. Current neck supports are either very restrictive (neck braces) or lack support (sponge collars), and patients tend to quickly stop using these devices.

The issue of insufficient and impractical neck support for patients was discovered through a BRC supported PPI panel; the Sheffield MND Research Advisory Group (SMNDRAG). Our BRC Deputy Director, Professor McDermott led a multi-disciplinary team of BRC Health Care Professionals (HCPs), patients and carers from the SMNDRAG, Project Management at NIHR Devices for Dignity (D4D), Engineers from our cross-cutting theme INSIGNEO and Designers from Sheffield Hallam University's Lab4Living, to co-design and co-produce a novel cervical orthosis to support neck muscle weakness, utilising a user-centred design approach (an iterative and rich knowledge transfer process driven by the requirements of patients). [DOI:10.1016/j.clinbiomech.2015.11.010]

MND patient Philip Hindle, testing a prototype of the HeadUp collar

The programme of work funded through the NIHR i4i programme, the MNDA and NIHR D4D (~£465,000), utilised facilities at another of our cross-cutting themes, the Sheffield NIHR Clinical Research Facility for the pilot study of 20 patients in Sheffield [DOI:10.3109/21678421.2016.1148170]; before further assessment in 140 patients in 10 centres across the UK. 80% of patients continued using the collar after the experimental trial period, reporting that it provided equivalent support to the fixed collars, whilst permitting more freedom of movement.

The ability to modify the collar according to the tasks being undertaken by the patient (e.g. driving, eating or reading) was highlighted as a key advantage to the newly designed collar. [DOI:10.3109/03091902.2015.1088092]

The NIHR D4D team managed the Intellectual Property to ensure the product is licensed with suitable return for the NHS at an affordable price to users, and the Chesterfield based company TalarMade was selected to manufacturer the collar.
Their expertise in clinical product development has improved the now available collar employing a cooling material utilised by NASA.

Final Head Up product

With only one currently available disease modifying treatment for MND (Riluzole), which has limited effect on survival; symptomatic treatments are often the mainstay of what HCPs can offer to MND patients.

The Head-Up collar is the first product which can fit easily into service delivery to offer patients with MND and other conditions causing neck muscle weakness (e.g. stroke, myopathy, dystonia and multiple sclerosis) a solution to head drop and which will therefore dramatically improve the quality of life for both affected patients and their carers.

The collar is easily fitted by a carer and offers a comfortable, flexible, wearable device which can fit under clothing easily and quickly and which is cosmetically acceptable. The Head-Up collar is available to purchase internationally and has been adopted across UK Trusts.

Our short video demonstrates the impact the collar has had on a local couple, enabling the patient to continue driving, to enjoy eating out with family, socialising and communicating better.

Get in touch

NIHR | Leeds Biomedical Research Centre

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Core Facilities

- Centre of Innovative Manufacturing in Medical Devices
- Medical Technology Innovation Centre
- Gait Analysis Centre, Muscle Lab and Biopsy Room
- NIHR Leeds Clinical Research Facility
- Institute of Medical and Biological Engineering Facilities

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Core Facilities

- Christabel Pankhurst Institute for Health Technology Research and Innovation
- Greater Manchester Clinical Research Network
- Manchester Cancer Research Centre
- Manchester Hearing Device Research Centre
- Manchester University NHS Foundation Trust Clinical Data Science Unit
- Manchester University NHS Foundation Trust Diagnostic and Technology Accelerator (DiTA)
- NIHR BioResource Centre Manchester
- NIHR Manchester BRC Rapid Translational Incubator
- NIHR Manchester Clinical Research Facility
- Translation Manchester
- Stoller Biomarker Discovery Centre

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Core Facilities

- Clinics for Research and Service in Themed Assessments
- Clinical Ageing Research Unit (CARU)
- Newcastle Brain Tissue Resource
- Positron Emission Tomography and Magnetic Resonance Imaging Centres

NIHR | Sheffield Biomedical Research Centre

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Core Facilities

- NIHR Sheffield Clinical Research Facility
- Sheffield Institute of Translational Neuroscience
- Gene Therapy Innovation and Manufacturing Centre (GTIMC), opening 2022
- INSIGNEO – Europe's largest computational medicine research institute
- Sheffield PET MRI facility