



*National Institute for
Health Research*



NIHR Stratified Medicine Capabilities

Supporting innovation and expertise in stratified medicine

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Delivering Research with Stratified Medicine Approaches

Stratified Medicine Approaches

Genotype

Patient cohorts / data

Phenotype

Stratified clinical trials

Biomarker expertise

Diagnostic development expertise

Clinical assessment

Clinical sampling / processing

Drug development expertise

Building blocks of stratified medicine

NIHR BRCs / BRUs

UK Biobank

NIHR BioResource

NIHR CRFs ECMCs

NIHR TRPs / TRCs

CPRD
D-CRIS
NIHR HIC

NIHR Research Programmes

NIHR DECs

NIHR Clinical Research Network

NIHR CLAHRCs

Genomics England

MRC-NIHR Phenome Centre

NIHR-supported capabilities in stratified medicine

The UK, with its cradle-to-grave National Health Service and integrated health research system provided by the National Institute for Health Research (NIHR), is uniquely placed as a location for stratified medicine research.

It can deliver the key elements required to carry out world-leading stratified medicine research, including comprehensive and linked genotypic and phenotypic patient data, expertise in the discovery, development and validation of biomarkers and diagnostics, access to well characterised cohorts of patients, and the ability to design and deliver stratified approaches in both early and later phase clinical trials.

The NIHR supports a broad range of expert investigators, cutting-edge research facilities and technologies, and specific initiatives that span the innovation pathway. These enable stratified medicine approaches from experimental medicine studies, through to multi-centre clinical trials and on to applied health research. For the life sciences industry this means that companies can access these resources across their clinical development pathway and benefit from the combination of comprehensive patient data, rich genotypic and phenotypic information and cohorts of patients that are able to take part in clinical studies.

The building blocks of stratified medicine

Employing a stratified medicine approach to health and disease requires a range of information, expertise and capabilities. These include knowledge about various aspects of an individual, or a group of individuals, expert knowledge about the aetiology and progression of disease, and specialised diagnostic and research techniques.

These 'building blocks' of stratified medicine include:

- Access to cohorts of patients and their data
- Genotypic information
- Phenotypic information
- Disease biomarker expertise
- Diagnostic development and validation expertise
- Drug development expertise
- Specialised clinical assessment techniques
- Specialised patient sampling and processing
- The ability to run cutting edge innovative design, multi-centre stratified clinical trials

NIHR-supported capabilities in stratified medicine

The NIHR has a range of expertise and capabilities that support and drive stratified medicine research approaches across the innovation pathway. Life science companies can access these resources at any stage in their clinical development process and the NIHR Office for Clinical Research Infrastructure (NOCRI) provides a streamlined point of contact for the NIHR's expert research infrastructure.

These capabilities are delivered through a range of NIHR-supported infrastructure and initiatives:

NIHR Biomedical Research Centres and Units carry out translational research to pull through scientific discoveries from the laboratory into the clinic. They focus on a range of research themes that are developing, utilising and benefiting from stratified medicine approaches, particularly in the **use of genotypic and phenotypic information to diagnose disease and focus treatments**. Investigators in these facilities have access to **well characterised cohorts of patients** that are able to participate in stratified medicine studies.

NIHR Translational Research Collaborations in Dementia and Rare Diseases bring together leading health researchers within Biomedical Research Centres and Units to pull discoveries from basic and translational research into real benefits for patients. Both Collaborations work with a range of academic and industry partners and have a focus on establishing groups of **deeply-phenotyped patients** that can support stratified medicine approaches.

NIHR Translational Research Partnerships bring together world-class

investigators in leading academic and NHS centres to focus on collaboration with the life sciences industry in early and exploratory development of new therapies in inflammatory diseases. NIHR Biomedical Research Centres and Units form the foundation of these partnerships, bringing expertise in stratified medicine, combined with access to **cohorts of patients** that are suitable to take part in stratified studies, across a range of inflammatory conditions.

NIHR Clinical Research Facilities provide purpose built facilities with specialist clinical research and support staff to conduct experimental medicine studies. Companies can access assistance throughout the research process from study design to data collection and management. CRFs are designed to conduct high-intensity studies and are perfectly positioned to support **early-phase stratified medicine** approaches.

Experimental Cancer Medicine Centres play a lead role in speeding up the process of cancer drug development and the search for cancer biomarkers through the design and execution of early phase trials. The network of Experimental Cancer Medicine Centres drives the development of new therapies to bring benefits to patients faster. [*Cancer Research UK's Stratified Medicine Programme*](#), which involves a number of Experimental Cancer Medicine Centres, is establishing the foundations for a national service that will ensure standardised, high quality, cost-effective genetic testing of tumours available for people with cancer. By demonstrating it is possible to routinely collect samples from consenting patients, the programme will build a **national database**

of tumour genetic information, treatments and outcomes that will help researchers design more effective cancer treatments.

The UK Biobank has recruited 500,000 people aged 40 to 69 from across the UK who have undergone clinical measurements, provided samples and agreed to be monitored over a number of years with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses – including cancer, heart diseases, diabetes, arthritis and forms of dementia. The Department of Health, through the NIHR, has co-funded the **genotyping of all 500,000 UK Biobank participants**, examining several hundred thousand genetic markers on each participant.

The NIHR BioResource is a collection of 75,000 volunteers, patients and their relatives who have consented to be approached about **experimental medicine studies on the basis of phenotypic and genotypic data**. The BioResource is undertaking an **ambitious in-depth programme to genotype its volunteers**. This powerful resource is ideally positioned to support the development of stratified studies.

The MRC-NIHR National Phenome Centre enables researchers to better understand and tackle diseases that are triggered by environment as well as genetic causes, and to develop strategies for their prevention and treatment. It uses nuclear magnetic resonance and mass spectrometry technology to give the most accurate readings to date of the exact chemical make-up of people's blood and urine. The **precision and depth of data** supports stratified approaches. This resource is complemented by the **NIHR Biosample**

Centre, which is a robotic **biosample repository**, enhancing the nation's capacity to support research into disease mechanisms, diagnosis and treatment.

NIHR Diagnostic Evidence Co-operatives are centres in which experts from across the NHS and industry work together to generate high-quality evidence of clinical validity, clinical utility, cost effectiveness and care pathway benefits of commercially-supplied in-vitro diagnostics. Access to **diagnostic tests** is key to the stratified medicine approach. The evidence generated by the Diagnostic Evidence Co-operatives will be important in helping to drive the uptake of IVDs.

Patient data

The NIHR supports a range of powerful informatics initiatives that can provide a strong foundation for stratified medicine studies.

The Clinical Practice Research Datalink (CPRD) is the English NHS **observational data and interventional research service**. CPRD services are designed to maximise the way anonymised NHS clinical data can be linked to enable many types of research. These include observational studies and, in conjunction with the NIHR Clinical Research Network, the conduct of clinical trials.

D-CRIS: the Dementia Clinical Record Interactive Search is a world-leading resource that will enable **large patient datasets** to be pooled so that dementia research can be conducted at scale, providing researchers with access to **one million patient records** and enabling them to identify trends in the data and investigate why treatments work for some patients and are not as effective for others.

The NIHR Health Informatics

Collaboration (NIHR HIC) brings together five of the country's leading NHS Trusts with large NIHR Biomedical Research Centres to make **NHS clinical data** more readily available and accessible to researchers, industry and the NHS community. It focuses on five scientific themes - viral hepatology, acute coronary syndrome, ovarian cancer, renal transplantation and critical care.

NIHR Services

The NIHR Clinical Research Network is the research delivery arm of the NHS, supporting a portfolio of approximately 3,000 clinical research studies across the pharmaceutical, biotechnology, diagnostics and medical technology industries, as well as Contract Research Organisations.

The Clinical Research Network has a portfolio of high quality clinical research studies spanning a core of 30 clinical specialties. It supports a number of stratified medicine protocols that are seeking to identify and treat niche cohorts of patients within an NHS clinic setting, in both children and adult patient groups. The ability to **rapidly set up and performance manage the delivery of multi-centre studies** is a great strength of the network, with notable successes in the recruitment of global first patients in rare disease patient cohorts.

NIHR Collaborations for Leadership in Applied Health Research and Care

bring together a collaboration of local providers of NHS services and NHS commissioners, Universities, other relevant local organisations and the relevant Academic Health Science Network. They conduct applied health research relevant across the NHS and work with the NHS on the **implementation of stratified treatment approaches**.

NIHR Research Programmes support a **range of research studies that investigate or utilise stratified medicine**. The NIHR may also have specific funding calls that focus on stratified approaches to specific disease areas, such as the recent **Efficacy and Mechanism Evaluation (EME) Programme** research funding opportunity for stratified medicine in non-cancerous conditions.

Genomics England

Genomics England, with the consent of participants and the support of the public, is creating a lasting legacy for patients, the NHS and the UK economy through the sequencing of 100,000 genomes. Genomics England has been set up by the Department of Health to deliver the 100,000 Genome Project. Launched by the UK Prime Minister in late 2012, this project aims to bring the predicted benefits of genomics to NHS patients.

The project is initially focusing on patients with a rare disease and their families, and patients with cancer. The first samples for sequencing are being taken from patients living in England, with discussions taking place with Scotland, Wales and Northern Ireland about potential future involvement.

There are extensive links between the 100,000 Genomes Project and the research infrastructure provided by the NIHR, including through the NIHR BioResource, the NIHR Rare Diseases Translational Research Collaboration, and the NIHR Biomedical Research Centres and Units.



National Institute for Health Research

NOCRI

CONNECTING EXCELLENCE

NIHR Office for
Clinical Research
Infrastructure

The [NIHR Office for Clinical Research Infrastructure](#) (NOCRI) is a unique resource for the global life sciences industry - improving the quality, efficiency and success of translational research. We enable this by providing:

- fast and easy access to the UK's clinical research infrastructure
- rapid connection to expert investigators and cutting edge technologies
- tools and processes to support collaborative research.

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