

Saving and Improving Lives: The Future of UK Clinical Research Delivery

Implementation plan 2021/22



Department
of Health &
Social Care



Llywodraeth Cymru
Welsh Government



Department of
Health

An Roinn Sláinte
Mánnystrie O Poustie



**CHIEF
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UK Clinical Research Recovery, Resilience & Growth

In March the UK government and the devolved administrations launched a bold and ambitious vision to transform the delivery of clinical research in the UK.

This was followed in June by the publication of the 2021 to 2022 implementation plan for the first phase of activity. This plan looks to ensure research will have better health outcomes and allow more patients to be involved in, and benefit from, research of relevance to them.

Linked closely to the recently published **UK Life Sciences Vision** launched on 6 July 2021.



Why now ?

- Support the recovery of research activity
- Using the lessons learned from COVID to build back a more resilient research system
- Modernise the environment in context of wider changes in the NHS
- Deliver on the commitment to make the UK the leading global hub for life sciences

Phased implementation

Our UK-wide vision for clinical research will be delivered in 2 key phases

- **Phase 1:** Phase 1 is the action plans and strategies for improvements to be delivered during 2021 to 2022 (published June 2021)
- **Phase 2:** Once delivery in 2021 to 2022 is underway, we will set our sights even higher, publishing detailed plans for the future, which will deliver on our vision and unleash the true potential of UK clinical research

A true partnership endeavour – together stronger



NHS RESEARCH SCOTLAND



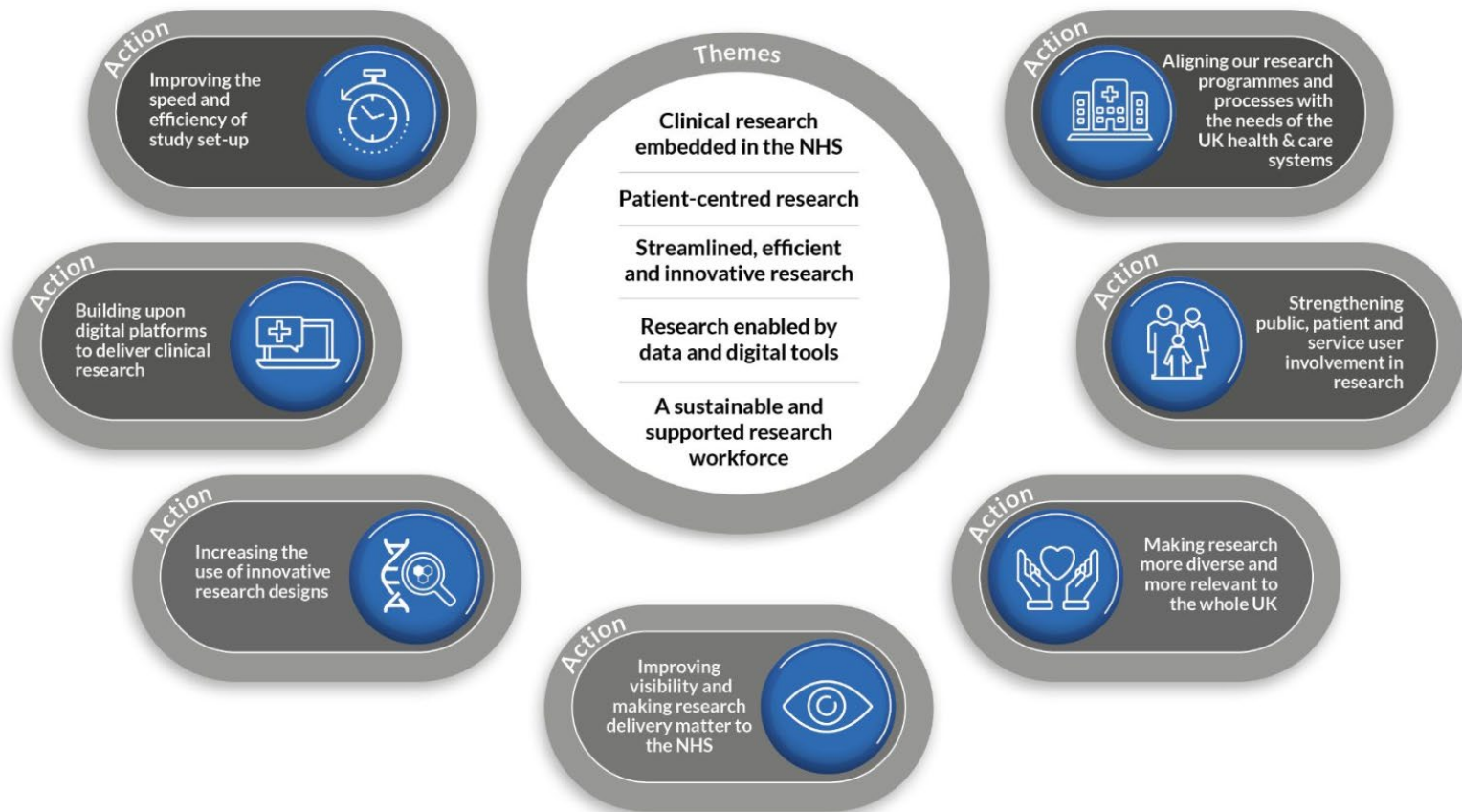
What does it mean for UK wide working ?

- Lots of current examples of working across the 4 nations so that's not new.

HOWEVER, the vision has enabled a refreshed impetus to

- Enhance ministerial focus on clinical research delivery
- Focus on activities pan-UK that adds value to patients, public, workforce
- Strengthen UK collaboration messaging to global partners

UK Vision - 7 areas for action



Themes

**Clinical research
embedded in the NHS**

Patient-centred research

**Streamlined, efficient
and innovative research**

**Research enabled by
data and digital tools**

**A sustainable and
supported research
workforce**

Action

Improving the
speed and
efficiency of
study set-up



Action

Aligning our research
programmes and
processes with
the needs of the
UK health & care
systems



Action

Building upon
digital platforms
to deliver clinical
research



Action

Strengthening
public, patient and
service user
involvement in
research



Action

Increasing the
use of innovative
research designs



Action

Making research
more diverse and
more relevant to
the whole UK



Action

Improving
visibility and
making research
delivery matter to
the NHS



Managed Recovery

RRG Activity

NIHR CRN is leading the UK process whereby funders are invited to identify the most pressing studies that require support to recover over the next 6-12 months.

Initially scope is:

- Interventional
- multi-site
- urgent
- can fully recruit and/or close in the next year
- require delivery support

Process (active)

<https://www.nihr.ac.uk/researchers/managing-research-recovery.htm>

UK Process

Funders submit sequenced list
Each study is assessed by Lead LCRN/ DA for deliverability:

- Recruiting in >50% of sites (UK)
- Participants available
- Feedback from sites indicates no known issues

UK Managed Recovery Operational Group review

Wales process

One Wales process - central team oversight/ coordinate feedback to NIHR (as per UK process)

Central team liaising with sites via Research Delivery Operational Group (RDOG)/ tracker

Progress

- 226 studies (UK) confirmed for managed recovery (6 July 2021)
- 75 of those active in Wales
- Current status:
 - 66 studies open to recruitment (5 in set up/ 4 in follow up)
 - Of those open all but 4 studies are fully reopened in Wales

Improving the speed and efficiency of study set-up

RRG Activity

The RRG Programme will ensure strategic coordination of work to improve the speed and efficiency of the UK clinical research ecosystem, supporting progress and ensuring alignment of current initiatives, as well as identifying key areas for improvement and investment necessary to fully realise the overarching vision.

Progress

UK working group 'Speed and efficiency' being established

HCRW 'study support service' will support implementation of UK processes as they evolve

- Coordinated early engagement and Wales-wide feasibility
- Coordinated rapid site identification/selection
- Coordinated contracts/costings (linked to NCVR action)
- • Coordinated study set-up
- Coordinated study delivery performance oversight

All-Wales screening/appointment bookings service established for vaccine trials, now used to support remote recruitment/delivery/follow-up - ongoing needs TBC.

Improving the speed and efficiency of study set-up

RRG Activity *Ethical Review*

HRA, working with relevant partners, will streamline and accelerate the UK ethics review service.

This will involve offering rapid REC review as an option for clinical trials across the UK, including Phase I trials in healthy volunteers.

HRA will continue work on developing IRAS as a UK portal for research approvals and ongoing study oversight, streamlining approval processes, improving communication with digital interfaces and workflow tools.

NIHR, working with DAs, will ensure development of digital solutions that link research approvals portals with delivery management systems

Progress

Ethics Review Programme

- Programme plan agreed
- Oversight via Research Ethics Service Review Programme Board (UK)
- UK working groups in set-up:
 - Method of review
 - Information and consent
 - Streamlining documentation
 - Decision making and committee culture
 - Committee format and membership
 - Communications
- Stakeholder workshops planned



IRAS

Major redevelopment already in progress
Oversight via IRAS Partners Board

Improving the speed and efficiency of study set-up

RRG Activity

Clinical Research Facilities

The UK government and devolved administrations will ensure late-phase commercial clinical research is delivered through efficient and responsive models.

Progress

- NIHR Patient Recruitment Centres operational in England
 - <https://www.nihr.ac.uk/explore-nihr/support/national-patient-recruitment-centres.htm>
 - [PRC: Blackpool](#)
 - [PRC: Bradford](#)
 - [PRC: Exeter](#)
 - [PRC: Leicester](#)
 - [PRC: Newcastle](#)

Wales



- Development complete of additional clinical research facilities in Llantrisant, Wrexham, West Wales as part of the COVID19 vaccine trial programme
- Established CRFs in Cardiff and Swansea
- Next step - discussion on responsive delivery models for Wales and relationship to models in other nations, to inform policy position

Improving the speed and efficiency of study set-up

RRG Activity

Costing and contracting

Implement a UK-wide national contract value review (NCVR) process for commercial contract research.

HRA, through the UK contracts group, will expand the range of model UK contracts agreed with Industry and the NHS.

- including templates to support innovative trial delivery through hub and spoke models

Process (under development)

<https://www.nihr.ac.uk/partners-and-industry/industry/run-your-study-in-the-nhs/faster-costing-and-contracting.htm>

- Design of NCVR process underway
- Standardised costing methodology in place for all commercial studies – via interactive costing tool (iCT)
- Wales has and continues to lead the drafting of model contracts, including hub and spoke models

UK Contracts and costing group
Wales Contract and costing operational group

Progress

- NIHR tariffs agreed for use across all NHS organisations in Wales
- One Cost One Contract (optional) process in place (mutual recognition across Wales)
- Wales policy position on NCVR TBC
- Wales has and continues to lead the drafting of model contracts, including hub and spoke models.
- Publication due of model Non-Disclosure Agreements (UK)

Aligning our research programmes and processes with the needs of the UK health and care systems

RRG Activity *Workforce*

NIHR, on behalf of the UK, will develop the professional identity, standards and regulatory accountability for Clinical Research Practitioners (CRP) and further develop the Associate Principal Investigator role.

The use of flexible workforce and delivery models will be increased – particularly to support research delivery in primary and community care.

Progress - Initial focus on workforce.

UK CRP register in place for some years, and this has been promoted in Wales via NMAHP forum and more recently relaunched (June 2021)

The Associate PI role has been promoted across the UK

<https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040>

→ In Wales, work continues to complete a suite of standardised job descriptions for research delivery staff - Research Nurse (Band 5 and Band 6); Senior Clinical Research Officer (Band 6); Clinical Research Officer (Band 5) already available for use.

Support for flexible workforce models is part of criteria in HCRW funding model for delivery support, prioritising resources that support across organisational boundaries.

A request for Wales COVID19 recovery funding has been submitted to boost capacity and expand out of hospital support.

Improving visibility and making research matter to the NHS

RRG Activity Embedding Research in the NHS

Across the UK we will make clear to all staff the different ways they can get involved in research and increase awareness of the value of research and innovation amongst staff and NHS leaders.

This includes promoting evidence that research active settings have lower mortality rates and increased staff retention.



Progress – initial focus includes UK agreement on changing the ‘culture of the NHS’

The need to raise awareness of why research is important - building on the enthusiasm for research seen through pandemic

Involvement of all health professionals who interface with patients daily encouraging them to be advocates for research even if they are not actively involved in the research process themselves

Wales – this work is linked to the NHS organisation annual planning process where research is a key enabler of high quality care

- greater visibility of research aligned to care pathway
- greater understanding by NHS planners of research for patient benefit

Improving visibility and making research matter to the NHS

RRG Activity Embedding Research in the NHS

Across the UK, the NHS will facilitate recognition of the professional contribution of nurses, midwives, allied health professions, pharmacists and healthcare scientists to the research workforce, and the value of research and innovation amongst NHS leaders, making clear to these professions the different ways they can get involved in research

Progress - initial focus on recognition of research as core activity

Includes research in non-medical job plans across all bands and is aligned with work in Wales to strengthen the support for research within current UK Agenda for Change (A4C) job planning guidelines

Wales

- Review is underway to map the research career pathway for all professionals with the intention of clarifying what programmes are available or not available to support research careers.
- Build on feedback from NHS RTA evaluation to explore buy-in from NHS organisations to support protected time for successful awardees after the NHS Research Time Award (NHS RTA) ends

[Career development | Health Care Research Wales
\(healthandcareresearchwales.org\)](https://healthandcareresearchwales.org)

Improving visibility and making research matter to the NHS

RRG Activity Embedding Research in the NHS

NIHR, on behalf of the UK, will engage with regulatory bodies for registered professionals around the inclusion of research delivery activity in standards and revalidation requirements.

we will explore ways in which metrics and reporting can increase the visibility of research across the NHS and strengthen the incentive for trusts and boards to support clinical research

Progress - initial focus empowering and supporting staff to participate in clinical research delivery as part of their job.

Drive greater recognition of research in continuous professional development and working with professional bodies to achieve this

In Wales, this links with work to identify national processes / best practice for honouring SPA sessions /protected time in job plans



This includes a campaign to promote benefits of research active professionals to workforce / staff managers focused on:

- Improved patient care
- Retention and recruitment of staff
- Opportunities for patients

Increasing the use of innovative research designs

RRG Activity

Key stakeholders – MHRA HRA, sponsors, funders and patients

The RRG Programme will lead work to understand the barriers and enablers facing researchers in delivering patient centred, innovative research designs as standard, and use this as a basis for the design of interventions that will enable a step change in practice

includes joined-up advice from NICE, SMC and HRA on innovative trial designs through ILAP

Progress - initial focus is to build resilience and drive innovation

Includes a programme of work to assess and develop capability to support virtual and decentralised trials

Emphasis on sponsors to consider how 'other ways of working' become business as usual, so that the best research is taking place where it is best suited across the ecosystem.

- Increased appetite for innovative trial designs – guidance through **ILAP** (Innovative Licensing and Access Pathway)
- Adaptive approaches to recruitment
- Making trials more accessible to patients
- Example: **RELIEVE IBS-D** study – move to virtual model resulting in faster recruitment across more sites

Building upon digital platforms to deliver clinical research


RRG Activity

Developing a more cohesive data enabled digital research environment

The RRG programme will work across the UK to develop a seamless UK-wide system of digital platforms for research sponsors, ensuring they can bring research, particularly those with a digital component, to any part of the UK effectively.

HRA and NIHR CRN, working with the devolved administrations, will establish guidance and support services that support data-enabled recruitment and help researchers understand, navigate and use data services as part of effective study delivery. Initially, this will focus on mature, large-scale data and digital infrastructure and expand in future years.

Progress – mapping and developing the Wales “offer”

- Includes a mapping exercise across the UK to produce a clear articulation of all available systems/ platforms across the UK and what they can offer to Sponsors. Timescales to be confirmed
 - Wales will continue to work closely with NIHR and HRA to ensure that any support service offered to research sponsors includes Wales and that the systems/ platforms developed for Wales meets the needs of researchers and Sponsors.
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- Wales will be working to develop a use case for a system that can offer the same service/ functionality as part of a UK offer (currently being referred to as Find, Recruit, Follow up).
 - Development of use case to be done over the next 2 months.
 - Existing systems including SAIL and Wales data through CPRD sign up will be assessed to determine what offer is being made through these anonymised trusted research environments.

Making research more diverse and more relevant to the whole of the UK

RRG Activity

Ensuring research is more diverse and reflective of all communities

NIHR, on behalf of the UK, will work with existing centres of excellence and other partners to develop systems and processes that enable health research to be directed to and supported within areas and communities traditionally under-served by research (e.g. by deprivation, ethnicity or geography) to tackle health inequalities.

NIHR, NHS Digital and the devolved administrations will scope the use of national datasets to analyse the diversity of research participants.



Progress – Discover Your Role action plan in Wales underway

The **Discover Your Role** action plan developed in partnership to enhance the environment for public involvement and engagement in research

Public engagement strategy in development, which aims to ensure that:

- People involved with and participating in research are reflective of the population with the specific condition being researched; or reflective of the area of research demographically.
- We have clear strategies to reach under-represented communities across Wales.

We will continue to work with NIHR on joined up developments and initiatives.

Work on use of national data sets to analyse demographics/ diversity of research participants not yet started, but may include consideration of systems like LPMS that are already being used to capture participant level data in parts of the UK.

Wales is also involved in ongoing work e.g. implementation of the **UK Transparency Strategy** led by HRA, including automatic registration of clinical trials into a public registry.

Strengthening public, patient and service user involvement in research

RRG Activity

Expand public, patient and service-user involvement in research

NIHR and devolved administrations will build on their local and regional capacity to work on community engagement with patients and communities to shape priorities and study designs for research

The UK will work to address practical barriers to enable increased and easy-to-administer involvement of the public, working with key partner organisations.

Progress

- Wales already includes people with lived experience in research prioritisation (e.g. social care research prioritisation undertaken recently). We will continue to engage in UK wide work to build on this.
- Wales is leading work as part of a **5 nations group** to tackle the significant barriers around payment for the contribution that people with lived experience make to research.
- High profile project supported by policy colleagues and will report into DHSC and Welsh Government. Work involves liaising with HMRC to update guidance and to create a practical guide for HR and Finance colleagues in implementing payment processes that are as simple and pragmatic as possible.
- The ***Discover Your Role*** action plan has several areas of focus delivering against this RRG action area.

Collaboration will be critical to our success!



Questions?