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

Implementation plan 2021/22
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
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

Actions

- Improving the speed and efficiency of study set-up
- Aligning our research programmes and processes with the needs of the UK health & care systems
- Building upon digital platforms to deliver clinical research
- Strengthening public, patient and service user involvement in research
- Increasing the use of innovative research designs
- Making research more diverse and more relevant to the whole UK
- 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](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.

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**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
  o PRC: Blackpool
  o PRC: Bradford
  o PRC: Exeter
  o PRC: Leicester
  o 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)


  - 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

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<th>RRG Activity</th>
<th>Workforce</th>
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<td>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.</td>
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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](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

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
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](healthandcarereresearchwales.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

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 (Innovative Licensing and Access Pathway).

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
- 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.

• 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?