Update from the UK Clinical Research Recovery, Resilience & Growth Programme

Department of Health & Social Care

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HSC Health and Social Care

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Introduction

In March 2021, the UK Clinical Research Recovery, Resilience and Growth (RRG) Programme published the vision for "*The Future of UK Clinical Research Delivery*". It has now been 6 months since the launch of the 2021 to 2022 implementation plan for this vision. The plan, published in June, includes the tangible steps underway this year through UK-wide cross-sector partnership to begin to turn the vision into reality.

This was complemented by the July publication of the Government's Life Sciences Vision which highlights the work of the RRG programme and included the overarching clinical research ambition to: "*drive value creation for industry and patients through faster, cheaper, better-quality and more diverse clinical research, delivered through a digitally enabled and pro-innovation clinical research environment, with research embedded across the NHS as a core part of effective patient care."*

In this update, the RRG delivery partners set out the key achievements and milestones that have already been accomplished and provide further detail on what you can expect from the programme in the coming months.

Managed Recovery

The impact of the pandemic on non-COVID-19 research has been significant, with many studies paused to focus on urgent COVID-19 research. Over the last 6 months, the RRG programme has developed and implemented a managed approach to the recovery of the UK clinical research portfolio to restore activity to pre-pandemic levels and ensure the UK is able to deliver the levels of activity needed for contribution to global studies.

NIHR is leading this process of managed recovery on behalf of all UK partners. Public funders, medical research charities and industry have sequenced their most urgent studies for completion. The aim is to complete the most urgent studies in tranches in order to clear backlogs and speed up the delivery of the overall portfolio. Over 290 studies are now part of the managed recovery process and are in active set-up, open to recruitment, or in follow-up stage. At time of publication, 30 studies have completed recruitment and are in follow-up stage.

Managed recovery is operating in an environment that remains challenging with ongoing NHS pressures and continued COVID-19 impacts. Therefore, some studies which were considered to be complex prior to the pandemic continue to experience delays despite best efforts. NIHR and the devolved administrations are working with local teams to identify and unblock local challenges where possible, whilst remaining sensitive to the pressures that NHS colleagues are working under. Despite these challenges there has been a general improvement, with recruitment across the entire portfolio continuing to increase.

In England, to support this drive to recover the portfolio, DHSC has provided over £40m of additional funding to the NIHR Clinical Research Network (CRN) in the 2021/22 financial year to increase research delivery capacity.

In Wales, the focus remains on the recovery of all non-COVID-19 research, including those studies identified via the managed recovery process. The Welsh Government has provided £1.7m to support additional capacity in order to achieve the recovery of non-COVID-19 research, including development of research capacity outside of hospital settings.

In Scotland, a Strategic Oversight Group proactively gathers views and intelligence on the progress of recovery and provides advice. The group comprises representatives from NHS Research Scotland, NHS Scotland, patients and public, and representative bodies of key stakeholder groups. Scotland's Cancer Trials Resilience subgroup brings together NHS Research Scotland, commercial and third party stakeholders to implement resilience within cancer clinical trials. The group advises on, and monitors, data to support the recovery of the cancer clinical trials portfolio across Scotland, identifies and proposes solutions to recruitment barriers, and explores innovative approaches to build increased resilience.

The Northern Irish Public Health Agency R&D Division established a Taskforce in March 2021 to prepare an Implementation Plan for clinical research recovery, resilience and

growth in Northern Ireland. Members are from across clinical research in Northern Ireland, representing our clinical research infrastructure, Health and Social Care Trusts, the Northern Ireland Universities, clinical researchers and the public. £3m funding from the Department of Health in Northern Ireland has been provided to support the work of the Taskforce. The Northern Ireland Implementation Plan will sit alongside the UK-wide Implementation Plan and will contain proposed actions that are specific to Northern Ireland. As a key element of this, the Northern Ireland Clinical Research Network, has played a full part in the managed recovery process and reports back to the Taskforce on progress with resuming clinical research activity.

Action area 1

Improving the speed and efficiency of study set-up

By simplifying and streamlining the route to study set up, incorporating greater transparency and consistency in research approvals and by expediting the processes for costing and contracting, we can reduce delays and speed up all aspects of study set-up. This will bring fresh business and investment to the UK to bolster economic growth and job creation. More importantly, it will set the pace for innovation and ensure research is rapidly translated into improved patient care.

The Health Research Authority (HRA) has continued to bring about **improvements to the Integrated Research Application System (IRAS)**, with new digital functionality for research approvals and study set-up across the UK. This is to ensure IRAS is fit for the future, with streamlined approval processes, improved communication, digital interfaces and workflow tools to make it easier for researchers to carry out responsible research that complies with legal and ethical expectations.

New functionality allows trial sponsors to manage their complete Clinical Trials of Investigational Medicinal Products (CTIMPs) lifecycle via combined review using IRAS – from initial application through to amendments, safety reporting, end of trial notification and submission of summary results, to submitting their amendments online rather than via email. Additional functionality has also made it easier for applicants to book Research Ethics Committee (REC) review meetings online, enabling 24/7 access.

In the longer term the new functionality will apply to all applications made in IRAS, help deliver the UK's research transparency strategy and will give sponsors, Chief Investigators (CIs) and NHS sites better visibility of research projects and their status.

The combined review from the Medicines and Healthcare products Regulatory Agency (MHRA) and the UK Research Ethics Services, in collaboration with the HRA, facilitates speedier set up for clinical research trials by requiring applicants to only make a single application for both Clinical Trial Authorisation (CTA) and REC approval. Guidance is available to support applicants in using the new part of IRAS to make applications and manage projects through the combined review process. From January 2022, all new CTIMPS in the UK will benefit from the combined review.

The MHRA has also been working with developers who plan to run studies involving investigation of both a medicine and a medical device to offer a combined regulatory assessment. Four applications have already been assessed this way and the MHRA, working with the HRA, will begin to explore how this service can be incorporated into a

fully combined regulatory and REC review, within the combined review service via IRAS.

Similarly, the MHRA has identified the minimum regulatory requirements for review of In Vitro Diagnostic Medical Devices (IVDs) used with medical purpose in CTIMPs i.e. those IVDs used to determine trial eligibility and/or treatment assignment in CTIMPs. MHRA is engaging with external stakeholders to discuss this risk-based approach and identify volunteers willing to test it in a pilot.

HRA continued to offer **50% faster REC review** for non-COVID clinical trials in the UK as part of a pilot earlier this year. The pilot of this service ended in June 2021 and has shown a median time for review between 12 and 14 calendar days, excluding time for applicant response. This Fast Track service has been incorporated into standard business, and since June has started reviewing studies under combined review arrangements with MHRA.

For innovative medicinal products, the **Innovative Licensing and Access Pathway (ILAP)**, a joint initiative between MHRA, National Institute for Health and Care Excellence, Scottish Medicines Consortium (SMC) and All Wales Therapeutics and Toxicology Centre, formally launched this year. The ILAP is an entirely new approach to the licensing and regulation of the most innovative, transformative treatments. This new pathway has established partnerships to robustly and safely support the development of the most innovative and needed new medicines.

The entry point to ILAP is the award of an Innovation Passport which enables applicants to work with product-specific experts at the MHRA and partner organisations to develop a roadmap for delivering early patient access, called the Target Development Profile (TDP). Passport holders also have access to the TDP Toolkit, a suite of innovative and flexible activities designed to support innovative trial design and rapid set-up, including:

- access to expert guidance on the collection and use of real world evidence,
- Clinical Practice Research Datalink (CPRD) assisted patient recruitment,
- a Novel Methodology and Innovative Clinical Trial Design tool,
- Rapid Clinical Trial Dossier Pre-Assessment.

The first Tool being used in ILAP is the Rapid Clinical Trial Dossier Pre-Assessment service which provides sponsors of clinical trials with expert feedback from MHRA clinical trial unit assessors on their CTA application dossier before it is formally submitted.

Guidance for applicants to the ILAP was published in March. This guidance includes eligibility information, as well as how to apply for an Innovation Passport and when to enter the pathway, helping users to benefit from the ILAP and hence accelerate the time to market, facilitating patient access to medicines. Already we are seeing the benefits of MHRA's Transformation Programme. MHRA issued its first licence through Project Orbis only four months after joining the scheme, and over 35 Innovation Passports have been issued so far, following establishment of the ILAP.

Additionally the MHRA ran a consultation on the future regulation of medical devices in the UK. The consultation set out a series of proposals to make the UK the most attractive place to research, develop, produce, and supply safe and innovative medical devices.

The Experimental Cancer Medicine Centre (ECMC) Network, with support from MHRA and HRA, is beginning work on delivering a **pilot to set up phase 1 oncology trials within 80 days of IRAS submission**. The new ways of working are being co-created by all of the relevant stakeholders, including regulators, sponsors, R&D teams and investigators to create a scalable system that has benefits beyond cancer.

Experimental Cancer Trial Finder, the ECMC network's new tool to support trial recruitment, is in its second phase of development. Delivered by Cancer Research UK and part-funded by NIHR and the devolved administrations, the EC Trial Finder will shortly be made available beyond the ECMC network.

Work to design and implement a **National Contract Value Review process** for commercial contract research is ongoing. Once data has been gathered from all NHS organisations and guidance created, the process will be implemented in England and Wales. This mirrors existing support available in Scotland. Engagement with stakeholders, including industry is planned. Northern Ireland is also a member of the National Contract Value Review Group, and all administrations are working towards full adoption of the process as it rolls out to create an aligned UK service.

The range of **model UK contracts agreed with industry and the NHS will be expanded**. Use of model agreements simplifies and speeds up the study setup process. Two are published in IRAS help and the rest will be available online shortly.

Published

- The first UK-wide model Clinical Investigations Agreement (UK mCIA) for research in medical devices
- Commercial and non-commercial stand-alone data processing agreement template, to allow sponsors to bring all studies at a site, that were contracted on pre-GDPR templates (or not formally contracted), in line with GDPR

Agreed for publication

- m-NISA: The first ever commercial non-interventional agreement template (model non-interventional Site Agreement)
- MTA: A Stand-alone material transfer agreement (MTA) for studies that involve only the provision of human biological material by the site.
- Advanced Therapy Investigational Medicinal Product (ATIMPs) mCTA: The first ever commercial ATIMP model clinical trial agreement.
- UK mCDA: Model Confidentiality Disclosure Agreement for commercially driven research that aims to improve the speedy provision of study documents to facilitate quick assessment and decision making for commercial contract research.

In development

- Hub and spoke: A model agreement to support hub and spoke arrangements where the PI is not located at the trial site.

The hub and spoke agreement will be used alongside new published guidance by the HRA and MHRA to support the 'Set up of Interventional Research' with oversight across organisational boundaries by outlining the oversight arrangements that should be in place for an activity associated with an interventional research study, prior to that activity commencing. Specifically, it describes sponsor considerations for:

- Determining whether an activity associated with an interventional research study should be overseen by a Principal Investigator (PI).
- Whether such oversight may only be effective if provided by an individual employed by the organisation delivering the activity, or if effective oversight could be provided by a PI employed by another organisation.

Action area 2

Building upon digital platforms to deliver clinical research

The UK has high-quality data assets and has invested in a range of digital platforms which are already providing valuable services to support research delivery. We are now working to increase the scale and interoperability between systems, to support feasibility assessments, improve diverse recruitment and to reduce the burden and costs of clinical research delivery, at both a national and local level.

Building on the Life Sciences Vision and draft Data Strategy published in June 2021, the upcoming ***Data Saves Lives*** **Strategy** will set out NHSX's bold vision to harness the potential of data in health and care, including for cutting edge clinical research, while maintaining the highest standards of privacy and ethics.

To enable more widespread use of NHS data, NHSX is bringing together its partners across the system to **detail the role of Trusted Research Environments (TREs)** in the health and care system. The output of this work will include a minimum technical specification for TREs, standards and policy, and an accreditation framework.

Scotland's Digital Health and Care Strategy Enabling, Connecting and Empowering: Care in the Digital Age published on 21 October 2021 sets out commitments to promote and facilitate appropriate, safe and secure access to clinical, biomedical, care and other data for approved research, development and innovation.

A short life working group on Data and Digitally enabled approaches to ensuring recruitment and retention in clinical trials has been set up in Scotland. Report and recommendations are due in early 2022.

Work is ongoing on a UK-wide ***Find, Recruit and Follow-up*** service to make it quicker and easier to set up and deliver clinical studies across the UK, with R&D-ready data strengthening the ability to place studies and increase the diversity of participants. NHSX, DHSC, the Department for Business, Energy and Industrial Strategy and the devolved administrations are working together to coordinate scoping work to optimise the system across the whole of the UK. Work progressed as part of *Find Recruit and Follow-up* this year includes:

We have already seen how data and digitally enabled services such as **NHS DigiTrials** helped researchers to develop vital COVID treatments through platform trials like RECOVERY at record speed and efficiency. Innovative data-enabled approaches such as platform and precision trials have great potential beyond the pandemic and there is a lot of interest in how we build on this to make it faster and more efficient to find safe, effective

treatments for other common illnesses. For example, in cancer, NHS DigiTrials is supporting recruitment of patients to studies of the cutting-edge Galleri Test to diagnose and treat cancer earlier, including the NHS-Galleri Trial and the SYMPLIFY study.

The MHRA CPRD has launched SPRINT (Speedy Recruitment into Trials), a data-enabled research service that facilitates rapid feasibility and patient recruitment into industry sponsored phase 2 to 4 clinical trials in any setting across the UK. The pharmaceutical industry has recognised the value of CPRD services, with recruitment into the first three clinical trials using CPRD SPRINT commencing between September and November 2021.

Functionality of **The Scottish Health Research Register and Biobank (SHARE)** has been expanded to provide researchers more options to identify potential research participants. This includes health board, age range and condition. Over 286,000 people, aged 11 years and over have consented to be contacted for medical research.

NIHR is creating **more capabilities for the Be Part of Research (BPoR) website**, where patients, carers and the public can find out about health and social care research taking place in their area and ask to take part.

Over the past six months, BPoR has implemented some new features. These include a new dynamic filter that will be more intuitive for the public to use for example, encouraging users to specify a location when they search. Additionally, the website branding has been updated to include the devolved administrations to highlight that BPoR is a UK-wise resource. Integration of NIHR CRN Central Portfolio Management System (CPMS) into BPoR is planned to start in 2021 and is due to be complete in 2022, this will ensure all research that the NIHR CRN is supporting is available on BPoR.

Launching in March 2022, NIHR's Digital Trial Engagement programme of work will include: account registration for the public to take part in research, researcher portal to enable studies to recruit from BPoR, and features that enable improved digital study communication including thank yous for taking part.

Access to Electronic Health Records by Sponsor representatives in clinical trials, guidance jointly developed by the HRA and MHRA, in consultation with the Information Commissioner's Office (ICO), was updated in September 2021 to include revised guidance for viewing Electronic Health Records (EHR) remotely.

HRA and NIHR CRN are in the process of establishing guidance and support services that facilitate data-enabled recruitment and help researchers understand, navigate and use data services as part of effective study delivery.

Action area 3

Increasing the use of innovative research designs

We have committed to enable delivery of faster, more efficient and more innovative clinical research in the UK. Changing the way we design and deliver studies will allow us to build system resilience and increase system capacity, by freeing up NHS and research delivery staff to work on the activities that really need their involvement and skills.

NHSE and GRAIL, a US Biotechnology company, launched a trial of a **new blood test that can detect more than 50 types of cancer** before symptoms appear. The Accelerated Access Collaborative, embedded in NHS England, coordinated the design and set up of a two-part, real-world demonstration project, coordinated clinical data capture from NHS Digital and NIHR, and coordinated partners to prepare for recruitment once regulatory approval was confirmed. This ensured the UK was the most attractive place to undertake the studies.

The first participant was enrolled onto the asymptomatic study 35 days following study approval, much faster than the average 218 days for UK studies. Over 4,500 participants have been recruited since August and the symptomatic study has enrolled over 4,000 participants. The success of the GRAIL studies shows that high numbers of patients can be recruited quickly into trials following regulatory approval without the impetus of a global pandemic.

The **NIHR UK Working Group On Remote Trial Delivery** published a report in June on the challenges and enablers to remote trial delivery and provided guidance for researchers to support the transition to remote delivery.

A stakeholder workshop in November 2021 further explored current considerations for decentralised trials to inform future actions of the group into 2022.

Additionally, a **Decentralised Clinical Trials (DCT) Offer** is being developed led by NIHR. DCTs, also referred to as virtual clinical trials and remote trials, offer an alternate method of conducting clinical trials. The overall aim of this project is to highlight and make visible the UK's ability to conduct DCTs by understanding the NIHR's key strengths and challenges in the delivery of DCTs, and to enable more people to participate in clinical research, including those from under-served populations.

NIHR is planning an Innovative Trials Symposium in March 2022 to follow on from development of a joint podcast series with HRA. The full details and focus of the Symposium next year will be confirmed in the near future.

NIHR-funded Researchers have published a paper highlighting innovative ways and best practice for using fully consented patient data in clinical trials for public benefit.

A mapping project has taken place across the NIHR Infrastructure and the UK Clinical Research Collaboration (UKCRC) Registered Clinical Trials Units (CTU) Network to gain a broad understanding of the **existing expertise in the development and delivery of complex design and innovative trials** as well as trials with innovative delivery.

Additionally, the UKCRC Registered CTU Network has completed a study on 'Costs and staffing resource requirements for adaptive clinical trials' as well as developing a guidance paper from the study.

The MHRA Clinical Trials Unit continues to support use of novel trial designs through interactions with companies but also through interactions at external meetings and conferences. Feedback is being collated to input to future work and potential publications, either as stand-alone guidance and/or through the ILAP novel methodology tool.

Use of novel trial designs or use of novel methodology elements within clinical trials and during the development lifecycle is a specific consideration in one of the ILAP tools. The tool is under development and has been requested as part of a recent TDP discussion.

A subgroup of the Northern Ireland clinical research Taskforce has been set up to focus on innovative trial design possibilities in Northern Ireland, and where possible to link with other UK-wide opportunities and initiatives in this space.

Action area 4

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

Aligning programmes with current and future demands for UK health services will enable us to direct clinical research capability towards the most pressing challenges facing the NHS - to bring the greatest benefits to patients across the UK and around the world.

In June, **NIHR published** **Best Research for Best Health: The Next Chapter**, which sets out NIHR's operational priorities now and into the future. It re-affirms NIHR's core workstreams and sets out seven areas of strategic focus. These areas have been identified as where the health environment is changing or there are potential structural weaknesses and NIHR needs to work with urgency and in fundamentally different ways to deliver transformative change over the next five to ten years.

At the centre of Health and Care Research Wales efforts in the coming year, as detailed in their annual report, will be to **support and develop the capacity and capability for research in Wales**:

- ensuring that research is of the highest quality
- is internationally competitive in its science and relevance
- is used to help shape health and care services in Wales and brings about improvements for patients and communities.

The Scottish Government has established **The Scottish Health and Industry Partnership** (SHIP), an initiative hosted by the Chief Scientist Office (CSO) of the Chief Medical Officer Directorate and the Enterprise and Innovation Division of the Economic Development Directorate. It is aimed towards strengthening Scotland's innovation activities in health and social care in order to solve real problems and improve quality, efficiency and sustainability of healthcare.

Key priorities within the **Northern Ireland HSC R&D Strategy, Research for Better Health & Social Care** 2016-2025 are to increase the emphasis on research relevant to the priorities of the local population, and to disseminate research findings in such a way as to promote understanding and knowledge, support and best practice, stimulate further research and celebrate achievement. This has been picked up as one of the sub-groups within the Northern Ireland Taskforce, which is being co-chaired by a PPI representative and a healthcare professional. This group is making recommendations for the Northern Ireland Implementation Plan around making research relevant and also improving visibility for the public, practitioners and policy makers, and developing possible resources to achieve this.

In June, NIHR launched a new **UK-wide professional accreditation scheme for Clinical Research Practitioners** (CRP) as part of efforts to double the number of this important workforce over the next few years. Over 1,000 members have already signed up to the CRP directory.

In November, the **NIHR Associate Principal Investigator Scheme** Virtual Launch Event took place. The scheme aims to make research a routine part of clinical training, to develop doctors, nurses, and allied health professionals to be the PIs of the future and to recognise and promote health professionals' engagement in NIHR portfolio research in a consistent manner. Since its launch in early November, over 700 individuals have registered to the scheme.

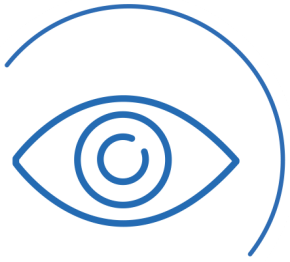
The UK Early Access to Medicines Scheme (EAMS) is one of the ways through which a patient with a life threatening or seriously debilitating condition can gain access to a medicine before it has gained approval from the UK's medicines regulatory authority.

The MHRA recently ran a public consultation with proposals to make the legal basis for EAMS supply clear and minimise the burden on those supplying EAMS medicines and for those companies wishing to collect real-world data during the scheme.

The goal is to ensure that EAMS remains an attractive option for patients, healthcare professionals and companies, so that cutting-edge therapies are available for patients where there is an unmet clinical need.

Action area 5

Improving visibility and making research matter to the NHS



NHS sites that are active in clinical research see improved health outcomes not just for those participating in research, but for all patients. Despite these many benefits, research delivery is not as visible across the NHS as it should be. We are working to increase awareness of research among NHS leaders and with regulatory bodies to embed research in standards for registered professionals.

NHS Chief Nursing Officer (CNO) for England's strategic plan for research was published in November 2021. The strategy is for all nurses working in health and social care, whether they are involved in research or thinking about getting involved in research. It aims to create a people-centred research environment that empowers nurses to lead, participate in and deliver research, where research is fully embedded in practice and professional decision making, bringing about public benefit. The CNO's strategic plan will be delivered in three phases: Discover, Build and Sustain, with a detailed delivery plan due to be published in Spring 2022, which will set out how it will be delivered Over the next year.

To help facilitate recognition of the nursing and midwifery workforce and to identify any 'gaps', NIHR has launched a first-of-its-kind census open to all registered nurses and midwives working either full or part time in a clinical research role in any setting across the UK and the Republic of Ireland. Additionally, the NIHR 70@70 Senior Nurse Research Leader programme continues this year and programme members have reflected on the discrepancy between national expectations of research activity within nursing and reality at a local level.

NHSE has published Integrated Care Systems (ICS) Guidance. These documents set out the headlines for how NHS leaders and organisations will be asked to operate with their partners in ICSs from April 2022. Many of these include references to "Fostering a culture of research and innovation" including in the ICS Design Framework and the job descriptions for ICS Chairs and CEOs. In addition, NHSE have hosted a series of regional engagement events in collaboration with regional Medical Directors and NIHR CRN to support local health and research leaders, including ICS representatives, to prioritise embedding research.

The Coordinated Approaches to Research and care Embedded Group (CARE), brings together a wide collaboration of policy, membership and service organisations from across the research and care community. This group, co-founded and supported by the NIHR, is

developing joined up approaches to tackling the separation of research and care in the NHS.

In recent discussions between NIHR and the Care Quality Commission (CQC), research metrics for provider monitoring have been discussed now that CQC is reaching a point in their strategy implementation to consider this again. **The CQC's strategy published in May includes substantive references to the role of research in best care**.

'Best Patient Care, Clinical Research and You' is an online guide to help busy non-research staff become more aware of their impact on research in their Trust. The guide, developed in a collaboration between UK Research & Development (UKRD) and NHS R&D Forum, and led by NIHR, is designed to be incorporated into Trusts' websites or intranet. The Rotherham NHS Foundation Trust is a great example of how the guide has been used and work continues to encourage more Trusts to use the guide on their sites.

A spotlight session titled **Saving and Improving Lives – Clinical Research in our NHS** was delivered at NHS Scotland Event on 24 June. This is the leading health event in Scotland providing an opportunity for those working in, and with, the NHS in Scotland to come together to consider challenges, share best practice and the most innovative approaches to delivering the highest quality of care.

In September, **NHSE published refreshed guidance on Excess Treatment Costs** (ETCs). The guidance sets out the framework for how Clinical Commissioning Group commissioned studies which incur ETCs are paid for and the provider types which can utilise the national payment system. The purpose of the guidance is to assist researchers navigate the ETC system.

NIHR's annual Your Path in Research campaign ran throughout October with support from all the RRG delivery partners, with the aim to inspire UK healthcare professionals to get involved in research, or take the next step in their research career.

Action area 6

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

We are committed to diversifying research demographics and democratising research access, particularly for communities under-served by research. We will learn from centres of excellence to understand the practices and approaches which increase confidence and willingness to participate in research and identify the mechanisms that can appropriately increase their use and access across the research ecosystem.

HRA, in partnership with ISRCTN, will begin **automatic registration for clinical trials** in early 2022, taking the burden away from research sponsors and researchers, with no additional cost to the study team. Registering trials automatically reduces the burden on sponsors and trial managers. A single source of information for all UK clinical trials supports work to increase participation and diversity in research. MHRA has been monitoring compliance with trial registration and reporting, following up applicants to ensure compliance with expectations. In the first six months of this year registration was 97% and results reporting at 86%, significantly above international averages.
NHSX's NHS AI Lab and the Health Foundation, supported by NIHR, **awarded £1.4 million in October to four projects to address racial and ethnic health inequalities using artificial intelligence**. The winning projects range from using AI to investigate disparities in maternal health outcomes to developing standards and guidance to ensure that datasets for training and testing AI systems are inclusive and generalisable.
NIHR is currently developing a comprehensive Equality, Diversity and Inclusion strategy and are engaging with stakeholders from across the ecosystem. As well as introducing an Equality and Data Reporting System in 2020, NIHR has started implementing activities required to break down structural barriers. In addition, NIHR, NHS Digital and the devolved administrations continue to scope the use of national datasets to analyse the diversity of research participants.
NIHR's INCLUDE (Innovations in Clinical Trial Design and Delivery for the Underserved) guidance was published in August 2020 to improve inclusion of under-served groups in clinical research. Work has continued to disseminate the guidance and embed it into the clinical research ecosystem. A free INCLUDE online course has been recently launched in

addition to a stakeholder event held in October to explore evidence of progress and next steps for the guidance. More information can be found on the NIHR INCLUDE microsite.

Building on the work of the INCLUDE guidance, in September 2020, NIHR commissioned a cross-organisational programme to examine how to address the lack of inclusion for under-served groups in clinical research. The Under-served Communities programme aims to create a common understanding across the research landscape to encourage delivery of research where the need is greatest, prompting a cultural shift in attitudes and embedding more inclusive ways of working. The programme's current work includes:

- Design and development of a new, accessible research targeting tool
- Circulation and analysis of a survey to understand key barriers and enablers for engaging with research in under-served communities
- Promotion of pre-doctoral awards within Trusts or Academic Institutions which historically have fewer applications/ successful applications.
- Funding calls which specifically encourage the inclusion of geographic populations which have been historically under-served in order to ensure that research is conducted in the areas where health needs are greatest. Examples of these include three launched funding calls launched in October:
    - What are the health and health inequality impacts of being outdoors for children and young people?
    - Digital health inclusion and inequalities
    - Increasing uptake of vaccinations in populations where there is low uptake

NHS England have commissioned research to better understand specific barriers and enablers that different communities experience in regard to taking part in research. This will build on and complement existing work currently being undertaken by NIHR. The research will inform work with a number of different community groups to co-develop communications and engagement toolkits and resources that support diverse communities to take part in research.

Led by NIHR, a number of research organisations will trial a new framework to assess how their current policies, practices and organisational culture could be changed to better serve diverse communities, foster improved race relations and ultimately improve healthcare delivery.

ABPI and the NHS Confederation have completed a series of reports aiming to share lessons and look at the opportunities for greater cross-sector collaboration between industry and the NHS to address health inequalities.

- An examination of health inequalities in cancer care in Kent and Medway
- An examination of health inequalities in chronic obstructive pulmonary disease (COPD) care in the North West
- An examination of health inequalities in diabetes care in Leicester

Through policy and practice, Northern Ireland seeks to ensure that health and social care research is accessible to and inclusive of all sectors of the community, with a portfolio that

includes schemes focused on delivery of healthcare interventions in communities and locations that would normally be underserved.
Scotland's Cancer Trials Resilience subgroup brings together NHS Research Scotland, commercial and third party stakeholders to implement resilience within cancer clinical trials. The group advises on, and monitors, data to support the recovery of the cancer clinical trials portfolio across Scotland, identifies and proposes solutions to recruitment barriers, and explores innovative approaches to build increased resilience The Cancer Trials Resilience group convened a short life working group on ensuring Equity to Access to cancer clinical trials. The Group report and recommendations are expected in early 2022.
HRA, working with the MHRA, is developing guidance to improve standards in diversity and inclusion whilst seeking to review where research applications can be strengthened.

Action area 7

Strengthening public, patient and service user involvement in research

Our commitment is to continue to set the global standard for good practice in public involvement in research design and management. This will ensure the public, patients and service users feel increasingly empowered to contribute to clinical research, and that researchers are supported to work effectively with them.

The **Think Ethics campaign** from the HRA is putting research participants at the heart of ethics review by encouraging researchers and the committees that review research to focus on what really matters to those who take part in studies. It aims to make ethics review more innovative, efficient and trusted – building on many of the changes made to respond to the COVID pandemic and lessons from running RECs with fellow regulators in Scotland, Wales and Northern Ireland.
MHRA published their first **Patient Involvement Strategy** 2021-25 that sets out how they will engage and involve the public and patients at every step of the regulatory journey. Additionally, the MHRA's recently published Delivery Plan 2021-2023 also focuses on putting patients first and protecting public health through excellence in regulation and science.
ABPI also published their **Patient Engagement Strategy** to ensure that patient engagement is consistently at the heart of their work. The strategy includes developing practical resources to make collaboration between industry and patient organisations easier and creating an ABPI Patient Advisory Council to reflect the patient voice in leadership decision making.
NIHR updated its 'Going the Extra Mile' strategy and reaffirmed its commitment to PPIE. To further inform this work, NIHR carried out a series of workshops with public contributors and the research community, these generated 16 priority actions. NIHR and HRA hosted a **Shared Commitment to Public Involvement** roundtable event in September. Fifteen partners, including HRA, NIHR and the devolved administrations, agreed to sign up to a commitment to public involvement in research to ensure involvement is built into study design, delivery, and dissemination. There will be resources and guidance developed to support researchers. NHS Research Scotland patient and public involvement workshop series completed and reported in September 2021. Findings from the workshops and the Scottish Patient Public

Involvement Survey are informing work to support greater visibility and connectivity, increased diversity and representation and a review of the current mechanisms for pre-award funding.

Northern Ireland continues to be fully engaged in all of the PPI activities at the UK-wide level. Work is guided by a **Strategy for Personal and Public Involvement in Health & Social Care Research**. A PPI Group, Public Involvement Enhancing Research (PIER), whose members are embedded across the HSC R&D ecosystem, are contributing to all of Northern Ireland's Taskforce meetings and sub-groups.

During 2021, Health and Care Research Wales published an action plan which sets out tangible actions for increasing public involvement in research by addressing barriers and increasing engagement with more diverse communities. The **Discover Your Role in Health and Care Research Action Plan** was co-designed with members of the public, researcher and public involvement leads during a series of community of practice events and online consultation. A Public Involvement Forum has been established, with the inaugural event involving more than 100 people. Through small working parties, activity is underway to address areas of priority identified by the Forum, including challenges with payment for public contributors, and the development of a public engagement strategy.

Working with partners across the devolved administrations, NIHR has launched two new UK-wide newsletters. "*Take part"* highlights research studies that need volunteers to take part, including both healthy volunteers and those living with different physical and mental health conditions. "*Shape"* provides opportunities for patients and the public to get involved in the design and delivery of research by providing their valuable views and experiences of health and social care.

The UK project on removing administrative barriers for payment to public contributors continues, co-led by Wales, HRA and NIHR. Guidance and categorisation documents have been drafted in consultation with a wider interest group comprising public contributors, researchers and Principal Investigators. Discussions are underway with HMRC to update and provide greater clarity in the guidance.

ILAP includes a dedicated patient and public reference group which integrates the patient voice at every stage of development. Members of this group are involved in discussions on whether a product should be awarded an Innovation Passport designation for entry into ILAP, alongside experts from the MHRA, NICE and the SMC. This will build into the goal of embedding patient engagement and patient reported outcome measures into the development programmes of ILAP medicines.

An enhanced **patient engagement tool has been developed as part of ILAP**. This was co-developed by MHRA, NICE and SMC and is now being driven forward by the ILAP patient and public reference group. The tool will provide opportunities throughout the ILAP for companies to consider the patient's experience and voice in a meaningful way in how they develop their innovative products.

The Medicines and Medical Devices Act 2021 provides the UK with the opportunity to embed good practice into our regulations. MHRA in collaboration with HRA, and colleagues from across the research ecosystem, including patients and patient representatives, have developed plans to consult on a potential requirement to involve people with relevant lived experience (patients, service users, carers, the public) in the design, management, conduct and dissemination of the trial, or justify to the ethics committee as part of the application, why such involvement is not appropriate for each of these trial elements.

Next steps

The RRG programme is now planning for the next phase of work to realise the full potential of our vision for clinical research delivery and will publish the next implementation plan in Spring 2022. As the outcome of the spending review is becoming clearer, we are working with our partners and stakeholders on the specific actions we will take in the next phase. We encourage all partners to consider what they can do to help achieve our shared vision for the future.