# Chief Executive Officer Report to the Board May 2022

## Part 1 Public session

**Wider policy environment roundup**

## This section is provided for wider interest and awareness of the Board. It does not need to be reviewed in detail.

## NIHR Annual report

NIHR released its [2020/21 annual report](https://www.nihr.ac.uk/documents/annual-report-20202021/30206). It covers the breadth of NIHR activity and highlights the major contribution NIHR has made to the global scientific fight against COVID-19. It also highlights the current focus on managing the recovery and revitalisation of the wider research portfolio (see below as well).

Also, in this period NIHR have changed their name (though not initialism) to the National Institute for Health and **Social Care** Research. This is clearly a welcome fresh emphasis on social care although it should be noted that NIHR has been a major funder of social care research for many years.

## UKRI strategy 2022 to 2027: transforming tomorrow together

UKRI published a new [five-year strategy](https://www.ukri.org/publications/ukri-strategy-2022-to-2027/). It is set within the overarching policy of the Governments of the Research and Development (R&D) Roadmap pledge to reach R&D spend of 2.4% of GDP by 2027.

### Objective 1: world-class people and careers: Making the UK the top destination for talented people and teams

Objective 2: world-class places: Securing the UK’s position as a globally leading research and innovation nation with outstanding institutions, infrastructures, sectors, and clusters across the breadth of the country

Objective 3: world-class ideas: Advancing the frontiers of human knowledge and innovation by enabling the UK to seize opportunities from emerging research trends, multidisciplinary approaches and new concepts and markets

Objective 4: world-class innovation: Delivering the government’s vision for the UK as an innovation nation, through concerted action of Innovate UK and wider UKRI

Objective 5: world-class impacts: Focusing the UK’s world-class science and innovation to target global and national challenges, create and exploit tomorrow’s technologies, and build the high-growth business sectors of the future

## Objective 6: a world-class organisation: Making UKRI the most efficient, effective, and agile organisation it can be

## Health and Social Care Bill

### The Health and Care Act 2022 completed the parliamentary process and received Royal Assent on 28 April. This is an important step towards establishing Integrated Care Systems on a statutory footing. From 1 July 2022, there will be 42 statutory ICSs covering the whole of England. The Bill provides a firmer legislative basis and a platform for embedding research in the health and care system by:

### Clarifying the research duty of Integrated Care Boards (ICBs), as well as the corresponding existing duties for NHS England and the Secretary of State. The Bill states that it is a duty to "facilitate or otherwise promote" research, highlighting that "promote" covers a spectrum of activity including actively facilitating research.

### Requiring that research must be covered in ICB plans, annual reports and performance assessments, as well as in NHSE's business plan and annual report. This will enable better transparency and scrutiny of the exercise of their research duties.

### The Health and Care Bill will enable the statutory merger of NHS England, Monitor and the NHS Trust Development Authority (the two organisations which make up NHS Improvement). It is expected the transfer of the roles, responsibilities, and all functions of TDA to NHSE will take place on 1 July this year, when NHS England and NHS Improvement will be named NHS England.

**HRA updates**

## Clinical trials legislation consultation

The HRA and MHRA have been working together to develop a framework for clinical trials in the UK. The proposed approach, which has recently been out to public consultation, is to move to proportionate legislation, which is complemented by guidance. These changes are designed to facilitate well-designed research and provide a more agile framework that can adapt more easily to innovation in clinical trials and clinical trial design. The changes are also part of a wider programme of work being taken forward as part of the UK vision for future clinical research.

The proposed new legislative framework aims to:

* promote public health and retain the protection of participants at the heart of the new legislation
* streamline the regulations that apply to clinical trials of medicines
* enable innovation
* improve research transparency
* allow approaches more proportionate to risk
* promote patient and public involvement
* build on international interoperability so that the UK continues to be attractive to multi-national trials

The public consultation on the proposed approach closed in March 2022. Analysis of responses is underway, with some aspects being reviewed by MHRA and some by HRA.

**For more information, see** [**Government consultation on legislative changes for clinical trials**](https://www.gov.uk/government/consultations/consultation-on-proposals-for-legislative-changes-for-clinical-trials) **or contact Sue Bourne, Head of Guidance and Advice**

## Arrangements for handling changes, amendments, or closure of studies as a result of the DHSC initiative to revitalise the NHS research portfolio.

On 22 March 2022, the Department of Health and Social Care (DHSC) issued an important communication to research sponsors and funders to specify that urgent action must be taken to address the current research delivery challenges in the NHS. We have issued guidance to sponsors on how to approach this and how to work with HRA through the amendments process.

**For more information, see** [**guidance on our website**](https://www.hra.nhs.uk/approvals-amendments/arrangements-handling-changes-amendments-or-closure-studies-result-dhsc-initiative-revitalise-nhs-research-portfolio/) **or contact Janet Messer, Director of Approvals**

## Fast-track research review for studies affected by the war in Ukraine

Utilising our experience during COVID-19 we launched a similar [expedited review process for studies affected by the war in Ukraine](https://www.hra.nhs.uk/about-us/news-updates/fast-track-research-review-studies-affected-war-ukraine/)**.**

**For more information contact Janet Messer, Director of Approvals**

## Research Ethics Development Day

On 7 April 2022 we held the first of our REC Member Development Days. This took place in London Euston, as was the first of seven face-to-face development days hosted by HRA. The Development Days are an opportunity for REC members to connect and network, and to develop their relationships and team working as a REC.

As well as networking, the day also featured updates on new clinical trials legislation, the HRA’s Think Ethics programme, and an extended session with a presentation on the ASSENT project.

Feedback from REC members has been overwhelmingly positive. 90% of members who attended said the event reflected the right balance between updates and networking, an 100% of attendees saying the opportunity to meet with fellow REC members worked well and they would like to attend a similar event next year.

**For more information contact Zoe Turner, Digital Learning Operations Manager, and Louise Braley, Membership Development Manager**

## Think Ethics public conversation about new pathways for ethics review

Since Think Ethics was launched, we have been having a conversation with a wide range of interested people, including members of the public, about how ethics review should be changed to make sure that people and ethics at the heart of research.

In June, we will be announcing our new UK-wide policy on participant information. Developed with and for research participants, the policy aims to help researchers to produce great participant information, co-produced with patients and the public and reviewed by ethics committees in a consistent and focussed way.

At the same time, we will start a public conversation about how ethics review itself could be improved – who does it and how it is done. We will launch a 12-week public consultation, seeking views about our ideas for change. Our aim to make sure that each research study gets the right level of scrutiny, according to the nature of the research and the ethical issues it gives rise to.

We will also publish findings of the Think Ethics public dialogue, conducted earlier this year by Hopkins Van Mil, giving an insight into who the public trusts to review the ethics of research and how they think it could be improved.

**For more information, contact Juliet Tizzard, Director of Policy and Partnerships**

## Senior leadership stakeholder engagement presentations

The Executive Committee and senior leadership engage widely to support the delivery of HRA’s social mission. This includes a wide range of informal and formal meetings. Listed here are some of the invited talks and stakeholder engagement events we have delivered.

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| **Speaker**  | **Event**  | **Title**  | **HRA Objective**  |
| Matt Westmore, CEO | Science and Technology Select Committee inquiry into right to privacy: Digital Data | N/A | To provide evidence to the select committee. To raise the issues of public and patient involvement and transparency to ensure the use of data is trustworthy. |
| Matt Westmore, CEO | Trends shaping the future of Clinical Trials, hosted by Microsoft and New Market Strategy.  | N/A | To understand what we need to do to enable innovations in clinical trials and promote the importance of patient and public involvement and trust. |
| Matt Westmore, CEO | All Party Parliamentary Group on Medical Research Parliamentary reception - ‘Tackling COVID-19: Recognising the exceptional research response | N/A | To celebrate the work of the HRA community in the scientific response to COVID-19.  |
| Janet Messer, Director of Approvals | Westminster Health Forum – Use of patient records and data, 29th April | ‘Next steps for balancing success, privacy and transparency in clinical research’ | To promote HRA role and priorities around use of patient data and transparency in research. |
| Janet Messer, Director of Approvals | Bournemouth University Presentation, 17th May | Keynote lecture | To promote the HRA and its role in research integrity as part of University ‘Integrity Week’. |