

Chief Executive Officer Report to the Board January 2022

Part 1 Public session

Connecting up the end-to-end system

Combined Review roll out

<u>Combined review</u> offers a streamlined, coordinated, and efficient application route leading to a single UK decision for Clinical Trials of Investigational Medicinal Products (CTIMPs).

Our combined review with the Medicines and Healthcare products Regulatory Agency (MHRA) is now the way all new applications for clinical trials of medicines are made.

The benefits of combined review are intended to be broad, one among them though is to reduce the time taken for the combined processes of MHRA and HRA. More detailed information is included in the Strategic Performance report. The headline improvement is that combined review cuts the time from application to recruiting a first patient by 50 days.

Contact Janet Messer, Director of Approvals for more information.

Improving, coordinating, and standardising research practice across the UK

Shared commitment on public involvement

In partnership with the NIHR, we are leading on a cross-sector statement of shared commitment to public involvement in health and care research. The origin of this was the evaluation of the COVID-19 public involvement matching service. That highlighted that public involvement isn't always integrated as normal practice into health and social care research across all sectors and throughout the UK. The reasons identified were a lack of national leadership and a consistent message that public involvement is always important, necessary, and possible.

The workshop attendees were drawn from across the research sector and across the UK. Around half of attendees were public or lay members.

We have now confirmed all 15 organisations involved will support the initiative and have executive sponsors at the CEO or executive director level for all but one organisation. The shared commitment launch date for Shared Commitment Statement confirmed $11^{\text{th}} - 22^{\text{nd}}$ of March to coincide with Science Week.

Contact Barbara Molonyoates in the Public Involvement team for more information.

ABPI-NHS confederation senior leaders roundtable on diversity and inclusion in clinical research

ABPI and NHS Confederation have a partnership working on health inequality. This led to a senior leader round table convening to address the lack of diversity in clinical research involvement and participation. Matt Westmore, CEO attended for HRA as this aligns well with our own ambitions and that of the DHSC coordinated Recovery, Resilience and Growth Programme.

We have agreed to a shared pledge statement and to publicise our specific commitments. Those statements are currently being developed.

For more information, contact Kate Greenwood, Senior Improvement Development Manager in HRA Approvals

Make It Public

Make It Public Annual report

We published our first report on the sector's performance against the Make it Public Strategy bit.ly/MiPAR2021

Key findings are:



Make it Public Conference

Post-event feedback summary



We recently hosted the inaugural Make It Public Conference – an event aimed at encouraging and sharing best practices in research Transparency. The two-day virtual event saw a host of partners and public participants present on a range of topics, from Make It Public strategy to research transparency in action.

Over 1,000 people registered for the event, on Wednesday, 627 people attended, and on Thursday, 528 people attended. The average audience feedback score was 8.5 out of 10 for excellence.

Automatic registration of clinical trials.

We have implemented an automatic registration service or CTIMPs. We will register trials submitted through combined review after 1 January, on ISRCTN Registry when they are given full approval. This is free to trialists and will reduce the burden on them.

Contact Naho Yamazaki in the Policy and Engagement team for more information.

Strategy and Business planning

Review of the 2021/22 Business plan

On the 3 November 2021 the Executive Committee reviewed progress across all commitments in the 2020/21 business plan.

Major areas of delivery are controlled and reported through the Portfolio Delivery Group and associated programme board. They are covered elsewhere in the agenda

This was an important opportunity to review the large number for commitments that are managed outside of PDG or formal projects.

HRA Executive Committee and Board Awayday 16/17 November 2021

We held a successful HRA Board and Executive Committee Awayday.

The strategic dinner on the 16 November discussions centred on the two aspects of our social mission – protecting the interests of people in research, supported by Juliet Tizzard, and ensuring the UK has a vibrant research sector, supported by a keynote talk from Richard Torbett, ABPI Chief Executive.

The awayday focussed on our future strategy. The Executive Committee continued the work and is a separate agenda item for today's meeting.

Ten-year anniversary reflection and celebration

1 December 2021 marked ten years since the HRA was established. We are delivering a programme of activities to recognise the HRA's achievements, thank those that contributed to these and look to the future, informing our strategy development.

We launched tenth-anniversary content on our website on 1 December, including an infographic summarising key stats about us and our achievements and quotes from staff, the broader HRA Community (REC, CAG and PIN members) and external stakeholders. We promoted this on social media, reaching almost half a million people in the first ten days with support from 75 external partners. Sentiment was 1005 favourable (79% positive, 21% neutral).

In December we held a celebration for staff, inviting our former CEOs to join us to mark our anniversary, and in January we hosted an evening with invited speakers for the whole HRA Community – our Board, staff, REC, CAG and PIN members. This focused on how our work is making a difference, hearing from Professor Sir Chris Whitty, Lynn Laidlaw – Patient/ Public Contributor and Patient researcher – and Professor Sir Leszek Borysiewicz, Chair of Cancer Research UK and provided us with an opportunity to recognise and thank the contribution of our many volunteers (approx. 400 attendees signed up at time of writing)

Going forward we are holding a workshop with the Academy of Medical Sciences (AMS), whose 2011 report led to our creation, *The HRA at ten: progress to date and future gazing*, which will help inform our strategy development. This is co-chaired by a PIN member, Jennifer Bostock, and Professor Chris Butler FMedSci, Professor of Primary Care at the University of Oxford. The workshop is invite-only with a blog and report planned to publicly share the findings. AMS have invited Lord Kamall to speak. We are also planning a workshop with the Nuffield Council on Bioethics *What could be the big issues for research ethics over the next ten years?* drawing on the expertise of our REC members and PIN to inform horizon-scanning.

Contact Becky Purvis in Policy and Partnership directorate for more information.

HRA's Approach to Change and Innovation workshop 1 December 2021

HRA was created to bring about change in research approvals in the UK. We have been successful over the last ten years in doing that and particularly over the course of the pandemic. There are areas nonetheless where the Executive Committee have identified that we need to increase capacity and competencies. In particular, our ability to innovate and implement change at pace and a broader approach to change as is best practice for portfolio management and set out in the relevant government functional standard. To this end we hosted an exploratory workshop on this topic.

Next steps are to commission some learning and development support in this area.

Contact Matt Westmore for more information.

Other items

Ways of working under COVID-19 restrictions

On 8 December, the Prime Minister announced that England will move to 'plan B' following the rapid spread of the Omicron variant in the UK.

As a result, new guidance, was issued that from Monday 13 telling all HRA staff to work from home if they can. For those who need to work from an office to support their mental or physical health, or who don't have a home environment suitable for working, we will maintain some office provision.

Contact Katherine Guerin, Transformation and Corporate Services for more information

Recruitment of a permanent Chief Digital Transformation Officer

Following a highly competitive recruitment process, I am delighted to confirm that Ian Robinson will be joining us on the 24 January 2022. Helen Ainsbury, our interim CDTO will remain with us until the 11 February to ensure a good handover.

The recruitment process included a panel interview, psychometric assessment, and engagement with public members, researchers, and commercial sponsors. Ian impressed us at every stage.

lan has a blend of commercial experience, with public sector experience in local authorities more recently. Ian has led a number of digital transformation programmes during his career. What also impressed us most was his clear commitment to our values – he is very driven to use his skills and experience for societal good.

Contact Matt Westmore for more information

Executive Committee presentations

The Executive Committee engages widely in order 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 we have given.

Speaker	Event	Title	HRA Objective
Elizabeth Bohm, Head of Data and Al Policy	Westminster eForum policy conference - Next steps for improving the use of data across the UK economy - policy, strategy and regulation, market development, and key working relationships, 8 December 2021	Panel session on The use of data to improve service design and economic growth - opportunities for business growth and improving organisational productivity, meeting the skills challenge, and managing organisational relationships	Promote the data and AI policy work of the HRA, the role of data in health research and the importance of patient and public involvement when using for health and care data for research.
Janet Messer, Director of Approvals	Faculty of Pharmaceutical Medicine, Annual conference 12 November 2021	Clinical Trials of the Future – Policy Forum	To share HRA and wider sector responses to current developments in clinical trials, and role of HRA in promoting opportunities in the future.
Janet Messer, Director of Approvals	The Future of UK Clinical Research, Department of International Trade briefing, 2 December 2021	Faster Regulatory Approvals	To help promote UK clinical research capabilities to US research-interested audiences in collaboration with Department of International Trade
Matt Westmore, CEO	Westminster Health Forum Clinical Research – Clinical Research Priorities, 11 November 2021	Priorities for clinical research in the UK - funding, efficiency, and improving patient involvement	Promote the importance and positive outlook for clinical research Raise the importance and profile of patient and public involvement Share HRA's work on streamlining and simplifying regulation
Matt Westmore, CEO On behalf of Sir Terence Stephenson	Faculty of Pharmaceutical Medicine Annual Symposium, A revolution in early phase development - FPM Annual Symposium, 12 November 2021	Trials and tribulations	Share HRA's work in support of COVID-19 research Promote diversity and inclusion in research, especially with vulnerable groups.

Matt Westmore, CEO	UK Clinical Research Collaborative Board Meeting, 14 October 2021	Priorities for regulators	Present a unified and coordinated approach from regulators. Agreed priorities are Streamlining and connecting up the system and, innovation in regulation
Matt Westmore, CEO	Ensuring Value in Research [international] Funders' Forum	Panel discussion on the future of research funding	Raise to profile the importance of and our work in public involvement and transparency Raise the profile of the
			HRA and UK research internationally.
Matt Westmore, CEO	Invitation from Danish Ambassador to meet representatives from Danish pharmaceutical industry	N/A	Learn from the commercial research sector
			Promote the UK as a great place to deliver research.
			Discuss Research, Resilience and Growth programme
Naho Yamazaki, Head of Policy and Engagement	DIA Conference	Clinical Trial Disclosure and Data Transparency	To promote HRA's Make it Public strategy and clarify our transparency requirements