

Chief Executive Officer Report to the Board January 2021

Part 1 Public session

1 Exiting the EU

Following the announcement that we were exiting the EU with a deal, we made a number of updates to information on the HRA website to ensure that the research community are clear about the actions that they need to take to ensure that their studies can continue to be processed without delay. All communications were aligned to both Government and MHRA communications. Further detail is expected in the following months and we will continue to ensure that we work across the system to ensure that things run smoothly and are involved in discussions with respect to legislative change. All HRA systems and services are fully operational and the small number of staff who have been impacted by EU exit have been supported to complete the necessary paperwork.

2 COVID-19

The pandemic is still taking its toll on the NHS health and care systems where management of all patients who are admitted as emergency cases remain the priority. Janet Messer has prepared a short update for the board which shows the impact of COVID on HRA Approval activity levels during the last 12 months which shows that at an aggregate level HRA has only seen a 10% drop in new applications. Whilst COVID-19 specific study applications were approved very quickly, there have still been high volumes of applications for non-COVID research only some of which have been progressed to date and our staff and volunteers have worked incredibly hard to not only maintain services but to improve them.

3 Research Review Programme

This programme is the HRA response to what we have learned from COVID-19 with respect to how we deliver our Research Ethics service and has progressed at pace over the last few months. There are a number of strands to this work. The first is a Fast-Track Research Ethics pilot. This pilot will test at a small scale whether the HRA on behalf of the UK can establish a sustainable model for providing consistent, rapid Research Ethics review 75% quicker than statutory timelines for global clinical trials and phase I trials in both healthy volunteers and patients. This initial work will focus solely on the Research Ethics process and will run alongside our existing Combined Ways of Working pilot. Consideration will also be given to how these two pilots can be merged into a single service offer in the coming months.

The HRA successfully launched this fast track pilot on the first of January. The second strand of work which is supported by Deloitte is the Ethics Review project which aims to deliver a more streamlined, proportionate and user friendly service for the applicants, our volunteers and our staff and the early engagement work has already started with a number of stakeholders participating in workshops which have taken place during the last two weeks. HRA will use savings generated from the “virtual working” model that has sustained our service since March 2020 to fund the pilot and we have submitted a bid into the Comprehensive Spending review to translate what we anticipate will be a positive outcome into a new service model for the future.

4 Research Cross-systems working and HRA Business Planning Priorities

Together with representatives from a number of organisations across the research system, HRA has been involved in a number of pieces of work supporting the Research Recovery, Resilience and Growth agenda and the Find, Recruit and Follow up service. These are being overseen by the DSHC SRE team led by Louise Wood and we will be prioritising support to these projects in the coming months. Janet Messer is our organisational lead on this work and Janet will provide regular updates to the HRA Strategic Leadership Team and the Board. We have also been progressing our own Business Planning prioritisation for the forthcoming year and are working hard to ensure that the resources and expertise needed to support this work are aligned to other work in the existing HRA portfolio. This will result in some work being re-prioritised on our delivery plan.

5. HRA and MHRA software developments in new IRAS

During the run up to the New Year the HRA Research Systems team were working hard on some developments which were deployed into the live environment to support the Combined Ways of Working pilot. These were initiated in response to applicants change requests in the first set of developments which should make the process easier for them.

6. Chief Executive Handover

I am delighted that Professor Matt Westmore is joining us shortly and we have already had a number of handover sessions to ensure a seamless transition next month. This will be my final HRA board meeting and I would like to express my thanks to everyone who has supported me during the last few years at the HRA. It has been a real pleasure to have led an organisation that always puts patients and the public at the heart of all of its activities whilst transforming itself into a modern, agile regulator that can respond to the huge challenges that we have faced during the last few years to support world class research in the UK.

It has been a real privilege getting to know many of our volunteers who support the Research Ethics Service and the Confidentiality Advisory Group. We have finally reached the stage where our engagement with them all as individuals is possible and

I know that the team in the HRA are keen to enhance that engagement in the forthcoming months.

We have worked incredibly closely with the Policy and Operational Leads from the Devolved Administrations to ensure that researchers from around the world could access the NHS and built strong relationships with partner organisations in the MHRA, the NIHR, ABPI, AMRC, MRC, NHSE, NHSX, HTA, HFEA, just to name a few and the HRA has been stronger for it.

External meetings

Contact	Name of organisation	Purpose of meeting
Dr William van't Hoff (CEO)	NIHR	Monthly catch-up meeting and follow up meeting with other colleagues to discuss HRA support to work on underserved communities in Research
Chris Day (Chair)	OSCHR	To provide an update on HRA progress and current initiatives
Dr June Raine (CEO)	MHRA	Regular catch-up meeting to discuss shared interest agenda and strategic priorities.
Prof Sir John Bell	Office for Life Science	Meeting to share HRA Progress during the last 12 months and to discuss strategic priorities
Gary Cook	Office for Life Science	To discuss UK Vision for Life Science
Dr Richard Torbett (CEO)	ABPI	To provide an update on HRA activity and strategic priorities of shared interest
Jacqueline Johnson-North & Angela O'Connor	IAOCR & GCSA	Regular Catch up meeting to discuss launch of new Global Research on Accreditation Scheme & TA Spotlight on Leadership
NHS Leadership Conference		To deliver a presentation on HRA response to COVID-19 pandemic
Phase 1 Advisory Group		Regular meeting – This session included session on HRA Research Review Programme at which Juliet Tizzard presented overview and

		collected feedback on Fast Track proposals pre-go live
4 Nations Policy Group		Continuing work on UK compatibility agenda and Policy Change
Prof Matt Westmore	University of Southampton	CEO Handover meetings
UNISON	Joint Negotiating Committee and Staff Representatives	Regular Meeting with HRA staff side reps and Union to discuss changes to HRA Policies and Staff support during COVID-19
West Midlands & Coventry Research Ethics Committee		To observe meeting and hear feedback from members of their current experience of virtual working
Nottingham Research Ethics Committee		To observe meeting and hear feedback from members of their current experience of virtual working
SRE team	HRA Accountability meeting	Quarterly meeting with DHSC colleagues to review HRA performance and updates on Key Priorities
National Patient Recruitment Centre Board		To provide HRA input into the progress of the NPRCs which are now all operating and attracting new work including support to vaccine trials
Digitrials Board		To receive an update on programme progress and provide input from HRA
Liz Hampson and team	Deloitte	Regular catch-up meetings on work to support Research Review