Health Research Authority

Chief Executive Report to the Board July 2021

Part 1 Public session

External environment for Board awareness and HRA relevance

HM Government Life Sciences Vision (bit.ly/LSV_gov), and The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan (aka Recover Resilience and Growth) (bit.ly/RRG_imp_plan).

The Government has published a new Life Sciences Vision. The HRA supported the drafting of this and are credited for our involvement. Some of our work, e.g. fast track ethics and the multi-agency advisory service, are also noted as critical advancements in delivering the Vision.

The Vision sets out a mission-led approach in critical areas of health (p9) and the required infrastructure, enablers and preconditions. The whole Vision is exciting, and we will play an active and positive role in delivering it.

Much of our activity in support of the Vision will be delivered in partnership with others under the coordinating arrangements of the DHSC Recovery, Resilience and Growth programme (bit.ly/RRG_imp_plan). The implementation plan for RRG has also recently been published under the title of *The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan*.

There will be a follow-up meeting between Lord Bethel, Chairs and CEOs in September to review progress. In the meantime, leads within each agency will meet at the working level (Naho Yamazaki is leading for us) and the RRG programme and steering group continue to meet.

MHRA delivery plan 2021-2023 (bit.ly/MHRA_DevPlan)

Our close partners, the Medicines and Healthcare products Regulatory Agency, published a two-year delivery plan. This includes a range of interesting areas relevant to us, focusing on putting patients first and being a world-leading and innovative regulator. In addition, our close ways of working and specific work areas were mentioned, such as our collaboration on establishing a new legislative framework for clinical trials, combined review, fast track, and integration at the systems and data level with ourselves and NIHR. We have mirrored these commitments in our business plan and build on them below with separate work around a longer-term combined Vision.

Connecting up the end-to-end system

Combined Vision with MHRA

Myself, Sir Terence and Janet Messer met with the Chair, Chief Executive and the Head of the Clinical Trials Unit of the MHRA. The initial plan was to share lessons from working together on the combined review (hitherto Combined Ways of Working) project. This rapidly developed into a discussion about our joint longer-term Vision for combined reviews – well beyond what we are currently planning to deliver. This took us into a new policy area and so now involves the Policy and Partnerships team.

A fuller paper will come back to the HRA Board for discussion and approval at a later date, but the headlines (with the caveat that this is draft and unconfirmed by either organisation) are:

Our Vision is to make the UK

- the safest place for participants to take part in research
- the easiest place in the world to apply for clinical trial approvals, and
- the quickest to start a study for sponsors.

We have now started to develop the specific actions that are required to deliver on this rhetoric. Much of which is already in train – the agreement for a combined vision will clarify where we are heading for the future.

NIHR business cases approved

Interoperability across the system is a strategic priority for HRA. This will reduce the burden on the research community by reducing duplication, improve the quality of data collected by establishing 'sources of truth', and streamline the end-to-end process. We have been working with NIHR to support the development of new programmes of work under their digital strategy. We fully support the NIHR's overall plans. However, we have needed to be cautious not to overpromise what can be realistically achieved given our time-critical primary objective of migrating off our current platforms. The specific areas of work we are significantly involved in are:

- Interface with NIHR Clinical Research Network: Migrating the existing interoperability. Pre-populating and syncing data between NIHR portfolio systems and IRAS.
- Integration of a common reference terminology service. This will mean that we, NIHR and MHRA, will all use the same standard data set for the organisation's names. It will prevent the current situation where users across the system can enter different names for the same organisation.
- Interface with NIHR funding and the use of the IRAS ID as the cross-system study level unique identifier. This is an important advancement although it does not require much work from us in this phase of development, it will unlock essential interoperability opportunities later on.

Internal

Implementing the executive committee

As agreed at the last HRA Board, we have started to streamline and standardise our internal governance and decision-making bodies. The first stage was to merge the Strategic Leadership Team and Leadership Team into one Executive Team. As well as simplifying the decision making arrangements we are also working in new ways, for example, making fuller use of MS Teams as a digital collaboration platform around the meeting, rather than just a video conference solution. We have met twice in this mode so far.

The first meeting of the new Volunteer Group

As part of the Valuing-our-Volunteer programme, we have established a volunteers' Group. This will allow us to hear ongoing feedback from all types of volunteers (Research Ethics Committees, Confidentiality Advisory Group and Public Involvement Network), discuss ideas for improving the volunteer experience, and seek early reactions to relevant policy or service changes. The Group's work will focus on how we can better support volunteers, such as helping us make sense of our volunteer survey findings, suggesting ways to improve the volunteer experience and exploring ways to attract new volunteers.

User research within research systems.

We have been trying to recruit specialist expertise in user research and user-led design. But, unfortunately, we have failed to appoint twice. This is a critical capability (a) because we have committed to a user-led designed IRAS and other systems, and (b) because it is a requirement of obtaining a Government Data Service, service assessment. The latter is required to be able to releases live systems.

The HRA Digital team have changed tack on getting expertise into the organisation to cover this area. We are now appointing an expert through a services agreement rather than go straight back out to recruitment. This high-level expert in user research will help us collate what user research we have already done and plan a more comprehensive strategy for the remaining development of IRAS.

Raising HRA's profile through presentations and media work

The wider team and communications, in general, deliver a vibrant and large amount of external engagement and communications. I report here just some activities I have personally been directly involved with.

- 26 May 2021 – talk at Public Health England's Public Health Research and Science Conference 2021 on how HRA adds value by simplifying the approvals process.
- 29 June 2021 - Panelist for the launch of a new Research-on-Research registry and community of interest.
- Interview for the Purposeful Strategist podcast – a general leadership podcast (and so less relevant to raising our profile with key stakeholders) discussing driving an organisational and its strategy on the ideas of purpose and social mission.
- Interview by Politico – a widely read online news and commentary site. I was interviewed about what we delivered during COVID, what we learnt from it and how we think things will be different in the future.