Health Research Authority

Chief Executive Officer Report to the Board September 2021

Part 1 Public session

External environment for HRA Board Member awareness

Good Clinical Trials Collaborative draft guidance

A range of guidelines for clinical trials exist. Still, most fail to provide guidance on the underpinning principles of randomised controlled clinical trials (RCTs) necessary to generate reliable results safely and ethically, regardless of context. Many guidelines have focused on standards required of trials (including non-randomised studies) intended to be submitted to regulatory authorities to support a new drug license. There is an unmet need for guidance to promote the unique benefits of RCTs across all contexts. The Good Clinical Trials Collaborative was established to develop and promote new guidance to address this issue.

HRA has been involved in the Good Clinical Trials Collaborative throughout, and we intend to respond to this call to comment on the draft guidance – contact Clive Collett in the Policy and Engagement team for more information.

Department for Business, Energy and Industrial Strategy (BEIS) Independent review of research bureaucracy call for evidence

This call for evidence is seeking views on ways to substantially reduce research bureaucracy, primarily for the benefit of individuals and teams conducting research. Responses will feed into the interim and final reports of the Independent review of research bureaucracy in response to the Taskforce on Innovation, Growth and Regulatory Reform independent report (TIGRR).

We intend to respond to this call – contact Clive Collett in the Policy and Engagement team for more information.

Science and Technology Select Committee Call for Evidence: Reproducibility and research integrity

The Committee is seeking written submissions addressing any or all the following topics:

- the breadth of the reproducibility crisis and in which areas it is most prevalent.
- the issues in academia that have led to the reproducibility crisis.
- the role of funders, institutions, researchers, publishers, and Governments
- what policies or schemes could have a positive impact on academia's approach to reproducible research; and
- how establishing a national committee on research integrity under UKRI could impact the reproducibility crisis.

We intend to respond to this call – contact Teagan Allen in the Policy and Engagement team for more information.

Connecting up the end-to-end system

Combined Review roll out

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

We have completed the final (private beta) deployment of the technical solution needed to support the combined review service. This was achieved on time, meeting critical deadlines

for both HRA and MHRA broader development plans. It means that we will be ready for the combined review service to be the single route into both organisations for clinical trials of interventional medicinal products (CTIMPS) from January 2022 onwards.

It also makes a significant step forward in developing new IRAS functionality as it is the first service to be developed and deployed in the new platform.

New guidance on Access to Electronic Health Records by Sponsor representatives in clinical trials

Guidance has been jointly developed by the HRA and MHRA, in consultation with the Information Commissioners Office (ICO), on behalf of the UK. The guidance supports source data validation in clinical trials, where clinical records are compared to the information held by the research team. This requires access to both research systems and clinical patient records. Given the importance of maintaining confidentiality, this is a complex area to navigate under normal circumstances and has been made more challenging due to the pandemic necessitating remote monitoring. Nevertheless, positive feedback on the importance, usefulness and proportionate and pragmatic nature of the guidance has been received.

Contact Alastair Nicholson or Janet Messer in the Approvals directorate for more information

Convening conversations on improving, coordinating, and standardising research practice across the UK

Round table on sector-wide shared commitment on public involvement

In partnership with the NIHR, we hosted a round table discussion to develop 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.

Attendees were drawn from across the research sector and across the UK. Around half of attendees were public or lay members. The meeting was a great success with clear enthusiasm to proceed. In doing so, there was wise counsel that this should be done to reduce the burden on the research and public member community.

Contact Jim Elliot in the Public Involvement team for more information.

Make It Public Conference

As an element of the Make It Public Campaign Group's work, which in turn is one of the ways we are taking forward the Make It Public strategy, we are excited to announce our first research transparency conference. This is taking place on 3 and 4 November. Invitations to the Conference will be sent out in the next few weeks.

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

Strategy Development

Strategy and purpose development

We have begun work to refresh the HRA's strategy, aiming to publish a new three-year strategy in spring 2022. The current strategy emphasises our work to streamline our systems and research review services, to promote good practice in research and to invest in our people. Much of that work will continue into next year. The new strategy will guide our next development phase as an organisation: our purpose and ambitions in the new environment and learning from our successes and challenges over the last ten years and, more recently, over the pandemic.

The Executive Committee believes that the strategy should be centred on our social mission and be specific enough to prioritise and discriminate how and what we will do to deliver it. The first stage of clarifying HRA's social mission is to discuss fundamental questions, such as - what is our unique role in the system, what does 'protect and promote the interests of patients and the public' mean for us, our community and our stakeholders in the current environment?

We want to take time at the Board meeting in November to discuss that mission and strategy, with a view to discussing it with our community and stakeholders at events to mark our 10th birthday. That, in turn, will lead to a full strategy and description of what we practically do - the detailed list of programs, projects, activities needed to deliver our social mission.

Contact Juliet Tizzard or Matt Westmore for more information.

Ten-year anniversary planning

The Health Research Authority was formally established in December 2011. We are planning a suite of outputs and activities centred on our tenth anniversary, which will balance celebrating past success and looking to future challenges. This will raise the profile of HRA and feed into our strategy development.

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

Proposal for an in-person Executive Committee and Board Awayday 16/17 November

Proposal

- Replace the November HRA Board with a combined Board and Executive Committee dinner the night of the 16 November and a full day combined Executive Committee and Board meeting 17 November at Redman Place, London.
    - The working dinner will be an opportunity to get to know each other but also a chance to think more openly about the future strategic direction of the HRA over the 5-10 year period.
    - The full-day away day will be constituted, in part, to ensure we deliver a formal November HRA Board meeting, but the majority of the time will be spent in a more workshop-like mode. We are exploring the current change portfolio and our objectives over the next 1-3 years.

Rationale

- Many of the HRA Board and the newly constituted Executive Committee are yet to meet face-to-face.

- We are reflecting on past achievements and future challenges through a range of threads that are coming together. The post-covid and post EU exit environments; new/refreshed policy directions such as the Life Sciences Vision, Saving and Improving Lives: the future of UK Clinical Research Delivery; HRA Strategy refresh and ten-year anniversary reflections.
- The Research Systems Program team is in the midst of a programme review to ensure the structures, delivery methods, and capabilities are robust and resilient for the next phase of the programme. This includes developing an integrated plan building on our development roadmap, with inter-dependencies within and beyond RSP. In addition, we are taking the learning from the last year to identify risks to delivery. The outputs from this work will be presented at the Board away day.
- The Executive Committee has been reviewing the current change portfolio and its relation to delivering this year's business plan. Sharing that with the HRA Board and discussing both progress and any in-year prioritisation would be helpful.

Contact Matt Westmore for more information.

Update on business contingency

We are keeping an on-going view of the pandemic situation and Government guidelines and continue to have a flexible model that will allow us to continue with our service delivery and projects without disruption should the Government guidance require working form home where possible.

With increased concerns about the possible increase in respiratory illnesses and flu we’re encouraging staff to consider having the flu vaccine and have offered to reimburse the cost for those not eligible for the free vaccine which we hope will reduce the risk of reduced capacity and have a positive impact in reducing potential sickness absence.