

<b>Agenda item:</b>	10
<b>Attachment:</b>	A

## HRA Board Cover sheet

### 21 September 2022

<b>Title of paper:</b>	Communications, Engagement and Involvement update including RRG activities & Approvals Directorate
<b>Submitted by:</b>	Will Griffiths-Stent, Senior Engagement Manager Contributed to by members of: <ul style="list-style-type: none"> <li>• HRA Approvals</li> <li>• HRA Policy &amp; Partnerships directorate (Communications, Policy and Engagement, Public Involvement, Data and AI)</li> </ul>
<b>Summary of paper:</b>	This paper: <ul style="list-style-type: none"> <li>• provides an overview of HRA communications, engagement and involvement activity from mid-July to mid-September 2022</li> <li>• gives detail on the stakeholders we have engaged with, the reason for engaging, and the value of this engagement</li> </ul>
<b>Reason for submission:</b>	For discussion
<b>Further information:</b>	N/A
<b>Budget / cost implication:</b>	N/A
<b>Dissemination:</b>	HRA website
<b>Time required:</b>	10 minutes

## Communications, Engagement and Involvement update

### Background

The HRA's communications strategy sets out a strategic approach to how we use communications to support the delivery of the organisation's strategy and ambitious business plan. This is complemented by HRA's stakeholder engagement strategy, to ensure that we have greater influence over behaviour in the research community and greater impact across the research system nationally. We undertake a range of communication, engagement, and involvement activities to meet the objectives outlined in these strategies, in support of the organisation's wider objectives.

This paper provides a summary of activities from mid-July to mid-September 2022, so that the Board is informed of our work in this area.

### 1. Promotes the HRA as a thought leader (who we are, what we do, why it matters)

#### 1.1. People Centred Clinical Research steering group meeting, 18 July 2022

- The third meeting of the people centred clinical research steering group meeting.
- Attendees: public contributors, members of the researcher community, HRA approvals and P&P staff and University of Lincoln.
- The project aims to find new ways to deliver clinical research in the UK and use what we find to make them more likely to happen.
- The group worked together at the meeting to:
  - Agree what the group members mean by people centred clinical research.
  - Discuss who the project team needs to speak to in the next stage of the project for a deeper understanding of the issues.
  - Discuss how we reach out to people in ways that help people to share their stories. Particularly those we might not usually hear from.
  - Discuss how we will know we have diverse and inclusive information and whether we should collect data on protected characteristics.
  - Confirm the next part of the plan.
- Regular project team meetings were also held with the University of Lincoln and Barbara Molony-Oates held conversations with a public contributor to capture her experiences for sharing with the group.
- For more information contact: Kate Greenwood or Barbara Molony-Oates

#### 1.2. Continued work as a lead for the Recovery, Resilience and Growth (RRG) programme

- Dr Janet Messer attended the regular meeting of the RRG Programme Board, currently overseeing the delivery of Phase 2 of the RRG plan recently published. This is a reoccurring meeting of UK-wider stakeholders.
- Janet and team held several conversations with DHSC to support the development of streamlining efficiency of study set up workstream within the RRG programme, including a discussion about some planned DHSC roundtable events with the NHS R&D Community. Discussions also covered proposed developments to UK AcoRD guidance.
- Janet attended regular meetings of the RRG Reset Oversight Group, overseeing the delivery of the review of the research portfolio following the COVID-19 pandemic.

### 1.3. Continued Think Ethics work to accompany the public conversation

- The programme is in the process of delivering a series workshops to ensure stakeholders are and feel heard. Qualitative information from workshop conversations will enrich the data collected in the online survey and help with analysis.
- Workshops have been Chaired by Professor Andrew George and have involved a Q&A plenary session and breakout sessions allowing for more in-depth small group discussions.
  - **UK-wide REC member workshop (online)** - over 40 REC members from across the UK expressed interest and around 30 members attended on the day.
  - **Scottish REC workshop (hybrid)** - REC members from Scotland attended online and in person in Edinburgh.
  - **Researcher and sponsor workshop (online)** - there were over 150 expressions of interest for this workshop. We selected around 30 attendees representing researchers (early career and experienced), sponsor organisations (university and NHS) and industry to attend the workshop.

### 1.4. European Forum for Good Clinical Practice (EFCGP) eConsent and Inclusiveness Taskforce, 11 July 2022

- Attendees: Hilde Vanaken, Chair of the EFCGP eConsent Taskforce, and HRA
- The objective of this multi-stakeholder initiative is to ensure eConsent is better defined, to reduce barriers in Europe (and globally) and enable clinical trial access to anyone, anytime, anywhere using eConsent as the first step to take.
- The EFCGP asked for HRA's opinion on the initiative, due to previous input on the eConsent Transcelerate workshop and the HRA/MHRA joint position statement on eConsent.
- HRA has been invited to attend the initial taskforce meeting in September.
- For further information, please contact Jane Morrin O'Rourke.

### 1.5. Response to the Tickell Review. 31<sup>st</sup> August 2022

- HRA has issued a formal response to [the Independent Review of Research Bureaucracy](#), otherwise known as the Tickell review after its lead Professor Adam Tickell. The Review, launched in March 2021, covered a number of key findings and recommendations to reduce unnecessary bureaucracy in the research system.
- Whilst the focus is largely on research funders, there are elements directed at regulators and the report makes some references to the HRA's work to make it easier to do research that people can trust, including the HRA's fast-track ethics review process and HRA/MHRA's combined review.
- Recommendation 17 is particularly relevant to the HRA's work. The Government response provides an opportunity to highlight more of the HRA's work and we are providing our response to the Department for Health and Social Care and Department for Business, Energy & Industrial Strategy, to highlight relevant current and planned activity against the recommendations in the report.
- We are also planning to write a blog about the work that we are doing to standardise and coordinate, some of which is mentioned in the Independent Review.

### 1.6. Exploring research governance in the new NHS structure (ICB and ICS) and outside of traditional settings (social care and non-NHS/hospital)

- Regular meeting with West Yorkshire NHS RD operational team on the implications of delivering research in the newly established ICBs. Specifically looking at what issues

are arising and where further guidance from the HRA or other bodies is needed. For more information, please contact Jen Harrison.

- Planning for NHS RD Forum ICB research symposium in October 2022.
- For further information contact Jen Harrison or Alastair Nicholson.

### **1.7. Meetings with commercial organisations to advise on involving patients in clinical trials**

- Jim Elliot met with [Seagan](#), a biotechnology company development oncology therapies, and [ICON](#), a global clinical research organisation, to advise on options for involving patients in their clinical trials.
- These were organised following feedback from RECs that they needed to involve the public in the trials that they submitted for approval.
- Our advice included organisations to develop working arrangements with, engaging with NIHR Study Support Service for the Lifesciences Industry, and guidance on how to set up their own public involvement infrastructure.

### **1.8. NHS Digital Data Access meeting with NIHR Policy Research Programme and Independent Group Advising on the Release of Data (IGARD) participation**

- Dr Alison Knight was invited to join this meeting convened by NHS Digital engage with discussions between NIHR [Policy Research Programme](#) (funding committee chair) and [IGARD](#) (chair) around data access challenges and to explore opportunities for more streamlined engagement (including potentially with HRA/CAG processes).
- Discussion points included around NHS Digital data not being what was requested, quality issues, receipt issues, and governance issues. There is a desire by all to consider future direction of travel on data strategy and possibilities around streamlining approval criteria review (e.g. are similar issues being considered at different sequential approvals, or could REC and IGARD approvals take place concurrently or share review analysis when it comes to common issues – such as PPIE or public interest assessments?).
- This work will be taken forward by the [RAG](#) Streamlining Group being reformed by NHSD, with Dr Alison Knight and Dr Janet Messer invited.

### **1.9. Continued contribution to the development of a National Contract Value Review (NCVR) through NCVR governance group, working group and communications group**

- Janet Messer and Alastair Nicholson attended several working group meetings to prepare for the introduction of mandatory use of NCVR: NIHR, NHSE, DHSC, HRA
- NCVR aims to speed up the set-up of clinical research by providing a rapid, predictable and efficient mechanism for establishing the value of a commercial contract between the commercial sponsor and sites, without the need for local renegotiation.
- Janet and Alastair are key instigators and contributors to the design and development of NCVR. This is a particularly important RRG commitment to streamline and accelerate study set up and is being developed with partners across the UK. For more information contact Alastair Nicholson, Janet Messer or Kate Greenwood.

### **1.10. Continued Sponsorship of the ECMC pilot project to improve clinical research for phase 1 oncology trials**

- Three meetings were held in August with the ECMC project team to shape the next phase of the ECMC pilot. This includes a planned ECMC webinar and insight gathering events via roundtables.

- For further information contact Janet Messer or Kate Greenwood

#### **1.11. Data Science Discussion Forum with University College London and Turing Institute, and invite to Conference of Research Software Engineering, 5 September 2022**

- In response to our blog '[The Users are the Co-designers](#)', UCL contacted HRA to participate in developing the Data Decision Tool. In addition, they have asked for our input on a range of projects within the data science field, specifically on the impact of machine learning and artificial intelligence. This are being led in partnership with the Turing Institute.
- This joint working has led to a number of benefits:
  - Collaborative ongoing relationship between HRA, UCL and Turing Institute on specific areas with data science.
  - Alan Smith (HRA) being invited to attend and speak at The Conference of Research Software Engineering at Newcastle University on Monday 5<sup>th</sup> September, focusing on Trusted Research Environments.

#### **1.12. Contribution to Multi Agency Advise Service (MAAS) Policy Oversight Group**

- Alan Smith has provided subject matter knowledge for Data and AI in the Policy Oversight Group, specifically on Model Drift. This is a mechanism that occurs when a machine learning system moves into real world scenarios and encounters distributions of patients who were underrepresented in the original training and design process. This can result in bias and poor performance in interpreting those groups of patients.
- We have been exploring methodologies that may address this, in collaboration with the Oversight Group and wider stakeholders.

#### **1.13. Ideal Path engagement**

- Meeting held 16 August with senior management team within Barts NHS RD department to discuss concept of the ideal path and ask specific questions about stages of the research journey.
- A series of meetings are planned with stakeholders across the research landscape (delivery and operational staff from Universities, CTU, NHS and commercial) across the UK to collect intelligence to inform the development of the UK Ideal Path for study set up.
- For more information, please contact Jen Harrison or Alastair Nicholson

#### **1.13. Corporate communications**

- Parliamentary recess and the Conservative party leadership election over the summer period has meant limited opportunity to announce significant policy changes, pushing some planned work into the autumn.
- The HRA's annual report is ready to be laid before parliament this month. The 90-page document presents progress against the strategy to 2021 and ambition for 2022-3 in support of the new three-year strategy.
- A development manager has been appointed to lead the work on the new HRA corporate website, and a supplier will be appointed later this month.

## **2. Promotes our service offer, and builds our relationship with users and researchers**

### **2.1. NHS Digital [Data Access Request Service \(DARS\)](#) team meeting with HRA's Data and Privacy Specialist**

- Dr Alison Knight joined a group of DARS advisors, including a legal advisor, to discuss four studies where for different reasons data could not be accessed to enable the research in each case. In each case, issues had been flagged to HRA/CAG as lacking apparent rationale.
- Discussion points included topics such as consultee consent (under the Mental Capacity Act 2005) and the application of the National Data Opt-out. More generally, the reasons for decisions that seemed contrary to NHS Digital guidance on its website was explored. It was agreed by all that it would be useful to continue these meetings on a bi-monthly basis as a forum to discuss issues arising and thereby better communicate new position approaches being taken by NHSD that might affect HRA advice (or vice versa).

### **2.2. Research Champions meeting 17 August**

- Attendees: NHS R&D Managers, covering all Clinical Research Network regions across England. Additional representation from NIHR, and R&D Forum.
- NED Neelam Patel joined the August meeting as an observer.
- Topics of discussion included, feedback on the results of the amendments survey and a snapshot of the IG survey, HRA strategy and Business plan, and group discussion on the NIHR early identification of sites service.
- The purpose of this quarterly forum is to engage, update and hear directly from NHS RD Managers, to understand better how our initiatives are supporting and influencing the delivery and management of research on the ground.
- For more information, please contact Jen Harrison.

### **2.3. 'The Users are the Designers' blog and follow-on engagement**

- There were a range of productive conversations with external stakeholders in response to our blog 'The Users are the Designers.' The blog encouraged participation in the development processes for designing support tools.
- This has led to extended stakeholder involvement in the testing and design of current and proposed tools to support data centric research adoption.

### **2.4. IT in Primary care CRN NHS RD Forum HRA meeting 26 August**

- Attendees: NIHR Clinical Research Network, NHS R&D Forum, HRA
- A series of meetings to explore issues with use of data in primary care, as a result of concerns raised by GP researchers
- This forum has explored the sources of delays and confusion relating to different research situations, and is developing escalation routes and guidance
- For more information, please contact Janet Messer and Alison Knight

### **2.5. HRA Study set up partnership board – 8 August**

- Attendees: HRA staff and partners from industry, NHS R&D, HEI Sponsor and CTUs.
- Meeting to support the HRA to improve study set up practice at sites across England and to feed into the 4 nations operations and policy leads.

- This month the meeting looked at responses to the HRA amendments survey coordinated by Jen Harrison, a question about electronic payment systems raised by the REC chairs (led by Charlotte Allen).
- The meeting heard about the operational challenges on the ground and discussed how the HRA might support them by feeding through to the RRG programme and our developing projects.
- For more information, please contact Kate Greenwood and Nicola Burgess.

## **2.6. Continued partners meetings**

- Several 1:1 meetings were held between Approvals and individual RRG partners to support relationships, join up the various workstreams and to help support the vision for improved clinical research delivery. These include meetings with NIHR funders, NHSE senior research team, MHRA and NIHR CRN CC.
- Attendance at the NHS R&D Forum HIVE mind meeting, providing updates, responding to queries with the NHS RD community. Steer good practice as it is shared across the group to ensure it aligns with national process and policy direction. Attended by Jen Harrison
- Four nations contracting Leads took place on 9 August, finalising two agreements for publication. Final touches are being made to three further agreements. Further work ongoing to update existing agreements and develop new agreements. All work on contracts and agreements benefits streamlining study set up through reducing requirements for local negotiation and resource for contracts. Contracts are standardised across the UK. For further information contact Alastair Nicholson.
- Four Nations policy meeting took place on 9 August, attended by various members of HRA.
- NHS Genomic Medicines Service – collaboration steering committee, attended by Janet Messer, 15 July.

## **2.7. Operational communications**

- Janet Messer blogged about clinical trial timelines in response to the annual Life Sciences Competitive Indicators published by OLS, BEIS and DHSC. In 2020 the UK spent £2.7bn on health research, third in the world behind America and Japan. Timelines for clinical trial set up place the UK as seventh out of ten nations, predominately because of delays to site set up.
- IRAS partners were supported with questions about the research systems programme on request, using agreed lines and slides to communicate progress so far and known next steps.

### **3. Promotes the need for research to be done with and for everyone**

#### **3.1. Re-imagining Research Ecosystems: Addressing Intersectional causes of Inequality in Research, 10<sup>th</sup> August 2022**

- Attendees: Dr Maria Arruda (University of Nottingham), Naho Yamazaki (HRA), Kate Greenwood (HRA), Barbara Molonyoates (HRA), Jane Morrin O'Rourke (HRA).
- Dr Arruda is submitting an application for funding for a UKRI initiative on establishing an [Equality, Diversity and Inclusion caucus](#) and was interested in collaborating with the HRA. NIHR and Wellcome are supporters.
- HRA is encouraging their proposal and are keen to hear about the progress of the project if it is successful in funding.

#### **3.2. Faculty of Pharmaceutical Medicine (FPM) Patient Engagement Group first meeting**

- A new group set up by FPM Vice President Sheuli Porkess, involving four FPM members including HRA's Jim Elliott as newly elected honorary member.
- The purpose of the group is to develop an approach FPM can take to contribute to the involvement of patients in 'medicine making' and 'medicine taking' through its members as influencers and change agents.
- This first meeting was an initial opportunity to share knowledge, skills and influencing networks and opportunities and to discuss who else from FPM members to involve. Further meetings to be arranged to build on the initial discussion.

#### **3.3. Research informed by the Cass Review**

- The HRA brought together a specialist REC to consider an application for research involving health data from people treated at Tavistock and Portman NHS Foundation Trust's gender identity service.
- Members of the specialist REC, and CAG, along with HRA staff involved in the review of the study, attended a specially commissioned media training session on handling high-profile research, run by the Head of Communications.

#### **3.4. Meeting with MHRA on diversity guidance, 1 August and 7 September 2022**

- Attendees: Members of HRA and MHRA.
- Monthly meeting of the group to discuss developing joint HRA-MHRA guidance for researchers to support, encourage and overall improve diversity in research.
- For further information, contact Barbara Molonyoates.

#### **3.5. Arms-Length Bodies (ALBs) People and Communities Forum Payments Sub-Committee**

- Jim Elliott (Public Involvement Lead) chaired the second meeting of this group, which is working towards consistency in the amounts and ways people are paid for getting involved in our work
- This was the first meeting since the launch of the guidance we co-authored with Health and Care Research Wales and the NIHR Centre for Engagement and Dissemination, the first having been held in late 2021
- The focus was an initial stocktake of policies and processes used by the ALBs present with a view to systematically collating what all ALBs do, reviewing and discussing differences and negotiating and developing areas where we can move towards consistency in all ALBs.



## **4. Internal communications and engagement**

### **4.1 Supporting staff following the death of HM Queen Elizabeth II**

- The communications team provided guidance and advice for staff on observing the period of national mourning following the death of the Queen, including supporting work to postpone planned events and activities not appropriate at this time.
- With the HR team, we also pointed to support for staff impacted by the loss, the period of change and the ongoing media coverage.

### **4.2 Supporting staff with increased costs of living**

- The communications team is working with the HR, finance teams and others to support staff impacted by increased costs of living. This includes more regular signposting to resources including the Employee Assistance Programme (which can provide financial support) and our Mental Health First Aiders.
- Communications have been developed to support staff who may be impacted by the backdated pay award and increased pension contributions, leaving them temporarily out of pocket.

### **4.2 Equality, diversity and inclusion communications**

- The communications team is working with the ED&I Lead, the ED&I Steering Group and staff led interest groups on a communications plan for the year to come. This includes increasing the amount of external communications about ED&I campaigns, a move which supports the HRA's wider diversity work.