Agenda item:	9
Attachment:	A

HRA Board meeting

18 January 2022

Title of paper:	Strategic Engagement Update: who we are talking to, about what, and why – January 2023
Submitted by:	Will Griffiths-Stent (Senior Engagement Manager, HRA), on behalf of colleagues across the HRA.
Summary of paper:	This paper provides an overview of the HRA's strategic engagement activity from late October to late December 2022 to support our strategic objectives.
Reason for submission:	For discussion
Further information:	N/A
Budget / cost implication:	N/A
Dissemination:	HRA website
Time required:	10 minutes

HRA Update

Communications, Engagement and Involvement update

This paper provides a summary of the HRA's strategic engagement activities from late October to late December 2022 to support our strategic objectives.

The paper begins with a series of wider relevant updates on the political environment, as well as ongoing consultations we are responding to. It then moves on to information on HRA's engagement activities in this period, beginning with a visual overview of this activity through three timelines.

Where expected engagement with stakeholders does not appear this may be due to regular stakeholder engagement activities not falling within this reporting period. We are currently seeking assurance on our engagement with industry stakeholders, which will inform whether we need to make any changes to how we do this going forward to ensure we are engaging with all of our industry stakeholders appropriately.

Any text highlighted in red denotes an activity that also represents a Recovery, Resilience and Growth (RRG) programme commitment.

Wider Updates:

Political environment

Funding for research into four healthcare missions
On 28 November when the Health and Social Care Secretary attended the Life Sciences Council meeting, the Government announced £113 million funding for research into cancer, obesity, mental health and addiction. The Vaccine Taskforce model will be used for each of the four healthcare missions, led by an independent chair – an expert in that field – to accelerate the development and introduction of the latest treatments and technology into the NHS, as well as drive collaboration across partners. The aim is to build on previous investment since publication of Life Sciences Vision and the delivery on commitments to cement the UK as a life science superpower.

Prime Minister's commitment to innovation
At the CBI conference in November, the Prime Minister gave a speech focused on innovation, namechecking the life sciences and AI and data

> *"we're absolutely committed to using our new Brexit freedoms…*
>
> *…to create the most pro-innovation regulatory environment in the world…*
>
> *…in sectors like life sciences, financial services, AI and data."*

Pfizer report setting out a ten-point agenda for change
In November, Pfizer published Breakthrough nation II: A bold agenda for change, which set out a ten recommendations for how industry and government can work better together. These included:

- Realise the Brexit opportunity for patients by matching the goal of rapid regulatory approval for new medicines with rapid patient access
- Create a digitally enabled and pro-innovation clinical research environment which leads to increased investment in UK clinical trials

NHS innovation and life sciences commission co-chaired by Lord James O'Shaughnessy and Professor Mike Bewick
Curia published the findings of its NHS innovation and life sciences commission, co-chaired by Lord James O'Shaughnessy and Professor Mike Bewick. HRA Non-Executive Director Neelam Patel was one of the Commissioners, and HRA Non-Executive Director Dr Nicole Mather took part in one of its evidence panels.

The report includes sections focused on health data and clinical research and makes a recommendation:

> *The NIHR should lead on establishing a task and finish group to develop a more streamlined UK ethical approval process, and a task and finish group should be established to consider how to streamline the process, including consideration of a single national approval process.*

We coordinate the ethical approval process for research in England, working closely across the four nations – and are leading work to join up research approvals across the UK with a new, simple to use accessible system that will guide researchers through the ideal path for a study.

Through this we are seeking to make contact with the commission team to learn more about the discussions that led to this recommendation and any further work planned, using this as an opportunity to ensure that we are joined up with other initiatives. We already provide a single approval for studies in the NHS through HRA and HCRW Approval, including a combined approval for CTIMPs.

MHRA to receive nearly £1m BEIS funding to unlock digital, data and scientific regulatory innovation
The Medicines and Healthcare products Regulatory Agency (MHRA) has received a total of £970,688 from BEIS' Regulators' Pioneer Fund for three projects that aim to unlock cutting edge regulatory innovation.

The three projects are:

- **Synthetic data in clinical trials** (£750,387) – to improve how patients can access life-changing treatments in clinical trials by creating entirely artificial control group through the development of synthetic datasets.
- **Complex AI algorithm interpretability for clinicians** (£167,863) – to find a way to introduce complex AI safely into front line clinical settings so that clinicians can be confident that the decision from the AI device is appropriate and suitable in that specific context. and
- **Bringing microbiome expertise into the UK** (£52,438) - make the UK the place to launch advanced microbiome products, a rapidly emerging field that poses a challenge for regulators and companies due to its novel and complex nature, that can support the development of personalised medicine.

The use of synthetic data raises data protection issues. ICO has provided guidance on Synthetic Data and how it could be used as part of its AI and data protection risk toolkit | ICO. It intends to include further guidance on Synthetic Data in its new Anonymisation, pseudonymisation and privacy enhancing technologies guidance, while noting that there are risks associated with Synthetic Data being de-identified. Thus, researchers should also consider whether they are using synthetic data to make decisions that have consequences (i.e. legal or health consequences) for individuals. HRA may need to consider implications of synthetic data/*In Silico* trials and governance implications including REC review. Please see section 2.3.6 for an update on our recent activity in this area.

Association of Medical Research Charities members commit to public involvement
At AMRC's AGM in December, the membership supported a new AMRC position statement, which all AMRC members support, on the importance of public involvement in medical research.
This commits all AMRC members to:

- recognising the importance of involving the public in producing high quality research that has meaningful outcomes and that it should be encouraged in all types of health and social care research.

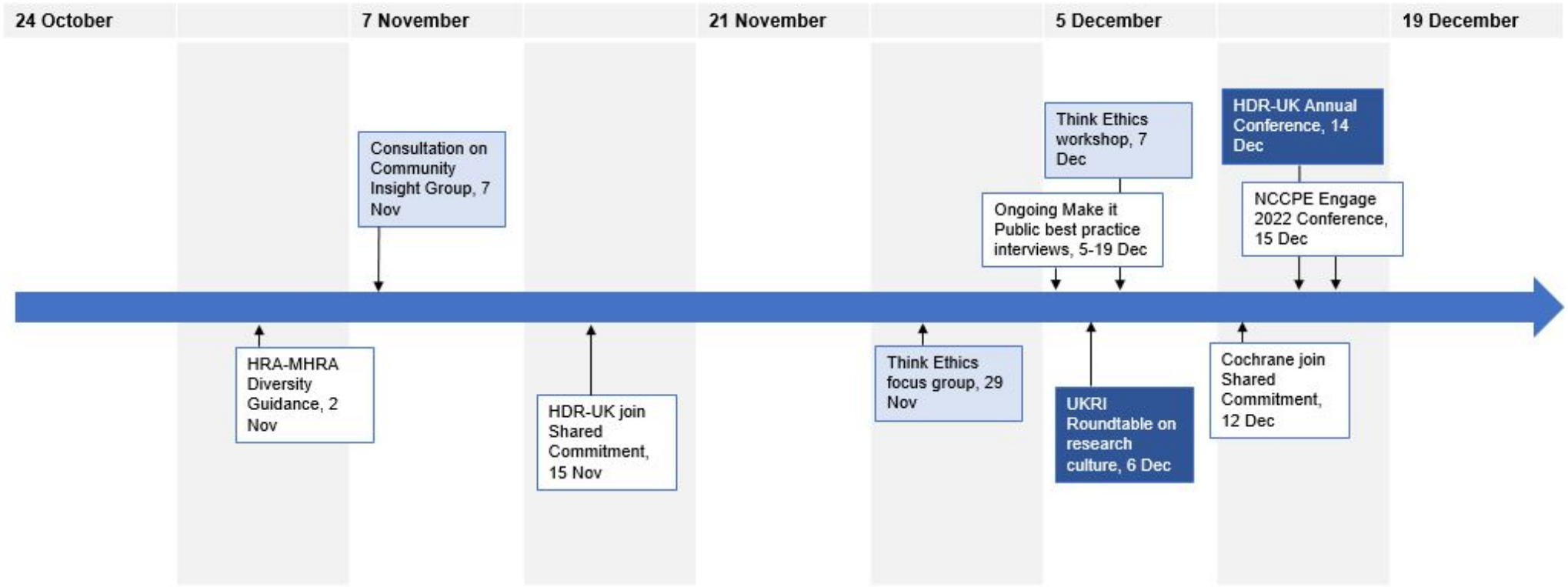
- exploring how their organisation and the researchers they fund can involve the public most effectively.

AMRC are one of the founder-signatories or the Shared commitment to embed public involvement in health and social care research and this forms part of their work to act on this commitment.

New home for Understanding Patient Data
Understanding Patient Data (UPD) will be hosted by NHS Confederation from early 2023. This follows Wellcome Trust's decision to cease hosting the programme due to changes in its new strategy, published in 2020. NIHR and MRC will continue to fund UPD when it moves to NHS Confederation.

Ada Lovelace report Data and AI
The Ada Lovelace Institute, in partnership with the Alan Turing Institute and the University of Exeter, explored the role of corporate and academic research ethics committees (RECs) and what steps they can take to support a culture of ethical AI research practices. Three of the seven recommendations in the report are aimed at RECs: to incorporate broader societal impact statements from researchers; to adopt multi-stage ethics review processes of high-risk AI and data science research; and to include interdisciplinary and experiential expertise in REC membership.

Our activity supporting our 'Include' strategic commitment



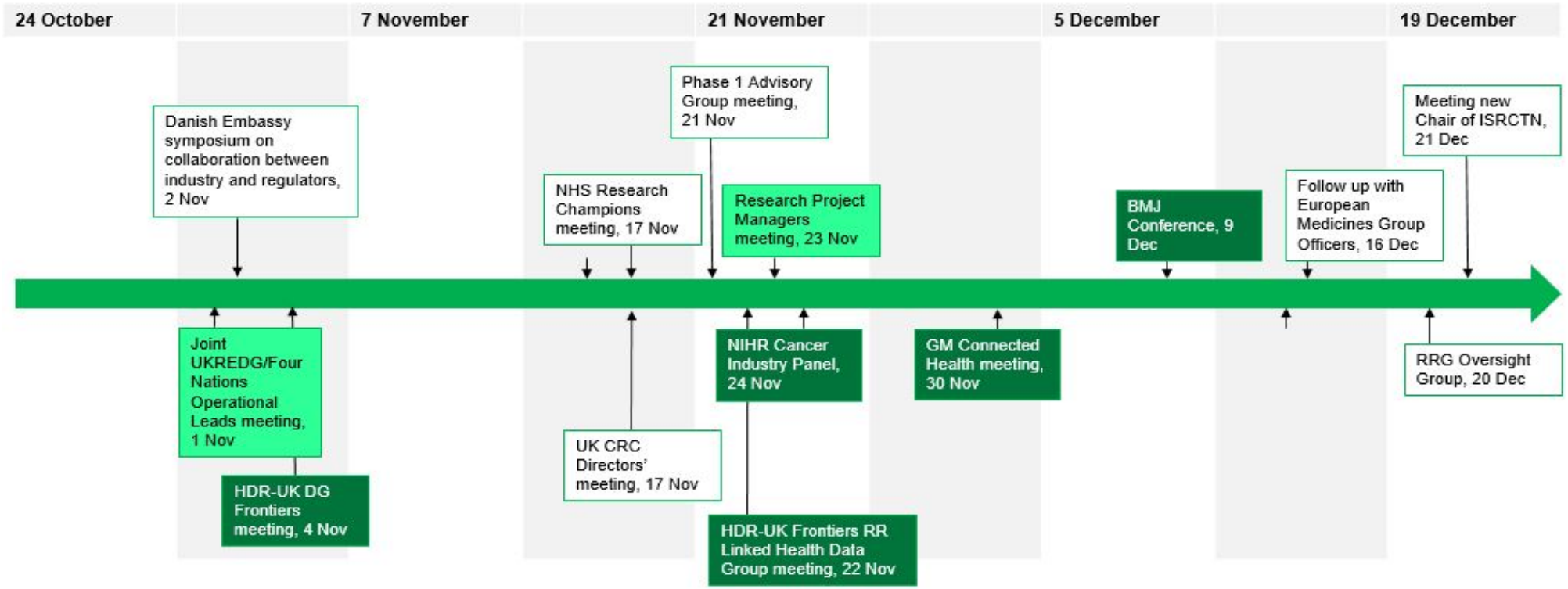
HRA Strategic Engagement update

Activity relating to 1.1. – 'Include everyone in research'

Activity relating to 1.2. – 'Ask what you want research to look like and act on this'

Activity relating to 1.3. – 'Involve you in the HRA'

Our activity supporting our 'Accelerate' strategic commitment



Activity relating to 2.1. – 'Save money and time so that you can focus on doing good research'

Activity relating to 2.2. – 'Create a new online system to help you make research'

Activity relating to 2.3. – 'Support new ways to do research'

1. Activity supporting 'Include' - 'Health and social care research that people can trust is done with and for everyone'

1.1. Include everyone in research

We will:
- *Push for change to increase diversity and inclusion in research*
- *Increase public involvement in research*
- *Make transparency the norm in research*

1.1.1. Shared Commitment to Public Involvement

- We continue to recruit new organisations to make their own commitment and to join the wider group. This period both HDR UK and Cochrane became official members of the Commitment, joining on the 15 November and 12 December respectively. NHS England have informed us they wish to join, as do both Patient Focused Medicines Development (PFMD) and The Health Foundation.
- We also facilitated a workshop on the Shared Commitment at the National Co-ordinating Centre for Public Engagement's (NCCPE) Engage 22 Conference. This workshop was run with three of the public contributors, and received rich, positive feedback from conference attendees. We will look to run more of these workshops in the future.

1.1.2. Make it Public Campaign Group meeting, 15 November

- We hosted the November meeting of the cross-sector campaign group driving progress to make transparency the norm in research.
- The group continued planning for the Make it Public Annual Report and accompanying workshops, taking place across the week commencing 20 March 2023. The Group is reviewing plans to host the workshops as part of a Make it Public Transparency Week.

1.1.3. Make it Public Annual Report

- We continue to develop content on best practice in research transparency for the Make it Public Annual Report. In this period we have interviewed and are collaborating with a number of studies for their input into the report:
    - UCL Covid-19 Social Study, understanding the psychological and social impact of the pandemic
    - INHALE Project on potential of molecular diagnostics for hospital acquired and ventilator-associated pneumonia in UK Critical Care
    - Covid Voices, co-produced research to explore the shielding experiences of people with inflammatory musculoskeletal disease
- We have also sought further feedback on the wider landscape of research transparency from the following organisation:
    - NIHR Be Part of Research
    - Knowledge Mobilisation Alliance
    - ISRCTN
- We have further interviews scheduled for January, covering more studies and organisations representing industry, academia, and R&D.

1.1.4. Meeting with MHRA to produce Diversity Guidance, 2 November

- We met with leads from the MHRA, to continuing development of joint guidance on

improving the diversity of participants in research.

1.2. Ask you what you want research to look like and act on this

We will:
- *Champion issues that are important to people in research*
- *Create public conversations about research issues that matter to people*
- *Encourage researchers to do a better job of putting people first*

1.2.1. Attendance at the UKRI roundtable on research culture, 6 December

- We joined the UKRI roundtable, which was focused on the Good Practice Exchange, and exploring lots of different ideas under the 'research culture' banner and how improvements to research culture will allow more research to excel.
- In conversations around winning hearts and minds in relation to research, we repeatedly shared the need and importance for trust in research.
- UKRI is developing ideas further based on this feedback, and will come back for further input at a later date.

1.2.2. Partnering with Health Data Research UK (HDR-UK) the HDR-UK Annual Scientific Conference: Data for global health and society, 14 December

- We attended HDR-UK's virtual conference via a virtual presentation booth, and staff across the HRA attending. Topics included creating trustworthy research environments, exploring who is being left behind in the health data revolution, lightning talks from early career researchers, and data and its role in shaping the Covid-19 health data research landscape.
- We had limited interaction on the virtual stand, but when we did we pushed messages across our strategy, in particular the need for patient and public trust in the use of data.

1.2.3. Supporting the NHS R&D Forum Annual Conference 2023

- At the RD Forum annual conference running in May 2023, the HRA will hold two "hot topic" breakout sessions. It is anticipated these sessions will focus on activities around streamlining study set up and people centre research. Further to this the HRA submitted two abstracts for oral presentations which have been accepted.
    - Better regulation for better health: Exploring the changes in clinical trial legislation and what this will mean for researchers and sponsors. – Dr Janet Messer
    - UK Site Agreements - Safer, Faster, Better. This is a collaboration of the 4 nationals contracting leads. Alastair Nicholson (HRA), Fiona Dunn (HCRW), Doug Young (NRS) and David Brownlee (HSC Innovations)
- Matt is scheduled to address the conference and chair a plenary session.
- The HRA continues to work with the NHS R&D Forum on programme planning and promoting the event.

1.3. Involve you in the HRA

We will:
- *Increase public involvement in how we make decisions*
- *Listen to and involve a diverse group of people in our work*
- *Talk in a way that everyone can access and understand*

1.3.1. Rethinking Ethics Review (Think Ethics) focus groups

- As part of Think Ethics programme, we held two sets of focus groups to hear feedback on the benefits and challenges to our three proposals are for changing ethics review.
- We held two focus groups for members of the public involvement network, which gave members of the public the opportunity to input on our ideas, and allowed further context behind responses to the survey.
- We also held a focus group with Northern Ireland staff and REC members, to again add further detail and qualitative context to responses to the consultation.

1.3.2. Continuing of consultation to changes to the Community Insight Group

- Launched on 7 November, our consultation on changes to the Community Insight Group to become a Community Committee, which will advise the Board and increase the voice of our community in our governance as part of this strategic commitment.
- The consultation will be open for four weeks, when we will then use the findings to develop proposals for the future of the Group, which will come to HRA Board for approval.

2. Activity supporting 'Accelerate' – 'Making it easier to do research'

2.1. Save money and time so that you can focus on doing good research

We will:
- *Join up research approvals across the UK*
- *Make it easier to put people first in research*
- *Support action to ensure precious NHS resources are focused on research that will help improve care*

2.1.1. Follow-up meeting with the European Medicines Group (EMG) Officers, 16 December

- The EMG brings together UK operating companies of 22 continental European-headquartered research-based pharmaceutical companies. This includes Almirall, Bayer, Ipsen, Lundbeck, Merck, Novo Nordisk, Novartis, Roche, and Sanofi.
- Matt, Naho and Janet attended

2.1.2. Engagement with NIHR to reset the research portfolio via the Reset Oversight Group, 20 December

- We continue to advise on actions to reset the NIHR portfolio to create capacity to improve the set-up and delivery of clinical research.

2.1.3. NHS Research Champions quarterly meeting 17 November 2023

- This quarterly meeting, attended by NHS R&D Managers covering all clinical research network regions across England, covered a review of the ABPI report, update on streamlining implementation of amendments, and a review of a proposed pilot for studies with minimal impact on the NHS.
- We sought feedback how the ABPI report had been received by the wider community, and on the proposals for the pilot, which was positive.
- Matt Rogerson presented the project that he is working on titled "Alternative Approaches to UK-wide Studies with Minimal Impact on the NHS" which was welcomed with interest

2.1.4. Engagement and steering best practice via the NHS R&D Forum HIVE mind meeting

- At this regular monthly meeting we responded to queries from the NHS R&D community, to steer good practice in supporting members of the R&D community to work in alignment with national process and policy direction. It is an important source of information to understand the current hot topics affecting the delivery of research; resource implications for RESET, issues over local IG requirements affecting study set up and impact of shortage/ sickness of staff within R&D.

2.1.5. Training session to MHRA Clinical Investigation and Trials team

- We delivered a session on our Approvals service to the MHRA Clinical Investigation and Trials team. This covered the scope and remit of the HRA, with particular focus on the Approvals service and our role in processing and reviewing applications for HRA/HCRW Approval.
- This gave us another opportunity to engage with MHRA on an operational level, enhancing their understanding of the role the HRA has in setting up research.

2.1.6. Meeting with new Chair of ISRCTN, 21 December

- Matt Westmore met with Andrew Freeman, new Chair of ISRCTN, for an introductory meeting to discuss the future relationship.

2.1.7. Royal Danish Embassy Symposium on regulatory science and clinical trials, 2 November

- Co-hosted by the Danish Medicines Agency, Danish national Centre for Ethics, Trial Nation Denmark and healthcare DENMARK, we joined the panel with relevant organisations such as National Institute for Health and care Research, Office for Life Sciences, Department of Health and Social Care.
- The session focused on the regulatory landscape of clinical trials, and the difference in this and perspectives from the UK, Denmark and wider Europe. Through a deep dive we explored the opportunities and challenges for Decentralised Clinical Trials and available support for cross-border R&D and commercial collaboration between UK and Denmark.

2.2. Create a new online system to help you make research happen

We will:

- *Connect the steps that are part of doing research and make them easy to follow*
- *Work with others so that each step you take informs the next*

2.2.1. Remote presentations given to Research Project Managers Network (RPMN) meeting, 23 November

- Remote presentation given to RPMN (Research Project Managers Network) Meeting, a group of research project managers/trial managers across NHS and University of Manchester. A brief update was provided virtually to a hybrid meeting. Topics covered included HRA Strategy, Process updates, Surveys & Results, Template Model Agreements and Ideal paths.

2.2.2. Continued engagement with NHS

- We met with Oxford, hospital research managers in North West London, South London, West Midlands to discuss operational updates and respond to queries to drive nation alignment to processes.
- We met with Barts Health and Coventry Hospital to discuss in depth current local process around service support department study set up and authorisation and sponsor review respectively. This work was in relation to the concept of the ideal path to understand “as is” and information requirements. Further meeting are planned for the new year.

2.3. Support new ways to do research

We will:
- *Work with research teams to explore new ways to do research and make these happen*
- *Learn together to make sure that regulation keeps up with research so that you can trust our decisions*

2.3.1. Panel at the NIHR Cancer Industry Event, 24 Nov

- We joined representatives from the Medicines and Healthcare Products Regulator Agency (MHRA) and industry on a panel hosted by NIHR. The question to address was: 'What are the operational challenges in setting up trials in the UK, and how will these be overcome?'
- The audience was mostly Clinical Research Network cancer leads, and representatives from Clinical Trials Units (CTUs). The event primarily focused on barriers to trial set up, recruitment and delivery, as well as the importance of including patients and the public in trial design.

2.3.2. Presenting at the British Medical Journal (BMJ) Conference, 9 December

- We co-presented the BMJ Conference to create visibility for the Multi-Agency Advisory Service (MAAS). This also allowed us to receive valuable feedback on the regulatory concerns from adopters.

2.3.3. Attendance at HDR UK's Innovative Data Governance Frontiers meeting, 4 November

- We joined HDR UK's workshop to discuss the importance of trustworthy data, and its use for the benefit of health research. Topics included how to enable data research at scale in a frictionless manner, and how to deliver a trustworthy data ecosystem and co-create governance models with the public to enable trustworthy data use. This has helped inform our strategic thinking on this topic area.

2.3.4. Attendance at HDR UK's Frontiers meeting of Rapid Regional Linked Health Data Group, 22 November

- We joined this meeting to explore the feasibility of enabling regional linked data to enhance data driven research, and to understand further the data connectivity for health and care nationally. The audience included researchers, academia, representatives from the NHS and regulators, and commercial entities.
- This session also gave a wider view on the public perception on harmonised data processing and views on data access.

2.3.5. Involvement in the Greater Manchester Connected Health Ecosystem, 30 November

- We joined this session to build our understanding of the GM Secure Data Environment for Research and Development. We were particularly focusing on how this will obtain HRA approval and seek support for REC and CAG, with a view to developing processes for data access approvals.

2.3.6. Publishing guidance on Accessing Health and Care Data

- In this period we launched two pieces of guidance: a step-by-step guide and glossary on accessing health and care data, and; legal requirements for using health and care data.

- These webpages have been shared via HRA Latest and through Transformation Directorate IG newsletter, and the IG portal will link to this guidance with the hope of resolving some of the misinterpretations and confusion surrounding data access.

3. Activity supporting our work on clinical trial regulations

We continue to work collaboratively with MHRA on preparation of the legal text, and will continue to progress on wider engagement once the government response is signed off.

4. Internal communications and engagement

We will always look to do things better.

Our people deliver our strategy. We will enable a diverse and inclusive organisation giving our people the tools and support that they need to do so, we well:

- *Always learn, improve and innovate*
- *Be a great place to work*
- *Commit to environmental sustainability and achieving net zero*

4.1. <u>'Respect at the HRA' video</u>

- As part of the delivery of our people strategy, the communications team is working alongside the EDI lead to produce a short video which will illustrate what 'respect at the HRA' mean outlines the expectations we place upon both staff and our community members.
- The aim of the video is to demonstrate that we want the HRA to be an organisation where everyone feels safe and valued being their authentic selves, and where making mistakes is an accepted part of people's learning journey.

4.2. <u>Communications on support for staff around cost of living</u>

- To help support staff with the added pressures of the cost of living increase, the communications team have established a new feature in HRA News (our weekly all staff newsletter) to highlight the range of wellbeing support available to staff.
- So far items have included support to stop smoking and drinking through our Employee Assistance Programme, financial wellbeing and cost of living support, and access to free wellbeing apps.

4.3. <u>Continuing commitment to environmental sustainability and achieving net zero</u>

- The HRA is part of a new DHSC group working to support staff with eco-anxiety, a new policy priority for the department. Resources are in production, with a suggested launch date of 2 February. Communications, the Green Team and the Mental Health Staff Led Group are represented.