

Agenda item:	11
Attachment:	A

## HRA Board meeting

20 March 2024

<b>Title of paper:</b>	Strategic Engagement Update: who we are talking to, about what, and why – March 2024
<b>Submitted by:</b>	Will Griffiths-Stent (Senior Engagement Manager, HRA), on behalf of colleagues across the HRA.
<b>Summary of paper:</b>	This paper provides an overview of the HRA's strategic engagement activity from early January to mid-March 2024 to support our strategic objectives.
<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

## HRA Update

### Communications, Engagement and Involvement update

This paper provides a summary of the HRA's strategic engagement activities from the broader period of early January to mid March 2024 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.

#### Wider Updates:

- [Secretary of State priorities](#)
- [Pre-budget life sciences investment announced, 4 March](#)
- [DSIT Areas of Research Interest 2024, 26 February](#)
- [UK Government response to the Independent Review of Research Bureaucracy](#)
- [IQVIA Global Trends in R&D 2024](#)
- [Times Health Commission response and publication](#)

#### Consultation responses:

- [HRA response to proposed revisions to Declaration of Helsinki](#)
- [NICE integrated topic prioritisation and strategic principles consultation](#)

#### Secretary of State Priorities

The Secretary of State for Health and Social Care, The Rt Hon Victoria Atkins MP, shared their strategic priorities in February.

**Headline ambition:** to reform the health and social care system – 'taking the hard by necessary long-term decisions to build a 21<sup>st</sup> century service that is faster, simpler and fairer, for people who rely on it and staff who work in it.

- **Faster:** more timely and convenient access for people who need health and care services.
- **Simpler:** more streamlined, easier to navigate and modern health and care services for the public and staff
- **Fairer:** A system that works for all, reducing variation across the country and making sure the vulnerable and future generations are protected

## **Pre-budget life sciences investment announced, 4 March**

The Chancellor announced an investment package of £360 million in the UK's life science and manufacturing sector. This includes £92 million joint government and industry investment to expand facilities. Within this, there is £7.5 million to support two pharmaceutical companies who are investing a combined £84 million to expand their manufacturing plants in the UK:

- Almac, a pharmaceutical company in Northern Ireland produces drugs to treat diseases such as cancer, heart disease and depression.
- Ortho Clinical diagnostics in Pencoed, Wales, is expanding its facilities producing testing products used to identify a variety of diseases and conditions.

Also announced, companies will soon be able to apply for a share of the £520 million funding for life sciences manufacturing announced at Autumn Statement, with competitions for large scale investments opening for expressions of interest this summer and medium and smaller sized companies in the autumn. The fund is designed to build resilience for future health emergencies such as influenza pandemics and capitalise on the UK's world-leading research and development.

## **DSIT Areas of Research Interest 2024, 26 February**

The Department for Science, Innovation and Technology announced its areas of research interest in February. These areas highlight 'topics where DSIT is keen to enrich and develop its evidence'. Areas most relevant to health and life sciences include:

- Government Office for Life Sciences
- International Research and Innovation
- Science, Research and Innovation
- Technologies and Innovative Regulation

## **UK Government response to the Independent Review of Research Bureaucracy**

The Secretary of State for Science, Innovation and Technology, Michelle Donelan announces a rapid action plan to support the establishment of an agile, streamlined, and fast-moving research system. The government's response replies to all the recommendations within the original review. With a total of 32 recommendations the review provides essential next steps for how the sector will work collaboratively to reshape the research system and unleash its full potential.

The government's response states:

***“a more streamlined, joined up UK ethical and regulatory approval service for health and social care research will reduce duplication and speed up-decision making.”***

The response itself showcases several HRA initiatives including, our collaborative working with devolved nations to bring a more streamlined UK approvals system. Our joint working with MHRA on combined review. The Think Ethics consultation and the subsequent work by the Coordination and Standardisation Team on the approval of programmes of research.

There is recognition of the HRA creating more opportunities for people with lived experiences to be involved in internal decision making and to include a more diverse group of people in our REC's. HRA Now is also showcased as a best practice tool when proactively communicating on new and emerging regulatory issues. More broadly the review outlines a series of measures that will lead to a reduction in bureaucracy across the research system. You can read more about the measures and the specific recommendations the HRA is cited in, in the attached policy briefing. Finally, the government has set up a steering group, with funders and research sector representatives, to sustain progress against the commitments.

## **National Institute for Health and care Research (NIHR) 2022/23 Annual Report**

In January 2024 NIHR released its annual report, covering activity and expenditure over 2022/23. A headline statistic from the report is that for every £1 invested in NIHR, society receives £19 of benefits. From the NIHR's spend of £1.3 billion there is an expected return of around £20 billion (discounted net present value) over the next 20 years.

The full report can be found [here](#), and is broken down into chapters.

## **IQVIA Global Trends in R&D 2024**

Clinical trial activity has slowed down compared to pre-pandemic levels, mainly due to reduced COVID-19-related trials and shifting research priorities. **In 2023, trial starts decreased by 15% compared to the prior year and were down by 22% from 2021**, which saw the peak of COVID-19-related trial activity. Factors contributing to this slowdown include fewer COVID-19 trials, reduced non-COVID-19 trials by larger and emerging biopharma companies. Chinese companies have significantly increased their trial starts, with a shift towards international trials.

The top four diseases for trial starts are **oncology, immunology, metabolic/endocrinology, and neurology**, which account for 79% of trials and have declined less than others. Rare disease trials remain high and have slowed less than trials for larger populations. Rare disease research primarily focuses on oncology. Within oncology, novel mechanisms like cell and gene therapies have risen to 25% of trials, with industry-sponsored trials tripling over the past decade.

Obesity trials have significantly increased, with 124 drugs in development, mainly GIP/GLP glucagon receptor agonists and oral formulations. Neurology research concentrates on Alzheimer's, Parkinson's, and epilepsy, among others. Depression trials decreased by 25% in 2023, with a notable increase in trials involving psychedelics. Infectious disease trials have slowed, including COVID-19 trials, and there's a notable reduction in antibacterial trials.

In terms of new drug approvals and launches, 69 novel active substances (NASs) were launched globally in 2023, reflecting a return to pre-COVID-19 trends. Over the past five years, 362 NASs have been launched globally, with an increasing gap between the U.S., the EU4+UK, and China. China has become the second-largest market for NAS launches, with an increasing number of domestically available drugs. Excluding China-only NASs, global NAS launches were 52 in 2023.

The full report can be found [here](#).

### **Times Health Commission response and publication**

The Times Health Commission, which Matt Westmore gave evidence to, launched on 5 February. The report focused primarily on the NHS, with 10 recommendations (those most relevant to HRA highlighted in bold):

- **Creating digital health accounts for patients, accessed through the NHS app.**
- Introduce a national programme of weekend High Intensity Theatre.
- Reform the GP contract to focus on wider health outcomes.
- Write off student loans for doctors, nurses and midwives who stay in the NHS.
- Introduce no-blame compensation for medical errors.
- Establish a National care System – equal to the NHS, administered locally, delivered by a mixture of the public and private sectors.
- Guaranteed mental health support for all children and young people.
- Expanding the sugar tax, taxing salt to tackle obesity.
- **Incentivise NHS staff to take part in research.**
- Establish a Healthy Lives Committee.

The full Commission report can be found [here](#).

### **Consultations:**

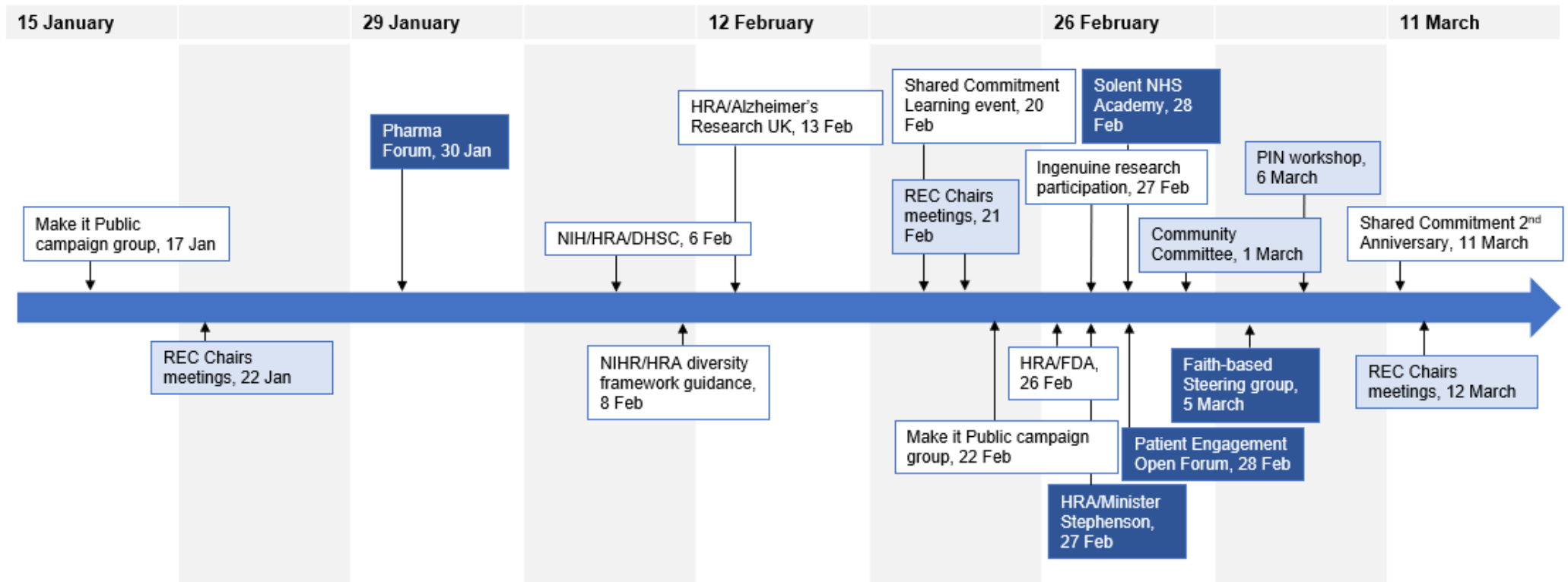
#### **HRA response to proposed revisions to Declaration of Helsinki**

We responded to phase 1 of a public Consultation on proposed updates to the Declaration of Helsinki. The proposed edits in this first phase of the consultation clarify and update wording around research waste, new ways of consenting and resource demands on Ethics Committees. We engaged with REC members and PIN members who were part of the Think Ethics Advisory group to contribute to our organisational response, which was submitted on Wednesday 7 February.

#### **NICE integrated topic prioritisation and strategic principles consultation**

NICE are introducing a new approach to prioritisation and topic selection, to support greater integration. The new approach will see the creation of a central and integrated prioritisation board. It will mean multiple processes and products can emerge, to develop integrated guidance that will lead to a more joined-up way of thinking and working. They hope this will ensure they are producing guidance for the health and care system that is relevant, timely, accessible and creates demonstrable impact. The consultation closed Thursday 4 April 2024.

## Our activity supporting our 'Include' strategic commitment



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

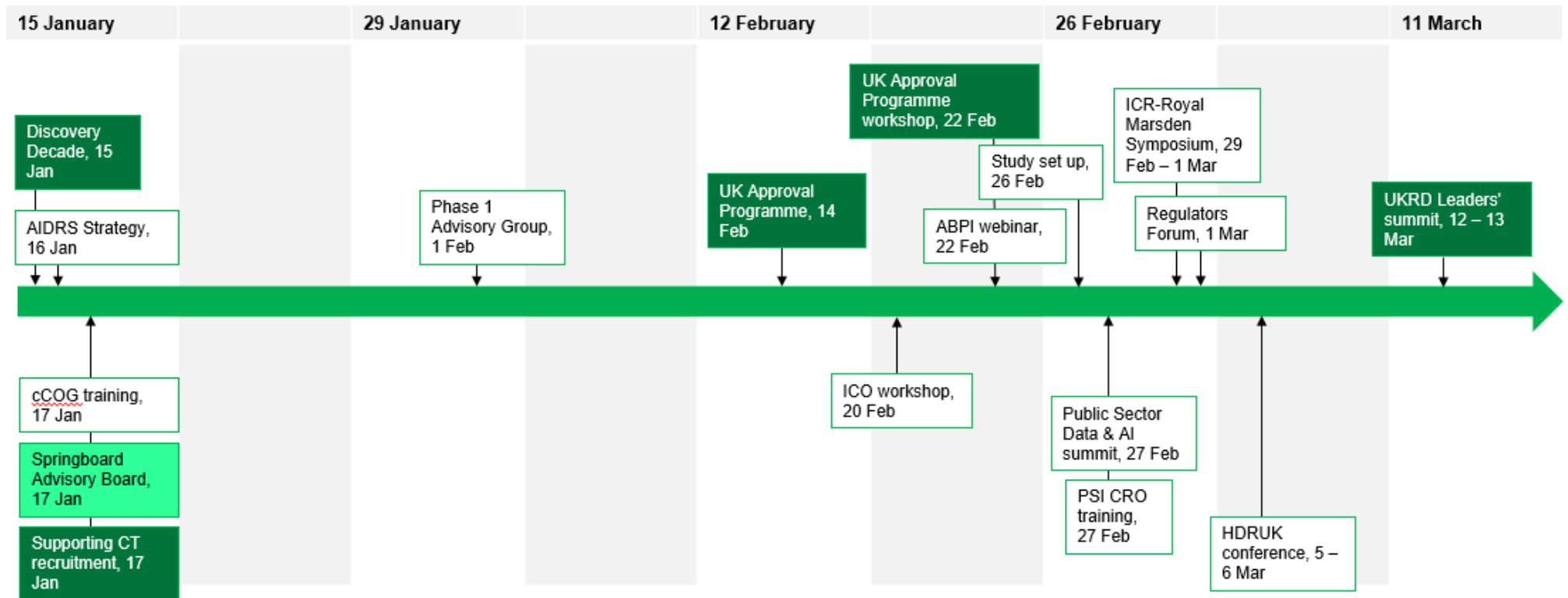


Activity relating to 1.2. – 'Ask what you want research to look like and act on this'



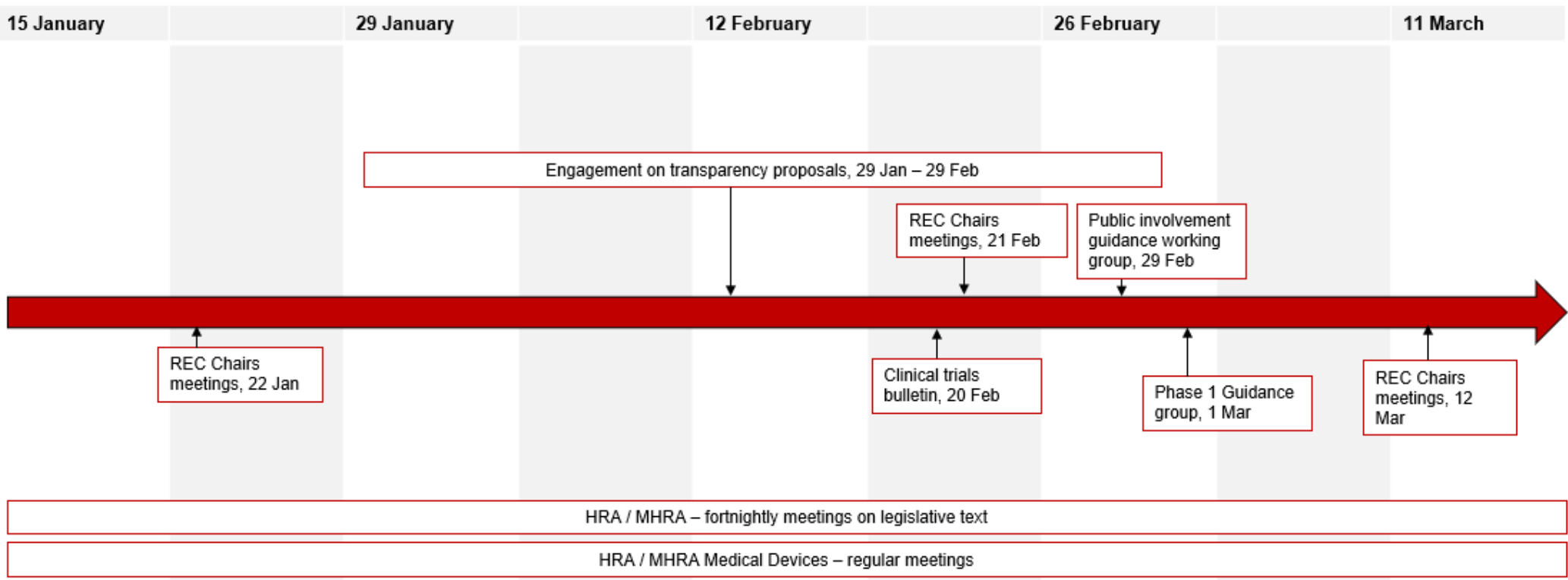
Activity relating to 1.3. – 'Involve you in the HRA'

## 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'

# HRA activity supporting proposed changes to the regulation of clinical trials





## 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 - Learning and Sharing Event (20 February 2024), direct meetings, and second anniversary of the Shared Commitment (11 March)

- We hosted an event for the public involvement leads from the 21 partners of the Shared Commitment, plus representatives from other interested parties, including PPI Ignite (Ireland), FUSE Centre for Translational Health, and Shaping our Lives.
- We have also held additional meetings with the International Patient and Public Involvement Network (7 March) and NIHR ARC East of England (26 February), the latter of whom will become official partners on 11 March.
- 11 March marks the second anniversary of the Shared Commitment. HRA and Commitment partners will be celebrating and promoting the wider importance of public involvement throughout the day, to raise of the commitment and its principles.

#### 1.1.2. Make it Public campaign group meetings (17 January, 22 February), workshop registration and promotion ahead of Make it Public Week (18 to 22 March)

- Make it Public Week 2024 will be from 18-22 March, and this year the campaign is focusing on the registration of clinical trials.
  - There will be a #MakeitPublic workshop on Thursday 21 March, which aims to address the barriers to registering research and facilitate discussions to understand how the research community can work together to achieve 100% registration. The event has sold out, and registered attendees include researchers, members of the public, and industry professionals.
  - Event communications were launched 21 February, using our Clinical Trials Bulletin, Public Involvement newsletter, REC Member Bulletin, social media, and via other promotions from the Make it Public Campaign Group.
  - During Make it Public Week we will also publish the data we gather on research transparency. This year, as well as the numbers of clinical trials that are not registered, we will be publishing data on the registration status of clinical trials approved in 2022, including study title, IRAS number and the name of the sponsor organisation. This is being published in alignment with our legal duty to be fully transparent. We have emailed chief investigators and sponsors to inform them of this, as well as reminded them to send us their details before any information is published. A paper summarising our plans to publish this data was sent to the DHSC Sponsor Team.

#### 1.1.3. National Institute of Health (NIH) and HRA/Department of Health and Social Care (DHSC) discussion on increasing diversity of clinical trials, 6 February

- We met with representatives from the US NIH to share respective work on inclusion

and diversity, which gave us an opportunity to share learning and better understanding of what is being done internationally in this space.

- 1.1.4. Meeting with the US Federal Drug Administration (FDA) on the HRA diversity plan and confidentiality commitment, 26 February
  - We met with representatives from the FDA, as well as colleagues from the MHRA, to hear an update on their draft guidance on improving enrolment of participants from underrepresented racial and ethnic populations in clinical trials.
- 1.1.5. National Institute of Health and Care Research (NIHR) & HRA meeting on new Equality, Diversity and Inclusion framework guidance for trusts, sponsors and investigators, 8 February
  - We met with NIHR Clinical Research Network North West London to discuss their new framework, ensuring that their and our work aligns with each other, as well as with other work being undertaken in this space.
- 1.1.6. Meeting with Alzheimer's Research UK on diversity and people centred research, 13 February
  - Opportunity to talk through HRA work in the inclusion and diversity space, and our hallmarks of people centred research, with a leading charity partner also working across diversity.
- 1.1.7. Meeting with Cancer Research UK on clinical research and science policy
  - We met with CRUK's Head of Clinical Research and wider colleagues to discuss common areas of interest (ongoing development of updates to clinical trials regulations, decentralised trials guidance, barriers to clinical research). We explored areas of overlap and potential ways of syncing up activities around these priorities.
- 1.1.8. Meeting with Professor Rachael Goberman-Hill, Director of Elizabeth Blackwell Institute and University of Bristol, on ingenuine research participation, 27 February 2024
  - This meeting follows a series of meetings with representatives from Health and Care Research Wales, Chief Scientist Office Scotland, NIHR and Institute of Global Health Innovation.

## 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. Introductory meeting with Minister Andrew Stephenson, 27 February
  - Matt and Terence met with Minister Stephenson, Minister of State for Health and Secondary Care with sponsorship responsibilities of the HRA (as well as MHRA, NICE, and NHS England). It was an introductory meeting focused on information gathering. Leadership and representatives from DHSC were present, and we received strong praise and support from DHSC colleagues.

- Questions from the Minister revolved around our profile, our role in delivering objectives of the O’Shaughnessy review, and how we balance supporting innovation and public and patient safety and security.

1.2.2. Meeting with External Relations Lead at DHSC for Minister Stephenson.

- We met with Mark Covey, External Relations Lead at DHSC, to discuss HRA remit and areas of external activity. We focused on areas where DHSC could further support publicly. This gives us another avenue into DHSC.

1.2.3. Presentation to the Solent NHS Academy Conference on Hallmarks of People-Centred Clinical Research, 28 February

- This session explored the origins and development of the Hallmarks, and their use for and by researchers and members of the public.

1.2.4. Equality, Diversity, and Inclusion webinar for Pharma Forum, 30 January 2024.

- We presented adaptive strategies to diversity and inclusion in research to an industry audience, alongside representatives from Parexel, the National Institute for Health and Care Research’s Clinical Research Network, and patient advocates.
- The webinar explored common challenges in offering equal participation opportunities in research in the UK.

1.2.5. Faith-based research engagement steering group, 5 March

- Alongside ourselves, NIHR, University of Oxford, Wellcome Trust, VOCAL and HDRUK are represented in the steering group. The group’s focus is to understand what success looks like for faith-based research engagement from a community’s point of view.
- Group members met and reviewed a design framework for the engagement, draft participant information sheet and findings from two initial conversations the core group have had with faith leaders. This work aligns with our community engagement work and provides important insights of how best to approach our work.

1.2.6. Attendance at Patient Engagement Open Forum event on Ethics Committees and Patient Engagement, 28 February

**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. Meetings of the HRA Community Committee, 1 March

- The Community Committee had its second official meeting on 1 March. The meeting included:

- Agreeing processes to shape the Committee's ways of working and interaction with HRA Board – the Terms of Reference are due to be agreed at the Committee's next meeting in May 2024.
- A presentation on the history and objectives of the HRA's Research Systems Programme
- Discussion of how the HRA plans to develop its next strategy.
- Discussion of the HRA's community engagement work.
- The Committee has made a series of recommendations that will be presented to the Board at this session (20 March).

### 1.3.2. Workshop with public contributors on reviewing the ways of working of the Public Involvement team, in support of the HRA Strategy, 6 March

- We met with six newer public contributors, to review the Public Involvement team plan, to give contributors and opportunity to feed into and influence the ways of working and proposed focus on the team's activities in supporting the HRA strategy.

### 1.3.2. Discussion and proposal development on clinical trials regulations relating to Research Ethics Committees (RECs) with UK REC leads (22 January, 21 February, 12 March)

- We met with the Chairs from Welsh, Scottish, and Northern Irish RECs across the first three months of 2024, to discuss and review proposals on changes to the definition of RECs (item repeated in section 3).

## 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. Workshop on defining the strategy of the [AI and Digital Regulations Service \(AIDRS\)](#), 16 January

- We met with our counterparts who make up the AIDRS - (National Institute for Health and Care Excellence (NICE), Medicines and Health products Regulatory Agency (MHRA), Care Quality Commission (CQC) – to find and set common strategic objectives for the service for 2024/25.

#### 2.1.2. New standards and principles for research participant information - Training session for Clinical Commercial Operations Group (17 January), Webinar for Association of British Pharmaceutical Industry (22 February)

- In conjunction with the cCOG, Approvals Operations delivered a training session for cCOG members on the Quality Standards and Principles for Participant Information which were fully rolled out on 01 Dec 2024. A webinar on the same topic was

delivered in partnership with ABPI the following month to over 80 industry and pharmaceutical representatives.

- The purpose of the event was to clearly outline the purpose of the Quality Standards and Principles and how they should be applied to participant information and form part of a study submission.

#### 2.1.3. Information Commissioner's Office (ICO) workshop (20 February) and Regulators Forum (1 March)

- At the workshop, we discussed applications of privacy enhancing technologies in various healthcare settings, including research governance considerations of synthetic data.
- At the Regulators Forum, we contributed to discussions around biometric recognition, an introduction to the ICO's generative AI consultation series, and an overview of the EU Artificial Intelligence Act from the European Parliament.

#### 2.1.4. Training to PSI CRO, 27 February

- We delivered commercial training on the Approvals process to operational and regulatory staff within PSI. The Purpose of the training was clearly outlining all stages of the Approvals process (new applications and amendments).
- The intended benefits are improving understanding of the Approvals process and study submissions to lead to a more successful outcome and enable quicker study set up.

#### 2.1.5. Presentations to Recovery, Resilience and Growth (RRG) partners at RRG Board, February

- We presented to RRG members on approaches to consent, and on the Hallmarks of People-Centred Clinical Research, in this period.

#### 2.1.6. Symposium at ICR-Royal Marsden, 29 to 1 March

- We delivered session on the Approvals Process at the ICR Royal Marsden Symposium. There were about 40 attendees that included sandwich year students from a variety of commercial and non-commercial organisations.
- The aim of the symposium was to raise the profile of clinical research professionals and encourage the next generation to work in these areas.

#### 2.1.7. Joint industry/NHS/health and social care meeting, 21 February

- We hosted a second face-to face-meeting with representatives from Industry (via cCOG) and NHS/HSC R&D management representatives from across the UK, to look at resolving issues relating to study set up. Approximately 35 attendees, split 50:50 industry to NHS.
- The aim of the meeting was to bring both industry sponsors and NHS organisations together to look at the issues impacting clinical study set up and discuss ways they could take forward to unblock these. Supporting this is several smaller joint working groups looking at specific issues. This work supports RGG.

#### 2.1.8. Presentations at the Public Sector Data and AI Summit, 27 February

- We participated in discussions on the application of generative AI across various sectors, including challenges on the use of NHS data for secondary purposes.

### 2.1.9. Health Data Research UK Conference, 5 to 6 March

- We attended both days of the Conference, which is split between covering the grand challenges in health data, and the subsequent technology ecosystem and current activities within the sector that are addressing these challenges.

### 2.1.10. HRA Study set up partnership board meeting, 26 February

- This is a regular monthly meeting with stakeholders to review study set up practice, challenges and the work of the HRA. The group brings members together including industry and NHS colleagues in operational set up roles, with policy partners. The group has recently broadened its membership to include DHSC and R&D members from an Integrated Care System (ICS).
- This group allows HRA to hear directly about challenges to study set up on the ground, and is an opportunity to ensure users shape and influence HRA activities in support of study set-up.

### 2.1.11. Meeting with [Experimental Cancer Medical Centre \(ECMC\)](#)

- These regular sessions with ECMC senior management support joint working to improve the study set up in early phase trials.

### 2.1.12. Phase 1 Advisory Board meeting, 1 February

- This is a regular meeting HRA staff, Phase 1 community, and Research Ethics Committee members to share stakeholder advice and practice for Phase 1 studies.

## 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. Attended National Institute for Health and care Research (NIHR) Regional Research Delivery Network's Springboard Transformation Advisory Board, 17 January

- We met with NIHR colleagues to discuss the NIHR Clinical Research Network's transition to the Research Delivery Network. We were invited to feed back on the current process, and will continue to do so in the coming months.

### 2.2.2. Regular meetings with Medicines and Healthcare products Regulatory Agency (MHRA) and National Institute for Health and care Research (NIHR) around online system development

- With the NIHR meetings ensure collaborative working and understanding of the development of online systems (HRA RSP, NIHR – DDaT Digital, Data and Technology).

## 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. Discovery Decade Public Dialogue expert group, 15 January

- Campaign for Science and Engineering's (CaSE) Discovery Decade project is creating a space for the R&D advocacy community to consider how to best tell its story to the public through a public dialogue. The expert group includes representation from UKRI and Academy of Medical Sciences, Science Foundation Ireland, British Science Association and University of Manchester.
- The focus at this session was on refining the scope of the dialogue, themes that should be explored and expected outputs. CaSE will now run, and analyse the findings from, a series of stakeholder engagement workshops with representatives from R&D organisations and related stakeholders across the UK (including the HRA) to inform the dialogue.

#### 2.3.2. Meeting around supporting recruitment into clinical trials, 17 January

- We met with Professor Ruth Endacott and others to discuss how Advanced Clinical/Nurse Practitioners with Masters level training could support recruitment to clinical trials.

#### 2.3.3. UKRD Leaders Summit 2024, 12 – 13 March

- We presented at the Summit, attended by NHS R&D leads, on the Hallmarks of People-Centred Clinical Research,
- We also joined a panel on the future of clinical trials, along side representatives from DHSC, MHRA, and experts from areas of trials methodology and research delivery.

#### 2.3.4. Meeting with Department of Health and Social Care (DHSC), Home Office, Medicines and Healthcare products Regulatory Agency (MHRA), and NHS England

- This meeting focused on a recommendation to remove the requirement for a Home Office License for non-commercial clinical trials involving Schedule 1 drugs.

### **3. Activity supporting our work on clinical trial regulations**

#### 3.1. Ongoing meetings and collaboration with Medicines and Healthcare products Regulatory Agency (MHRA)

- We are collaborating with MHRA across a number of areas around clinical trials regulations. Specific to legislative areas:
  - Fortnightly meetings with MHRA clinical trials unit representatives to finalise legislative text for the regulations.
  - Similar meetings with Department of Health and Social Care lawyers to finalise text.
  - Meetings with MHRA Medical Devices division to agree process flows for the submission of IVD device applications where there are sites in Northern Ireland.
  - Meetings with MHRA Medical Devices division to provide text regarding informed consent for the revision of the BG Medical Device Regulations.

#### 3.2. Discussion and proposal development on regulations relating to Research Ethics Committees (RECs) with UK REC leads (22 January, 21 February, 12 March)

- We met with the Chairs from Welsh, Scottish, and Northern Irish RECs across the first three months of 2024, to discuss and review proposals on changes to the definition of RECs.

### 3.3. External engagement and request for input on transparency regulations, February

- We engaged with research sponsors on proposed transparency provisions for revised clinical trials regulations through a survey to the sponsor audience.
- The proposals we sought feedback on included:
  - Standard 30-month time period to fully comply with research transparency requirements for early phase trials.
  - Extension to standard 30-month time period where a patent application is ongoing
  - Fixed time point for registration
- Feedback is now with the MHRA and being assessed and incorporated by MHRA and HRA clinical trials leads.

### 3.4. Ongoing external engagement on developing supporting guidance on public involvement

- The guidance working group met on 29 February to review draft expectations, gaps for new areas of guidance, and initial list of existing guidance to share.
- A sub-group, focused public involvement in Phase 1 Healthy Volunteer Studies, met on 1 March to review current principles and expectations.

### 3.5. Engagement on developing guidance on diversity and inclusion in clinical trials

- We met with MHRA colleagues to discuss the planned informal consultation on diversity and inclusion requirements. This will now be delayed until late Spring, to allow MHRA time to explore potential impact on the notification scheme.
- We met with the Federal Drugs Authority to discuss their guidance in this area (captured above in section 1.1)

## 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. HRA Skills Project update

- This project has been developed by our learning and development team in response to a Government Internal Audit Agency (GIAA) audit which recommended we carry out a training needs analysis, to recognise the current skills, knowledge, experience, and qualifications our people have, and look to build upon these as part of our commitment to develop our staff and identify areas for growth.
- The communications team is supporting the learning and development team to communicate the project and milestones to wider staff.

### 4.2. Community ways of working



- We're developing a ways of working resource for our community members (Research Ethics Committee, Confidentiality Advisory Group and Public Involvement Network members).
- The resource will set out clearly and consistently what they can expect when they work with the HRA, and what is expected of them. It will include information about values and behaviours; legal requirements such as declaration of interests and data protection; and guidance and support including expenses / payments, talking about the HRA, raising concerns, and key contact details.
- Our community members are helping us to develop this resource. It has been reviewed by the Community Insight Group and Community Committee. The next stage is sign off which is expected to be in May.

#### 4.3. New Intranet site for staff

- During this period, the communications team has continued to work closely with IT and colleagues across the organisation to develop the new SharePoint intranet and its accompanying products. The team has been working with colleagues to draft new and engaging content, which will be migrated across to the new site in April for review and has received training delivered by IT on how to use the new site.
- Following feedback from the project's working group, the team has also drafted guidance for staff to help establish what each internal platform (intranet, Central Library and Teams) should be used for and hosted their second working group session in February to collate additional feedback on the project's activities.