

Agenda item:	14
Attachment:	A

## HRA Board meeting

15 November 2023

<b>Title of paper:</b>	Interim Strategic Update – November 2023
<b>Submitted by:</b>	Will Griffiths-Stent (Senior Engagement Manager, HRA), on behalf of colleagues across the HRA.
<b>Summary of paper:</b>	<p>This paper provides an interim update on strategic activity relevant to the HRA. This includes updates on recent and upcoming publications and announcements from stakeholders, updates on ongoing consultations we are involved in, and recent and upcoming headline activities.</p> <p>This paper will be supported with more detail through the larger Strategic Engagement Update paper, that will now be reported on to Board on a quarterly basis.</p>
<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

## Interim Strategic Update – November 2023

This paper provides an interim update on strategic activity relevant to the HRA. This includes updates on recent and upcoming publications and announcements from stakeholders, updates on ongoing consultations we are involved in, key HRA communications activities, and recent and upcoming headline activities.

This paper will be supported with more detail through the larger Strategic Engagement Update paper, that will now be reported on to Board on a quarterly basis.

### Wider updates from stakeholders:

#### [DSIT announce new £100 million fund to capitalise on AI's game-changing potential in life sciences and healthcare](#)

The Prime Minister announced in a speech on Thursday (26<sup>th</sup> October) a new £100 million government investment, targeted towards areas where rapid development of AI has the greatest potential to create transformational breakthroughs in treatments for previously incurable diseases. This investment – the AI Life Sciences Accelerator Mission – has been said will 'capitalise on the UK's unique strengths in secure health data and cutting-edge AI.'

#### [Nuffield Council on Bioethics publish 2023 horizon scan infographic](#)

The Nuffield Council on Bioethics (NCOB) published (9 November) their 2023 horizon scan infographic, which highlights where technological developments in bioscience and health may require acute ethical considerations.

NCOB state that 'if a topic is present in our horizon scan it signifies that there is a potential for a development in that area to spark ethical concern. The infographic [can be viewed here](#), and covers five areas: animals, food and environment; beginning of life; health and society; data and technology, and; research ethics.

#### [Chief Medical Officer's Annual Report 2023: Health in an ageing society](#)

Professor Chris Whitty, the government's Chief Medical Officer, has published (10 November) his annual report. This year's report is entitled 'Health in an ageing society' and recommends actions to improve quality of life for older adults and prioritise areas with the fastest growth in older people.

Of note to the HRA, point 12 of the Executive summary states:

***Research often excludes older adults; they should be the main focus of much of our research.***

*Research often systematically excludes older adults, despite the fact that the great majority of ill health is concentrated in this population. It should not be acceptable, for scientific reasons if no other, to have trials and studies where age or multimorbidity are contraindications to enrolment. There is extremely exciting research into the processes of ageing and how these can be delayed. Although there are significant research programmes on improving the health of older adults, there is a relative dearth of research activity in the older age group. Some areas, such as social care and frailty in older age, and ageing in ethnic minority populations, are significantly under researched.*

*There are several research gaps, including into the much greater risk of infections in older adults, outlined in this report.*

The executive summary and recommendations can be read [here](#), and the full report [here](#).

### **[AMRC publishes Life Sciences Manifesto](#)**

AMRC has published [a manifesto](#) that calls for strong government support for life sciences to tackle the UK's health crisis. It provides a framework for the next government, to accelerate access to innovation, improve health outcomes for everyone, reduce the burden on the NHS and cement the UK's position as a world-leader in R&D.

The manifesto covers three key areas that should be included in a long-term, Cabinet-led science strategy that delivers faster and more equitable patient access to transformative diagnostics, treatments, and cures:

- Investing in a thriving R&D system
- Supporting a skilled and diverse workforce
- Embedding research in the NHS

Within each area, the document provides practical recommendations.

### **[ABPI publishes people-centred research hub](#)**

ABPI recently published a new people-centred research hub that features 20 case studies showcasing industry best practice in research diversity, patient and public involvement, and research transparency. The Hub will continue to be expanded with additional case studies, in line with ABPI's stated commitment to increase diversity and inclusion in research.

The sub categories of the Hub – [study design](#), [study delivery](#), and [study follow-up](#) – can be accessed by the links quoted here.

### **[CRUK News: Research with integrity – What you need to know about generative AI](#)**

Cancer Research UK have published [guidance for the use of generative AI in research](#), alongside a new [policy for their use in relation to funding applications](#). Broadly, they highlight two areas of potential concern for researchers: considerations about what goes *into* generative AI programs, and concerns around what comes back *out*.

In this blog Dr Andrew Porter guides researchers through the potential impact on research integrity and offers advice on how to keep up with the pace AI tools, regulations, guidance, and policy.

### **Recent and ongoing reviews we are actively involved in:**

#### **Commission from Lord Markham around Priority Innovation Initiatives**

Along with several fellow regulators, we are responding via DHSC to a commission from Lord Markham about priority innovation initiatives from across DHSC and its ALBs. Responses are being compiled by DHSC, and will cover owners, deadlines, the government forums they report into, a short description, and key milestones over the next three months. We have highlighted the work of the AI and Digital Regulations Services and commissioned work on secure data environments.

## Communications update:

- Concerns about a study approved by the HRA were mentioned in the Houses of Parliament as part of a debate on the government's vaccine damage compensation scheme. As well as responding to the complainant directly, we've published a news story on our website which makes it clear what's within the scope of the HRA when complaints and concerns are raised with us, and how and when we take action. We are also supporting the REC that approved the study, to keep them in the loop.
- An increasing number of complaints and concerns are being raised via social media. We are updating our customer charter so we're explicit about the expected behaviour of people who engage with us via these channels, and the action we will take if needed.
- There has been an excellent response to the [launch of our hallmarks and principles of People Centred Clinical Research](#), with stakeholders sharing these widely and generating engagement by promoting via their own products and channels.
- A new clinical trials email bulletin has an engagement rate of more than twice the benchmark, almost 75%. The bulletin, intended to provide a single subject update on our work on clinical trials, was short and shareable and after one edition has increased its subscriber list by more than 200%, showing a desire for this sort of communications from the HRA.

## Key recent activities:

Below are some highlights of recent and upcoming external activities we are involved in. The full detail of these activities – as well as the rest of our external engagements – will be provided in the full Strategic Engagement paper for the January Board.

- We recently (9 November) attended the [International Accrediting Organization of Clinical Research's Clinical Research Industry Leaders Think Tank](#) in Liverpool. Matt Westmore gave the opening keynote, covering the role of the HRA and regulators in general in enabling innovative research. Kate Greenwood joined a panel focused on improving UK clinical research delivery.
- Janet Messer, Clive Collett and Catherine Blewitt attended (3 November) an in-person workshop hosted by the MHRA around the updates to clinical trials regulations, which we are partners in leading. The workshop sought views and input from stakeholders around a proportionate and flexible regulatory environment, and a regulatory framework that is streamlined, agile and responsive to innovation.
- Jane Morrin O'Rourke attended the [New Stateman's Future of Healthcare Conference](#) on 31 October, an annual event to discuss policy issues in health and social care. This year's conference focused on health inequalities, the role of data and technology in the NHS, and combatting health misinformation.
- Naho Yamazaki attended the [Clinical Data Disclosure Europe event](#) in Amsterdam (11 November). We presented on transparency, trust in research, upcoming changes to regulatory requirements, and shared newly-collated and analysed data around transparency performance and the clinical trial registration audit.

### Upcoming activities:

- Jane Oakley will present at the UK Clinical Research Collaboration Clinical Trials Unit Network directors bi-annual meeting on 17 November about the HRA's plans and priorities around public involvement and to discuss involvement practice within CTU networks.
- Becky Purvis will attend the [2023 FORUM Sir Colin Dollery Lecture](#), hosted by the Academy of Medical Sciences, on 23 November. The lecture is entitled 'How to innovate in health – applying implementation sciences', and will include a roundtable discussion.
- We will attend Moderna's parliamentary event on 27 November, where they will share the insights they have gathered from engagement with leaders and community groups with parliamentarians.
- Terence Stephenson has been invited to and will attend the Academy of Medical Sciences-Health Foundation dinner (4 December) to explore how the health and life sciences sectors can work together to strengthen the UK's approach to AI in healthcare.
- We will attend an in-person workshop on 7 December, hosted by the Earl of Minto (Minister for Regulatory Reform), to discuss the [call for evidence launched by the Department for Business and Trade](#) into the regulatory landscape as part of the Government's Smarter Regulation programme.