Health Research Authority

Agenda item:	7
Attachment:	**A**

HRA Board paper

17 May 2023

Title of paper:	**Strategic performance report: Quarter 4**
Submitted by:	Karen Williams, Deputy Chief Executive and Director of Resources
Summary of paper:	To provide the HRA Board with a review of strategic performance
Reason for submission:	For approval
Further information:	The paper presents the performance of the HRA in delivering the strategy. It focuses on four key areas: • Our people • Our customers and stakeholders • Our services • Finance It also provides an overview of activity since the last report, commentary on the external environment, key strategic risks and issues and the outlook for the next period. The report includes the most recent data available. For this meeting, we report on performance for quarter three. This report provides a high-level strategic dashboard as well as a more detailed performance report to the Board.
Budget / cost implication:	N/A
Dissemination:	Published on HRA website with Board papers
Time required:	10 minutes

Strategic performance report: Jan 2023 - Mar 2023

High level dashboard

Staff capacity

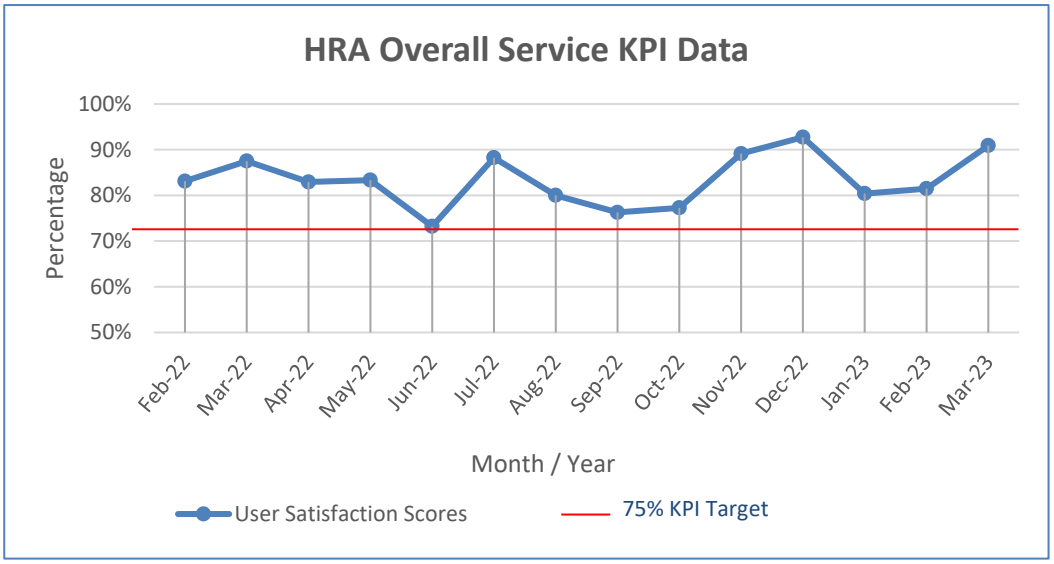
Apr/May: 92%; Jun/Jul: 85%; Aug/Sep: 86%; Q3: 84%; Q4: 84%

Maximum target: 91%.

Staff capacity has decreased this year reflecting tough external workforce environment and cost of living pressures requiring economies to meet fixed funding.

⇆

Customer satisfaction



Customer satisfaction outperforms our target of 75% throughout the period and achieved a significant improvement in March (91%).

⇆

Ethics review of CTIMPs

Median time to complete full review *34 days*

Proportion of full reviews completed in 60 days *97%*

97% (100 out of 103) combined review CTIMPs were reviewed within 60 days.

⇈

Forecast expenditure within 4% of funding

Overall	*Research systems programme*
✓	✗

Our forecast position is within 4% of funding allocated excluding our research systems programme which has been paused this year, with expenditure deferred to future years.

⇊

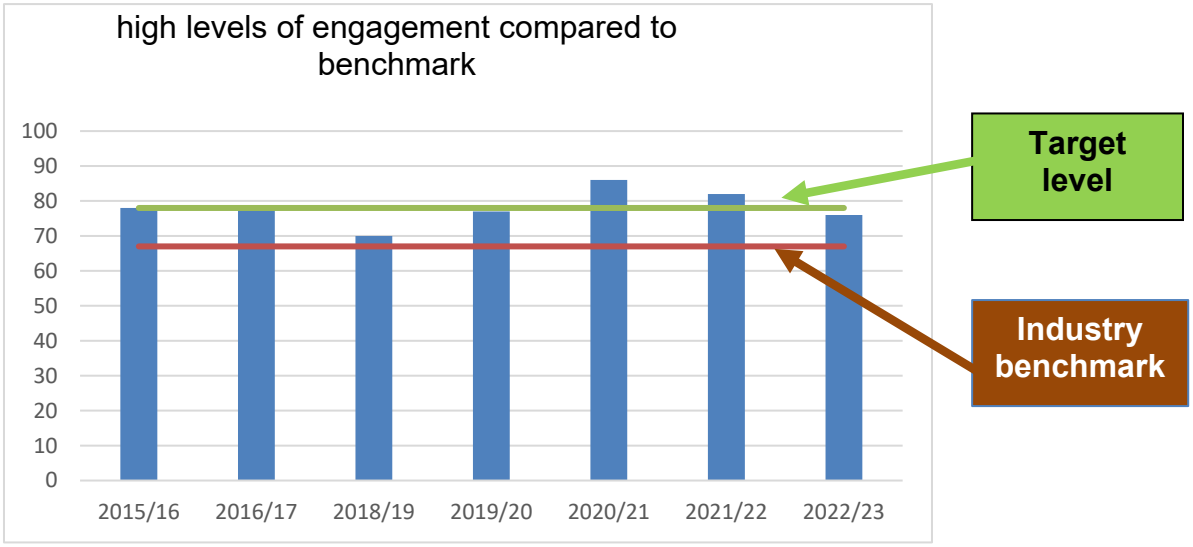
Strategic risk update

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
HRA1	**Research Systems -** The HRA is unable to deliver transformed research systems as it does not have the capacity to deliver a complex programme with multiple connections and dependencies across several organisations and is unable to understand or meet the requirements of the health research community.	**20**	**8**	↔	Appointment of delivery partner during initial procurement process (September 2022) not achieved. Further procurement process underway. Due to this delay the residual likelihood score increased in Q2 and remains as 20 for Q3 until a delivery partner is appointed.
HRA3	**Reputational -** The HRA has very low representation from individuals with protected characteristics at Board and senior management and is not representative of society and therefore risks making decisions that do not take account of a diverse range of views and undermines its effectiveness in meeting its public sector equality duty.	**6**	**6**	↔	Community Committee approved at January Board meeting. Community Committee to be established in HRA Standing Orders and recruited to in Q4.
HRA4	**Reputational -** The reputation of the HRA is adversely affected with fewer participants choosing to take part in research because of the HRA failing to perform its statutory functions, or an adverse event occurring resulting from the decision of a Research Ethics Committee, or poor research practice taking place or from lack of public involvement / influence within the HRA.	**8**	**8**	↓	Reduction in score due to a reduction of frequency, scale and risk of 3rd party complaints in recent weeks. Community Committee to be established will support the trust of the public.
HRA5	**Reputational -** There is a perception that the HRA is not prioritising the most important areas of improvement to the research landscape or is not communicating appropriately the success of programmes to external stakeholders.	**8**	**8**	↔	Business planning sessions held including involvement of HRA community in workshop to shape future direction and priority areas.

HRA6	**Information -** Risk to the operational delivery of the HRA due to a successful and destructive cyber-attack causing loss of systems, loss of data, damage to reputation.	**6**	**4**	↔	Although good controls are in place risk escalated to Board due to continued international cyber activity. GIAA cyber security audit recommendations incorporated into existing controls.
HRA7	**Regulatory –** There is a risk the HRA could be closed or merged with another ALB impacting on the delivery of our strategic vision for high quality health and social care research today, which improves everyone's health and wellbeing tomorrow.	**4**	**4**	↔	Working with DHSC and other ALBs as part of DHSC ALB landscape review to look at opportunities for efficiencies across ALBs. HRA Board seminar held in January 2023 regarding future scenario planning.

Our people

Staff engagement (based on annual staff survey) Industry benchmark



HRA staff 76% (target: 78%) (shown in green above)

Industry benchmark: 67% (shown in brown above)

March 2023

⇊

Staff capacity

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Maximum target: 91%.

Staff capacity has decreased this year reflecting tough external workforce environment and cost of living pressures requiring economies to meet fixed funding.

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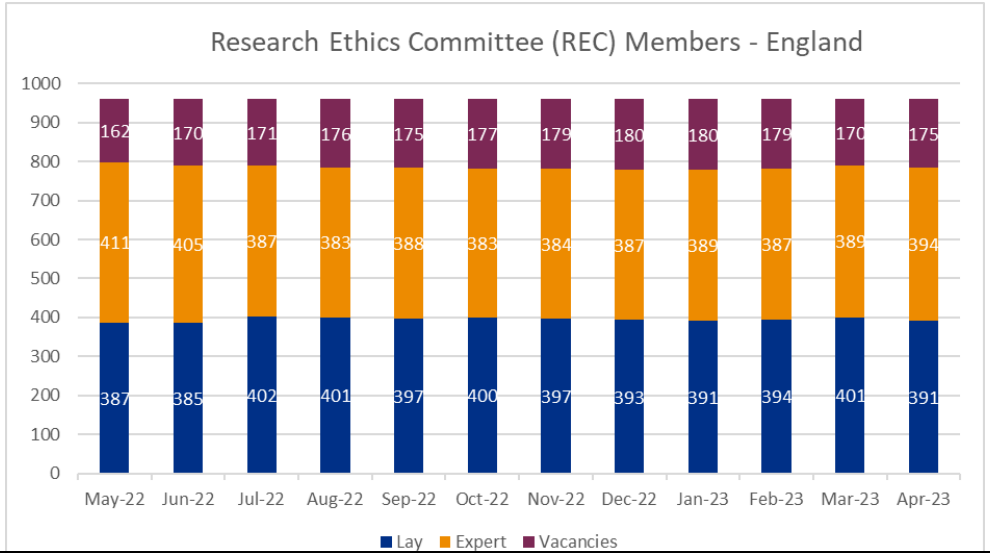
Research Ethics Committee (REC) members (England only)



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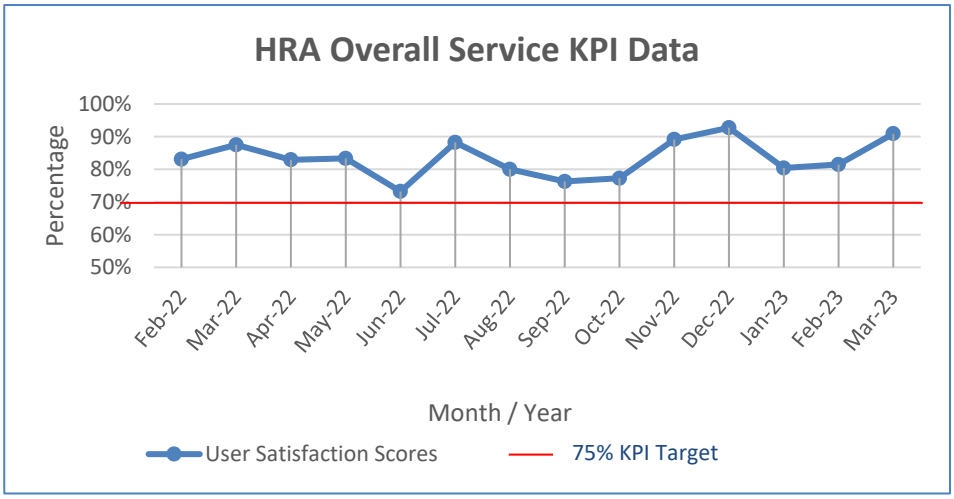
Vacancies: Based on 15 members per REC, target membership is 960. The chart above shows at the end of April 2023 we had 782 REC members of which 394 were expert and the service was operating with an 18% vacancy rate.

Membership: Expert members are members with who are registered health and social care professionals or members with expertise in clinical research. At the end of April 2023, 14% of RECs had five or less expert members, none had less than 4 expert members.

Recruitment activities
In March 2023, we started a recruitment campaign to recruit lay plus members to ensure RECs are correctly constituted in line with GAfREC and the Clinical Trials Regulations. By the end of April 2023, we had received 127 applications (34 expert, 43 lay and 50 lay plus).

Our customers and stakeholders

Customer satisfaction



Customer satisfaction outperforms our target of 75% throughout the period and achieved a significant improvement in March (91%).

Finance

Forecast expenditure within 4% of funding

Overall	Research systems programme
✓	✗

Our forecast position is within 4% of funding allocated excluding our research systems programme which has been paused this year, with expenditure deferred to future years.

Approvals service

Number of applications for HRA Approval

April 2019 – March 2020:	4739
April 2020 - March 2021:	4006
April 2021 - March 2022:	4148
April 2022 - March 2023:	3961

Number of applications for REC review only

April 2019 – March 2020:	1009
April 2020 - March 2021:	927
April 2021 - March 2022:	868
April 2022 - March 2023:	814

Long-term trends indicate new applications reduce by approximately 6% each year. Application numbers dropped by more than this during COVID-19 except in 2021/22 when we received a surge in applications for REC review only. These applications are now back to the numbers we would expect. This is due to phase 1 healthy volunteer studies returning to pre-pandemic levels balanced by a greater reduction in student applications compared to long-term trends following changes we made to eligibility criteria.

Ethics review of combined review CTIMPs (England only)

Combined review CTIMPS	**Oct-22**	**Nov-22**	**Dec-22**	**Jan-23**	**Feb-23**	**Mar-23**
Median time to complete full review	41	40	36	38	34	30
Full reviews completed in 60 days	85%	95%	95%	93%	100%	100%
Full reviews completed in 60 days	47	64	41	42	38	23
Total completed	40	61	39	39	38	23
Studies Submitted for Review	76	77	47	58	77	61

Combined review

Combined review is the way research teams seek approval for new Clinical Trials of Investigational Medicinal Products (CTIMPs) and combined medicine and device trials. Several bodies are involved in the review including the Medicines and Healthcare products Regulatory Agency (MHRA).

For statutory timelines applicable to the HRA, 97% of applications are processed within 60 days in the three months to 31 Dec22. These timelines reflect the time taken to provide an ethical opinion only. Applicants have been experiencing significantly longer timelines before receiving their joint approval due to the backlog and delays at the MHRA.

Three combined review CTIMPs were not approved within 60 days during the reporting period, all in January. In all three applications, the response to the RFI was received during the Christmas/New year period and so the review was delayed.

Fast-track Ethical Review (combined review, non-COVID-19 studies)

Fast Track ethical review	Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23
Median time to complete full review*	22	24	23.5	30	31	19.5
Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	6	15	10	8	7	9
Total completed in 60 days	6	15	10	8	7	9
Studies submitted for review	15	16	14	13	19	13

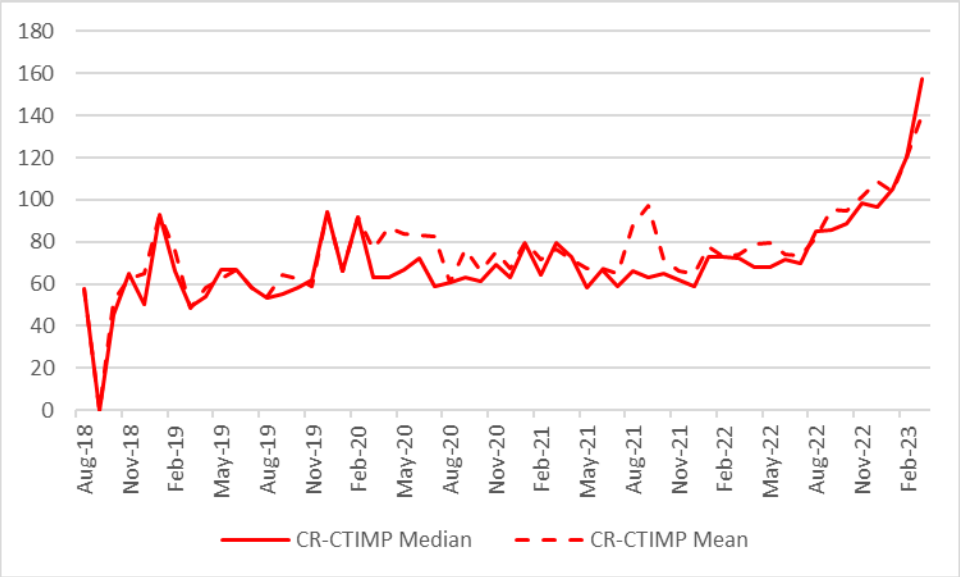
Fast-track combined review studies have comparable timelines to non-combined review studies for REC review. Phase I trials MHRA have a shorter timeline for review that aligns with our fast-track timeline. From Aug22 fast-tracked applications are reviewed as part of the existing ethics service. Median times given are for the ethics service element of our combined review service and do not reflect the time taken to issue the joint decision. The combined outcome of the process has been delayed in recent months due to delays at MHRA. Data (both median times and number of studies completed) is only shown for studies that do have a joint outcome – it is not possible to report on studies until the joint outcome is issued. More studies have been submitted for fast-track review than have been approved – MHRA delays are part of the reason but delays in applicants responding to the request for information (RFI) is also a factor.

HRA Approval

For HRA and HCRW Approval in England and Wales, the graph below shows the median and mean elapsed timeline for applications from submission to approval (no clock stops) for CTIMPs. Applications withdrawn or invalid have been omitted from the data set. Combined review median normally maps closely to mean showing a more predictable process, but divergence over summer 2021 shows that a small number of outliers (caused by IT issues and staff familiarising themselves with the new process) affected predictability. Steps have been taken to address these anomalies in the process and the median is once again mapping closely to the mean, showing a more consistent process.

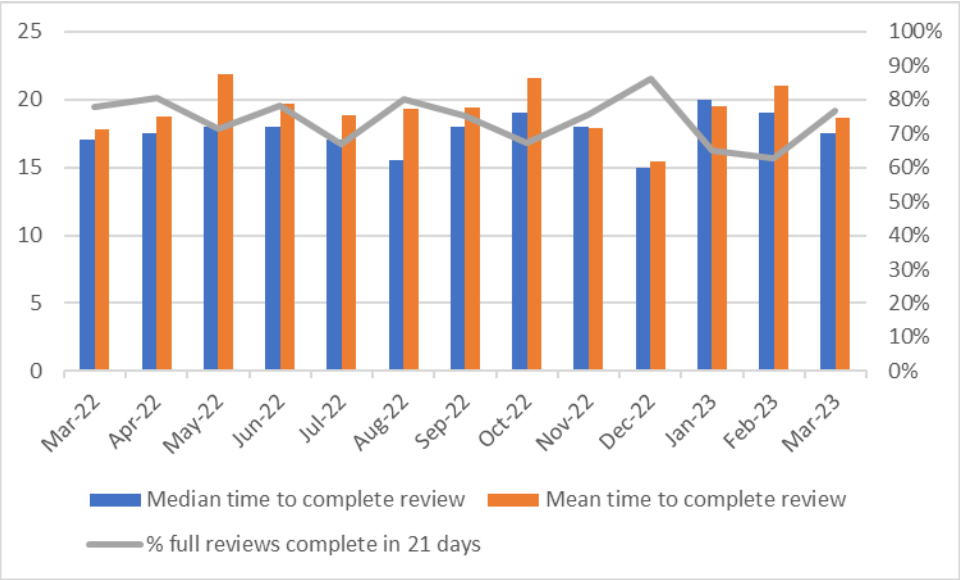
HRA Approval timelines for CTIMPs have risen since August 2022. There are two factors causing this rise

- pressure on REC slots (exacerbated due to the closure of the Fast Track REC during 2022 and the need to place these applications with other appropriately flagged RECs) meaning applications are seen at a later REC meeting. We are introducing a seasonal REC to help manage surges in applications as busy times.
- delays with the MHRA issuing joint outcomes. There are currently significant delays at the MHRA, both with the initial assessment of a CTIMP and issuing the joint outcome at the end of the process. To mitigate these as much as possible for applicants we have begun to send any points raised by the REC or Specialist independently of the MHRA. Although applicants do need to wait for the RFI before they can respond it does allow them to start work on their response while the MHRA are still assessing the study. Applicants are aware of these delays and are approaching us to see if we can expedite them. We are assisting with this wherever possible, particularly if there are sites ready to go and the MHRA delays are holding them up.



Proportionate Review (PR)

For applications suitable for proportionate review the final opinion from the REC should be issued within 21 days (minus any time the clock is paused for a provisional opinion). The Approvals Team are continuing to monitor the timelines and several factors have helped with this; changes to how Approval Specialists are assigned applications has smoothed their workflow allowing quicker validation, REC teams have a greater focus on timelines for this type of application, fully trained Approval Administrators are able to fulfil their part of the process with minimal supervision. Further changes such as the sharing of a PR toolkit externally as well as ensuring a more even distribution of REC PR meeting dates are ongoing with the aim of increasing performance further. Performance has steadily increased in the last quarter with 86% of applications receiving a final opinion within 21 days in December. Performance did drop in January and February, primarily due to the influence of the Christmas/New Year break on these applications.



Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	23 days	2
May	33 days	8
June	28 days	6
July	29 days	8
August	33 days	10
September	24 days	9
October	39 days	8
November	22 days	5
December	32 days	9
January	26 days	11

Month	Days from application to completion	Number of applications
February	27 days	3
March	34 days	6

Applications in progress that have exceeded target times: None

RAG Status criteria

Staff engagement	green >76%, amber 68%-75%, red <68%
Staff Capacity	green over 90%, amber 80%-90%, red <80%
REC membership vacancies	green <5%, amber 6%-14%, red >14%
Customer satisfaction	green >76%, amber 68%-75%, red <68%
Ethical review of CTIMPs (both the combined and non-combined processes)	green > 94%, amber 90%-94%, red <90%
Finance	Green +/- 4%, amber +/- 10%, red +/- 15%

Strategy delivery – interim report, Qtr4

2022/23

Include: Health and social care research is done with and for everyone	**G**

Include everyone in research:
We have published a webpage, working closely with MHRA, setting out why it is important to increase the diversity of people taking part in research and signposting resources to help researchers to do this. We have firmed up our plans to take this work forward over the coming year with the development of a diversity and inclusion template to be completed by applicants and have initiated discussions with partners about this approach. Following the government response to the consultation on changes to clinical trials legislation, we will be speaking with stakeholders on the use of this template for clinical trials of medicine along with a supporting guidance.

The Shared commitment to public involvement signatories marked the first anniversary of the commitment on 10 March by sharing information about their progress, reflections on the first year and what they plan to do next online – you can read about the impact of the commitment here . The signatories are meeting in April to agree how they will work together to embed public involvement in health and social care research over the next year.

The Make it Public campaign held the first transparency week in March 2023, with speakers including Professor Lucy Chappell is Chief Scientific Adviser to the Department of Health and Social Care and the publication of an annual report demonstrating progress and sharing best practice on 1) feeding outcomes back to participants, 2) publishing summary results of trials, and 3) raising awareness of research opportunities. There were over 300 attendees at our events during the week, as well as a high-level of engagement online. Work is also underway to develop guidance to support transparency requirements to be introduced in new legislation governing clinical trials, following the government response to the consultation on these changes. This includes developing and agreeing ways to take action where researchers and sponsors do not fulfil their research transparency responsibilities.

Ask you what you want research to look like and act on this
We are preparing to conduct a survey of public attitudes to research, to better understand what matters most to people in research. We will use these findings to inform our work going forward to address the issues that are important to earn people's trust in research.

We are working with partners to take forward work to help make clear how people will be treated if they lose capacity while taking part in longitudinal research.

The survey asking for people's view on proposed hallmarks of people-centred research that were developed by our steering group has closed. We received 415 responses and 1 organisational return and have now held 4 group conversations and continue to try and arrange this with groups we know we haven't heard from (seen in the demographics

collected). Some data has been analysed and draft recommendations presented to the steering group. Further analysis of the qualitative data is underway with a view to the steering group agreeing the hallmarks and recommendations for how to make them a reality in July. Work to embed the findings and the hallmarks will continue in the next year to ensure we bring change.

Involve you in the HRA
Proposals to establish a Community Committee were approved at our January Board meeting. Work is now underway to establish the Committee, with a plan to open applications in May 2023.

We have involved members of the HRA Community – including Research Ethics Committee members, members of the Confidentiality Advisory Group and members of the public who work with us through the Public Involvement Network – in the development of our 2023-24 business plan and annual report of 2022-23, including through a meeting with staff on 31 January 'making decisions about what we do next year'. We are improving how we meaningfully involve members of the public in our recruitment processes and are developing more resources for all staff to be confident to identify where public involvement may be appropriate to help us make better decisions and can access practical support to help them do this. This included holding a session for staff who have successfully involved the public in their work to share their experiences and insights with colleagues.

Work continues to develop the HRA Website so that we talk about what we do and why it matters in a way that everyone can access and understand.

Accelerate: Research findings improve care faster because the UK is the easiest place in the world to do research that people can trust.	**G**

Save money and time so that you can focus on doing good research
External factors affecting the review of clinical trials by MHRA, and the set-up of studies in the NHS have continued to impact on the wider delivery of clinical research. HRA have continued to be proactive in giving visibility of the outcome from the Research Ethics review so that applicants can prepare for the receipt of the formal Request for Information from MHRA. We also continue to work closely with MHRA as they make the necessary arrangements internally to address their resource pressures. We have continued to contribute to the wider NIHR processes to reset the portfolio of research, which is now beginning to see improvements to the number of studies progressing through the processes on schedule.

We continue to support the roll out of the National Contract Value Review Service with NHS England and NIHR Clinical Research Network. All new commercial contract trials are making use of the review by a national coordinator, and further steps in the roll out are being planned.

We continue to sponsor a project with the Experimental Cancer Medicine Centres to radically reduce the set-up time for clinical trials through these centres. We participated in

a workshop with a multi-disciplinary group of staff from the centres, and are now planning the follow-up actions with Cancer Research UK.

We have been planning next steps following the discovery work and public conversations that we undertook during our Think Ethics programme. A key area will be the implementation of new principles and standards for participant information. We will start by working with our Research Ethics Committees to develop a consistent approach to the review of participant information, so that researchers can better plan and prepare information that will be right first time.

Create a new online system to help you make research happen
Work on business process redesign for development of IRAS continues alongside the wider work on our digital systems. We continue to engage with users to test opportunities for improvements to our proposals for ideal path through the research journey. We have completed drafting a toolkit to support researchers conducting projects across more than one UK nation. This will provide an interim resource until we are able to support researchers to navigate the UK approval service through IRAS. This is now being reviewed through UK-wide groups.

Support new ways to do research
Following our work with public contributors and through a survey to identify the hallmarks of people-centred research, we are now planning to set up a group of researchers to develop and disseminate practice around innovative people-centred ways to conduct research.

We are working with colleagues in NHS England to support the development of the network of sub-national Secure Data Environments, to support new data-driven research.

Digital: Use digital technology well to do our work	**R**

User experience and engagement is at the heart of digital design.
Digital is currently showing red largely due to the risks it is tracking around securing a new delivery partner and associated DHSC investment committee approval for the RSP business case, plus the legacy infrastructure work to ensure business continuity**.** Positive steps are being made in several areas underpinning foundation work:

User experience and engagement is at the heart of digital design.
We have progressed our delivery partner procurement to help us design and build our digital systems in a human-centred way, to the stage that we are now seeking DHSC Investment Committee approval.

On 15 March, DHSC Investment Committee informed us that they had decided to delay approval of the RSP refreshed business case pending the outcome of an Infrastructure & Projects Authority's (IPA) Gateway '0' Review: Strategic Assessment.

The Gate Review process gives independent guidance to Senior Responsible Owners (SROs), research systems programme team and to DHSC who commission our work, on how best to ensure that our programme is successful. The review involved a mix of internal and external stakeholders being interviewed 27-30 March, and the final report was delivered 3 April.

HRA will be looking to implement the eight Review recommendations including filling the CDTO post permanently as soon as possible, and appointing a further five roles to ensure the HRA is able to act as an intelligent client. This will ensure our programme is established correctly.

Process automation and integration improves our work
Draft requirements have now been completed to move to an IT Service Management System (ITSM) for our research systems Helpdesk. Next stage is to present the requirements and the proposed phased implementation process to the Digital Strategy & Prioritisation Board for further approvals.

The data management workstream has moved into the second stage of option development, enhancing the details of each option for improving rigour around open/closed research applications and the housekeeping of inactive closed studies to archive, to ensure we have an accurate record of study status for HRA and the IRAS Partners.

Work continues to meet Category 1 assertions within the Data Security & Protection Toolkit (ALBs re-categorised this year, up from Cat. 2, meaning we're now measured against the most rigorous information security controls within DSPT), as does work with critical suppliers to address cyber risks, resulting in additional process and technical controls to improve our cyber resilience. Modern Desktop 2 rollout completed, reducing the HRAs attack surface via improved patching and the application of more stringent security policies.

Improve: Ensuring we have the right culture and capability to deliver our strategy	**A**

Continuously learn, improve and innovate.
Our leadership competencies and behaviours are drafted and will be discussed at People Group in April 23 ahead of the roll out in 2023/24. This builds on the successful launch of our 70:20:10 blended learning approach and the decision to move our learning platform to National Institute for Health and Care Research (NIHR) learning platform for members and staff.

We are building our confidence to have inclusive conversations with nine sessions delivered this year and fifty-one equality impact assessments (EIAs) completed and reviewed using the improved template. 51% of these assessments are new EIAs and 28% are updated Human Resources (HR) policies. Extending the EIA process beyond HR policies has meant we are making a positive impact on equality across the organisation.

Our new innovation and change delivery model is being fine-tuned following the initial workshop in 2021/22 and discovery conversations launched in June 2022. Richard Cooper, Non-Executive Director (NED), is confirmed as our innovation champion. In addition, we are improving our collective intelligence by changing our approach to planning, widening involvement and using different approaches (for example scenario planning) to look at strategy planning.

Our refreshed staff forum launched in January 2023. The group improved its membership and is focusing on staff well-being and innovation.

Be a great place to get involved and work.
Richard Cooper (NED)) is wellbeing champion for the HRA and we grew our Mental Health First Aider support with twenty-seven calls received. We also approved and published pay transparency guidance and revised our recruitment policy with a greater focus on equality, diversity and inclusion.

Social value was built into the evaluation process for the research systems delivery partner commercial exercise. We improved our commercial processes by implementing Atemis, a contract management system. This will help improve consistency of our processes and record keeping. Training has been developed (2 15mins sessions) to support the rollout of SharePoint and how it supports our records management policy. This includes how we manage third party providers. This is being piloted with Resources Directorate before the full roll out in 2023/24.

Strategic people planning has been deferred to 23/24 due to unexpected strategic recruitment pressure in the team. In addition, wellbeing related learning modules have had to be deferred to 23/24 again due to capacity challenges in the team.

Be committed to environmental sustainability and achieving net zero.
We have reorganised the team to increase capacity to launch and monitor our sustainability strategy without additional cost. The new post holder is working with DHSC sustainability lead and our Green Team to refresh our sustainability strategy.

We continue to maintain our travel and accommodation at over 60% reduction at pre-pandemic levels and limited our domestic flights to essential travel only. Green team launched a staff awareness programme of activities in September to encourage more sustainable living. We developed an easy guide to booking environmentally sustainable transport which will help our people make good choices when choosing business travel.

Four out of five of our offices offer at least 4 different types of recycling on site. Plans are in place to make this all offices in 2023/24.