Health Research Authority

Agenda item:	7
Attachment:	**A**

HRA Board paper

15 March 2023

Title of paper:	**Strategic performance report: Quarter 3**
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. The Board is also requested to consider the information provided in the report and consider if any further information would be beneficial to support the Board's understanding and decision making.
Budget / cost implication:	N/A
Dissemination:	Published on HRA website with Board papers
Time required:	10 minutes

Strategic performance report: Quarter 3 2022 - 2023

High level dashboard

Staff capacity

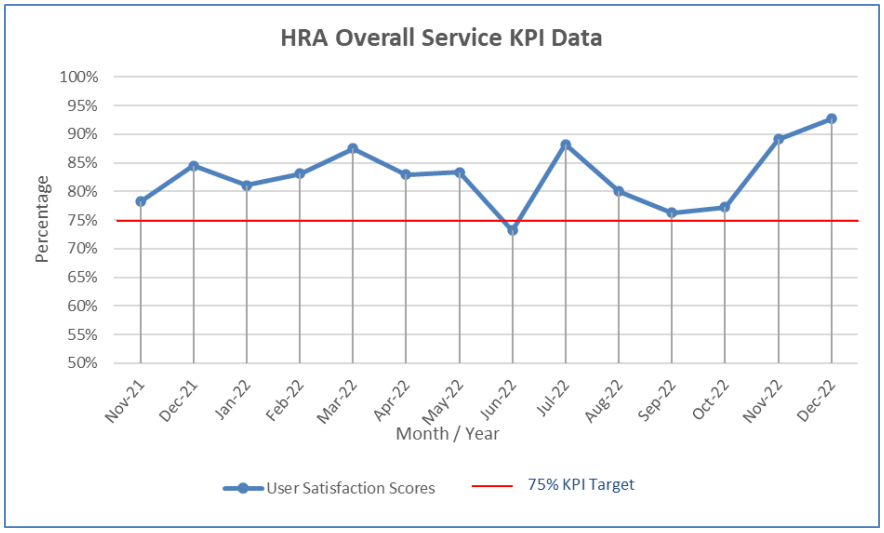
Apr/May: 92%; Jun/Jul: 85%; Aug/Sep: 86%; Q3: 84%

Maximum target: 91%.

Staff capacity has decreased over the year reflecting tough external environmental for recruitment. This is being closely monitored to ensure HRA has capacity to deliver our strategy and statutory functions.

⇆

Customer satisfaction



Customer satisfaction outperforms our target of 75% throughout the period and achieved a significant improvement in November (89%) and December (93%).

⇆

Ethics review of CTIMPs

Median time to complete full review 35 days

Proportion of full reviews completed in 60 days 92%

92% (138 out of 150) combined review CTIMPs were reviewed within 60 days.

⇊

Forecast expenditure within 4% of funding

Overall ✓

Research systems programme ✓

⇆

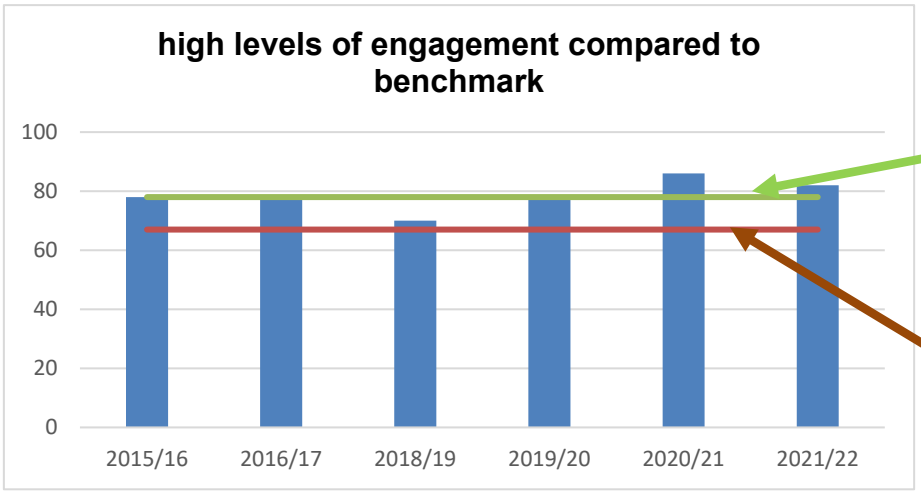
Our forecast position (based on our revised estimates for research systems business case) is within 4% of funding allocated. £0.6M forecast deferred spend on research systems and £0.4M related amortisation underspend due to programme pause.	

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 a number of 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 procurement 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	**8**	**8**	↔	Business planning sessions held including involvement of HRA

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
	research landscape or is not communicating appropriately the success of programmes to external stakeholders.				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.
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 82% (target: 78%) (shown in green above)

Industry benchmark: 67% (shown in brown above)

March 2022

↑↓

Staff capacity

Apr/May: 92%

Jun/Jul: 85%

Aug/Sep: 86%

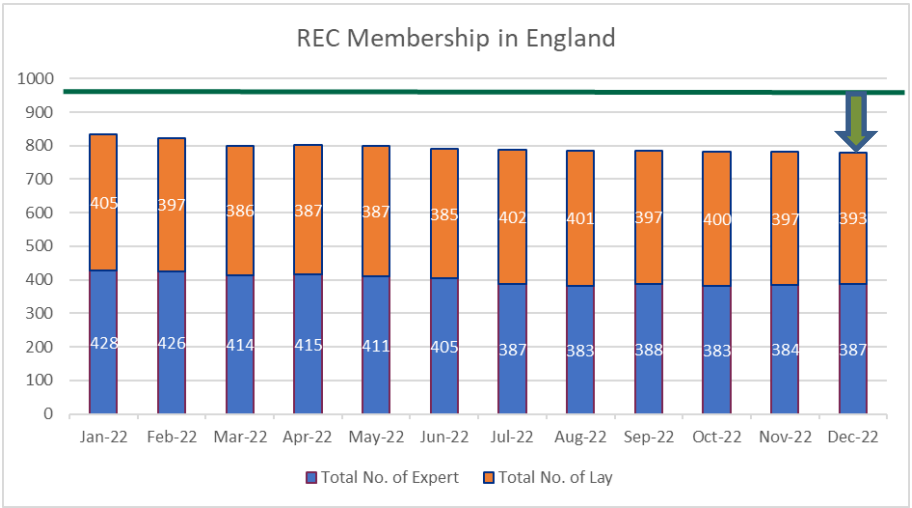
Q3: 84%

Target: 91%

Staff capacity has decreased over the year reflecting tough external environmental for recruitment. This is being closely monitored to ensure HRA has capacity to deliver our strategy and statutory functions.

↑↓

Research Ethics Committee (REC) members (England only)



Optimum number 960

Member vacancy rate 19%

↑↓

Vacancies: Based on 15 members per committee, the target REC membership is 960. The chart above shows at the end of December we have 780 members of which 387 are expert, representing 19% member vacancy rate.

Membership: Each REC has expert members to give technical expertise about research to the committee for the types of research considered by the REC including

- methodological and ethical expertise in care settings
- relevant fields of care, and
- professional expertise as care practitioners.

UK Clinical Trials Regulations define expert members as registered healthcare professionals and experts in clinical trials. Lay members are equally as important for committee effectiveness with lots of experience in health and care research e.g. retired nurses, pharmacists and other retired healthcare professions.

We monitor several key factors in our membership including those committees with five or less experts.

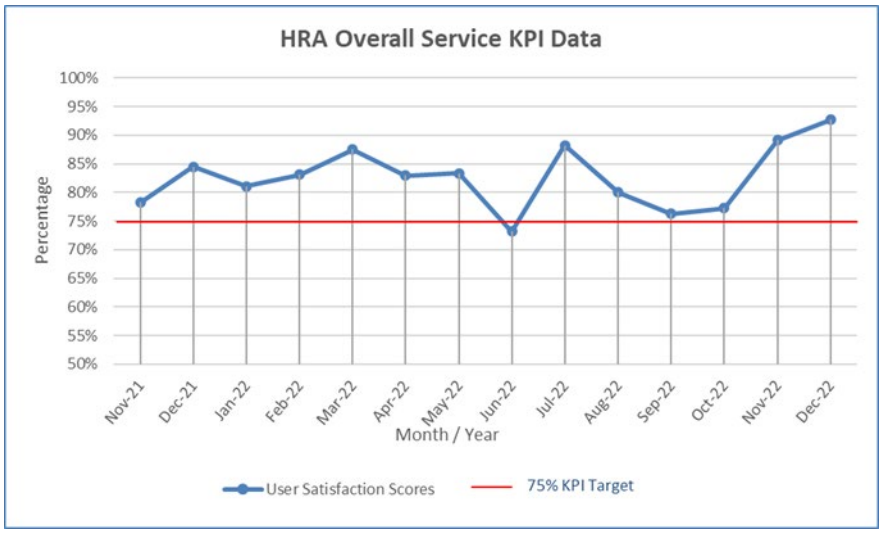
- percentage of RECs with more than 6 experts: 67%
- percentage of RECs with between 1 and 5 experts: 33%
- percentage of RECs with 0 experts: 0

Recruitment activities

Apr22: NHS Pensions newsletter & University medical schools
Aug & Sep 22: Writing to Royal Colleges, trusts and universities
Application packs requested in quarter 3: 247. Applications received 43

Our customers and stakeholders

Customer satisfaction



Customer satisfaction outperforms our target of 75% throughout the period and achieved a significant improvement in November (89%) and December (93%).

Finance

Forecast expenditure within 4% of funding

Overall	Research systems programme
✓	✓

Our forecast position (based on our revised estimates for research systems business case) is within 4% of funding allocated. £0.6M forecast deferred spend on research systems and £0.4M related amortisation underspend due to programme pause.

Approvals service

Number of applications for HRA Approval

April 2019 - December 2019:	3566
April 2020 - December 2020:	2918
April 2021 - December 2021:	3084
April 2022 - December 2022:	2959

Number of applications for REC review only

April 2019 – December 2019:	751
April 2020 - December 2020:	674
April 2021 - December 2021:	667
April 2022 - December 2022:	600

Long-term trends indicate new applications reduce by approximately 6% each year. Application numbers dropped by more than this during COVID-19. In 2021/22 we received a surge in applications for REC review only. They 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	**Jul-22**	**Aug-22**	**Sep-22**	**Oct-22**	**Nov-22**	**Dec-22**
Median time to complete full review	38	35	37	41	40	36
Full reviews completed in 60 days	97%	98%	94%	85%	95%	95%
Full reviews completed within 60 days	62	57	47	47	64	39
Total completed	60	56	44	40	61	37
Studies Submitted for Review	68	40	71	77	79	47

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, 92% 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.

Twelve combined review CTIMPs were not approved within 60 days during this quarter. In eight of these applications the principal reason for this was reduced meeting availability over the summer months following the absorption of Fast Track service into general REC service on the cessation of Fast Track funding and the continued effect that this has had on bookings since then. We are planning to introduce a seasonal REC this year to stop this happening again. This will provide us with more capacity in our peak times (Jan, Apr, Jun, Jul, Aug and Dec).

Two applications were delayed due to the chair's other commitments and two applications were delayed due to HRA staff not processing applications in the correct timelines. Increased tracking and management of studies is in place however these two applications

were missed due to the unusual circumstances. These issues have been addressed and additional training provided.

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

Fast Track ethical review	Aug-22	Sep-22	Oct-22	Nov-22	Dec-22
Median time to complete full review*	16	28	22	18	21
Full reviews completed in 60 days	100%	100%	100%	100%	100%
Total completed	2	3	6	10	8
Total completed within 60 days	2	3	6	10	8
Studies Submitted for Review	4	12	14	14	14

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.

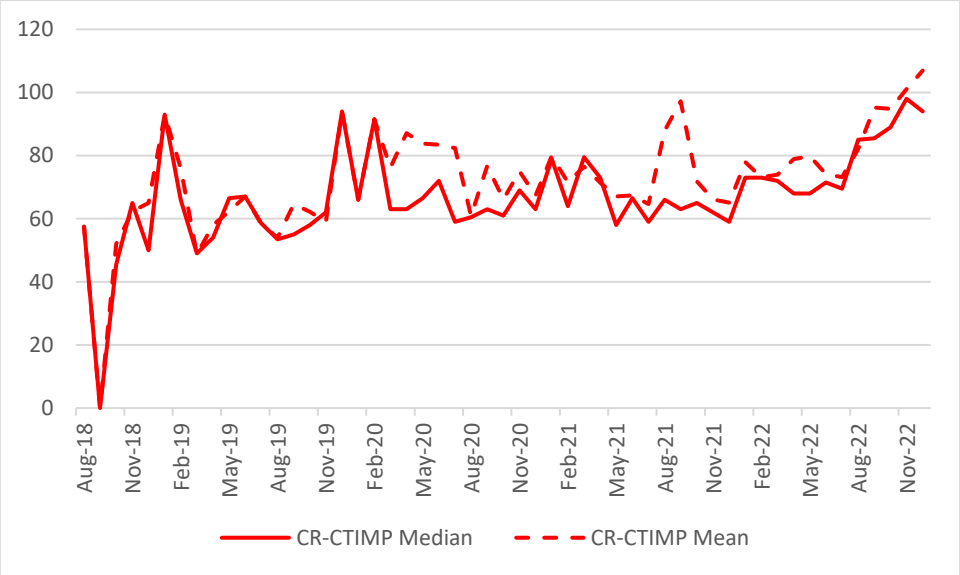
HRA Approval

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

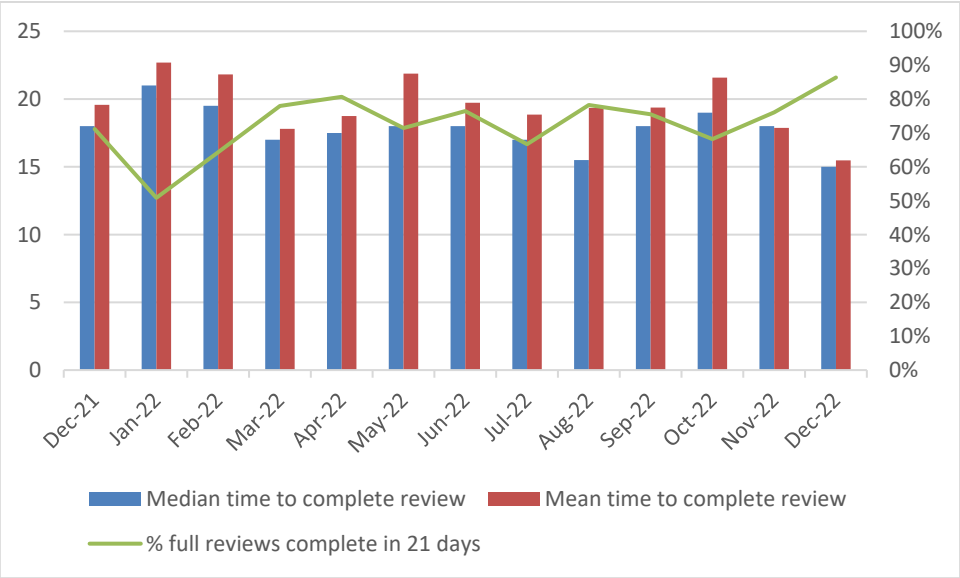
- pressure on REC slots (exacerbated due to the closure of the Fast Track REC during the summer and the need to place these applications with other appropriately flagged RECs) meaning applications are seen at a later REC meeting.
- delays with the MHRA issuing joint outcomes. There are currently significant 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.



Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	23 days	3
May	33 days	9
June	28 days	7
July	29 days	13
August	33 days	10
September	24 days	11
October	39 days	8
November	22 days	8
December	32 days	11

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, Qtr3 2022/23

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

Include everyone in research:

We continue to work closely with MHRA developing resources to support greater diversity and inclusion of research participants. We are also working closely with them to propose changes to clinical trials legislation following a consultation on proposals requiring public involvement, transparency and diversity and inclusion – the government response to this consultation is expected to be published in the coming months.

The Shared commitment to public involvement signatories are working together to shape plans to mark its first anniversary in March. Each signatory will publicly share information about their progress against the commitments that they made. A meeting is being planned in April for all signatories to discuss next steps, identifying areas where they can work together to embed public involvement in health and social care research.

The Make it Public campaign continues to work to make transparency the norm and will hold a Make it Public week in March 2023 alongside the publication of its annual report which focuses on 1) feeding outcomes back to participants, 2) publishing summary results of trials, and 3) raising awareness of research opportunities. Work is also underway to develop and agree 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, in the process of procuring a supplier to do so. 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 design some public conversations to better understand views on the inclusion of people who lose capacity in longitudinal research.

The steering group looking at how to do a better job of putting people first in research has now met seven times. Building on the rapid review, the group have now overseen the launch of a survey to ask for people's views on the hallmarks of people-centred clinical research that the group have developed and their experiences of research, good and bad. This will be open until 17 February 23 and will inform the development of the group's recommendations for the HRA and wider sector about people centred research. We are focused on promoting this survey to reach a diverse group of people with different experiences to inform our work

Involve you in the HRA

We closed our consultation on proposals to establish a Community Committee, replacing the current HRA Community Insight Group to place the HRA Community (members of Research Ethics Committees, the Confidentiality Advisory Group and public contributors that are part of our public involvement network) within the HRA's governance and decision-making. We analysed the responses and prepared to share the findings publicly in the new year and discuss these with our Community Insight Group in early January, informing a proposal to act on these at our January Board meeting.

We discussed business planning at our November Community Insight Group meeting and began developing plans to involve members of the HRA Community and staff in a meeting on 31 January 'making decisions about what we do next year' that will inform our business planning. Resources have been developed to support teams to build in appropriate resources to support meaningful public involvement from the outset of business planning.

Work is underway to develop the HRA Website, with a public involvement officer to support this process appointed.

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

As noted in the performance sections above, the HRA Approvals team have been taking a range of actions to continue to improve performance, with positive impact on the timelines attributable to HRA. However, external factors are affecting timelines for study set-up as perceived by applicants. NHS sites continue to experience delays in site set-up due to capacity constraints across a wide range of services. Feedback suggests that some NHS organisations are refusing to start site set-up activities until after approvals are issued, which is compounding the delays experienced by clinical trial sponsors. We are working to identify these NHS organisations so that we can advise accordingly. MHRA also has a significant review backlog which they are working to address. HRA is supporting applicants facing delays by communicating the outcome of our reviews as an interim update before MHRA completes their review. This enables applicants to prepare their responses while waiting for the formal request for information.

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.

HRA continues to support cross-sector actions to reset the national research portfolio. HRA is supporting communication with sponsors, and checks on accuracy of data held in NIHR systems.

Create a new online system to help you make research happen

Work on business process redesign for development of IRAS continues alongside the work to procure a new supplier. Analysis of feedback from user research has now been completed and has been used to iterate the proposed question set. Further work on workflows and interactions with other parties is informing further iteration of the question set. We continue to engage with users to test opportunities for improvements to our proposals for ideal path through the research journey.

We have completed work reviewing the approach to bioresources in future development of IRAS with input from users and colleagues across the UK. We will now incorporate this into the proposed question set.

We have identified several potential future opportunities to improve our processes as a result of our Think Ethics work, and the public conversation that we have now completed. Although it is unlikely that we will complete the discovery and development of these options in time to incorporate into our initial development of IRAS, we are working to identify flexibilities that we should build in that would make it easier to implement improvements to our processes in due course.

Support new ways to do research

We continue to liaise with NHS England to support the embedding of research in the new Integrated Care Systems, particularly in relation to supporting new pathways for participants to be identified, recruited and followed up across different settings across the geography of Integrated care Systems.

We have begun exploring opportunities to support innovative research and have identified from feedback that those undertaking data-driven research are experiencing several issues in navigating research journeys.

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**. P**ositive 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. Subject to that approval, we anticipate beginning the onboarding period with the chosen supplier last week March/early April.

One of the early activities we'll complete will be a review of the May 2022 quarterly delivery roadmap to reflect changes that have happened across the programme since it was produced.

Process automation and integration improves our work
Head of Service Delivery has undertaken a service desk operation review and re-published incident and request, problem and change management processes. This work aligns the team to industry standard practice (ITIL) and forms the foundation for the next stage to move to an IT Service Management System (ITSM) for our research systems Helpdesk. Requirements are being drafted.

The data management workstream continues to work up options 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.

We are working towards meeting the latest Category 1 assertions within the Data Security & Protection Toolkit - our baseline assessment was submitted at the end of Feb. ALBs were recently re-categorised, from Cat. 2, so we now match the likes of Acute Trusts, meaning that we're held to the highest standards within DSPT; consequently we're adopting more rigorous information security controls.

We continue to work with critical suppliers to gain more insight into cyber risks and have accordingly implemented additional process and technical controls to improve our cyber resilience.

We have addressed a number of penetration test findings and are currently engaging prospective testing partners via G-Cloud, having just finished a two-year engagement with Jumpsec. We have a shortlist and are reviewing rates for a 1 year engagement, to support IRAS and New IRAS.

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

Continuously learn, improve and innovate

Our pilot of NIHR learning platform for members and staff has been successful. Digital Strategy Prioritisation Group approved the move to the platform this quarter, next steps will be to understand how and when we will deliver this move given other digital priorities. We have launched and are now embedding the 70:20:10 blending learning approach, enabling staff to be responsible self-directed learners.

We are also building organisational confidence to have inclusive conversations with 6 sessions delivered this year and 40 equality impact assessments completed and reviewed this year. 55% of the policy / procedure assessments were new EIAs and 28% were updated HR policies using the new template. A key benefit has been extending the EIA

process beyond HR and incorporating positive impact on equality across all functional areas.

Our new innovation and change delivery model is being fine-tuned following the initial workshop in 21/22 and discover conversations throughout the year. Richard Cooper, non-executive director, has been confirmed as the HRA's innovation champion. Innovation hive discussions are also being taken forward with multiple groups and HRA Voices (staff forum) have taken on innovation as one of their main focus areas. In addition we have been targeting 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 from a different viewpoint.

Be a great place to get involved and work

We have confirmed a Board level wellbeing champion for the HRA and grown our Mental Health First Aider support. We have also approved and published pay transparency guidance and revised our recruitment policy with a greater focus on equality, diversity and inclusion.

HRA Voices have revised their terms of reference with an agreed refreshed focus on wellbeing and innovation. The forum will be responsible for delivering actions in our staff survey action plan that relate to these areas.

Social value has been built into the evaluation process for research systems delivery partner commercial exercise. We also have implemented Atemis, contract management system, which will help improve consistency or our commercial 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 will also include how we manage third party providers. This is now being piloted with Resources Directorate.

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 create capacity to implement and monitor our sustainability strategy without additional cost to the HRA. 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.

80% of our offices offer at least 4 different types of recycling on site. Our Manchester office doesn't currently offer this however plans are in place to move this office to NICE in Manchester which does offer at least four types of recycling on site.