

Agenda item:	7
Attachment:	A

HRA Board paper



20 July 2022

Title of paper:	Strategic performance report: April 2022 – May 2022
Submitted by:	Karen Williams, Deputy Chief Executive and Director of Finance
Summary of paper:	To provide the HRA Board with a review of strategic performance
Reason for submission:	For approval
Further information:	<p>The paper presents the performance of the HRA in delivering the strategy. It focuses on four key areas:</p> <ul style="list-style-type: none"> • Our people • Our customers and stakeholders • Our services • Finance <p>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 from April 2022 to May 2022.</p> <p>This report provides a high-level strategic dashboard as well as a more detailed performance report to the Board.</p>
Budget / cost implication:	N/A
Dissemination:	Published on HRA website with Board papers
Time required:	15 minutes

Strategic performance report: Apr-May 2022

High level dashboard

<div>Staff capacity</div> <div>Apr/May: 92%</div> <div>Maximum target: 91%.</div> <div>Staff capacity has increased on recent months as a result of strategies implemented by Executive. With workforce pressures in the system, this will continue to be closely monitored to ensure HRA has capacity to deliver our strategy.</div>	↑↑
<div>Customer satisfaction</div> <div><div><div>HRA Overall Service KPI Data</div><div><div><div>Percentage</div><div>100%</div><div>90%</div><div>80%</div><div>70%</div><div>60%</div><div>50%</div></div><div><div>Apr-21</div><div>May-21</div><div>Jun-21</div><div>Jul-21</div><div>Aug-21</div><div>Sep-21</div><div>Oct-21</div><div>Nov-21</div><div>Dec-21</div><div>Jan-22</div><div>Feb-22</div><div>Mar-22</div><div>Apr-22</div><div>May-22</div></div><div>Month / Year</div></div><div><div>User Satisfaction...</div><div>75% KPI Target</div></div></div></div> <div>Feedback received:</div> <div><div>"I found it very efficient and quick. We had the initial feedback then a decision in a short time."</div><div>"Excellent; no issues at all."</div></div> <div>Customer satisfaction outperforms our target, the UK Customer Satisfaction Index for public sector organisations (77%)</div>	↑↓
<div>Ethical review of CTIMPs (both the combined and non-combined processes)</div> <div><div>Median time to complete full review</div><div>37 days</div><div>Proportion of full reviews completed in 60 days</div><div>96%</div><div>97% (106 out of 109) Combined Review CTIMPs were reviewed within 60 days. 15 out of 17 standard process CTIMPs were reviewed within 60 days.</div></div>	↑↓
<div>Expenditure within 4% of funding (to May 2022)</div>	↑↑

Overall	Research systems programme	
		
£0.15m underspend to date (4%) of planned expenditure.		

Commentary

Our combined review service is now embedded within our core service delivering significant improvements to timelines for clinical trials research approval. We are now performing a review of our fast-track service, to understand how best to deliver this service following the successful launch of combined review. In this period, we

- Supported the launch of the first phase of the national contract value review to improve study set up. A high response rate has been achieved.
- Hosted our first in person member development day following the pandemic, attended by over 70 Research Ethics Committee members.
- Completed the strategic review of our research systems transformation and made recommendations to our Board on how to proceed, embracing human centred design and learning from our experience over the past 3 years of development
- Launched our environmental sustainability strategy, coproduced by our staff led green team.
- Confirmed the reappointment of Professor Sir Terence Stephenson as Chair of the Health Research Authority for three years from 1 September 2022.
- Put in place a new organisational development function for the HRA as well as merging all our enabling functions into one directorate. As a result, we said a fond farewell to Ian Cook, the Director of Transformation and Corporate Services who left the organisation after 10 successful years.
- Transformed our records management by rolling out HRA Atlas (SharePoint) to all staff.

External environment

- Dr Gail Marzetti was appointed as Director of Science, Research and Evidence at DHSC

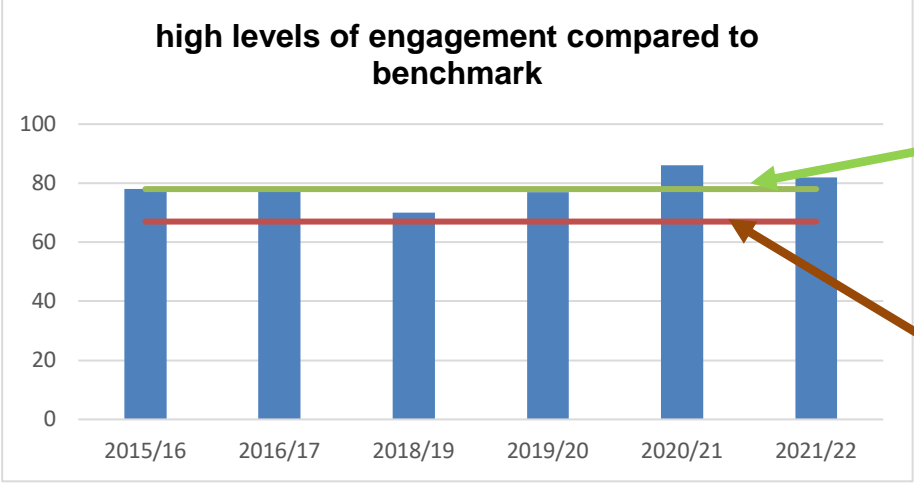
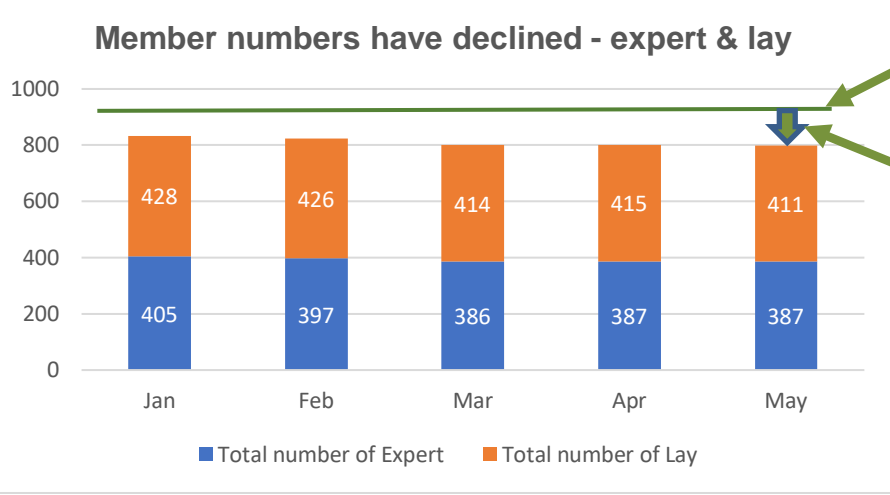
Outlook for the next period

We will publish our refreshed strategy for 2022 – 2025, working with public contributors to ensure it is accessible and easily understood. At the same time, we will publish our business plan for 2022/23.

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.	16	8	↔	Recommendations for RSP reset approved at May HRA Board. Work is proceeding towards issuing the new procurement specification to find a new delivery partner.
HRA2	Resources - The HRA is unable to deliver its business plan objectives due to limits in its ability to secure and deploy resources and capabilities in full.	12	9	↔	Once GIAA audit management action plan has been completed the risk score may be decrease.
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.	9	6	↔	Community insight group to feed into HRA Board via paper and attendance at each meeting. Expertise in inclusive approach to recruitment practices a key requirement of senior posts.
HRA4	Reputational - The reputation of the HRA is adversely affected with fewer participants choosing to take part in research because an adverse event resulting from the decision of a Research Ethics Committee, the conduct of a research study or from lack of public involvement / influence within the HRA occurs.	8	8	↔	Additional resources identified and posts to be recruited to support and strengthen assurance and third-party complaint handling.
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 plan to support focus on being led by data to help prioritise and lead our overall approach to delivery, capturing learning to aid decision making.
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.	9	3	New	Although good controls are in place risk escalated to Board due to growing international cyber activity.

Our people

<p>high levels of engagement compared to benchmark</p>  <p>Target level</p> <p>Industry benchmark</p> <p>2015/16 2016/17 2018/19 2019/20 2020/21 2021/22</p> <p>Staff engagement (based on annual staff survey) Industry benchmark</p> <p>HRA staff 82% (target: 78%) (shown in green above)</p> <p>Industry benchmark: 67% (shown in brown above)</p> <p>March 2022</p>	<p>↕</p>
<p>Staff capacity</p> <p>Apr/May: 92%</p> <p>Target: 91%</p> <p>Staff capacity has increased on recent months as a result of strategies implemented by Executive. With workforce pressures in the system, this will continue to be closely monitored to ensure HRA has capacity to deliver our strategy.</p>	<p>↑↑</p>
<p>Research Ethics Committee (REC) members (England only)</p> <p>Member numbers have declined - expert & lay</p>  <p>Optimum number 960</p> <p>Member vacancy rate 17%</p> <p>Jan Feb Mar Apr May</p> <p>■ Total number of Expert ■ Total number of Lay</p>	<p>↓↓</p>

Vacancies: the optimum number of REC members is 960. We currently have 798 members and are operating at a 17% REC member vacancy rate.

Expertise

Each REC has a mix of both expert and lay members. Expert members are registered healthcare professionals and experts in clinical trials. Lay members bring their lived experience and may also have experience in health and care research such as retired nurses, pharmacists and other retired healthcare professions. We monitor several key factors in REC membership including whether a REC has five or less experts. 30% of RECS meet this threshold.

Percentage of RECs with more than 6 experts: 70%

Percentage of RECs with between 1 and 5 experts: 30%

Number of RECs with 0 experts: 1%

Recruitment activities

March 2022: recruitment campaign to target expert members, particularly doctors
Application packs requested: 96; Applications submitted: 4

April 2022: NHS Pensions newsletter & University medical schools
Application packs requested: 184; Applications submitted: o/s

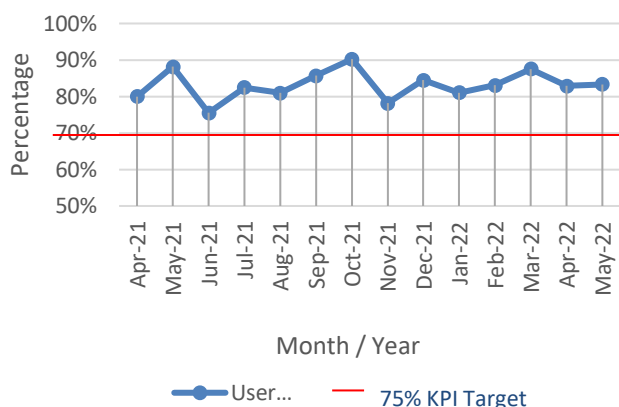
Our customers and stakeholders

Customer satisfaction

Customer satisfaction outperforms our target, the UK Customer Satisfaction Index for public sector organisations (78%)



HRA Overall Service KPI Data



Feedback received:

"I found it very efficient and quick. We had the initial feedback then a decision in a short time."

"Excellent; no issues at all."

Finance

Expenditure within 4% of funding

Overall



Research systems programme



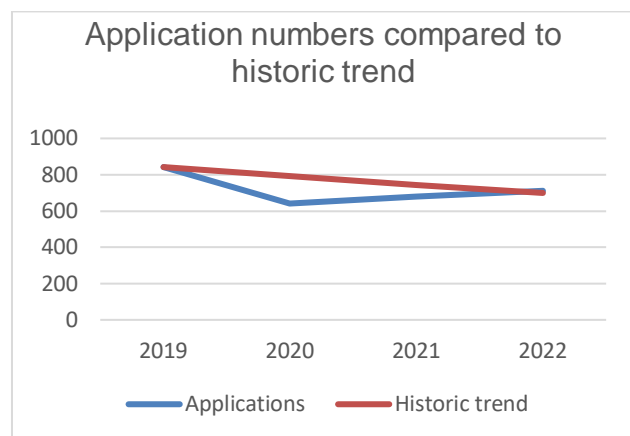
£0.15m underspend to date (4%) of planned expenditure.

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Approvals service

Number of applications for HRA Approval

April 2019 - May 2019:	842
April 2020 - May 2020:	641
April 2021 - May 2021:	678
April 2022 - May 2022:	710



Application numbers reduced during COVID-19 and have been slowly growing over the past two years. This is broadly in line with the long-term trend in reducing applications (approximately 6% a year). Whilst numbers have reduced, there has been increased complexity in some studies, including complex innovative designs for COVID-19 studies.

Number of applications for REC review only

April 2019 - May 2019:	179
April 2020 - May 2020:	156
April 2021 - May 2021:	145
April 2022 - May 2022:	152

Application numbers reduced during COVID-19 and have been slowly growing over the past two years balanced by a reduction in student applications.

Ethics review of clinical trials of investigational medicinal products (CTIMPs)

Our target is for 100% of applicable CTIMPs to be reviewed within 60 days. Where the CTIMP is for gene therapy or somatic cell therapy or the product contains a genetically modified organism, our target is for 100% to be reviewed within 90 days.

Ethics review of standard process CTIMPs (England only)

Standard review CTIMPS	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Median time to complete full review	30	30	30	28	37	50
Full reviews completed in 60 days	100%	97%	100%	93%	92%	75%
Full reviews completed within 60 days	33	34	23	14	12	3
Total completed	33	35	23	15	13	4

Ethics review of combined review CTIMPs (England only)

Combined review CTIMPS	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Median time to complete full review	36	24	39	30	36	39
Full reviews completed in 60 days	100%	100%	100%	98%	96%	98%
Full reviews completed within 60 days	27	35	32	50	45	61
Total completed	27	35	32	51	47	62

Combined review

For statutory timelines applicable to the HRA, 96% of applications are processed within 60 days in the two-month reporting period. Two standard review CTIMPs were not approved within 60 days during the reporting period – one was delayed by a combination of staff absence and needing expert comments after the REC meeting, the other due to a delay reviewing the response to a provisional opinion due to staff absence. Three combined review CTIMPs were not approved within 60 days during the reporting period – all due to a RFI response being overlooked due to staff absence.

Performance has been slightly lower than expected the last two months. The refreshed Approval Officer role will allow closer monitoring of timelines to prevent this re-occurring. A dedicated Approvals Manager continues to focus on service delivery to improve statutory compliance for combined review as well as researcher experience in general.

Fast-track REC (standard review, non-COVID-19 studies)

Fast Track REC	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Median time to complete full review	11	12.5	n/a	13	Service closed	Service closed
Full reviews completed in 60 days	100%	100%	n/a	100%	Service closed	Service closed
Total completed	3	4	0	1	Service closed	Service closed
Total completed within 60 days	3	4	0	1	Service closed	Service closed
Studies Submitted for Review	4	1	1	0	Service closed	Service closed

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

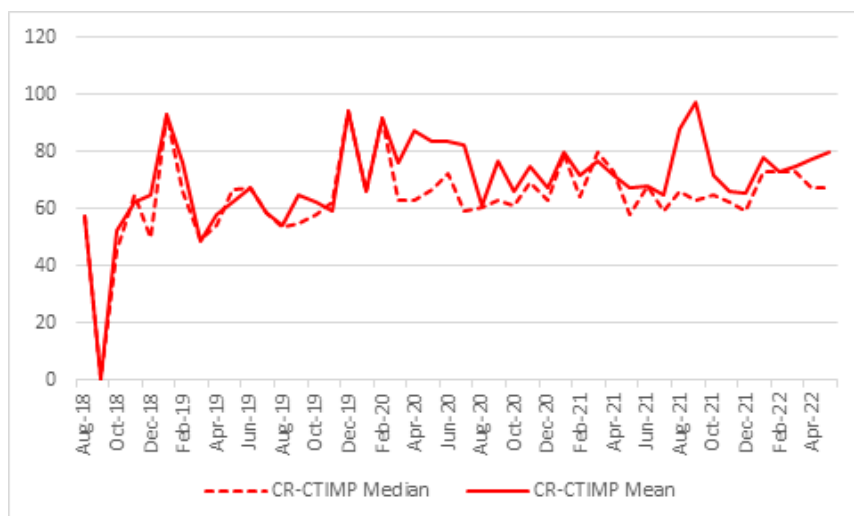
Fast Track REC	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22
Median time to complete full review*	15	15	10.5	11	15	15

Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	4	5	6	13	17	8
Total completed within 60 days	4	5	6	13	17	8
Studies Submitted for Review	5	9	13	18	6	14

Fast-track combined review studies have comparable timelines to non-combined review studies when just the REC review aspect is considered. For Phase I trials MHRA have a shorter timeline for review that aligns with our fast-track timeline. For other trials we are working with applicants to explore the added value of fast-track service as part of combined review.

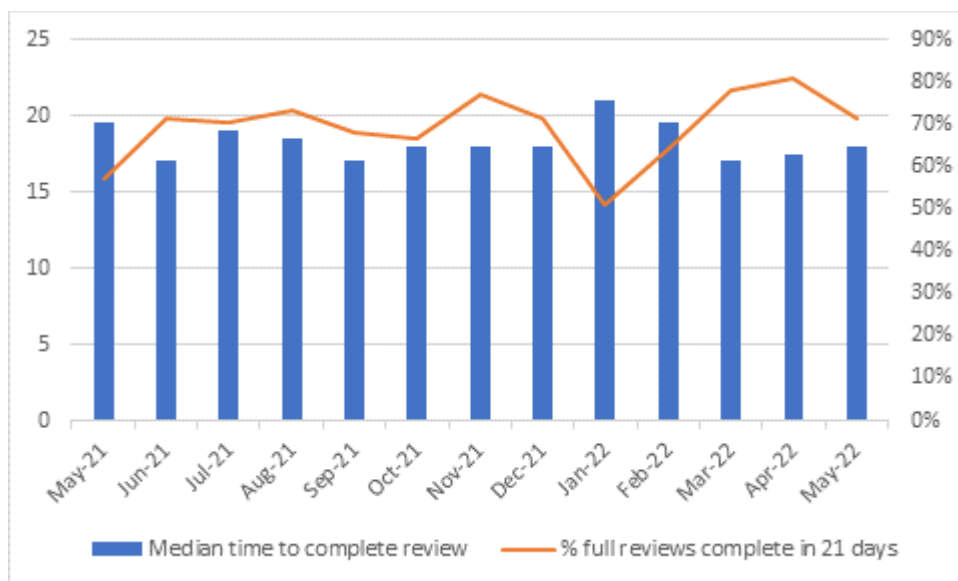
HRA Approval

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). 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.



Proportionate Review

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). Performance at English RECs has been below the expected level for some time due to COVID studies being prioritised. However, since March over 70% of applications each month have been reviewed within the expected timeframe, the best performance for some years. A number of factors have helped with this; the way Approval Specialists are assigned applications for validation has changed to smooth their workflow allowing them to be validated more quickly, REC teams have a greater focus on timelines for this type of application, Approval Administrators (who handle a large part of the interaction with the REC for this type of application) are now fully trained and able to fulfil their part of the process with minimal supervision. Further projects are ongoing to increase performance further.



Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	14 days	3
May	28 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

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

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Include everyone in research:

We are working closely with MHRA to develop 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.

A steering group to take forward the shared commitment to embed public involvement in health and social care research has been established and is starting work.

The Make it Public campaign continues to work to make transparency the norm with plans to hold the next virtual conference later this financial year.

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

We are preparing to launch a public dialogue to ask people what they want research to look like to earn their trust. This will inform some public-facing activities and events to discuss the issues that they tell us matter to them in research.

A steering group of researchers and public contributors have begun meeting to take forward a project to look at how we can make research happen in ways that we agree will be more 'people-centred'.

Involve you in the HRA

The HRA Community Insight Group is meeting on 18 July to discuss how the Group might evolve to better represent and include 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 held a workshop as part of our strategy launch, asking everyone that joined us how we can best deliver our ambitions to include everyone in health and social care research. Our Board will discuss these findings with public contributors on 20 July, and together we will develop proposals for how we can do things differently to discuss at our September Board meeting.

We are developing an approach to capture more comprehensive EDI data about our Community safely and securely so we can better understand how diverse and inclusive our Community is now and monitor our success as we work to make this open to everybody. We are beginning work with Community members to better understand some of the barriers to working with us.

Procurement has begun to redevelop the HRA website and a revised business case is being made to ensure that we are resourced to develop this.

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

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HRA has advised and supported the implementation of national contract value review. This is a priority project for Accelerate, included within the recovery, resilience & growth programme, with the aim to dramatically improve costing and contracting for commercial contract research in the NHS. The first stage was launched in April 22. This involves collection of data from the NHS to assess existing adherence to standard research tariffs. A high response rate has been achieved. Identification of national coordinators from across the NHS is underway.

HRA has advised on information governance aspects of the development of the new find, recruit & follow-up service. A soft launch commenced in April through the NIHR clinical research network, with early pilot work on a small scale to coordinate the offer of services from Digitrials, CPRD and Farsite.

HRA is leading a cross-sector project to identify, develop, coordinate and disseminate delivery of initiatives that support decentralised trials, virtual trials, novel designs and digitally-enabled clinical research. We have had significant interest in a new steering group we are establishing consisting of a mix of public contributors and research community.

Digital: Use digital technology well to do our work

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The aim is to design our digital systems in a human-centred way, i.e., place real emphasis on creating business processes that are informed by users' priorities and are acknowledged as not only being easy to use but also assists them in conducting their research.

To energise this type of approach, steps are underway to find a new delivery partner for the Research Systems Programme, a partner that has knowledge and experience to share with the HRA in new ways of working in this digital age. A new delivery dynamic is being sort, one that will cast new light on 'the art of the possible' and start to equip the HRA with the necessary skills and infrastructure to deliver for the long term.

To compliment this approach, plans are also being formulated to create strategic leadership teams that will provide crosscutting support and ensure all planned activities focus on strategic outcomes.

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

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Continuously learn, improve and innovate

We are piloting NIHR learning platform for members and staff and have put in place sessions on our 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 our 'Lets Talk' session, the first, on race was delivered in May.

Discovery and scoping work have commenced on developing our innovation and change delivery framework.

Be a great place to get involved and work

We have expanded our network of Mental Health First Aiders and work is underway to review and update our recruitment policy.

We also launched the first tranche of improvements to our commercial policies and processes with the introduction of a new procurement policy. We are ensuring that social value is incorporated into our commercial evaluation processes and how this can be utilised to deliver our sustainability strategy objectives.

Be committed to environmental sustainability and achieving net zero.

We launched our sustainability strategy and promoted this through several channels including our website, twitter and at our all staff meeting.

We maintained our travel and accommodation at over 60% reduction at pre-pandemic levels and limited our domestic flights to essential travel only.