

Agenda item:	8
Attachment:	A

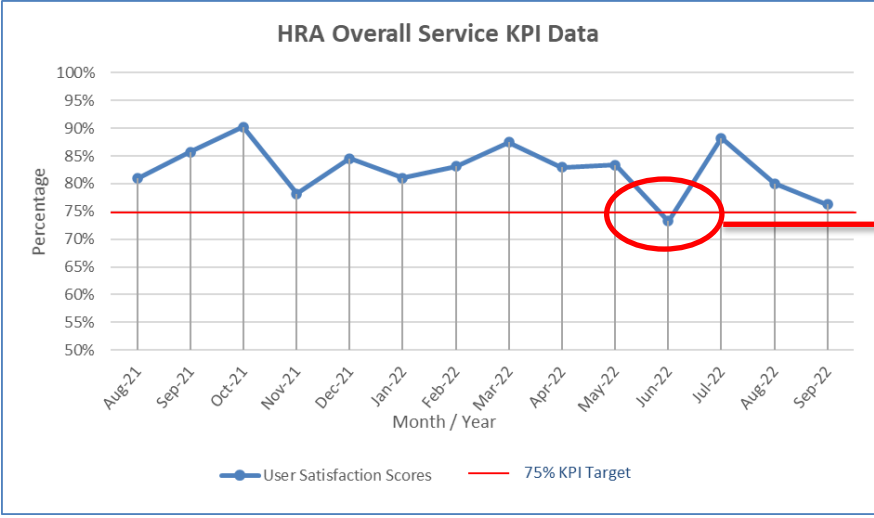
HRA Board paper

16 November 2022

Title of paper:	Strategic performance report: April 2022 – September 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 September 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:	10 minutes

Strategic performance report: Apr-Sep 2022

High level dashboard

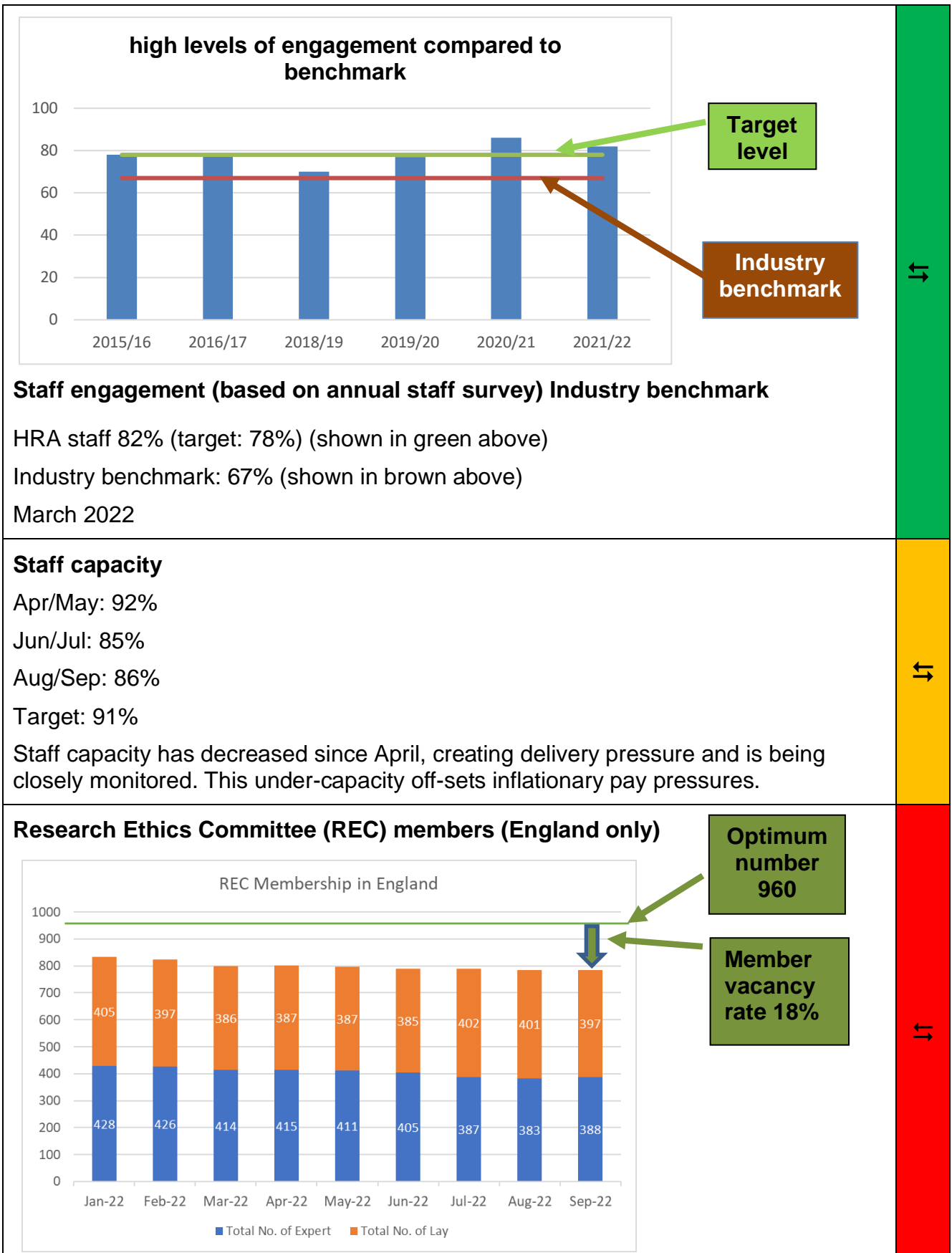
<p>Staff capacity</p> <p>Apr/May: 92%; Jun/Jul: 85%; Aug/Sep: 86%</p> <p>Maximum target: 91%.</p> <p>Staff capacity has decreased since April, creating delivery pressure and is being closely monitored. This under-capacity off-sets inflationary pay pressures.</p>	↕				
<p>Customer satisfaction</p>  <p>Customer satisfaction outperforms our target 75% throughout the period except in June 22 where it fell to 73%. No root cause has been identified for this drop below target which reversed in July.</p>	↕				
<p>Ethical review of CTIMPs (both the combined and non-combined processes)</p> <p>Median time to complete full review 36 days</p> <p>Proportion of full reviews completed in 60 days 97%</p> <p>97% (96 out of 99) combined review CTIMPs were reviewed within 60 days. 3 out of 3 standard process CTIMPs were reviewed within 60 days.</p>	↕				
<p>Forecast expenditure within 4% of funding</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Overall</td> <td style="width: 50%;">Research systems programme</td> </tr> <tr> <td style="text-align: center;">✓</td> <td style="text-align: center;">✓</td> </tr> </table> <p>Our forecast position is within 4% of funding allocated (adjusted for research systems programme refresh). £1m capital expenditure funding has been deferred following strategy refresh with development work rephased to 23/24.</p>	Overall	Research systems programme	✓	✓	↕
Overall	Research systems programme				
✓	✓				

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. Procurement process for new supplier underway, aiming to be appointed by October.
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 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	↔	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	↔	Although good controls are in place risk escalated to Board due to growing 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	New	Working with DHSC and other ALBs as part of DHSC ALB landscape review to look at opportunities for efficiencies across ALBs.

Our people



↕

Vacancies: Based on 15 members per committee, the optimum REC membership is 960. The chart above shows at the end of September we have 785 members of which 388 are expert, representing 18%-member vacancy rate.

Membership: Each REC has expert members to help ensure appropriate technical expertise about research is available 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.

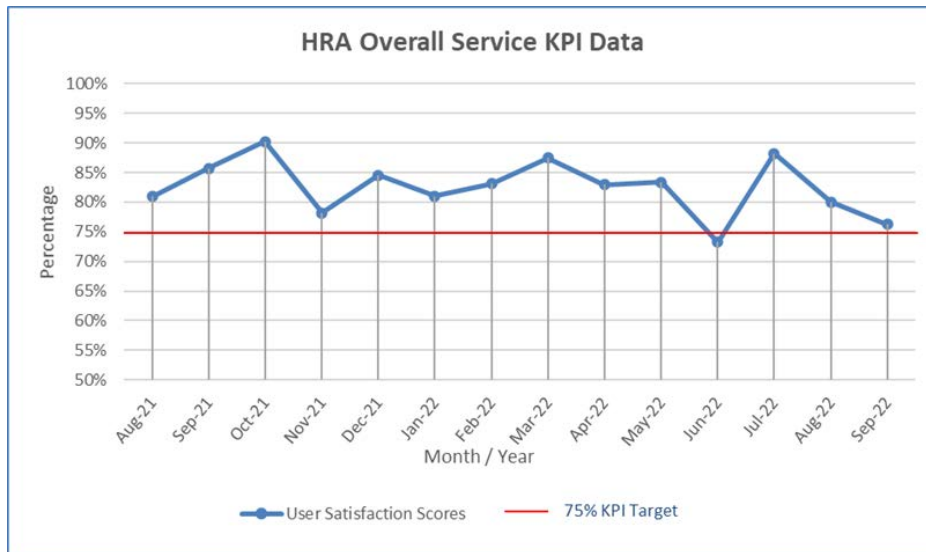
- percentage of RECs with more than 6 experts: 77%
- percentage of RECs with between 1 and 5 experts: 23%
- percentage of RECs with 0 experts: 0%

Recruitment activities

- April 2022: NHS Pensions newsletter & University medical schools
- August & September 2022: Writing to Royal Colleges, trusts and universities
- Application packs requested at end of September: 876
- Applications submitted at end of September: 102

Our customers and stakeholders

Customer satisfaction



Customer satisfaction outperforms our target 75% throughout the period except in June 22 where it fell to 73%. No root cause has been identified for this drop below target which reversed in July.



Finance

Forecast expenditure within 4% of funding

Overall



Research systems programme



Our forecast position is within 4% of funding allocated (adjusted for research systems programme refresh). £1m capital expenditure funding has been deferred following strategy refresh with development work rephased to 23/24.



Approvals service

Number of applications for HRA Approval

April 2019 - September 2019:	2451
April 2020 - September 2020:	1961
April 2021 - September 2021:	2086
April 2022 - September 2022:	2007

Application numbers reduced sharply during COVID-19 and have slowly increased since then. The overall picture is broadly in line with the long-term trend, around 6% reduction in applications each year. Whilst numbers have reduced, some applications are more complex, including innovative designs for COVID-19 studies.

Number of applications for REC review only

April 2019 - September 2019:	527
April 2020 - September 2020:	428
April 2021 - September 2021:	468
April 2022 - September 2022:	415

Long-term trends indicate new applications reduce by 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 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	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22
Median time to complete full review	37	45	54	46	30	44
Full reviews completed in 60 days	92%	80%	80%	100%	100%	100%
Full reviews completed in 60 days	13	5	5	2	2	1
Total completed	12	4	4	2	2	1

Ethics review of combined review CTIMPs (England only)

Combined review CTIMPS	Apr-22	May-22	Jun-22	Jul-22	Aug-22	Sep-22
Median time to complete full review	36	39	35	37	35	37
Full reviews completed in 60 days	96%	98%	95%	97%	98%	95%
Full reviews completed in 60 days	47	66	63	60	55	44
Total completed	45	65	60	58	54	42

Combined review

For statutory timelines applicable to the HRA, 97% of applications were processed within 60 days in August and September, this is in line with the year to date compliance rate 97%.

In the last two months, three combined review CTIMPs were not approved within 60 days – all were reviewed by the same REC and due to staff absence responses to RFIs were not actioned in the correct time. The modified Approvals Officer role aims to address this by monitoring timelines and escalating where action is needed

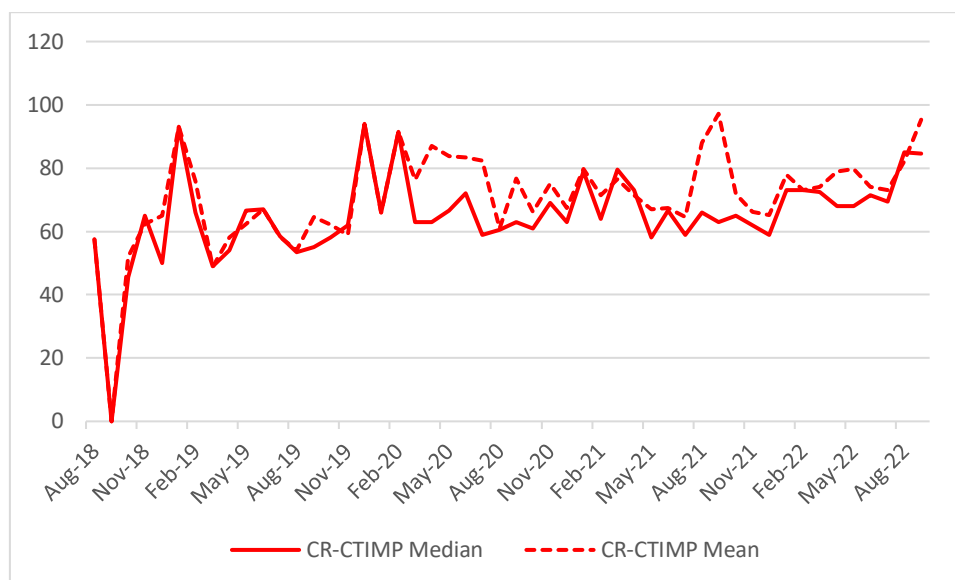
Fast-track Ethics Review (combined review, non-COVID-19 studies)

Fast Track ethics review	Aug-22	Sep-22
Median time to complete full review*	16	27
Full reviews completed in 60 days	100%	100%
Total completed	2	4
Total completed within 60 days	2	4
Studies Submitted for Review	6	14

*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. From August 2022 fast-tracked applications are reviewed as part of the existing REC structure.

HRA Approval

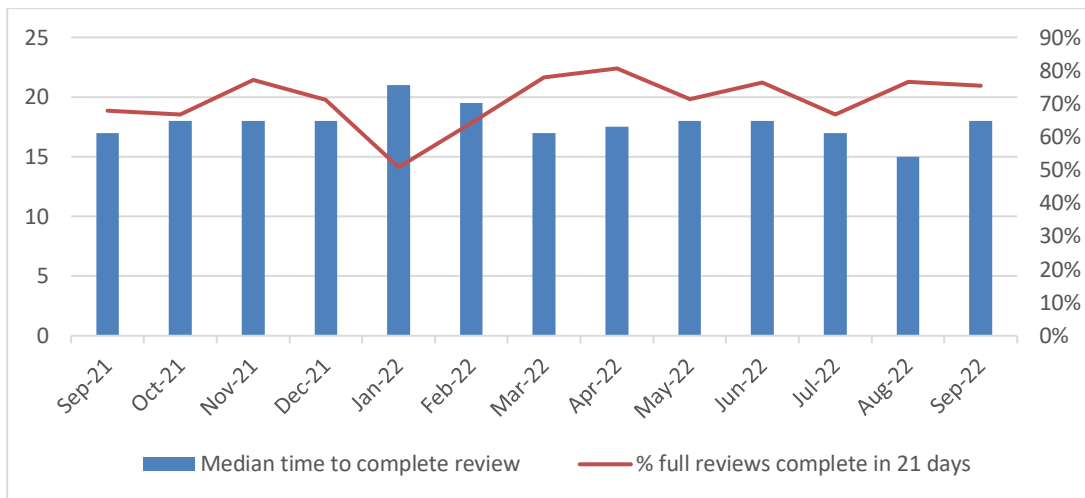
For HRA and HCRW Approval in England and Wales, the graph below shows the median and mean elapsed timeline for applications from submission to approval (no clock stops). Applications withdrawn or invalid have been omitted from the data set. Combined review median normally maps closely to mean showing 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.



The increase in HRA Approval timelines since July 2022 shown in the graph above is due to a combination of factors; closure of the Fast Track REC adding pressure on REC meeting slots, and as the timeline for HRA Approval is from submission to approval a longer wait for a REC meeting results in a longer HRA Approval time. Also delays in the MHRA issuing the joint output impacts on timelines as all regulatory approvals need to be in place before HRA Approval can be issued.

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). We are continuing to monitor timelines having introduced the following improvements; 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 role 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 improving performance further.



Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	14 days	2
May	35 days	8
June	27 days	6
July	28 days	8
August	33 days	10
September	25 days	9

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%
Ethics review of CTIMPs (both the combined and non-combined processes)	green = 100% 94%, amber 90%-99%, 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

G

Include everyone in research:

We continue to work closely with MHRA:

- developing resources to support greater diversity and inclusion of research participants, and
- proposing changes to clinical trials legislation requiring public involvement, transparency and diversity and inclusion following the consultation. The government response to this consultation is expected to be published later this year.

The steering group taking forward the shared commitment to embed public involvement in health and social care research is developing an action plan, which includes individual projects to move issues forward and plans to mark the first anniversary of the commitment with a meeting and annual report, giving all signatories the opportunity to hold themselves accountable for the commitments that they have made.

The Make it Public campaign continues to work to make transparency the norm with work underway to hold the next virtual conference in March 2023.

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

Desk research is underway to tighten the scope of the public dialogue to provide the most useful information to inform the HRA's work to make it easier to do research that people can trust. This has slightly delayed the original timeline for procuring a supplier to perform a public dialogue.

The steering group looking at how to do a better job of putting people first in research has met four times, completed a rapid review to inform its work and is now developing some hallmarks of people-centred clinical research.

Involve you in the HRA

We are preparing to launch a 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.

A Paper was taken to the September Board, developed with a group of people involved in or impacted by research, advising how the HRA can take forward the ambitions it has set out in its strategy to include. The Paper is informing our current work and our business planning processes going forward. We plan to continue involving our Community meaningfully throughout this process. We will also explore how we can increase accountability for this work through the proposed Community Committee.

We are developing guidance to support better planning for public involvement in our business planning process, so we can do this more successfully going forward.

Work is underway to develop the next stages of REC Recruitment campaign #StepForward, seeking to reach new people who may not have considered working with the HRA before. We are also planning a workshop with NHS employers to better understand how to make it easier for employers to support people to work with the HRA.

The staff Community Group is now operating to help us deliver a more consistent, positive experience for everyone who works with us as a member of a Research Ethics Committee, the Confidentiality Advisory Group or as a public contributor.

Procurement to redevelop the HRA website is continuing with recruitment to provide appropriate resourcing to support this almost complete.

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

A range of actions are underway to address delays in study set-up in the NHS.

A survey on issues relating to information governance in the NHS has been completed and analysis is underway, which will inform requirements for guidance and other actions. Engagement with the primary care sector is being taken forward through the NIHR Clinical Research Network, and new guidance is being drafted to resolve areas of confusion.

The pilot of a light touch combined review process between REC and MHRA has now been handed over to business as usual, and the option of using the combined review process is now available to applicants. Further work is now to be taken forward with MHRA to improve the IRAS question set for the future, to improve application quality and reduce long-standing issues with validation by MHRA.

The roll out of the National Contract Value Review service programme has successfully achieved the next milestone with implementation of national coordinator review for all commercial trials.

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. The first version of new question sets for all partners has been documented. A mock-up has been through a first round of user research, and

feedback is being considered in the next iteration. Further work on the sequencing of questions to support applicants to take ideal paths through the regulatory process is underway.

An engagement plan for the work on ideal paths and UK Approval service has been developed, and initial engagements have begun in England.

To support the direction of travel towards a UK Approval service when IRAS is developed, an interim cross-border toolkit is being developed. A draft has been tested with users and feedback is being actioned.

We have been able to obtain new information from NHSX about the expectations for Government Digital Service assessment of the new IRAS website. This has identified that more work on the content of the website is needed prior to submitting for assessment, which will delay the timetable.

Support new ways to do research

Guidance to make it easier to set up non-interventional studies in the NHS is being drafted, to ensure proportionate approaches are taken that enable decentralised models of research.

The HRA participated in a workshop run by the NHS R&D Forum exploring developments in support for research through Integrated Care Systems.

In response to feedback from industry, new guidance is under development on requirements for REC review of electronic tools for remote data collection.

HRA continues to support DHSC and NIHR with clarifying issues around the set-up of studies in non-NHS settings like care homes and schools.

Digital: Use digital technology well to do our work

A

User experience and engagement is at the heart of digital design.

We aim 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 enable this approach, we are procuring delivery partner services. A new delivery dynamic is being sought, 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. The procurement exercise is in process and is anticipated to complete in October.

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.

Process automation and integration improves our work

Head of Service Delivery is reviewing service desk operations review and re-publishing incident and request, problem and change management processes. The Helpdesk system has been updated to improve incident management and analytics/reporting on incidents.

Analytics discovery work has concluded and is due to be presented to the Digital Strategy & Prioritisation Group in October. A foundation data layer will be built first following data migration health check on legacy data.

Automation of process is being implemented for HRA core processes using Office365 functionality including MS Forms. We are on track to deliver 20 automations this year as planned.

Continued to improve our cyber security policies and procedures in response to recommendations from the internal audit on our data security and protection compliance, this included signing of the toolkit for 2021/22 as complete in this period.

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

G

Continuously learn, improve and innovate

Our pilot of NIHR learning platform for members and staff has been successful. Our recommended approach will be considered at the Digital Strategy Prioritisation Group in October. 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 and 35 equality impact assessments completed and reviewed this year. 57% were new EIAs 29% were updated. A key benefit has been extending the EIA process beyond HR and incorporating positive impact on equality across all functional areas.

Engagement work continues in developing our innovation and change delivery framework and Richard Cooper, non-executive director, has been confirmed as the HRA's innovation champion.

Be a great place to get involved and work

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

Our staff forum has revised its terms of reference with an agreed refreshed focus on wellbeing and innovation. The forum is 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 have also implemented Artemis, a contract management system, which will help improve consistency of our commercial processes and record keeping. Training is planned to support the rollout of SharePoint and how it supports our records management policy. This will also include how we manage third party providers and their responsibilities in relation to information governance and record keeping.

Be committed to environmental sustainability and achieving net zero.

We have appointed to a new role to provide additional capacity to implement and monitor our sustainability strategy. The new post holder will join the HRA in December. Their focus will be to understand what has and hasn't been achieved with our sustainability strategy and to agree further plans to achieve our environmental ambitions.

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.