Health Research Authority

Agenda item:	**10**
Attachment:	**A-C**

HRA Board Meeting

15 November 2023

Title of paper:	**Strategic performance report: Quarter 2**
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: Apr 2023 - Sep 2023

High level dashboard

People: staff capacity

Q1: 86% Q2: 84% Maximum target: 91%.

Staff capacity continues to fall despite improvements to the recruitment process. This is due to recruitment to new roles identified to enable the research systems programme following governance and assurance processes.

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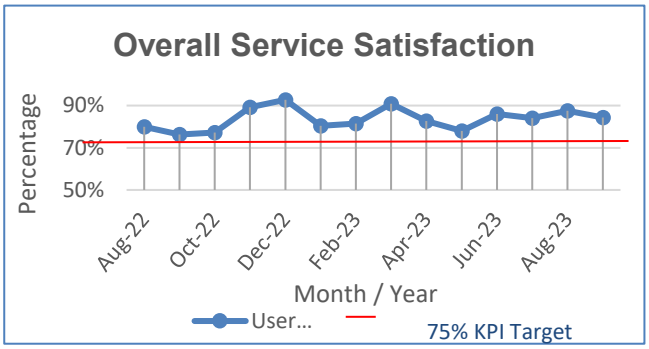
Customer satisfaction: overall service



Customer satisfaction outperforms our 75% target throughout the period and achieved 88% in August.

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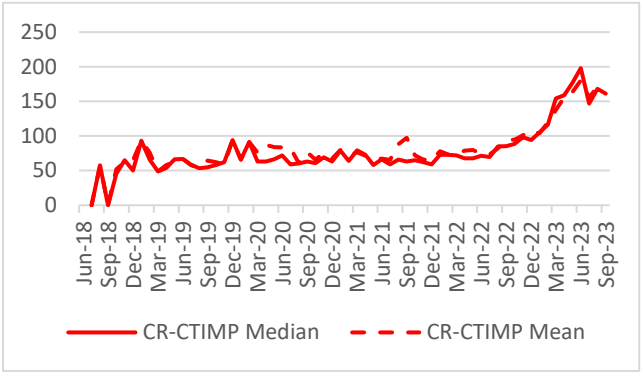
Our services: HRA approval



HRA Approval timelines peaked in June 2023 due to delays at MHRA and are now decreasing. These are expected to fall further in Q3.

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Our services: ethics review of CTIMPs

Median time to complete full review 33 days

Proportion of full reviews completed in 60 days 97%

97% (253 out of 260) combined review CTIMPs were reviewed within 60 days.

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Finance: forecast expenditure within 4% of funding

Overall ✓ *Research systems programme* ✓

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

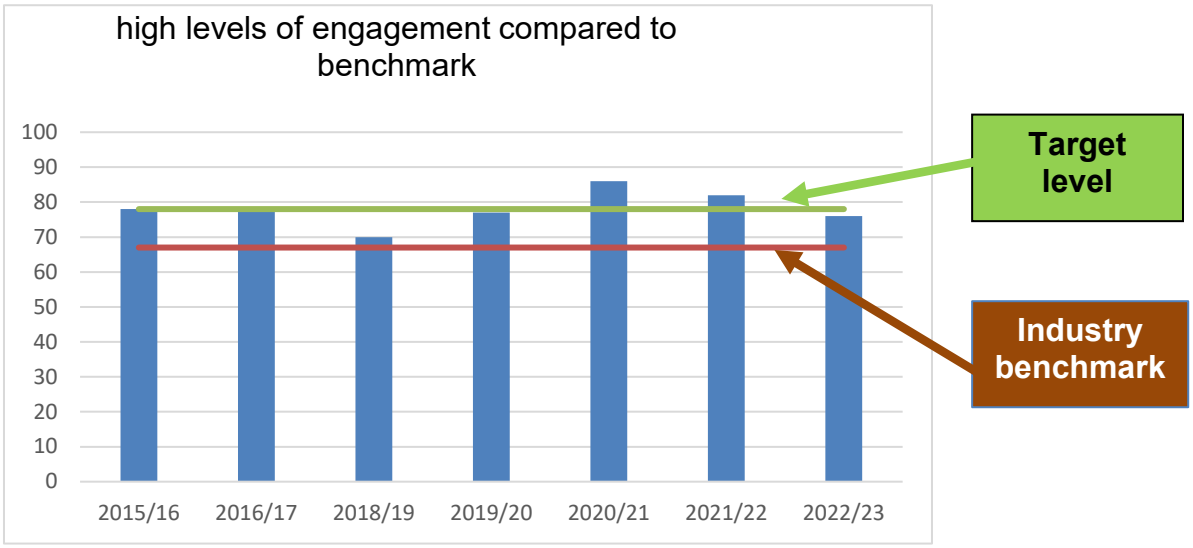
Strategic risks

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**	↔	Assurance action plan work underway with weekly meetings to prioritise and address requirements.
HRA3	**Reputational -** The HRA 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. 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 established which will help the HRA make better decisions by working with a diverse group of people with a range of lived experiences and make sure that anyone who wants to get involved in research is able to do so.
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**	↔	Community Committee established which will support the trust of the public. The committee is made up of members from across our community, including Research Ethics Committee (REC) members, a Confidentiality Advisory Group (CAG) member and members from our Public Involvement Network (PIN).

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
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**	**4**	↔	Good controls are in place, risk impact score remains the same.
HRA9	**Reputational** - The HRA may not be able to deliver its objectives due to financial pressures, which may reduce patient access to research and slow the process of research findings improving care.	**12**	**8**	**New**	Business change role being put in place to create greater capacity to focus on cash releasing efficiencies from process improvements. Business planning process to combine financial and resource planning.
HRA10	**Reputational** - Delays of approval from other regulators erodes trust in the whole regulatory system, including the HRA. This may reduce patient access to research and slows the process of research findings improving care, eroding patient trust in approved research and UK ability to become the easiest place in the world to do research that people can trust.	**8**	**4**	**New**	Meetings and discussion taking place with partner regulators. Transparent communications being held with applicants.
HRA11	**Information** - The HRA is unable to recruit or retain an effective workforce due to the current employment market. Because of the scarcity of candidates for all positions this results in under-resourcing, impacting on the HRA delivering against its business plan.	**16**	**8**	**New**	People strategy has been updated, annual staff survey completed and staff voices group continuing to be developed.

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

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Staff capacity

Q1: 86% Q2: 84% Maximum target: 91%.

Staff capacity continues to fall despite improvements to the recruitment process.

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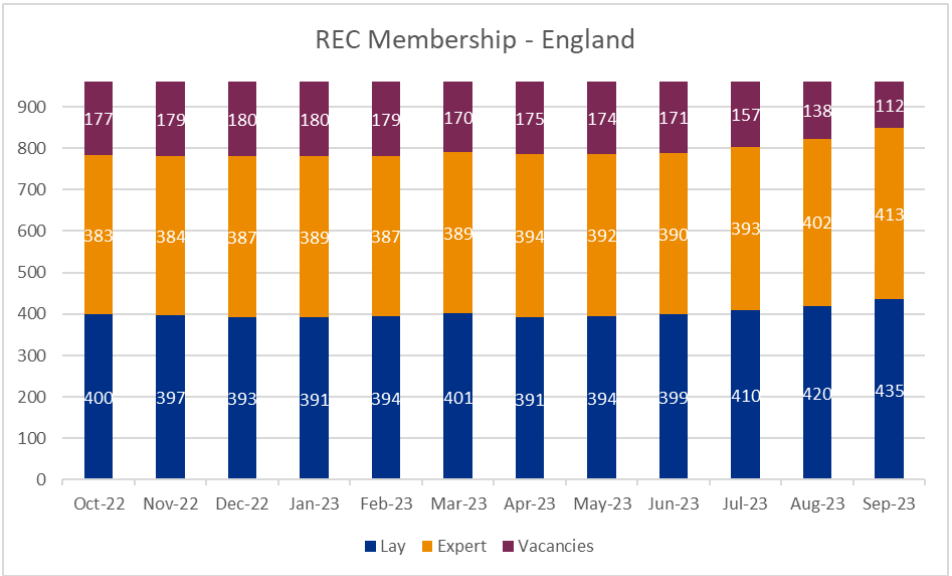
Research Ethics Committee (REC) members (England only)



Our target membership is 960 members, 15 each REC. The chart above shows 848 members, of which 413 are expert, 219 lay and 216 lay plus at the end of September 2023. This gives a 12% vacancy rate. This is a significant reduction on previous reports demonstrating improvements to the recruitment process.

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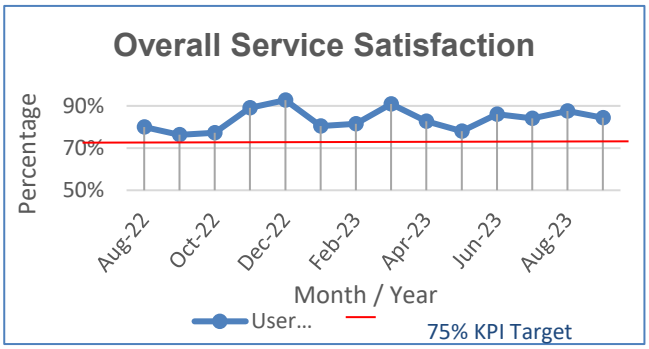
Membership: Expert members include members registered as health and social care professionals or members with expertise in clinical research. At the end of September 2023, 22% of RECs had five or less expert members, no REC has less than 4 expert members. **Recruitment activities** The recruitment campaign started in March 2023 has generated 316 applications for REC membership (103 expert, 109 Lay and 104 Lay Plus). We have also improved our application and interview processes so that we can place members on RECs more quickly.	

Our customers and stakeholders

Customer satisfaction



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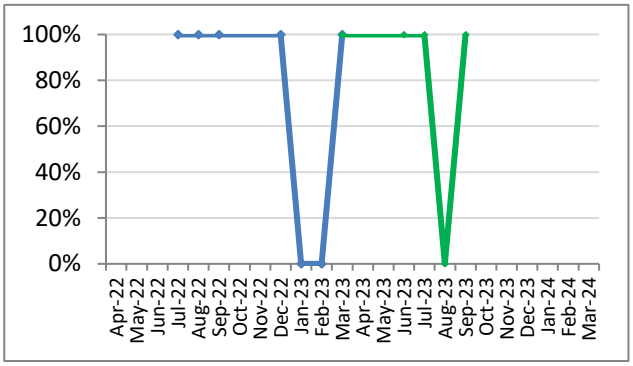
Customer satisfaction outperforms our 75% target throughout the period and achieved 88% in August.

Complaints: responded to within 25 days (target 100%)



new

This is a new KPI to provide greater understanding of how well we are meeting customer need. 4 complaints about the HRA were received this quarter. 1 was responded to within the 25 working day target. The target was missed due to unexpected staff absence and a higher than usual workload. All 3 complainants were kept updated about the delays. Additional capacity has been sourced to address this backlog.

Finance

Forecast expenditure within 4% of funding

Overall ✓

Research systems programme ✓ ✓

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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 – September 2019:	2302
April 2020 – September 2020:	1879
April 2021 – September 2021:	1983
April 2022 – September 2022:	1883
April 2023 – September 2023	1840

Number of applications for REC review only

April 2019 – September 2019:	527
April 2020 – September 2020:	427
April 2021 – September 2021:	466
April 2022 – September 2022:	413
April 2023 – September 2023	428

Application numbers for HRA Approval and REC only review dropped 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 following changes we made to eligibility criteria.

Ethics review of combined review CTIMPs (England only)

Combined review CTIMPS	**Apr-23**	**May-23**	**Jun-23**	**Jul-23**	**Aug-23**	**Sep-23**
Median time to complete full review	30	34	37	34	31	36
Full reviews completed in 60 days	100%	100%	89%	93%	99%	97%
Total Completed	28	31	27	30	106	124
Full reviews completed in 60 days	28	31	24	28	105	120

Studies Submitted for Review	61	61	71	48	56	67

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 30 September 2023. 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. The MHRA have been addressing their backlog of applications and amendments since July 2023, this has resulted in a significant increase in the number of applications approved in August and September.

Seven combined review CTIMPs were not approved within 60 days during the reporting period. Three applications overran due to a delay in the initial REC meeting – they were booked in December 2022 but due to the pressure on REC slots at that time not seen at a REC meeting until February 2023, this meant when the response was submitted very little time remained. Three applications overran due to the chair not reviewing the response in the appropriate time. The other application overran due to an error by HRA staff.

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

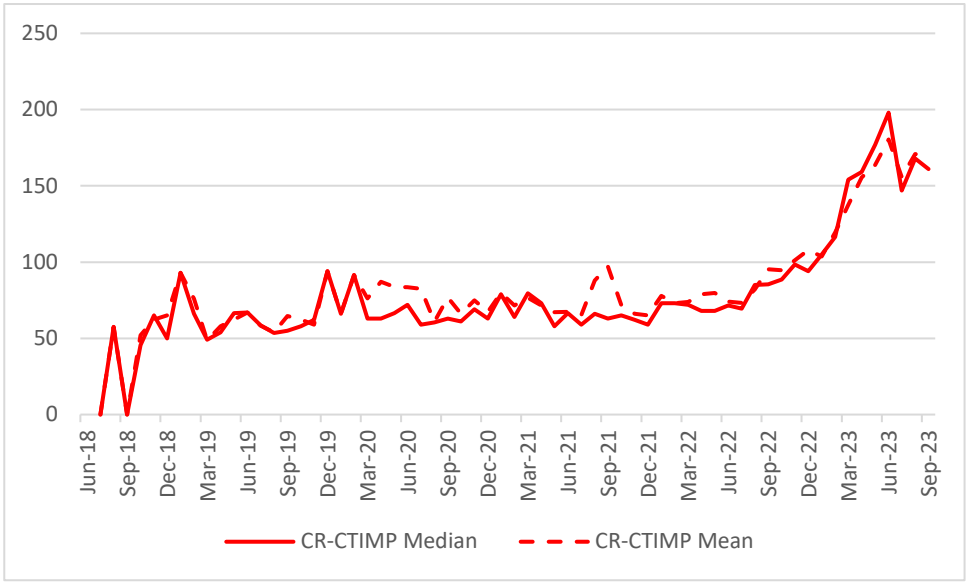
Fast Track ethical review	**Apr-23**	**May-23**	**Jun-23**	**Jul-23**	**Aug-23**	**Sep-23**
Median time to complete full review*	17	26	29	26.5	23	36
Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	7	9	9	8	27	30
Total completed in 60 days	7	9	9	8	27	30
Studies submitted for review	13	24	18	14	13	23

Phase I trials MHRA have a shorter timeline for review that aligns with our fast-track timeline. From August 2022 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.

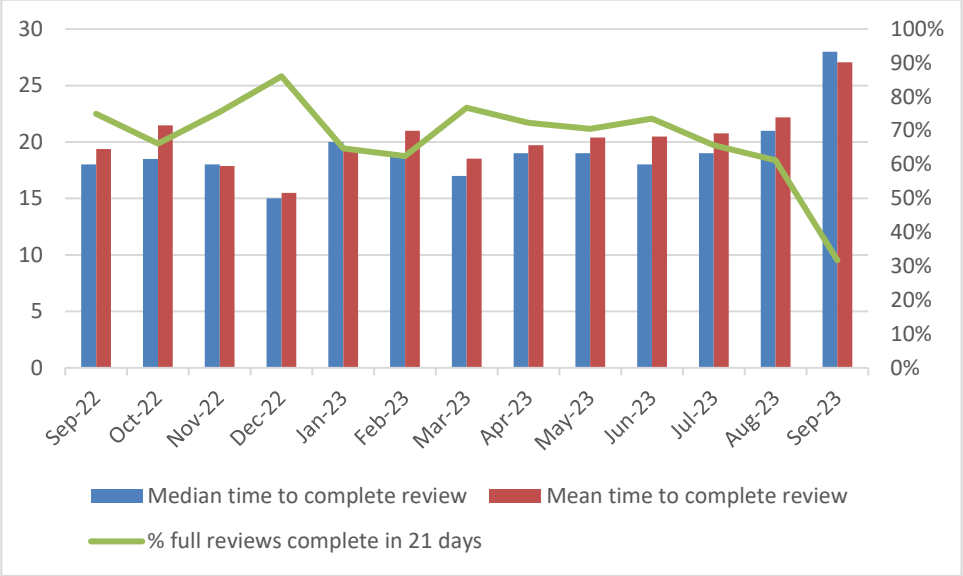
HRA Approval timelines for CTIMPs have risen since August 2022 and this rise is caused by delays with the MHRA issuing joint outcomes. There are currently significant delays at the MHRA with the initial assessment of a CTIMP and issuing the RFI to applicants. To mitigate these as much as possible for 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. HRA Approval timelines peaked in June 2023 and are now decreasing, we expect them to further decrease over the next few months until they return to the level they were at before the MHRA delays started.



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). We continue to monitor timelines to meet this target and have put in place several changes to help with this; changes to how applications are assigned in our teams has smoothed their workflow allowing quicker validation, a greater focus on timelines for this type of application and making sure our staff are fully trained 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.

Despite these changes, a higher demand for the PR service meant that timelines for PR applications did increase significantly during August and September 2023. This was the result of a pilot being run in England and Wales looking at the effects of a much-reduced screening process on these applications. This resulted in approximately 30% more applications reviewed by a PR sub-committee than usual. This increase put pressure on PR sub-committee slots and meant many applications passed 21 days before their allocated meeting. Additional capacity had been created by putting on extra sub-committee meetings but did not fully mitigate this. Although this did have a negative impact on PR timelines it did significantly reduce the burden on full REC meeting slots and is having a positive impact on full REC review timelines. The pilot showed that PR decision rates were not affected. Further work is ongoing to determine the learning from this pilot and what changes should be implemented going forward.



Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	36 days	11
May	39 days	8
June	35 days	14
July	23 days	7
August	50 days	2
September	45 days	12

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%
HRA Approval	
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%