Health Research Authority

Agenda item:	**7**
Attachment:	**A**

HRA Board

20 September 2023

Title of paper:	**Strategic performance report: Quarter 1**
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 - Jun 2023

High level dashboard

Staff capacity

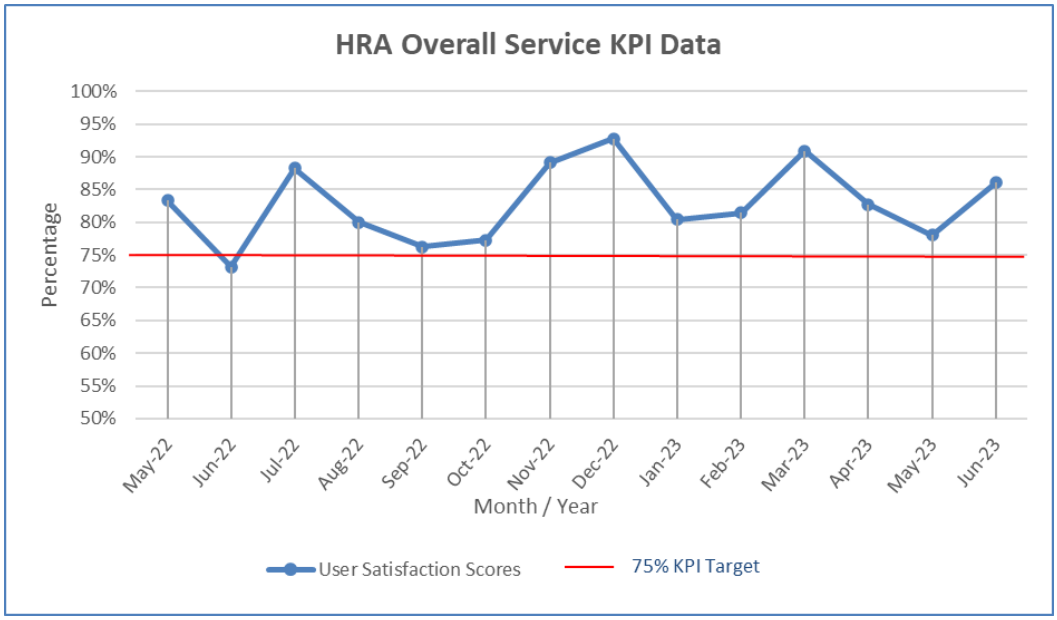
Q1: 86%

Maximum target: 91%.

Staff capacity has improved slightly from March 2023.

↮

Customer satisfaction



Customer satisfaction outperforms our target of 75% throughout the period and achieved an improvement in June (86%).

↮

Ethics review of CTIMPs

Median time to complete full review *34 days*

Proportion of full reviews completed in 60 days *96%*

96% (77 out of 80) combined review CTIMPs were reviewed within 60 days.

↮

Forecast expenditure within 4% of funding

Overall ✓ *Research systems programme* ✓

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

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Strategic risk update

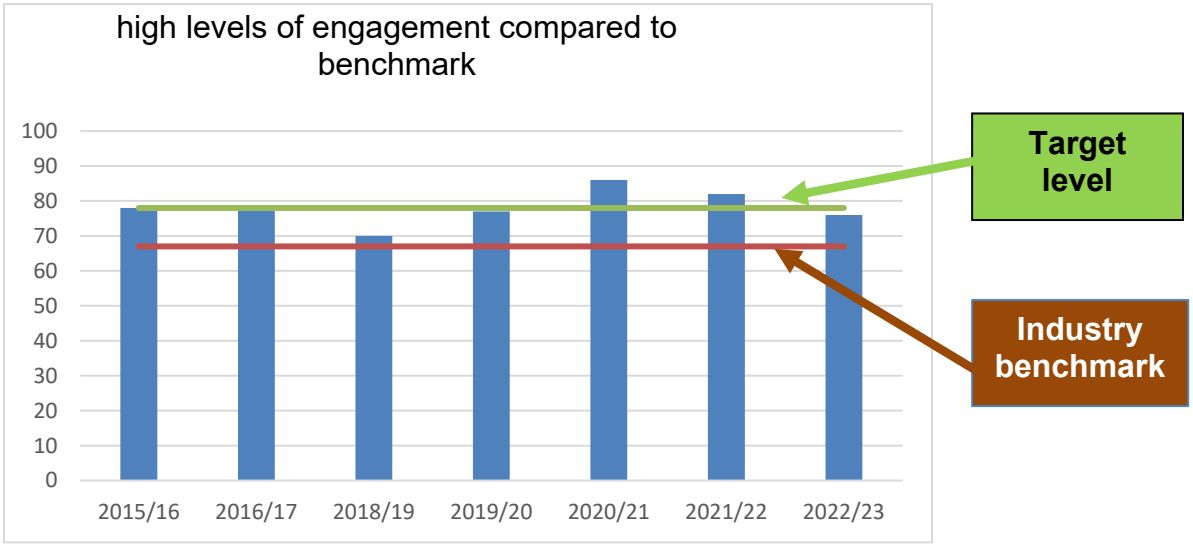
Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
HRA1	**Research Systems -** The HRA is unable to deliver transformed research systems as it does not have the capacity to deliver a complex programme with multiple connections and dependencies across a number of organisations 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 2022 and remains as 20 until a procurement partner is appointed. Weekly meetings taking place to prioritise and address actions.
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 approved at January Board meeting. Community Committee to be established in HRA Standing Orders and recruited to in 2023.
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**	↔	Score remains low due to a reduction of frequency, scale, and risk of 3rd party complaints. Community Committee to be established which will support the trust of the public.

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
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**		Closed
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**	↑	Although good controls are in place risk escalated to Board due to continued international cyber activity. Risk impact score has recently been increased along with the trend due to monitoring impact that MoveIT and Manchester University cyber-attacks have had on the HRA.
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**	↔	Closed
HRA9	**Financial -** The HRA may not be able to deliver its objectives due to financial pressures.	**12**	**8**	New	Predicted budget planning completed. Risks associated with budget shortfalls identified. Further business planning prioritisation session to take place in September.
HRA10	**Reputational -** Delays of approval from other regulators erodes trust in the whole regulatory system, including the HRA.	**8**	**4**	New	Transparent communication with researchers. Further communication to take place with other regulators.

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
HRA11	**Reputational -** The HRA is unable to recruit or retain an effective workforce due to the current employment market	**16**	**8**	New	Strategic workforce planning to report in December 2023 as part of business planning process.

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%

Maximum target: 91%.

Staff capacity has improved slightly from the end of last year.

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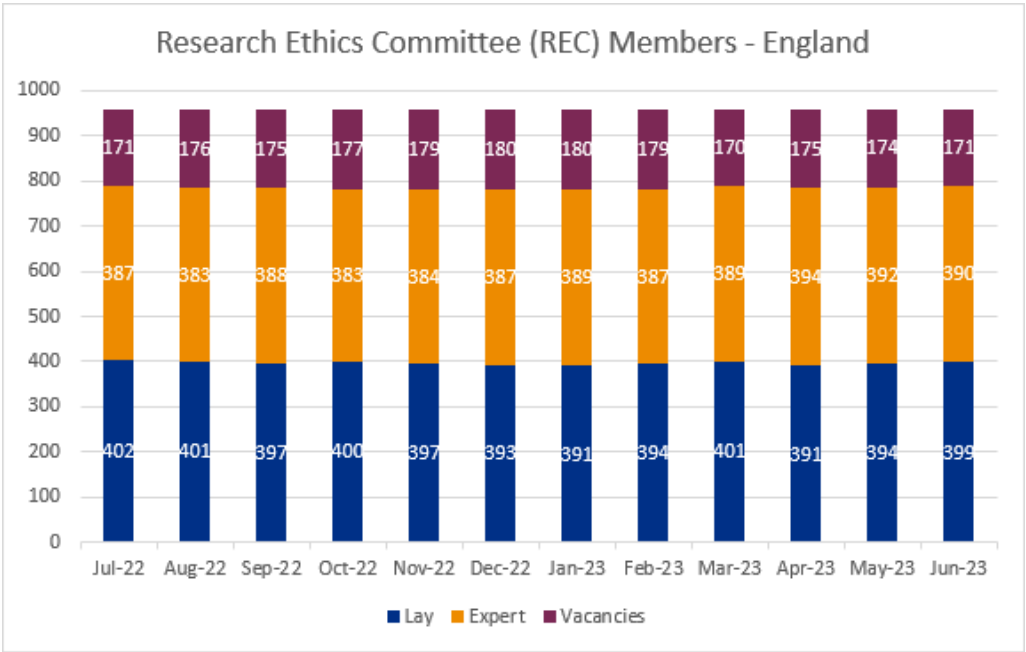
Research Ethics Committee (REC) members (England only)



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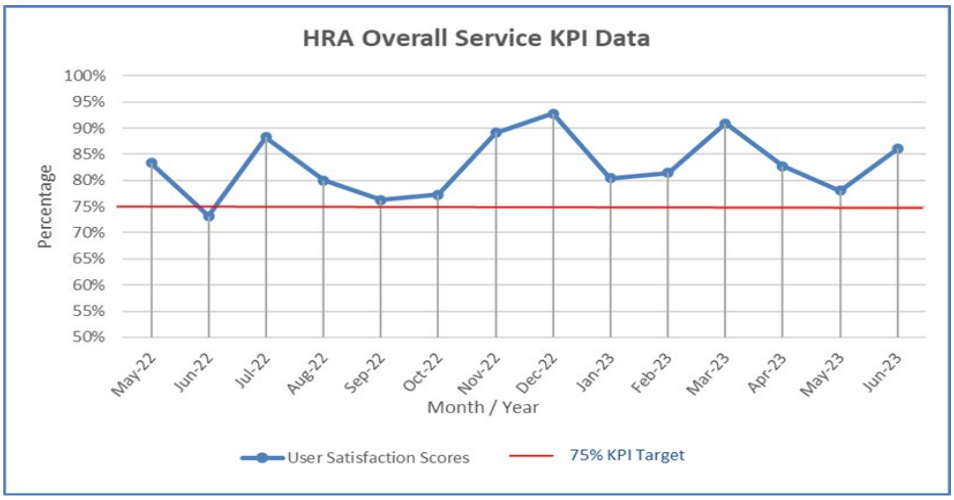
Vacancies: Based on 15 members per REC, target membership is 960. The chart above shows at the end of June 2023, we had 789 REC members of which 399 were expert and the service was operating with an 18% vacancy rate.

Membership: Expert members are members with who are registered health and social care professionals or members with expertise in clinical research. At the end of June 2023, 25% of RECs had five or less expert members, none had less than 4 expert members.

Recruitment activities
In March 2023, we started a recruitment campaign to recruit lay plus members to ensure RECs are correctly constituted in line with GAfREC and the Clinical Trials Regulations. By the end of June 2023, we had received 210 applications (66 expert, 68 lay and 76 lay plus).

Our customers and stakeholders

Customer satisfaction



Customer satisfaction outperforms our target of 75% throughout the period and achieved an improvement in June (86%).

Finance

Forecast expenditure within 4% of funding

Overall ✓ Research systems programme ✓

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

Approvals service

Number of applications for HRA Approval

April 2019 – June 2019:	1235
April 2020 – June 2020:	977
April 2021 – June 2021:	1043
April 2022 – June 2022:	998
April 2023 – June 2023	1062

Number of applications for REC review only

April 2019 – June 2019:	259
April 2020 – June 2020:	235
April 2021 – June 2021:	240
April 2022 – June 2022:	217
April 2023 – June 2023	205

Long-term trends indicate new applications reduce by approximately 6% each year. Application numbers dropped by more than this during COVID-19 except in 2021/22 when we received a surge in applications for REC review only. These applications are now back to the numbers we would expect. This is due to phase 1 healthy volunteer studies returning to pre-pandemic levels balanced by a greater reduction in student applications compared to long-term trends following changes we made to eligibility criteria. Applications for HRA and HCRW Approval increased in June 2023, it is currently not possible to determine if this is a one-off surge or the start of a trend.

Ethics review of combined review CTIMPs (England only)

Combined review CTIMPS	**Jan-23**	**Feb-23**	**Mar-23**	**Apr-23**	**May-23**	**Jun-23**
Median time to complete full review	38	33	30	28	34	39
Full reviews completed in 60 days	91%	100%	100%	100%	100%	86%
Full reviews completed in 60 days	43	39	27	27	31	22
Total completed	39	39	27	27	31	19
Studies Submitted for Review	58	76	61	63	61	71

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, 96% of applications are processed within 60 days in the three months to 30 June 2022. These timelines reflect the time taken to provide an ethical opinion only. Applicants have been experiencing significantly longer timelines before receiving their joint approval due to the backlog and delays at the MHRA.

Three combined review CTIMPs were not approved within 60 days during the reporting period, all in June. Two applications were not approved within 60 days due to members of the REC not responding within the required time, steps are being taken with the members in question to ensure they understand the importance of responding promptly when reviewing a RFI. The other application overran due to an error by HRA staff. This was compounded due to vacancies within the approval team which are now filled.

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

Fast Track ethical review	Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23
Median time to complete full review*	30	28.5	18.5	17	26	29
Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	8	8	11	7	9	7
Total completed in 60 days	8	8	11	7	9	7
Studies submitted for review	13	18	13	16	24	19

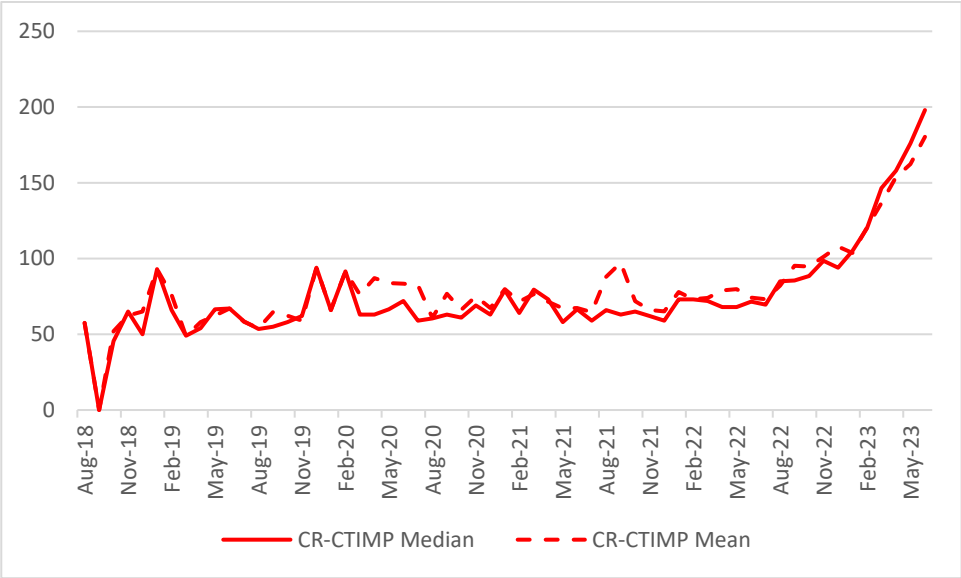
Fast-track combined review studies have comparable timelines to non-combined review studies for REC review. Phase I trials MHRA have a shorter timeline for review that aligns with our fast-track timeline. From Aug22 fast-tracked applications are reviewed as part of the existing ethics service. Median 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

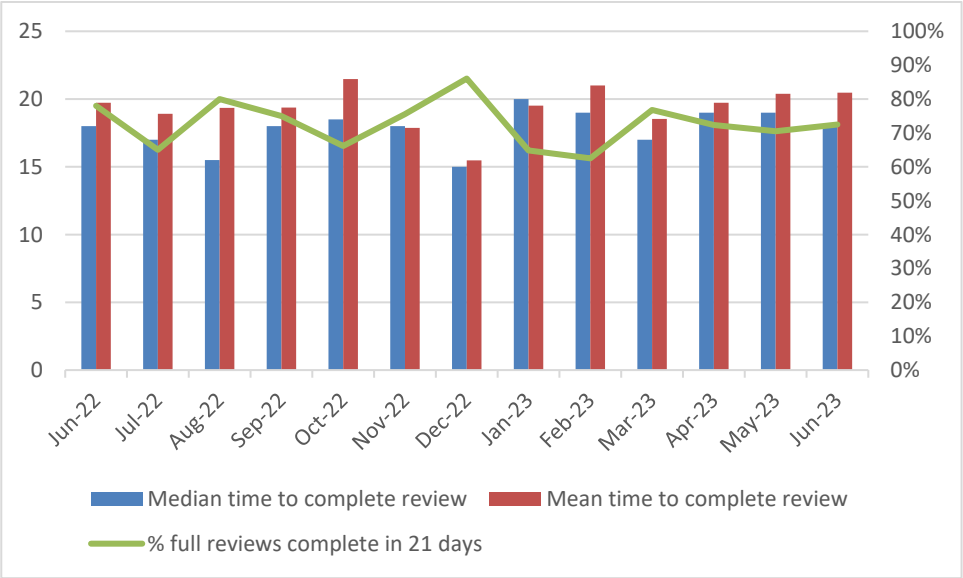
review median normally maps closely to mean showing a more predictable process, but divergence over summer 2021 shows that a small number of outliers (caused by IT issues and staff familiarising themselves with the new process) affected predictability. Steps have been taken to address these anomalies 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 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.



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 did improve in the last quarter 2022 but has since dropped back slightly and is has now plateaued with just over 70% of applications receiving an ethical opinion within 21 days. Further work is ongoing to try and improve the timelines.



Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	35 days	11
May	39 days	8
June	34 days	14

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%