

Agenda item:	9
Attachment:	A-C

HRA Board

20 March 2024

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:	<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 for quarter three.</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 2023 - Dec 2023

High level dashboard

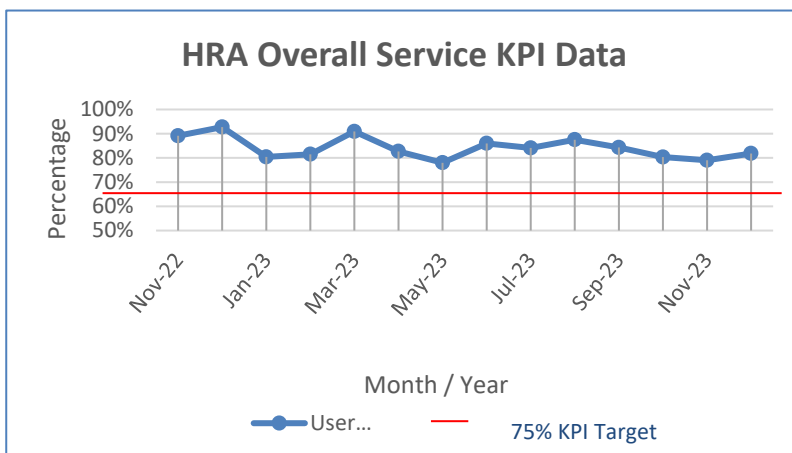
Staff capacity

Q1: 86% Q2: 84% Q3: 84% Maximum target: 91%.

Staff capacity has stabilised but is still lower than planned. Recruitment to new roles to enable the research systems programme is ongoing with roles beginning to join the programme in Q4.



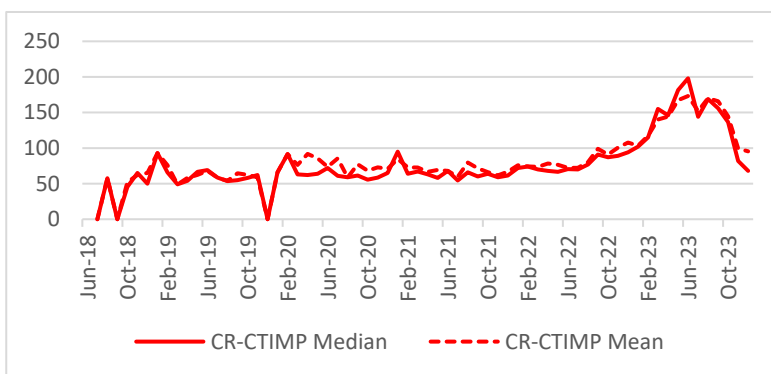
Customer satisfaction



Customer satisfaction outperforms our 75% target throughout the period and achieved 82% in December.



Our services: HRA approval



HRA Approval timelines are now in line with expected timelines following longer timelines earlier in the year due to MHRA service delays.



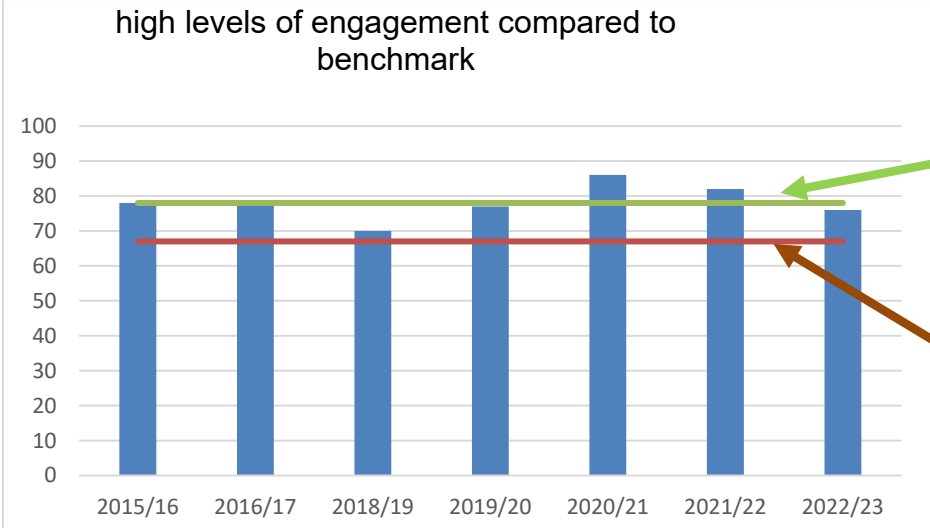
Our services: ethics review of CTIMPs		↑↑
Median time to complete full review	32 days	
Proportion of full reviews completed in 60 days	99%	
99% (245 out of 247) combined review CTIMPs were reviewed within 60 days.		
Forecast expenditure within 4% of funding		↓↓
Overall	Research systems programme	
✓	✗	
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.		

Strategic risk update

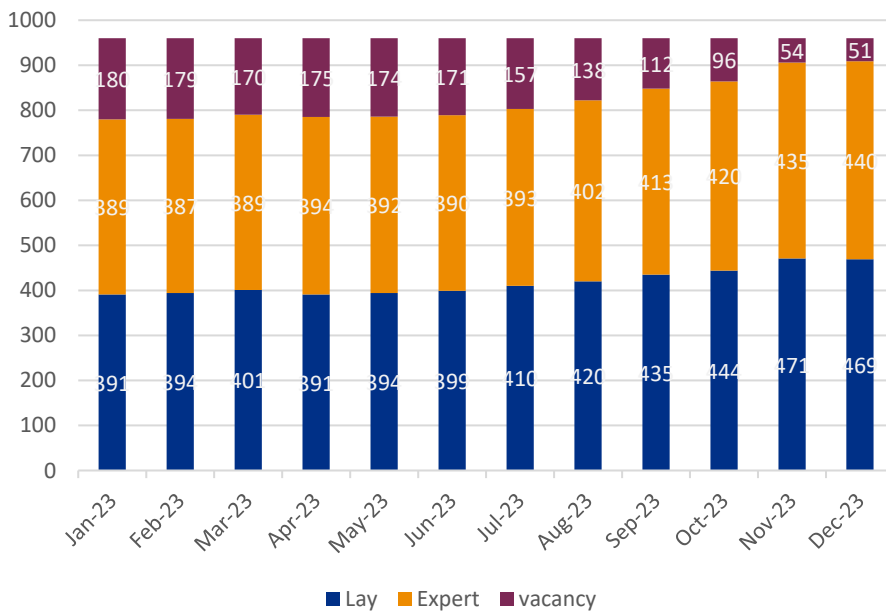
Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
HRA1	Research Systems - The HRA is unable to deliver transformed research systems as it does not have the capacity to deliver a complex programme with multiple connections and dependencies across a number of organisations and is unable to understand or meet the requirements of the health research community.	20	8	↔	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. Development of an EDI Strategy with built in accountability.
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.
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	↔	Introduction of Cloud access security Broker, Cyber awareness, continued engagement with providers, a full offsite immutable cloud backup, and a Vysiion

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
					hardware infrastructure upgrade completed October 2023
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	↔	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 with predicted budget planning completed.
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	↔	People strategy has been updated, annual staff survey completed and staff voices group continuing to be developed.
HRA14	Reputational - Loss of the data and AI team, including expert individuals and strong cross-sector networks and engagement due to significantly reduced ongoing funding. This will mean that the HRA is less able to support new ways to do research, as set out as a strategic objective in our strategy.	16	4	New	New Risk added to the register with Business Planning and Risk Management systems controlling the risk.

Our people

<p>Staff engagement (based on annual staff survey) Industry benchmark</p> <p>high levels of engagement compared to benchmark</p>  <table border="1" data-bbox="151 403 1085 929"> <caption>Staff Engagement Data</caption> <thead> <tr> <th>Year</th> <th>Engagement Level (%)</th> </tr> </thead> <tbody> <tr> <td>2015/16</td> <td>78</td> </tr> <tr> <td>2016/17</td> <td>78</td> </tr> <tr> <td>2018/19</td> <td>70</td> </tr> <tr> <td>2019/20</td> <td>78</td> </tr> <tr> <td>2020/21</td> <td>86</td> </tr> <tr> <td>2021/22</td> <td>82</td> </tr> <tr> <td>2022/23</td> <td>76</td> </tr> </tbody> </table> <p>HRA staff 76% (target: 78%) (shown in green above)</p> <p>Industry benchmark: 67% (shown in brown above)</p> <p>March 2023</p>	Year	Engagement Level (%)	2015/16	78	2016/17	78	2018/19	70	2019/20	78	2020/21	86	2021/22	82	2022/23	76	<p>↕</p>
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<p>Staff capacity</p> <p>Q1: 86% Q2: 84% Q3: 84% Maximum target: 91%.</p> <p><i>Staff capacity has stabilised but is still lower than planned. Recruitment to new roles to enable the research systems programme is ongoing with roles beginning to join the programme in Q4.</i></p>	<p>↕</p>																
<p>Research Ethics Committee (REC) members (England only)</p> <p>The table below shows REC membership over a 12-month period (January to December 2023).</p>	<p>↑↑</p>																

REC Membership in England



At the end of December 2023, there were 909 members (440 experts, 245 lay members and 224 lay plus members) with a 5% vacancy rate, based on 15 members per committee.

REC Membership RAG Register

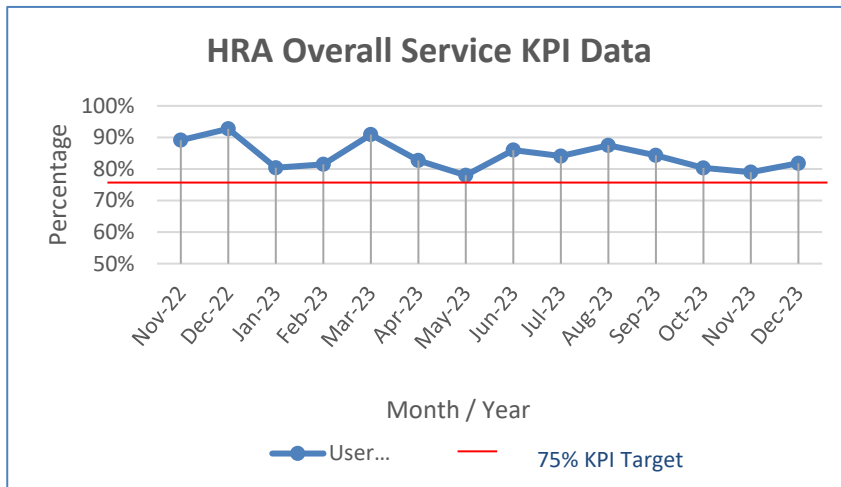
The Member Management and Development Team monitor each REC’s constitution. A RAG register is used to prioritise the placement of new REC members / officers. The text below summarises the RAG register as of 21 December 2023.

Criteria

- Less than one third of REC membership is Lay (1 REC)
- Less than half of lay membership is Lay Plus (Recognised RECs only) (0 RECs)
- Five or less Expert members (6 RECs)
- Less than 10 members (1 REC)
- Number of Breaks higher than 13% of membership (10 RECs)
- Chair vacancy (0 REC)
- Vice Chair vacancy (1 REC)
- Alternate Vice Chair vacancy (Recognised RECs only) (6 RECs)

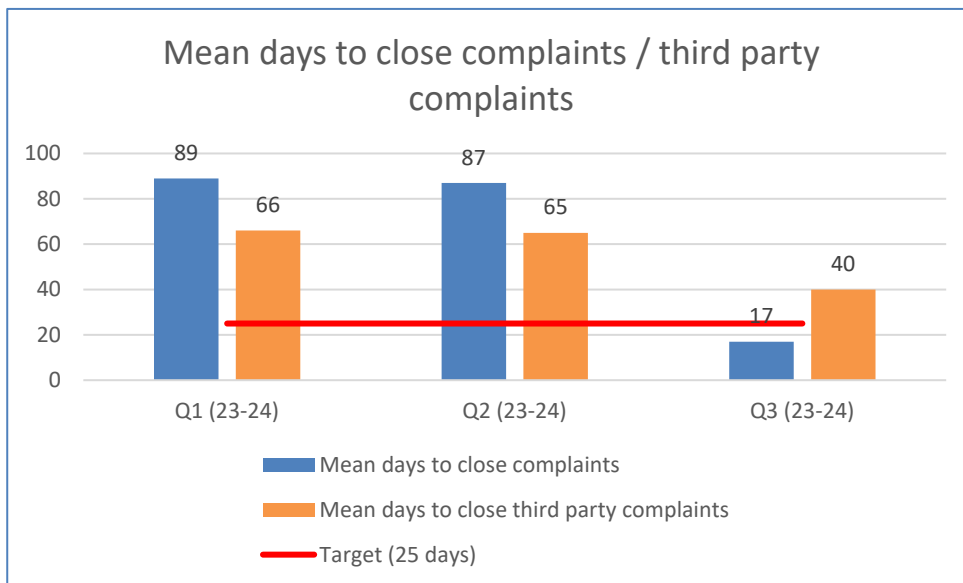
Our customers and stakeholders

Customer satisfaction



Customer satisfaction outperforms our 75% target throughout the period and achieved 82% in December.



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



The backlog of outstanding complaints has largely been addressed with the mean time to close complaints about the HRA down from 89 and 87 days in Q1 and Q2 respectively to 17 days in Q3. Three complaints were received in Q3 (between October and December 2023) with all 3 complaints responded to within the 25 working days deadline. One complaint remains outstanding from July 23.

Third party complaints, which relate to complaints about research approved by the HRA, and not directly about the HRA, take longer to resolve as this involves liaison with the third party, usually the research team or sponsor. Third party complaints do not have a target date for completion however we ensure the complainant is kept updated every 25 days as to the progress of their complaint.

Finance

Forecast expenditure within 4% of funding	
Overall	Research systems programme
	
<i>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.</i>	

⇓

Approvals service

Number of applications for HRA and HCRW Approval

April 2019 – December 2019:	3349
April 2020 – December 2020:	2772
April 2021 – December 2021:	2922
April 2022 – December 2022:	2782
April 2023 – December 2023:	2697

Number of applications for REC review only

April 2019 – December 2019:	751
April 2020 – December 2020:	670
April 2021 – December 2021:	664
April 2022 – December 2022:	591
April 2023 – December 2023:	587

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.

Ethics review of combined review CTIMPs (England only)

Combined review CTIMPS	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23
Median time to complete full review	34	31	36	33	31	30
% of Full reviews completed in 60 days	93%	99%	97%	99%	99%	100%
Total Completed	30	110	146	107	82	58
Total completed in 60 days	28	109	141	106	81	58
Studies Submitted for Review	48	56	65	65	61	41

Combined review

Combined review is the way Applicants 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, 99% of applications are processed within 60 days in the three months to 31 December 2023. These timelines reflect the time taken to provide an ethical opinion only.

Two combined review CTIMPs were not approved within 60 days during the reporting period (October – December 2023). The reasons for this are as follows:

- October 2023 – one application overran due to a delay in members reviewing the request for further information (RFI).
- November 2023 - one application overran due to a delay in members reviewing the RFI.

We have put in place additional steps to monitor and to prevent these overruns from happening in the future. It should be noted that these overruns were with different committees.

Data (both median times and number of studies completed) is only shown for studies that have a joint outcome from both the MHRA and REC. More studies have been submitted for review than have been approved due to outstanding responses from Applicants responding to the request for information (RFI).

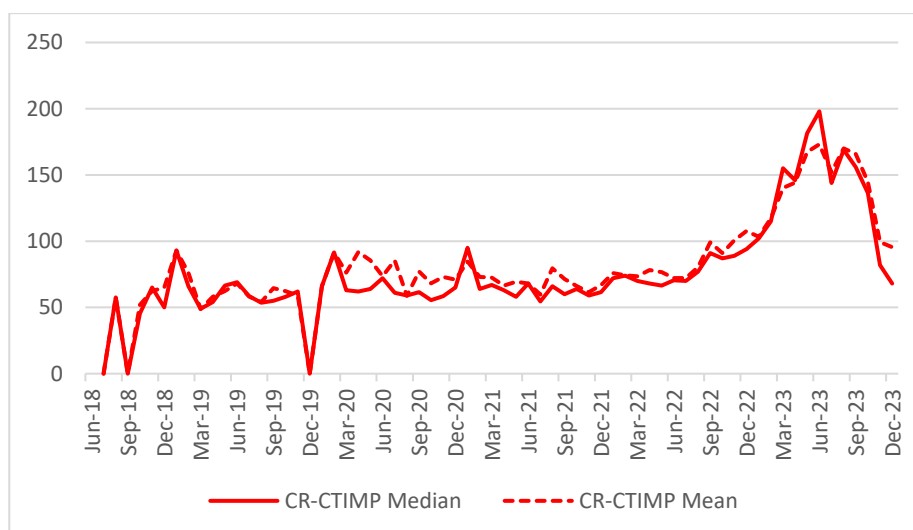
Fast-track Ethical Review (combined review, non-COVID-19 studies)

Fast Track ethical review	Jul-23	Aug-23	Sep-23	Oct-23	Nov-23	Dec-23
Median time to complete full review	27	23	34	23	30	27
%Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total Completed	7	23	31	19	28	20
Total completed in 60 days	7	23	31	19	28	20
Studies Submitted for Review	9	9	19	25	24	20

Data (both median times and number of studies completed) is only shown for studies that have a joint outcome from both the MHRA and REC. More studies have been submitted for fast-track review than have been approved due to outstanding responses from Applicants responding to the request for information (RFI).

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.



HRA Approval timelines are returning to expected timelines following an increase last summer caused by delays with the MHRA issuing joint outcomes. This has now been resolved and timelines are returning to historic levels. Median timelines are still slightly higher than experienced before the MHRA delays but are still dropping. However the mean timeline is significantly higher showing that work still needs to be done to improve the consistency of the process.

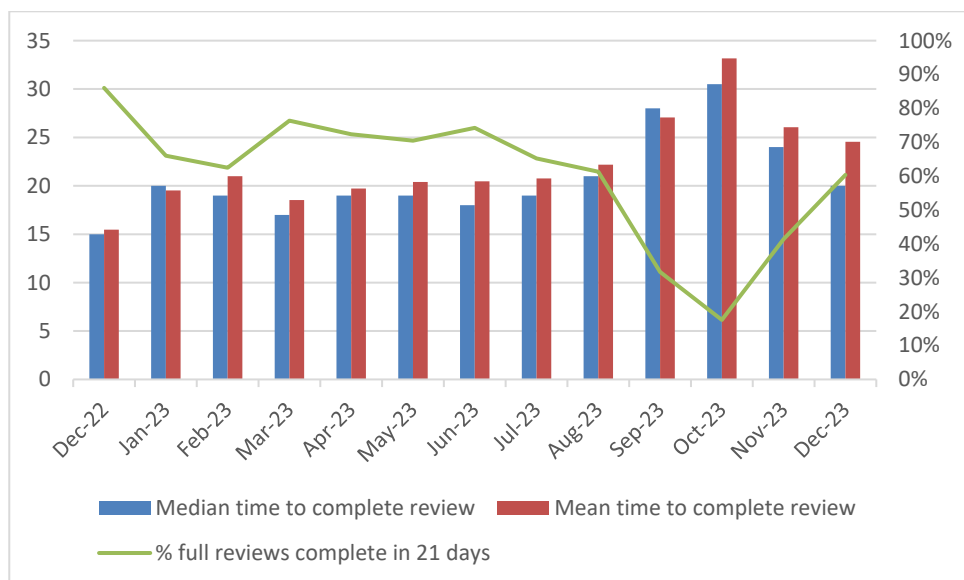
Proportionate Review (PR)

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.

During Summer 2023 there was a higher demand for the PR service due to the PR suitability pilot which meant that timelines for PR applications did increase significantly between August and November 2023. There were 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. Timelines improved in December with 60% of PR applications receiving a final opinion within 21 days – this is approaching similar levels before the pilot ran.

Learning from this pilot has been used to better plan for meetings in 24/25 as well as make some changes to how proportionate review applications are processed to simplify and speed up the process. From April 2024 HRA staff will only undertake a minimal screening of PR applications for suitability, this will alter the balance of applications of applications that are reviewed at full REC and PR sub-committee (PRSC) meetings. We have made changes to the number of slots at both full REC meetings and PRSC meetings to accommodate this new balance of applications. Recognised and Authorised RECs will have a different slot allocation to enable this.

We will also be aligning the cut-off date and meeting date for PRSC meetings, giving members 7 days to reach a decision and being clear about deadlines. Responses to a Provisional Opinion for a PR application will now be reviewed by staff which should reduce the time taken to review these responses. Guidance and training for REC members and HRA Staff will be given before this goes live in April.



Median approval timeline for CAG research studies

Month	Days from submission to completion	Number of applications
April	36 days	7
May	39 days	4
June	35 days	10
July	23 days	7
August	50 days	2
September	45 days	12
October	40 days	5
November	34 days	10
December	23 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%
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%