

<b>Agenda item:</b>	7
<b>Attachment:</b>	A

## HRA Board paper



**16 March 2022**

<b>Title of paper:</b>	<b>Strategic performance report: April 2021 - Jan 2022</b>
<b>Submitted by:</b>	Karen Williams, Deputy Chief Executive and Director of Finance
<b>Summary of paper:</b>	To provide the HRA Board with a review of strategic performance
<b>Reason for submission:</b>	For approval
<b>Further information:</b>	<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"> <li>• Our people</li> <li>• Our customers and stakeholders</li> <li>• Our services</li> <li>• Finance</li> </ul> <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 2021 to January 2022.</p> <p>This report provides a high-level strategic dashboard as well as a more detailed performance report to the Board.</p>
<b>Budget / cost implication:</b>	N/A
<b>Dissemination:</b>	Published on HRA website with Board papers
<b>Time required:</b>	15 minutes

# Strategic performance report 2021/22: April-Jan

## High level dashboard

<p><b>Staff capacity</b></p> <p>Apr/May: 74%</p> <p>Jun/Jul: 78%</p> <p>Aug/Sep 82%</p> <p>Oct/Nov:86%</p> <p>Dec/Jan: 86%</p> <p>Maximum target: 94.5%. Target is based on number of staff funded minus 4% sick leave KPI and vacancy rate. It is calculated on figures for staff working against figures for staff funded. Steady improvement evidenced and continues to be a key focus for executive committee.</p>	↕																																													
<div data-bbox="151 831 1002 1323" data-label="Figure"> <table border="1"> <caption>HRA Overall Service KPI Data</caption> <thead> <tr> <th>Month / Year</th> <th>User Satisfaction Scores (%)</th> <th>75% KPI Target (%)</th> </tr> </thead> <tbody> <tr><td>Dec-20</td><td>88</td><td>75</td></tr> <tr><td>Jan-21</td><td>93</td><td>75</td></tr> <tr><td>Feb-21</td><td>87</td><td>75</td></tr> <tr><td>Mar-21</td><td>87</td><td>75</td></tr> <tr><td>Apr-21</td><td>80</td><td>75</td></tr> <tr><td>May-21</td><td>88</td><td>75</td></tr> <tr><td>Jun-21</td><td>75</td><td>75</td></tr> <tr><td>Jul-21</td><td>82</td><td>75</td></tr> <tr><td>Aug-21</td><td>80</td><td>75</td></tr> <tr><td>Sep-21</td><td>85</td><td>75</td></tr> <tr><td>Oct-21</td><td>90</td><td>75</td></tr> <tr><td>Nov-21</td><td>78</td><td>75</td></tr> <tr><td>Dec-21</td><td>84</td><td>75</td></tr> <tr><td>Jan-22</td><td>81</td><td>75</td></tr> </tbody> </table> </div> <p><b>Customer satisfaction</b></p> <p>Customer satisfaction outperforms our target, the UK Customer Satisfaction Index for public sector organisations (77%)</p> <p>Feedback received:</p> <p><i>“Committee were brilliant to work with”</i></p> <p><i>“The admin team was really efficient and quick to respond”</i></p>	Month / Year	User Satisfaction Scores (%)	75% KPI Target (%)	Dec-20	88	75	Jan-21	93	75	Feb-21	87	75	Mar-21	87	75	Apr-21	80	75	May-21	88	75	Jun-21	75	75	Jul-21	82	75	Aug-21	80	75	Sep-21	85	75	Oct-21	90	75	Nov-21	78	75	Dec-21	84	75	Jan-22	81	75	↕
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<p><b>Ethical review of CTIMPs (both the combined and non-combined processes)</b></p> <p>Median time to complete full review <span style="float: right; font-size: 1.2em;">29 days</span></p> <p>Proportion of full reviews completed in 60 days <span style="float: right; font-size: 1.2em;">99%</span></p> <p>99% of standard process CTIMPs were reviewed within 60 days (67 out of 68 studies). 100% (60 out of 60) Combined Review CTIMPs were reviewed within 60 days.</p>	↕																																													
<p><b>Expenditure within 4% of funding (to Jan 2022)</b></p>	↕																																													

Overall	Research systems programme
	
<p>£0.7M underspend on core activities confirmed to DHSC mostly due to vacancy rate and virtual working. Research systems programme strategic refresh will look to reprofile delivery with expectation that programme will be within business case funding requirement in total.</p>	

## Commentary

There has been significant change delivered this period with a focus on improving our service offering, streamlining researcher experience and improving transparency in research. We have also celebrated our 10<sup>th</sup> anniversary, reflecting on our many achievements in this time and looking to the future to continue to deliver innovation and improvements. Key activities to note are:

- We launched our combined review service with the MHRA for all Clinical Trials of Investigational Medicinal Products (CTIMPS) applications, simplifying and speeding up research approval for these studies. At the same time, we introduced a free, automatic registration service of applications with full approval through the combined review service. Registration is provided by the ISRCTN Registry using data submitted as part of the approval process. This is a good development offering an improved service for most applicants. We are working with sponsors who already register their trials elsewhere to ensure the burden of registration is not unnecessarily increased by this new service.
- We improved transparency of research by implementing changes to registration deferral including a new maximum deferral timeline of 30 months and researchers expected to publish reduced information on the ISRCTN Registry for all deferrals.
- The Think Ethics programme has started to seek stakeholder views about changes designed to put patients at the heart of research. We have run a series of successful workshops about potential changes to how participant information is developed and reviewed by ethics committees. We have also sought views from a representative sample of the public about what matters to them, what makes research ethical and who they trust to review new research studies.

## External environment

The Medicines and Healthcare products Regulator (MHRA) launched an eight-week public consultation on a set of proposals to improve and strengthen the UK clinical trials legislation in the best interests of patients.

DHSC have asked for more information to inform the comprehensive spending review process including a request for 5% revenue and 20% capital efficiencies on our current baseline. It is anticipated that our funding will be confirmed the w/c 14 March 2022.

## **Outlook for the next period**

Our CAG pilot is due to start in Feb 2022 along with full transition to our combined review service for clinical trials.

We plan to publish our joint statement on public involvement as part of our recovery, resilience and growth programme.

We also will be progressing our strategic redesign of our research systems programme with some early outcomes reported.

## Strategic risk update

The Strategic risk register was reviewed at the 10 February 2022 Audit & Risk Committee with minor amendments.

## Strategic performance in detail

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
HRA1	<b>Research Systems</b> 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 and support the vision of the HRA.	16	8	↔	New CDTO now in post. Strategic review of programme underway.
HRA2	<b>Resources</b> 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 and must prioritise certain programmes or core business delivery.	12	8	↔	Business plan prioritisation taking place Jan/Feb 2022. Awaiting comprehensive spending review outcome.
HRA3	<b>Reputational</b> The HRA has very low representation from individuals with protected characteristics at Board and senior management level 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	↔	Implementation of E, D & I strategy underway
HRA4	<b>Reputational</b> 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	↔	Controls and mitigations are in place to manage this risk.
HRA5	<b>Reputational</b> There is a perception that the HRA is not prioritising the most important areas of improvement to the research landscape or is not communicating	8	8	↔	New approach to managing messaging agreed at

	appropriately the success of programmes to external stakeholders.				Executive Committee.
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## Our people

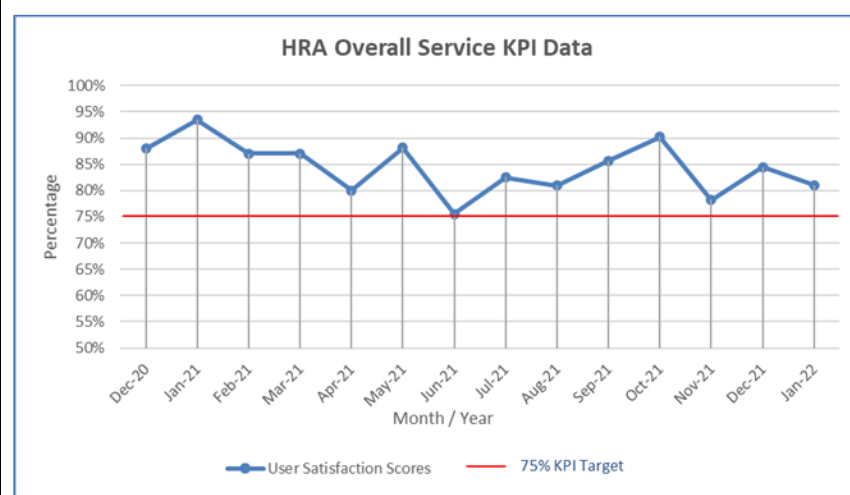
<div data-bbox="151 519 965 1008" data-label="Figure"> <table border="1"> <caption>Staff Engagement Data</caption> <thead> <tr> <th>Year</th> <th>Engagement Score</th> <th>Benchmark</th> </tr> </thead> <tbody> <tr> <td>2017 - 18</td> <td>78%</td> <td>67%</td> </tr> <tr> <td>2018 - 19</td> <td>68%</td> <td>67%</td> </tr> <tr> <td>2019 - 20</td> <td>78%</td> <td>67%</td> </tr> <tr> <td>2020 - 21</td> <td>86%</td> <td>67%</td> </tr> </tbody> </table> </div> <div data-bbox="151 1025 399 1064" data-label="Section-Header"> <h3>Staff engagement</h3> </div> <div data-bbox="151 1077 981 1115" data-label="Text"> <p>Staff engagement based on answers to the annual staff survey:</p> </div> <div data-bbox="151 1126 526 1164" data-label="Text"> <p>HRA staff 86% (target: 78%)</p> </div> <div data-bbox="151 1176 486 1214" data-label="Text"> <p>Industry benchmark: 67%</p> </div> <div data-bbox="151 1227 311 1265" data-label="Text"> <p>March 2021</p> </div> <div data-bbox="151 1276 1300 1344" data-label="Text"> <p>HRA continues to significantly out-perform the industry benchmark and our own internal target.</p> </div>	Year	Engagement Score	Benchmark	2017 - 18	78%	67%	2018 - 19	68%	67%	2019 - 20	78%	67%	2020 - 21	86%	67%	
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<div data-bbox="151 1473 343 1512" data-label="Section-Header"> <h3>Staff capacity</h3> </div> <div data-bbox="151 1525 343 1563" data-label="Text"> <p>Apr/May: 74%</p> </div> <div data-bbox="151 1574 327 1612" data-label="Text"> <p>Jun/Jul: 78%</p> </div> <div data-bbox="151 1624 335 1662" data-label="Text"> <p>Aug/Sep 82%</p> </div> <div data-bbox="151 1675 327 1713" data-label="Text"> <p>Oct/Nov:86%</p> </div> <div data-bbox="151 1724 335 1762" data-label="Text"> <p>Dec/Jan: 86%</p> </div> <div data-bbox="151 1821 343 1859" data-label="Text"> <p>Target: 94.5%</p> </div> <div data-bbox="151 1870 1364 1975" data-label="Text"> <p>Maximum target: 94.5%. Target is based on number of staff funded minus 4% sick leave KPI and vacancy rate. It is calculated on figures for staff working against figures for staff funded. Steady improvement evidenced and continues to be a key focus for executive committee.</p> </div>																
<div data-bbox="151 2004 941 2042" data-label="Section-Header"> <h3>Research Ethics Committee membership (England only)</h3> </div>																

**Number of members:** April (835), May (845), Jun (839), Jul (843), Aug (841), Sep (836), Oct (838), Nov (839), Dec (839), Jan (833)  
**Number of vacancies:** April (125), May (115), Jun (121), Jul (117), Aug (119), Sep (124), Oct (122), Nov (121), Dec (121), Jan (127)  
**Percentage vacancies:** April (13%), May (12%), Jun (13%), Jul (12%), Aug (12.5%), Sep (13%), Oct (13%), Nov (14%), Dec (13%), Jan (15%)

121 new members appointed this year. 17 new members have been interviewed and are awaiting appointment. These successful candidates are at various stages of the recruitment process, e.g. waiting for two suitable references, negotiating which Committees to join, etc. Looking forward, a balanced scorecard approach to monitoring member vacancies is being developed. This will include understanding recruitment pressures, for example in expert members.

## Our customers and stakeholders

### Customer satisfaction



Customer satisfaction outperforms our target, the UK Customer Satisfaction Index for public sector organisations (77%)

Feedback received:

*“Committee were brilliant to work with”*

*“The admin team was really efficient and quick to respond”*

## Finance

### Expenditure within 4% of funding

Overall



Research systems



£0.7M underspend on core activities confirmed to DHSC mostly due to vacancy rate and virtual working. Research systems programme strategic refresh will look to reprofile delivery and funding requirements will be adjusted accordingly.

## Approvals service

### *Number of applications for HRA Approval*

April - Jan 2020:	3990
April - Jan 2021:	3239
April - Jan 2022:	3432

This shows a 14% reduction in applications compared to the same period in 2019/2020. This is primarily due the reduction in research activity due to COVID-19 and our decision to change our approach to student research projects. However, whilst the number of studies reduced, there has been an increase in the complexity of the studies reviewed, particularly complex innovative designs for COVID-19 studies. We have also introduced fast-track REC review widening our service offering.

### *Number of applications for REC review only*

April- Jan 2010:	836
April- Jan 2021:	753
April- Jan 2022:	730

13% reduction in applications compared to the same period in 2019 (10% on 2020). This is primarily due to the reduction in research activity. After a brief pause most Phase I units have continued to undertake trials.

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

Our target is for 100% of applicable CTIMPs to be reviewed by the REC 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, by the Gene Therapy Advisory Committee.

### *Ethics review of standard process CTIMPs*

REC review of standard review CTIMPS (England only)	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22
Median time to complete full review	25	30	25	26	30	30
Full reviews completed in 60 days	100%	97%	100%	100%	100%	97%
Total completed	33	37	44	38	33	35
Total completed within 60 days	33	36	44	38	33	34



The numbers managed through this process will decrease over coming months whilst the transition for all CTIMPs to be processed through combined review is completed.

*Ethics review of combined review CTIMPs*

<b>REC review of combined review CTIMPS (England only)</b>	<b>Aug-21</b>	<b>Sep-21</b>	<b>Oct-21</b>	<b>Nov-21</b>	<b>Dec-21</b>	<b>Jan-22</b>
Median time to complete full review	41	48.5	41	39	36	24
Full reviews completed in 60 days	85%	85%	88%	100%	100%	100%
Total completed	13	20	25	27	27	33
Total completed within 60 days	11	17	22	27	27	33

For statutory timelines applicable to the HRA, 99% of applications are processed within 60 days in the two-month reporting period. One non-combined review CTIMP took over 60 days to be given an opinion in January – this delay was due to the response to the Provisional Opinion being received over the Christmas break. All CTIMP committees are now only accepting Combined Review CTIMPs offering an improved service to all. We saw a dip in performance whilst committees prepared for this service development and staff were trained on the enhanced system. However, performance has now returned to 100% being reviewed within the statutory timeframe in December and January and improvement to median timelines following the transition period. Median timelines for Feb were 37, similar to Nov21 and Dec 21. 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)**

<b>Fast Track REC</b>	<b>Aug-21</b>	<b>Sep-21</b>	<b>Oct-21</b>	<b>Nov-21</b>	<b>Dec-21</b>	<b>Jan-22</b>
Median time to complete full review	14	12	14.5	13	11	12.5
Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	11	8	16	11	3	4
Total completed within 60 days	11	8	16	11	3	4
Studies Submitted for Review	9	16	13	3	4	1

**Fast-track REC (combined review)**

**(Non-COVID-19 studies)**

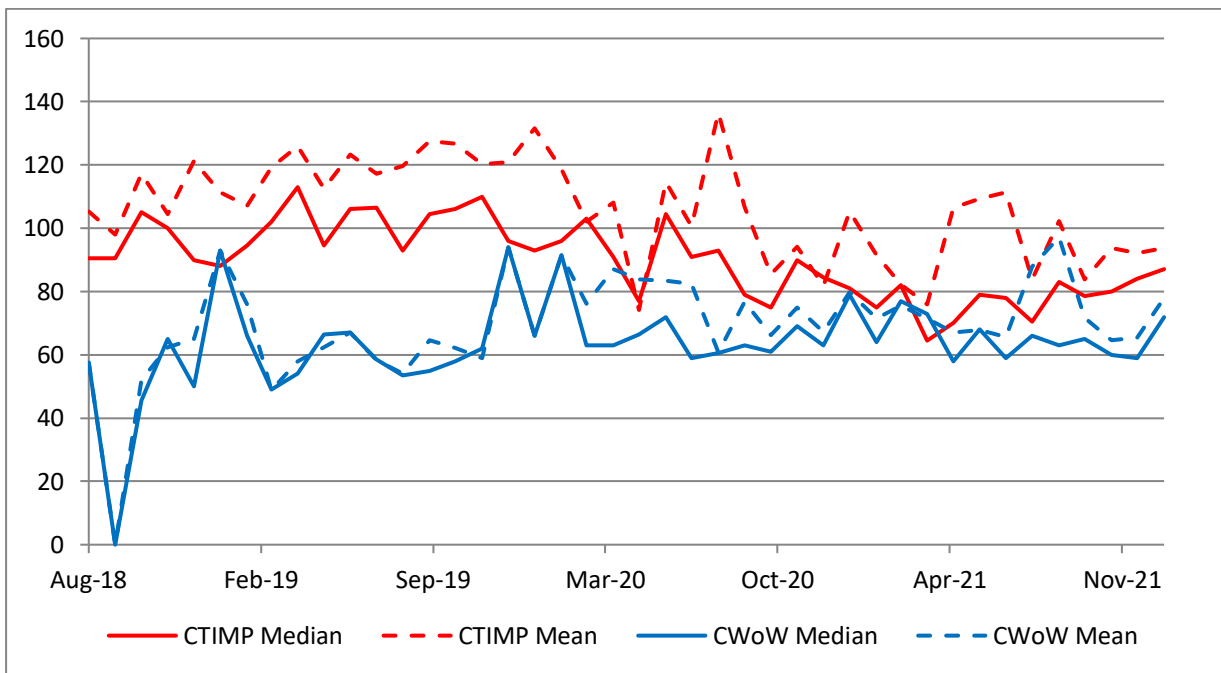
<b>Fast Track REC</b>	<b>Aug-21</b>	<b>Sep-21</b>	<b>Oct-21</b>	<b>Nov-21</b>	<b>Dec-21</b>	<b>Jan-22</b>
Median time to complete full review	19.5	40.5	24.5	15	15	15
Full reviews completed in 60 days	100%	100%	67%	100%	100%	100%
Total completed	2	2	6	1	4	5
Total completed within 60 days	2	2	4	1	4	5

Studies Submitted for Review	6	2	2	4	5	9
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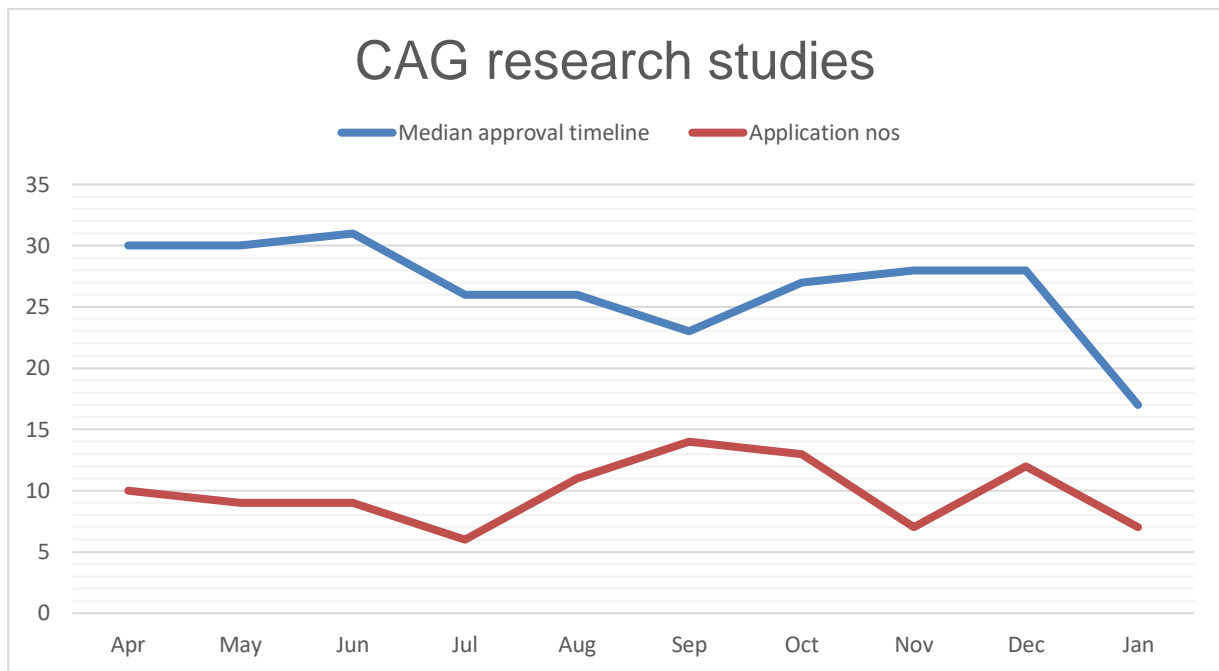
Previously combined review studies considered through our fast-track REC had longer timelines due to the REC review outcome being combined with the MHRA review. This has now been resolved.

### HRA Approval

For HRA and HCRW Approval in England and Wales, the graph (over the page) 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 the summer months 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.



## Median approval timeline for CAG research studies



Note that January is lower than long term median – thoughts are that the outcomes for January were predominantly precedent set applications (6 PS, 1 full), which have shorter timelines to work to.

**Applications not approved but taking a long time: 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%