Agenda item:	7
Attachment:	A

HRA Board paper

17 November 2021

Title of paper:	**Strategic performance report: April 2021- Sep 2021**
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:	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 from April 2021 to September 2021. 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:	15 minutes

Strategic performance report 2021/22: April-Sep

High level dashboard

Staff capacity

April/May 2021	**74%**	
June/July 2021	**78%**	⇈
August/September 2021	**82%**	

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.

Customer satisfaction

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

Feedback received:

"The Staff were extremely supportive and responded to any queries efficiently."

"Pretty smooth process"

"Easy to navigate"

⇄

Ethical review of CTIMPs (both the combined and non-combined processes)

Median time to complete full review	**36 days**	⇈
Proportion of full reviews completed in 60 days	**95%**	

70 out of 71 standard process CTIMPs were reviewed within 60 days. 29 out of 33 Combined review CTIMPs were reviewed within 60 days.

Expenditure within 4% of funding (to Sep 2021)

⇊

Overall   Research systems programme

✕	✕	
£0.5M underspend on core activities confirmed to DHSC mostly due to vacancy rate. Potential risk to achievement of business plan objectives due to delays in mobilisation.		

Commentary

Service delivery remains strong with high levels of user satisfaction despite workforce and capacity pressures. Improvements in staffing levels have been made and will continue over the coming months. In addition, progress continues on transformation and continuous improvement activities including:

- We launched our 'Think Ethics' programme aiming to make ethics review more innovative, efficient and trusted. This builds on many of the changes made to respond to Covid-19 pandemic and lessons from running Research Ethics Committees with fellow regulators in Scotland, Wales and Northern Ireland.
- New reporting standards have been implemented to improve transparency in research in line with the Make It Public research transparency strategy
- Changes have been put in place for standalone student research eligibility to ensure students' experience of research reflects how modern health and social care research is conducted

External environment

Preparations for the comprehensive spending review (CSR) have dominated this period with the HRA creating an ambitious submission including agreed research systems transformation programme and activities aligned with the recovery, resilience and growth programme.

During this period, the Department of Health and Social Care (DHSC) made the decision to extend the existing Control of Patient Information (COPI) notice for a further six months to March 2022 to support the continued use of data over the winter period.

Outlook for the next period

Our first annual 'Make it Public' conference will take place giving participants the opportunity to find out how we are helping to make transparency in research easy, and the impact the strategy is having on health and social care studies. We also anticipate the outcome of the CSR and what it means for the HRA, patients and the public for 2022/23 and beyond. In addition, we continue to support our people to work well wherever they may be, including a survey of our staff to understand their preferred working patterns following the pandemic.

Commentary on performance: Ethics Review of CTIMPs

- 95% of CTIMPs were reviewed within 60 days during the reporting period (70 / 71 standard review and 29 / 33 combined review).
  - Standard review: Delay in one application due to extended discussion between Ethics Committee and MHRA over potential safety issue

o Combined review: For two applications, the response from the applicant was not adequate and required further information. For two other applications, technical issues within digital systems caused delays in staff receiving notifications.

Strategic risk update

The Strategic risk register, following a comprehensive review, has been refreshed and was approved at the 9 November 2021 Audit & Risk Committee without amendment.

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
HRA1	**Digital** 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	↑	Options paper to be developed to outline potential changes to approach and programme design. New CDTO due to begin January 2022.
HRA2	**Resources** The HRA is unable to deliver its business plan objectives due to limited financial and human resources in full and must prioritise certain programmes or core business delivery.	12	8	↔	Awaiting outcome from comprehensive spending review
HRA3	**Reputational** 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	**Reputational** 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	New	A number of controls in place

Strategic performance in detail

Our people

Staff engagement

Staff engagement based on answers to the annual staff survey:

HRA staff 86% (target: 78%)

Industry benchmark: 67%

March 2021

HRA continues to significantly out-perform the industry benchmark and our own internal target.

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Staff capacity

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Target: 94.5%

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.

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Research Ethics Committee membership (England only)

Through routine work collating membership data, we have identified inaccuracies in our historical membership data. Data cleansing is now underway to address this and will be completed before December. We will provide an accurate report following this process.

Recruitment is still proceeding successfully. The move to virtual meetings has attracted new members who welcome the increased flexibility although unfortunately some members have

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left as they preferred not to work in this way. Overall membership has increased slightly over recent months.

Our customers and stakeholders

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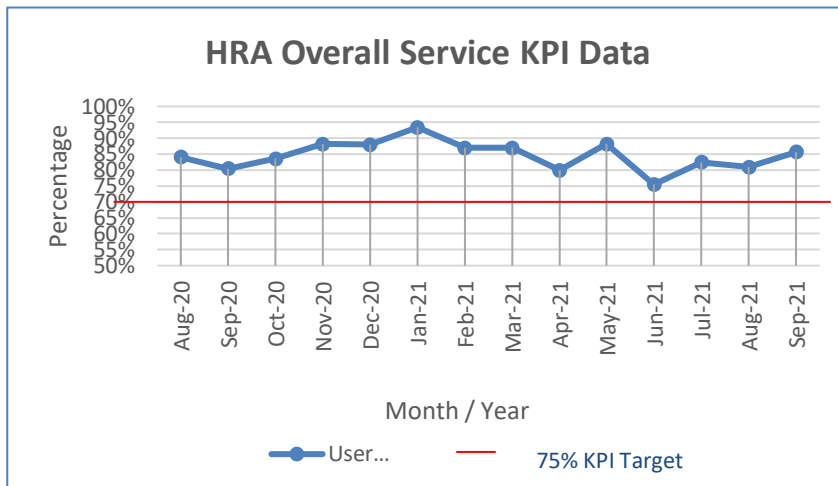
Customer satisfaction outperforms our target, the UK Customer Satisfaction Index for public sector organisations (77%)

Feedback received:

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Finance

Expenditure within 4% of funding

Overall   Research systems

£0.5M underspend on core activities confirmed to DHSC mostly due to vacancy rate. Risk to achievement of business plan objectives may not be achieved due to delays in mobilisation.

Approvals service

Number of applications for HRA Approval

April-Sep 2019:	2,451

April-Sep 2020:	1,958
April-Sep 2021:	2,086

This shows a 15% 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 pause accepting student research projects during this time. 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-Sep 2019:	527
April-Sep 2020:	432
April-Sep 2021:	466

12% reduction in applications compared to the same period in 2019 (18% 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 (KPI 95%). Where the CTIMP is for gene therapy or somatic cell therapy or the product contains a genetically modified organism, our target and KPI 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)	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21
Median time to complete full review	24	22	27	25	25	29.5
Full reviews completed in 60 days	100%	98%	100%	100%	100%	97%
Total completed	61	40	53	48	33	38
Total completed within 60 days	61	39	53	48	33	37

Ethics review of combined review CTIMPs

REC review of combined review CTIMPS (England only)	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21
Median time to complete full review	62	58	69	60	62	63
Full reviews completed in 60 days	100%	100%	69%	93%	86%	90%
Total completed	10	11	16	14	14	19

Total completed within 60 days	10	11	11	13	12	17

Combined review.

For statutory timelines applicable to the HRA, 88% of applications are processed within 60 days in the two-month reporting period. Technical issues (HARP alerts) within the new system have led to delays in staff receiving notifications which increased timelines, however this has now been resolved.

Considerable progress has been achieved in rolling out combined review with only 3 committees remaining (5%). This has increased the availability of the service to researchers. Unfortunately, there has been a dip in performance as staff and members familiarise themselves with the new process and document set. We anticipate that performance will recover as the process becomes business as usual over the coming months. 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)

Fast Track REC	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21
Median time to complete full review	13	14	12	13	14	12
Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	16	14	10	12	11	8
Total completed within 60 days	16	14	10	12	11	8
Studies Submitted for Review	9	12	14	6	9	16

Fast-track REC (combined review)

(Non-COVID-19 studies)

Fast Track REC	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21
Median time to complete full review	n/a	n/a	n/a	n/a	43	57
Full reviews completed in 60 days	n/a	n/a	n/a	n/a	100%	100%
Total completed	0	0	0	0	2	2
Total completed within 60 days	0	0	0	0	2	2
Studies Submitted for Review	0	0	1	1	6	2

Combined review studies considered through fast-track REC have longer timelines due to the REC review outcome being combined with the MHRA review. 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.

**Applications for full REC review of COVID-19 studies (Expedited Review)**

Most COVID-19 applications are reviewed by an appropriate REC within 1-2 weeks of submission and relate to the impact of pandemic on other therapy areas rather than diagnostic or therapy studies. Diagnostic and therapy studies (including vaccine studies) have faster timelines.

The table (over the page) shows the median timeline for studies considered at full REC meetings and studies fast-tracked by timeline category. Median timelines have increased reflecting the changing mix of studies. Clinical trials and investigations continued to be reviewed within a few days. Any COVID-19 fast-tracking is now conducted down the 1-2 week route.

HRA Approval

Full REC	Oct -20	Nov -20	Dec -20	Jan -21	Feb -21	Mar -21	Apr -21	May -21	Jun -21	Jul- 21	Aug -21	Sep -21
Days: Submission to approval	19	16	31	20	20	20	13	17	13	21	19	7
Applications approved	34	32	17	18	15	27	21	9	5	5	5	2
24h turnaround	5	2	2	0	3	3	2	0	0	0	0	0
36h–72h turnaround	17	12	11	13	20	24	5	3	1	0	0	0
1–2 weeks turnaround	14	4	1	0	0	0	4	7	2	6	1	1

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 recent divergence shows that a small number of outliers, as reported above, are affecting predictability. Steps have been taken to address these anomalies in the process and we anticipate a return to more predictable process over coming months.
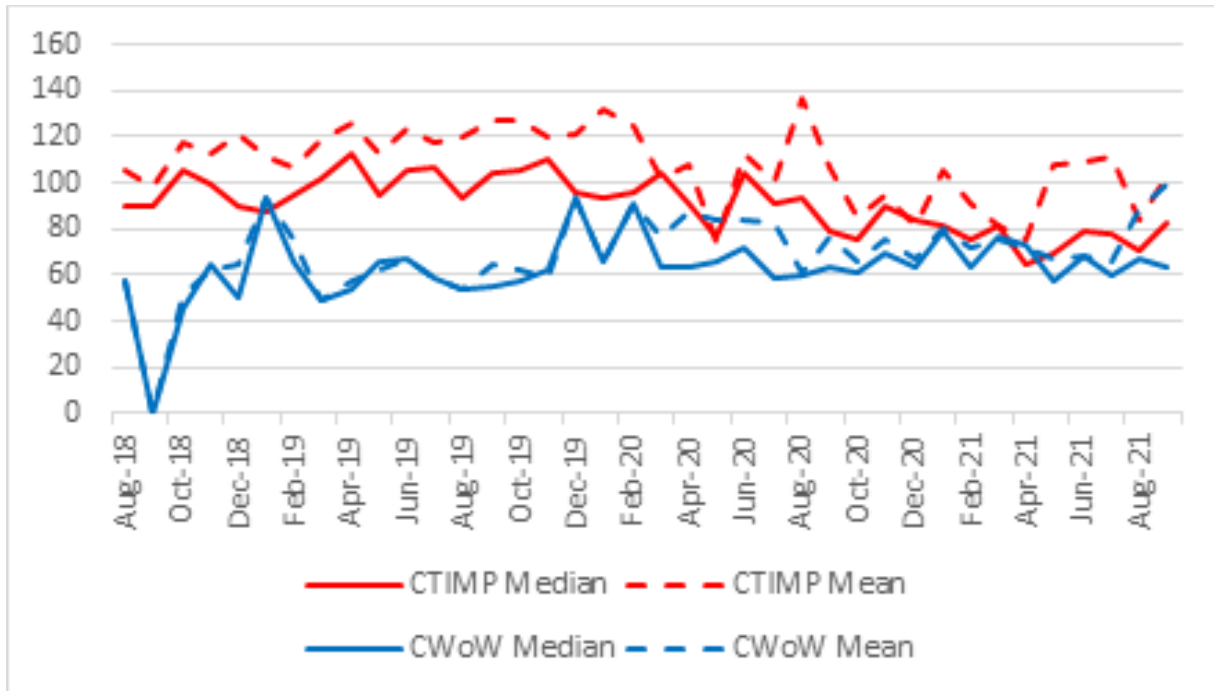
Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	30 days	10
May	30 days	9
June	31 days	9
July	26 days	6
August	26 days	11
September	23 days	14

Applications not approved but taking a long time:

There is one application in progress that is over KPI – this is a precedent set application that is over by 1 day and we are waiting for the response to provisional to be submitted.

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%