Agenda item:	7
Attachment:	A

HRA Board paper

22 September 2021

Title of paper:	**Strategic performance report: April 2021-July 2021**
Submitted by:	Karen Williams, Deputy Chief Executive and Director of Finance and Juliet Tizzard, Director of Policy and Partnerships
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 July 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-July

High level dashboard

Staff capacity

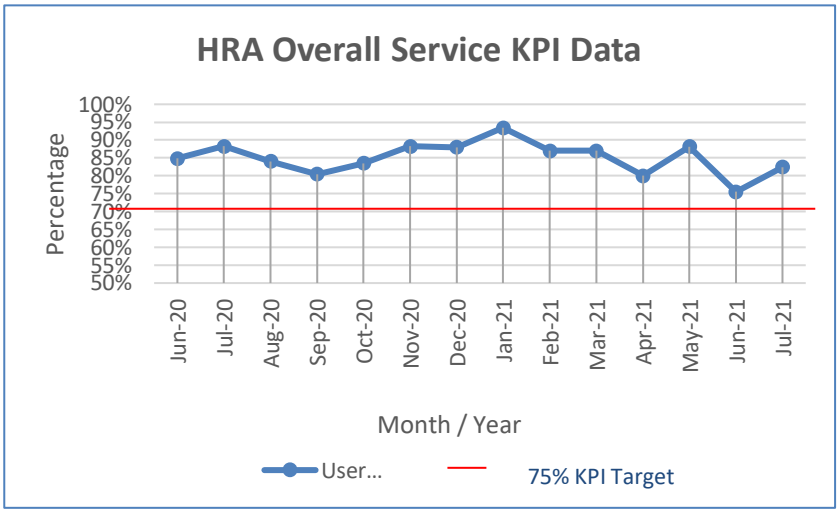
April/May 2021 — 74%

June/July 2021 — 78%

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. Some improvement to KPI although slow. Key focus for executive committee to address.

⇈

Customer satisfaction



Although a slight dip on previous performance, customer satisfaction still outperforms our target, the UK Customer Satisfaction Index for public sector organisations (77%)

Feedback received:

"Very clearly explained"

"Clear-cut and easy"

"Extremely efficient"

⇆

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

Median time to complete full review — 31 days

Proportion of full reviews completed in 60 days — 98%

All (101) standard process CTIMPs were within the statutory timeline for the period. 28 combined review CTIMPs (total 30) achieved the timeline.

⇈

Expenditure within 4% of funding (to July 2021)

⇊

Overall	Research systems programme	
✗	✓	
Underspend on planned expenditure growing. A forensic forecast is planned in September to understand barriers to delivery. If underspend continues there is a risk that business plan objectives may not be achieved due to delays in mobilisation.		

Commentary

In this period, 100% standard process CTIMPs met 60 days statutory timelines for ethics review. In addition, our new fast-track service delivered ethics review in 14 days or less for all applications. Our staff continue to be our strength with staff engagement remaining high.

Areas of focus for improvement are combined review CTIMPs where the 60 days statutory timeline is not being met in all cases. Improvements are being made, with reasons for this non-compliance understood, addressed and a new role created, responsible for improving performance in this area. Staff capacity continues to be a concern. Disappointingly recruitment is slower than anticipated but continues across several channels to resolve this. To help understand what steps can be taken to improve this further, an executive led discovery project has started with the aim to systemically address this perennial challenge.

Programme activity of note:

- Research systems transformation programme released new functionality including single sign on and identity gateway in collaboration with NIHR
- Research review advisory group initial meeting took place
- User research capabilities secured across a number of programmes including research systems and streamlining data driven research
- Volunteer survey published, volunteer group appointed and first meeting held
- HRA's equality diversity and inclusion strategy published

External environment

The Future of UK Clinical Research Delivery: 2021to 2022 Implementation Plan was published in June along with attention moving to the comprehensive spending review 2021.

Comment on performance (including areas of concern for KPIs)

Ethical review of CTIMPs statutory target has been met in 98 % of all cases, falling short of our 100% target. Whilst 100% of standard process CTIMPs met the target this was not the case for combined review where 2 studies out of 31 did not meet the statutory timelines due to problems experienced with the new technology that supports the combined review process. This has now been addressed and will not affect future studies.

Outlook for the next period

Capacity building continues to be a key focus to ensure the HRA delivers on our 2021/22 plans. Significant recruitment and commercial activity is driving this but capacity remains a

challenge Recruitment discovery project has been initiated to help address this. Comprehensive spending review is anticipated to be a priority next period as well as increased focus on supporting our people to return to offices as COVID restrictions reduce.

Strategic risk update

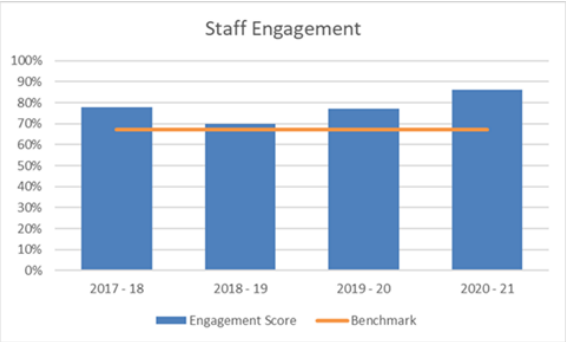
The Strategic risk register is in the process of being refreshed. A discussion on strategic risk was held at the Audit & Risk Committee in August with a revised register to be agreed at the November HRA Board meeting. Interim register detailed below.

Risk ref	Risk title	Residual risk score	Tolerance threshold	Trend	Latest update
SR012	**Research Systems transformation - delivery**	**8**	**8**	⇔	Challenge in meeting expectations / organisational capacity to support business change
SR008	**Research transparency – promotion & compliance**	**8**	**8**	⇔	At threshold, risk has decreased with full team in place and interim registry option agreed
SR011	**Diversity of Board and senior managers**	**6**	**3**	⇔	Above threshold, E, D & I manager in post and strategy published. Implementation plan to follow. Board seminar held in July on unconscious bias training.

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

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Staff capacity

April/May 2021 74%

June/July 2021 78%

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. Some improvement to KPI although slow. Key focus for executive committee to address.

⇈

Research Ethics Committee membership (England only)

Number of vacancies: 106 (Apr / May), 104 (Jun / Jul)

Number of members: 854 (April / May), 856 (Jun / Jul)

Vacancies percentage: 11% April / May, 10% Jun / Jul

There are 64 RECs in England. The maximum number of members is 960. 26 new members were appointed in Jun/Jul taking the total on new members appointed since Apr/May to 55. 33 existing members left the service during the same period. A total of 34 new applications were received in Jun/Jul.

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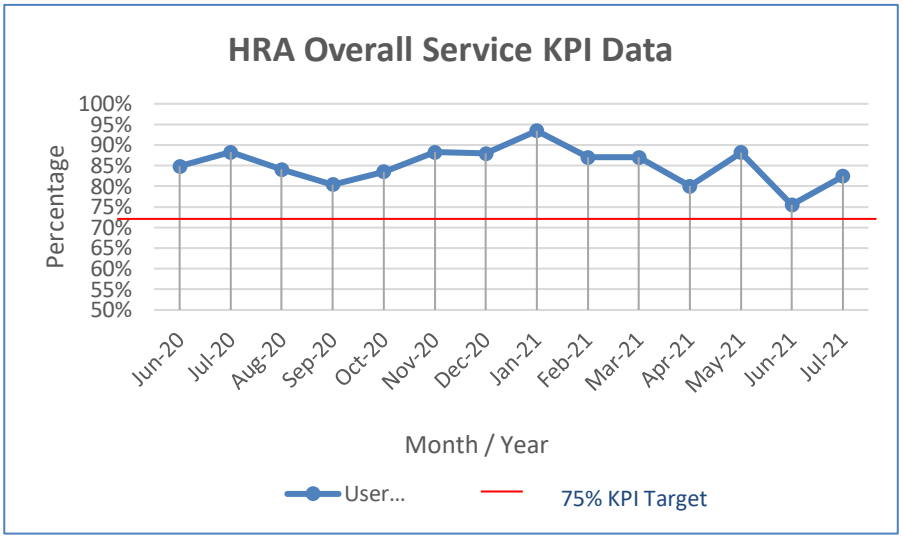
Our customers and stakeholders

Customer satisfaction



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⇅

Finance

Expenditure within 4% of funding

Overall	Research systems
✗	✓

Underspend on planned expenditure growing. A forensic forecast is planned in September to understand barriers to delivery. If underspend continues there is a risk that business plan objectives may not be achieved due to delays in mobilisation.

⇊

Approvals service

Number of applications for HRA Approval

April-July 2019:	1645
April-July 2020:	1303

April-July 2021:	1369

This shows a 17% 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 adding to the complexity.

Number of applications for REC review only

April-July 2019:	334
April-July 2020:	315
April-July 2021:	310

7% reduction in applications compared to the same period in 2019 (6% 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. This slowdown is due to reduced studies from research databases, research tissue banks or CTIMPs taking place solely outside the NHS.

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 (reviewed by the Gene Therapy Advisory Committee).

Ethical review of standard process CTIMPs

REC review of CTIMPS (England only)	**Feb-21**	**Mar-21**	**Apr-21**	**May-21**	**Jun-21**	**Jul-21**
Median time to complete full review	22	24	24	22	27	25
Proportion of full reviews completed in 60 days	100.0%	98.3%	100.0%	97.5%	100.0%	100.0%
Total completed	42	59	61	40	53	48
Total completed within 60 days	42	58	61	39	53	48

Reaching 100% compliance with our statutory target is a key performance indicator. Median time to complete full review remains low at well below 30 days.

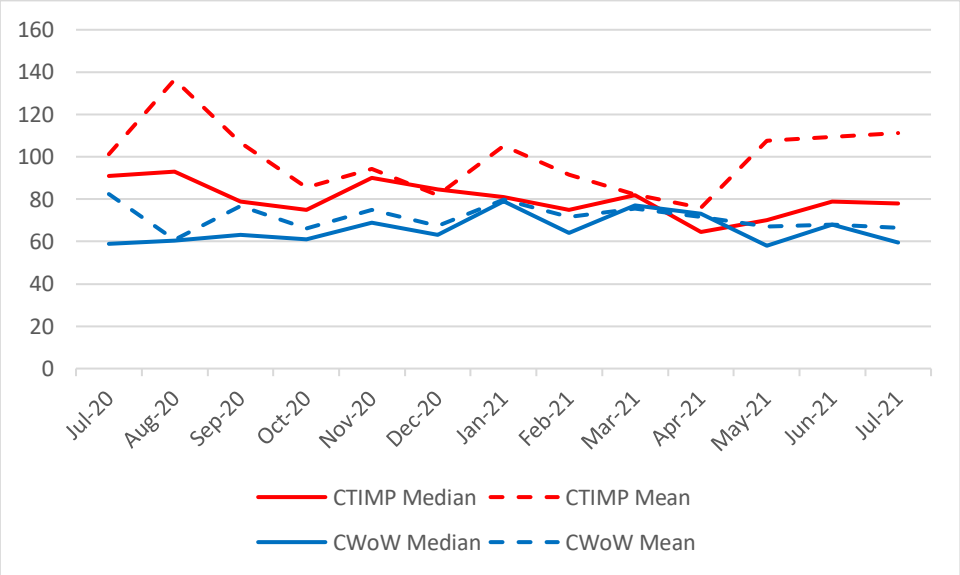
Combined review.

Our new combined review process with MHRA operates on different MHRA timelines as well as our statutory timelines for REC review. Key benefits of combined review include quality and streamlining from the applicant and sponsor perspective as well as existing timelines.

For HRA statutory timelines processing is within 60 days 93% of the time when compared with standard CTIMPs. In the reporting period, two applications exceeded this due to technology interface which has been rectified. HRA has also appointed a dedicated role to improve statutory compliance for combined review as well as researcher experience in general.

HRA Approval

This section covers applications proceeding through to HRA Approval in England and Wales. The graphs below show 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.



Fast-track REC

(Non-COVID-19 studies)

Fast Track REC	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21
Median time to complete full review	14.5	12	13	14	12	13
Proportion of full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	6	16	16	14	10	12
Total completed within 60 days	6	16	16	14	10	12
Studies Submitted for Review	12	18	9	12	15	7

Applications for full REC review of COVID-19 studies under Expedited Review Standard Operating Procedures

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 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.

	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21	Jul-21
Full REC meeting (submission to approval) (Calendar days)	25	19	19	16	30.5	20	20	20	12.5	14	8	10
Full REC numbers approved	30	41	34	32	17	18	15	27	21	9	5	5
24h turnaround submissions	2	5	5	2	2	0	3	3	2	0	0	0
36h – 72h turnaround submissions	7	8	17	12	11	13	20	24	5	3	0	0
1 – 2 weeks submissions	17	22	14	4	1	0	0	0	4	7	2	6

Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
June	31 days	9
July	26 days	6

Applications not approved but taking a long time:

0 applications are being processed with timelines exceeding our target of 35 or 60 days depending on the application type.

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%