Agenda item:	7
Attachment:	A

HRA Board paper

21 July 2021

Title of paper:	**Strategic performance report: April 2021-May 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 May 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-May

High level dashboard

Staff capacity

April/May 2021 74%

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. Capacity reduced for sickness rates above 4% and other types of leave.

Trend is improving (June 78%) with 11 further recruitments in the pipeline - people who have accepted positions but not yet joined.

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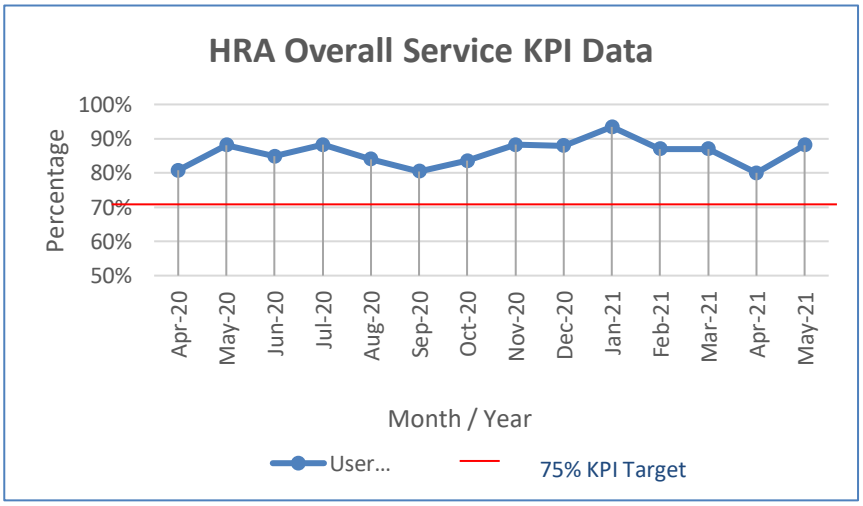
Customer satisfaction



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

Feedback received:

"I was very impressed with the speed of responses and the whole approval process"

"Incredibly quick turnaround"

⇆

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

(April 2021 /May 2021)

Median time to complete full review 26 days

Proportion of full reviews completed in 60 days 93%

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Expenditure within 4% of funding (to May 2021)

Overall Research systems programme

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  Programme activity is taking time to bed in. Full year forecast is expected to be in line with funding however as plans will be rephased to address initial delays.	

Commentary

This period has seen substantial programme activity including the successful completion of the fast track pilot and the launch of the fast track ethics review service to complement our existing services. Other activities to note include:

- UK clinical trials registry project kicked off with funding confirmed to December 2023
- Capacity building within the HRA to support UK research sector developments including 'recovery, resilience and growth', 'find, recruit and follow up' and our research systems transformation programme
- Staff survey report delivered, 76% response rate (up 6% on 2020) with 94% of staff committed to helping the HRA be successful and 82% would recommend the HRA as a good place to work (up 17% on 2020).
- Volunteer survey completed with high response rate (42%) and high levels of satisfaction (in excess of 89% for committee members).
- Annual Report and Accounts 2020/21 approved by Audit and Risk Committee with clean audit report.
- Successfully closed our Nottingham office and agreed head of terms with NHS Supply Chain to provide our future Nottingham base.
- Future ways of working programme launched to support our people to work well following the extended period working from home

External environment

The government's Health and Social Care Bill is due to be launched as well as the Life Sciences Vision. The HRA contributed to both these developments which will have implications for our future strategy.

Comment on performance (including areas of concern for KPIs)

Ethical review of CTIMPs statutory target has been met in 93% of all cases. This falls short of our 100% target. 99% of standard process CTIMPs met the target. Applications for research managed through our combined review process which provides overall timeline benefits to researchers but sometimes falls short on this specific timeline target reduced the overall percentage whilst delivering on other benefits for researchers.

Outlook for the next period

Capacity building is a key focus to ensure the HRA is able to deliver on our 2021/22 plans. Significant recruitment and commercial activity is driving this. Improvements will be delivered as part of our research systems programme offering increased functionality and improvements to single sign on. We also plan to hold our first research review advisory group meeting and volunteer group meeting as well as progress at pace user research work to inform many of our programmes as well as ensuring we achieve GDS assurance for our research systems programme.

Strategic risk update

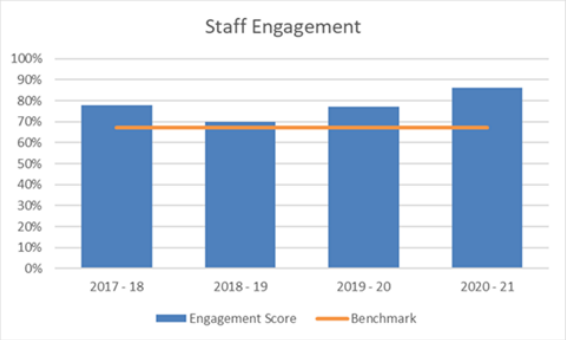
Please note the Executive Committee has held a workshop to brainstorm the strategic risks potentially impacting on delivery of the HRA's business plan 2021/22. The next iteration of the strategic risk register will include these updates.

Risk ref	Risk title	Residual risk score	Tolerance threshold	Trend	Latest update
SR012	**Research Systems transformation - delivery**	**8**	**8**	**NEW**	Challenge in meeting expectations / organisational capacity to support business change
SR008	**Research transparency – promotion & compliance**	**8**	**8**	**Down**	At threshold, risk has decreased with full team in place and UK registry option agreed
SR011	**Diversity of Board and senior managers**	**6**	**3**	**As before**	Above threshold, E, D & I manager now in post and strategy published. Implementation plan to follow.
SR007	**Research Systems transformation – funding and resourcing**	**N/A**	**N/A**	**Closed**	Funds and resourcing now in place. Risk now relates to delivery of complex programme with many interdependencies. New risk added (SR012)
SR002	**HRA long term financial resilience**	**N/A**	**N/A**	**Closed**	Funding provided for this year and baseline agreed for future CSRs
SR004	**UK transition and trade negotiations**	**N/A**	**N/A**	**Closed**	Likelihood of risk has reduced following UK transition on 31 December 2020.
SR010	**Transformation Programme – Risk to Delivery**	**N/A**	**N/A**	**Closed**	Business plan and resource in place / or in the process of being recruited.
SR009	**Impact of COVID-19 on research system and HRA**	**N/A**	**N/A**	**Closed**	HRA contributing to DHSC Recovery, Resilience and Growth programme

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%

Target: 94.5%

The staff capacity target is based on number of staff funded minus our maximum of 4% sick leave KPI and 1.5% vacancy factor. It is calculated based on figures for staff working against figures for staff funded.

Trend is improving (June 78%) with 11 further recruitments in the pipeline - people who have accepted positions but not yet joined.

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Research Ethics Committee membership (England only)

Number of vacancies in April / May: 106

Number of members in April / May: 854

Vacancies percentage in April / May: 11%

There are 64 RECs in England. The maximum number of members is 960. 29 new members were appointed in April/May. In April, a recruitment advert went out to retired NHS Professionals through the BSA pensioners newsletter. This resulted in 393 expressions of interest received for application packs. 30 new applications were received in May alone and when added to the figure for April, a total of 43 new applications have been received during the reporting period.

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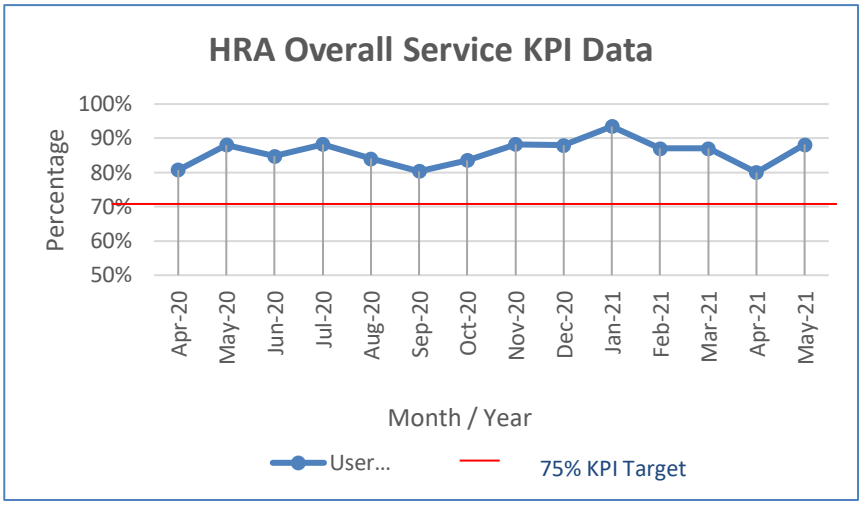
Our customers and stakeholders



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Customer satisfaction

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

Feedback received:

"I was very impressed with the speed of responses and the whole approval process"

"Incredibly quick turnaround"

Finance

Expenditure within 4% of funding

Overall	Research systems
✗	✓

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Programme activity is taking time to bed in. Full year forecast is expected to be in line with funding however as plans will be rephased to address initial delays.

Approvals service

Number of applications for HRA Approval

April-May 2019:	842
April-May 2020:	640
April-May 2021:	680

This shows a 19% reduction in applications compared to the same period in 2019/2020. This is primarily due the overall drop-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 for COVID-19 studies adding to the complexity.

Number of applications for REC review only

April-May 2019:	179
April-May 2020:	157
April-May 2021:	139

22% reduction in applications compared to the same period in 2019 (12% on 2020). This is primarily due to the overall drop 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 CTIMPs

REC review of CTIMPS (England only)	**Dec-20**	**Jan-21**	**Feb-21**	**Mar-21**	**Apr-21**	**May-21**
Median time to complete full review	30.5	28	22	24	24	22
Proportion of full reviews completed in 60 days	100.0%	95.1%	100.0%	98.3%	100.0%	97.6%
Total completed	64	61	42	59	61	41
Total completed within 60 days	64	58	42	58	61	40

Reaching 100% compliance with our statutory target is a key performance indicator and was achieved in December, February and April. Disappointingly, one study was not reviewed within the target in May, giving 99% for studies reviewed in our standard process within target rate for 2021/22 to date. Median time to complete full review remains low at well below 30 days.

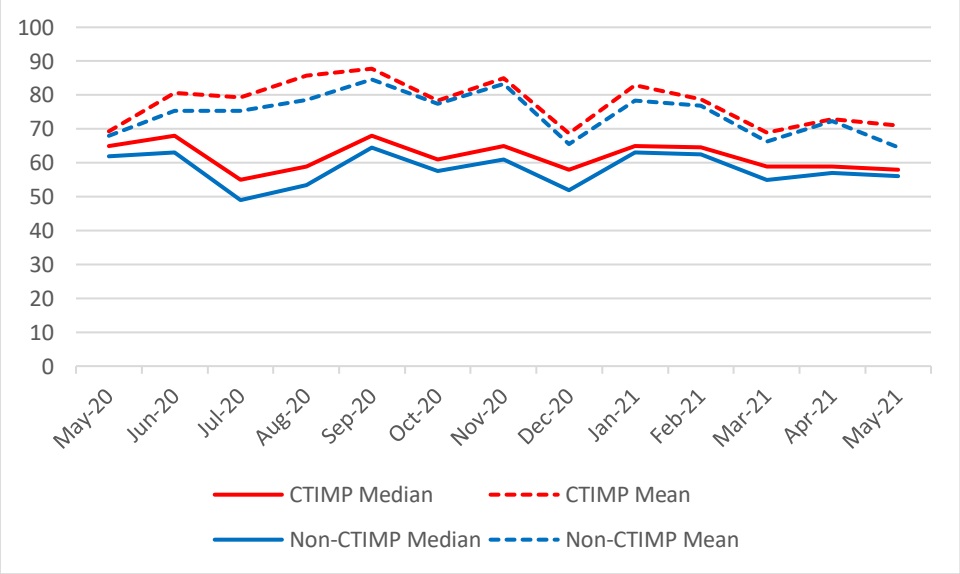
Combined review.

Combined review is not achieving this statutory target as it delivers other benefits to the user experience. Combined review key benefits are the reduction in touchpoints for applicants, the clarity of a combined set of questions, and the removal of early amendments to align requirements of different regulators.

Combined review timelines are not provided in this report as they are not directly comparable to standard process. There is a key difference in the time that is the responsibility of the regulators. For standard studies we can measure the time from the first application (REC or MHRA) to the time we issue the REC's first decision. For combined review studies, the REC's decisions are sent to MHRA who collate them with their decision, and the timepoint measured is the release of the combined decision. This may be delayed if either MHRA's decision is not yet ready or discussion is needed to agree a combined decision. This means that the combined review timeline for decision recorded by the HRA may often be longer than for standard process studies. The total end to end timeline including response time from the applicant is, however, usually quicker for combined review studies as the combined review removes the need for separate responses which delay the overall process.

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 pilot for ethics review

Fast Track REC	Jan-21	Feb-21	Mar-21	Apr-21	May-21
Median time to complete full review	13	14.5	12	13	14
Proportion of full reviews completed in 60 days	100%	100%	100%	100%	100%
Total completed	2	6	16	16	14
Total completed within 60 days	2	6	16	16	14
Studies Submitted for Review	13	12	18	9	12

Fast-track review of COVID-19 studies

Most COVID-19 applications are reviewed within 1-2 weeks of submission, as they relate to the impact of pandemic on other therapy areas rather than diagnostic or therapy studies.

The table below 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. Urgent public health studies and other clinical trials and investigations continued to be reviewed within a few days.

	Apr -20	May -20	Jun -20	Jul-20	Aug -20	Sep -20	Oct-20	Nov -20	Dec -20	Jan -21	Feb -21	Mar -21	Apr -21	May -21
Full REC meeting (submission to approval) (Calendar days)	8	12	20	32	26	18	19	16	30	21	20	17	12	10
Full REC numbers approved	66	94	73	64	33	45	36	34	18	18	16	29	21	9
24h turnaround submissions	18	8	4	2	2	5	5	2	2	0	3	3	2	0
36h – 72h turnaround submissions	21	49	27	11	7	8	17	12	11	13	20	24	5	2
1 – 2 weeks submissions	4	22	44	39	17	22	14	4	1	0	0	0	4	7

Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	30 days	10
May	30 days	9

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%