Agenda item:	7
Attachment:	A & B

HRA Board paper

19 January 2021

Title of paper:	**Strategic performance report: April 2021 - Nov 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 November 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-Nov

High level dashboard

Staff capacity ⇈

Apr/May: 74%

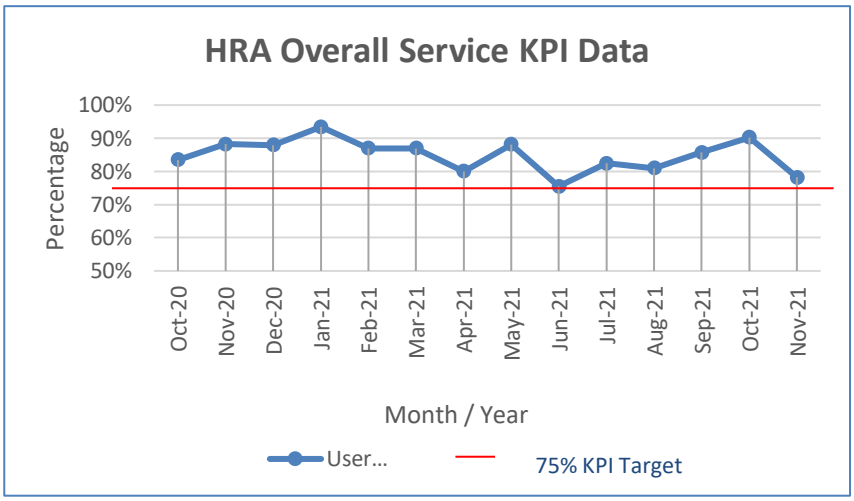
Jun/Jul: 78%

Aug/Sep: 82%

Oct/Nov: 86%

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:

"Efficient process, insightful questions"

"Quick and responsive"

"Prompt and professional"

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%

100% of standard process CTIMPs were reviewed within 60 days (82 studies). 96% (49 out of 51) Combined Review CTIMPs were reviewed within 60 days.

Expenditure within 4% of funding (to Nov 2021) Overall  Research systems programme  £0.5M 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.	↓↑

Commentary

Service delivery remains strong with high levels of user satisfaction despite workforce and capacity pressures. Improvements in staffing levels continue to be made despite challenging market conditions. In addition, good progress has been made on transformation and continuous improvement activities including:

- Significantly reducing approval timelines (approx. 50% lower) and cutting 50 days (on average) off the time it takes to recruit the first research participant through our combined review programme with the Medicines and Healthcare products Regulatory Agency (MHRA).
- Holding our first Make it Public research transparency conference in November with 550 attendees where we launched our first research transparency annual report, updating on the progress we have made towards the vision laid out in our Make it Public strategy.
- Announcing our partnership with ISRCTN, a leading trial registry recognised by the World Health Organisation, to automatically register clinical trials making it easier for researchers to carry out transparent research.
- Widening our radiation assurance service to accept all studies involving ionising radiation exposures taking place in NHS and HSC secondary care settings.
- Introducing improvements to new IRAS giving wider choices of REC meeting dates for applicants and a more flexible booking process that also benefits sponsors.
- Publishing the 2020-21 HRA equality data telling a broadly positive story of progress since the launch of our Equality, Diversity and Inclusion strategy.

External environment

The government published the Autumn Budget and Spending Review 2021. It sets departmental budgets up to 2024-25. Whilst DHSC budget has been set, how the funding is allocated has not. This is now expected to be determined in Qtr4 2021/22 with submissions requested in January 2022 following initial bids submitted summer 2021.

The Secretary of State for Health and Social Care announced that NHSX and NHS Digital are to merge into NHS England and NHS Improvement in order to accelerate the digital transformation of the NHS. This is likely to have implications for the HRA which are being considered as part of our 2022/23 business planning process.

Outlook for the next period

HRA will mark our 10-year anniversary on 1 December 2021 with several events celebrating our achievements as well as looking to our future plans.

From 1 January 2022, our combined review service will be available for all clinical trials of investigational medicinal products (CTIMPs) streamlining and speeding up research approval and study set up.

The pandemic and its continuing impact on NHS capacity to support research is a concern with potential impact on our improvement programmes such as Recovery, Resilience and Growth.

Strategic risk update

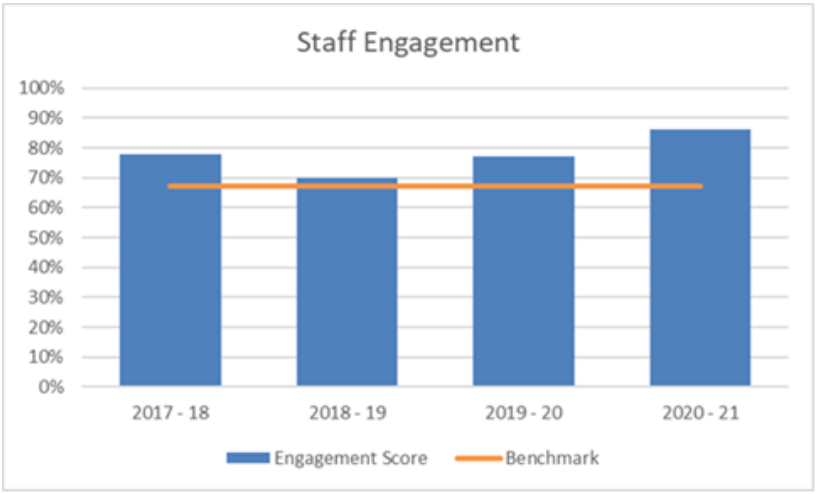
The Strategic risk register, following a comprehensive review, has been refreshed and was approved at the 9 November 2021 Audit & Risk Committee without amendment.

Risk ref	Risk description	Residual risk score	Tolerance threshold	Trend	Latest update
HRA1	**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 and support the vision of the HRA.	**16**	**8**	↔	Options paper considered with review of design refresh to take place in January. New CDTO due to begin 24 January 2022.
HRA2	**Resources** 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 to take place in January 2022. 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	**9**	**6**	↔	Implementation of E, D & I strategy underway

	meeting its public sector equality duty.				
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**	↔	A number of controls in place
HRA5	**Reputational** There is a perception that the HRA is not prioritising the most important areas of improvement to the research landscape or is not communicating appropriately the success of programmes to external stakeholders.	**8**	**8**	New	

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%

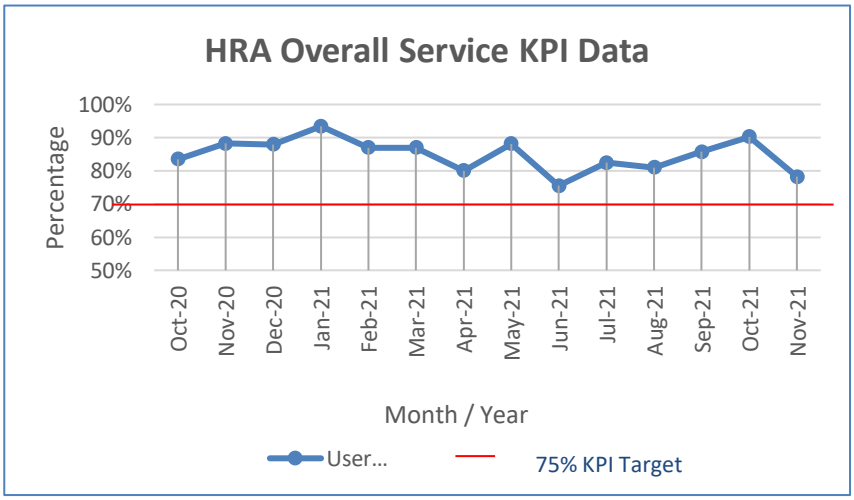
March 2021

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

↑

Staff capacity Apr/May: 74% Jun/Jul: 78% Aug/Sep: 82% Oct/Nov: 86% 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.	⇈
Research Ethics Committee membership (England only) **November** Number of members: 839 Number of vacancies: 121 Percentage vacancies: 13% 109 new members appointed this year to date compared to 105 members who left. This small increase has been helped by improved recruitment materials as well as a move to virtual meetings, although some members have left due to this change. A recruitment drive for the new year is planned as well as retention improvement activities to further bolster numbers.	⇆

Our customers and stakeholders

Customer satisfaction  Customer satisfaction outperforms our target, the UK Customer Satisfaction Index for public sector organisations (77%) Feedback received: *"Efficient process, insightful questions"*	⇆

“Quick and responsive” *“Prompt and professional”*	

Finance

Expenditure within 4% of funding Overall ✗ Research systems ✗ £0.5M 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-Nov 2019:	3272
April- Nov 2020:	2609
April- Nov 2021:	2789

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 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- Nov 2019:	703
April- Nov 2020:	626
April- Nov 2021:	603

14% reduction in applications compared to the same period in 2019 (11% 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)	**Jun-21**	**Jul-21**	**Aug-21**	**Sep-21**	**Oct-21**	**Nov-21**
Median time to complete full review	27	25	25	30	25	26
Full reviews completed in 60 days	100%	100%	100%	97%	100%	100%
Total completed	53	48	33	37	44	38
Total completed within 60 days	53	48	33	36	44	38

Ethics review of combined review CTIMPs

REC review of combined review CTIMPS (England only)	**Jun-21**	**Jul-21**	**Aug-21**	**Sep-21**	**Oct-21**	**Nov-21**
Median time to complete full review	46.5	43.5	41	48	41	38
Full reviews completed in 60 days	81%	93%	92%	90%	92%	100%
Total completed	16	14	13	20	25	26
Total completed within 60 days	11	13	11	17	23	26

Combined review.

For statutory timelines applicable to the HRA, 98% of applications are processed within 60 days in the two-month reporting period. The two Combined Review CTIMPs which did not meet this target had a much longer time between submission and the REC meeting than expected (28 and 39 days vs the 14 expected) due to a lack of REC meeting slots over the late summer months. 100% of Combined Review CTIMPs were processed within 60 days in November.

All CTIMP committees are ready to accept Combined Review CTIMPs when this service is fully launched in January widening our service offering to researchers. 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 November. 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	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21
Median time to complete full review	12	13	14	12	14.5	13
Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	10	12	11	8	16	11
Total completed within 60 days	10	12	11	8	16	11
Studies Submitted for Review	14	6	9	16	13	3

Fast-track REC (combined review)

(Non-COVID-19 studies)

Fast Track REC	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21
Median time to complete full review*	n/a	n/a	20	41	25	15
Full reviews completed in 60 days	n/a	n/a	100%	100%	100%	100%
Total completed	0	0	2	2	6	1
Total completed within 60 days	0	0	2	2	6	1
Studies Submitted for Review	1	1	6	2	2	4

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.

*In September approval timelines were greater than expected. For both studies there was a delay sending information to the MHRA. One study was also submitted well in advance of the submission window again adding to this timeline.

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

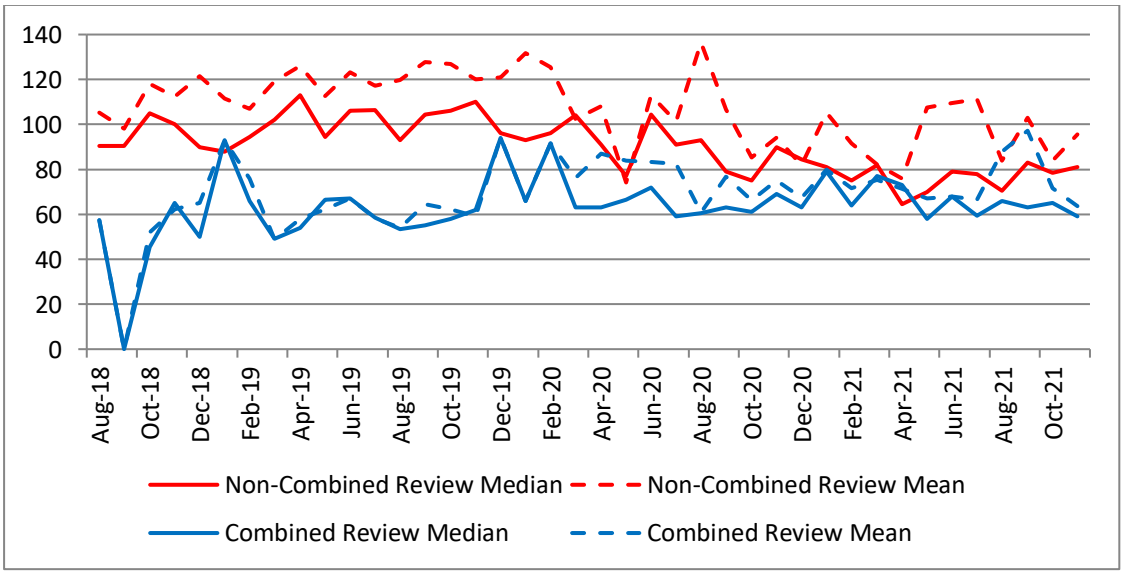
Most COVID-19 applications are reviewed by an appropriate REC within 1-2 weeks of submission and relate to the impact of pandemic on other therapy areas rather than diagnostic or therapy studies. Diagnostic and therapy studies (including vaccine studies) have faster timelines.

The table 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. The number of expedited COVID studies submitted has decreased substantially over the recent months.

Full REC	Dec -20	Jan -21	Feb -21	Mar -21	Apr -21	May -21	Jun -21	Jul-21	Aug -21	Sep -21	Oct -21	Nov -21
Days to approval	31	20	20	20	13	17	13	21	30	47	47	15
Applications approved	17	18	15	27	21	9	5	5	5	2	2	0
24h turnaround	2	0	3	3	2	0	0	0	0	0	0	0
36h–72h turnaround	11	13	20	24	5	3	1	0	0	0	0	0
1–2 weeks turnaround	1	0	0	0	4	7	2	6	2	1	1	1

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). 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

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
October	27 days	13
November	28 days	7

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%