Health Research Authority

Agenda item:	7
Attachment:	A

HRA Board paper

24 March 2021

Title of paper:	**Strategic performance report: April 2020-January 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 2020 to January 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 2020/21: April-January

High level dashboard

Staff capacity

December/January 2021 — 89%

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.

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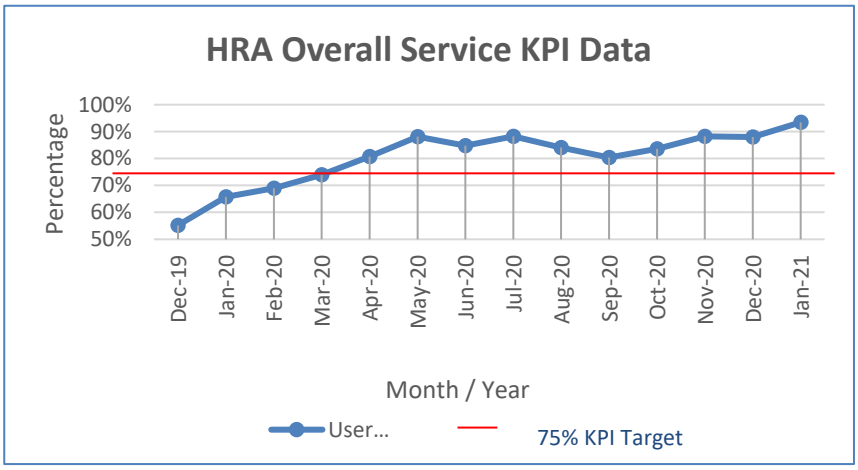
Customer satisfaction



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

Feedback received:

'The HRA staff member dealing with my project was superb'

'*I like the new online booking system… It's much better than trying to get through on the phone'*

⇈

Ethical review of standard CTIMPs (Dec 2020 /Jan 2021)

Median time to complete full review — 29 days

Proportion of full reviews completed in 60 days — 98%

⇈

Expenditure within 4% of funding (to Jan 2021)

Overall ✓ Research systems programme ✓

Forecast underspend on grant in aid is £700k. This is within 4% of our funding allocation.

⇊

Commentary

This period has seen the launch of our pilot of a new fast-track ethics review service for global clinical trials and first-in-human studies. This is a significant achievement and reflects our nimble operating ability, dedicated volunteer community and talented, expert workforce. It's also pleasing to see a further improvement in user satisfaction scores from research applicants in this reporting period following a sustained growth in positive feedback throughout 2020/21. Our staff have delivered exceptionally well throughout this period, bringing our statutory timelines within 60-day target for all studies in December as well as continuing to expedite COVID-19 research in support of the national effort to tackle the pandemic.

During this period, we have:

- Welcomed our new Chief Executive, Professor Matt Westmore.
- Launched our pilot of a fast-track ethics review service for pharmaceutical companies and research organisations seeking to start clinical trials of medicines. The service aims to reduce by 75% the statutory timeline for ethics review. Median approval timelines achieved so far are 13 days.
- Managed our response to UK Transition out of the European Union, supporting the research community with advice on UK registration requirements and data protection.
- Performed an options' appraisal for the future of registration of UK clinical trials and recommended a solution to provide easy access to registration for all clinical trials
- Successfully delivered a new module in IRAS, in partnership with MHRA, to improve researcher experience of clinical trials approval
- Gained approval from DHSC Investment Committee to fund an essential element of our transformation portfolio, research systems programme to 2027.
- Successfully closed our London office and moved into the DHSC Stratford office in collaboration with four other DHSC funded arms-length bodies.

External environment

The UK research ecosystem is redesigning itself to accelerate the research of the future, seizing the opportunity to build back better, transforming the researcher experience and reinforcing the UK as a leading global hub for life sciences. The HRA is supporting this work with our response to COVID-19 together with the recent launch of our pilot fast-track ethics review service. These streamlining initiatives align with our system partners such as MHRA and NIHR to shape the future across the UK health research ecosystem through the Recovery, Resilience and Growth programme. The programme brings together key stakeholders drawn from the research and health sector to meet current and future needs in this field and HRA is playing an active role.

Comment on performance (including areas of concern for KPIs)

Key achievement this period is 100% compliance with our statutory timelines for ethics review in December 2020. We are committed to achieving this for all relevant studies and work continues to speed up the small number of studies that fall outside of this 60-day statutory target.

Outlook for the next period

Our commitment to protect service quality, particularly ensuring we meet our statutory timelines is our key focus over the coming months whilst also looking to the future and driving forward on our transformation portfolio including our fast-track pilot service, plans for an all UK trials registry, student research and streamlining our ethics review service.

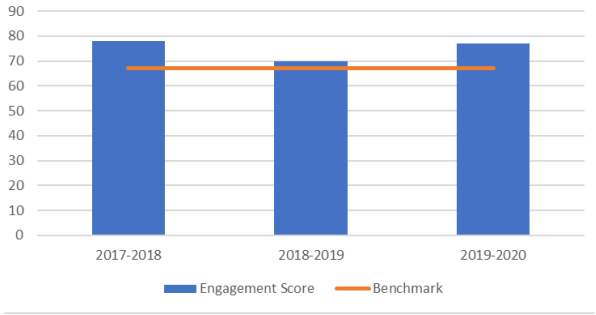
Strategic risk update

Risk ref	Risk title	Residual risk score	Tolerance threshold	Trend	Latest update
SR007	**Research Systems transformation**	**8**	**8**	**Down**	Supplier identified. Full business case approved by DHSC Investment Committee on 21 December 2020.
SR002	**HRA long term financial resilience**	**8**	**8**	**Down**	CSR 2020 to focus on 1 year's funding and not 3 years as previously reported. Full business case approved.
SR008	**Research transparency – promotion & compliance**	**12**	**8**	**Up**	Limited capacity with other priorities recently identified in DHSC Recovery, Resilience and Growth programme potentially impacting on delivery
SR004	**UK transition and trade negotiations**	**8**	**8**	**As before**	No further mitigation to be identified at present.
SR009	**Impact of COVID-19 on research system and HRA**	**6**	**6**	**As before**	HRA contributing to DHSC Recovery, Resilience and Growth programme
SR010	**Transformation Programme – Risk to Delivery**	**9**	**6**	**As before**	Further review during Business Planning process for 21/22 will assess programme resilience and determine priorities
SR011	**Diversity of Board and senior managers**	**6**	**3**	**As before**	Board review in March 2021 of E, D & I strategy and implementation plan.

Strategic performance in detail

Our people

Staff engagement



Staff engagement based on answers to the annual staff survey:

HRA staff 77% (target: 78%)

Industry benchmark: 67%

March 2020

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Staff satisfaction during COVID-19

'Overall, how well do you feel the HRA is managing the current situation for our staff?' (1=very poorly 5=very well)

April 2020	87%
June 2020	87%
September 2020	89%

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Staff capacity

August/September 2020	90%
October/November 2020	89%
December/January 2021	89%

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.

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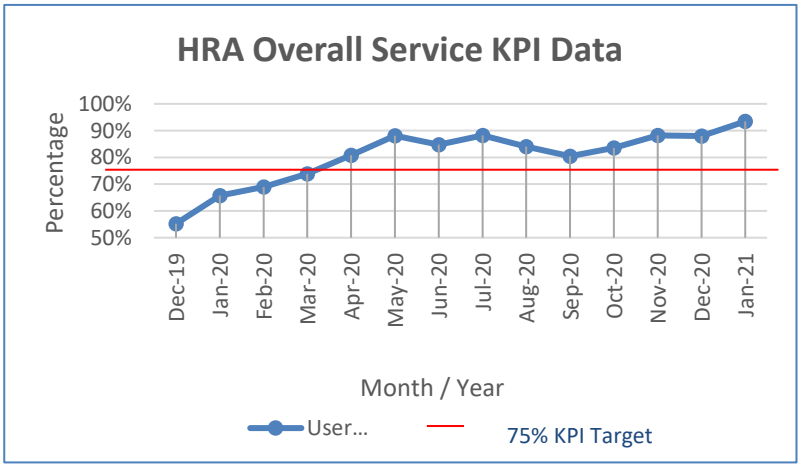
Research Ethics Committee membership (England only)

Number of vacancies: 150 in Aug / Sep, 145 in Oct / Nov, 65 in Dec / Jan

Number of members: 810 in Aug / Sep, 815 in Oct / Nov, 895 in Dec / Jan There are 64 RECs in England. The maximum number of members is 960. 80 members were recruited following a successful recruitment campaign in October 2020. This has addressed most of our lay and lay+ vacancies. Expert members are still required to address shortfalls.	⇈

Our customers and stakeholders



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Customer satisfaction

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Finance

Expenditure within 4% of funding

Overall	Research systems
✓	✓

⇆

Forecast underspend on grant in aid is £700k. This is within 4% of our funding allocation.

Approvals service

Number of applications for HRA Approval

April-Jan 2019:	**4377**

April-Jan 2020:	3988

This shows a 9% 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 (i.e. phase I studies not requiring HRA Approval)

April-Jan 2019:	**839**
April-Jan 2020:	758

This shows a 10% reduction in applications compared to the same period in 2019/2020. Again, this is primarily due to the overall drop-in research activity due to COVID-19. After a brief pause most Phase I units have now continued to undertake trials and demand is increasing.

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)	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21
Median time to complete full review	30.0	28.5	28.0	27.5	30.5	28.0
Proportion of full reviews completed in 60 days	97%	98%	98%	96%	100%	95%
Total completed	33	50	55	52	64	61
Total completed within 60 days	32	49	54	50	64	58

Reaching 100% compliance with our statutory target is a key performance indicator and was achieved in December 2020. Although a small number didn't meet the target in January 2021, these were all studies with a response to the Provisional Opinion received during the Christmas/New Year period which caused an unfortunate delay in their review.

Significant work is underway to track the progress of studies as evidenced by the decreased median time of approximately 30 days (well within limits). Work continues to ensure we meet this target for all applicable studies.

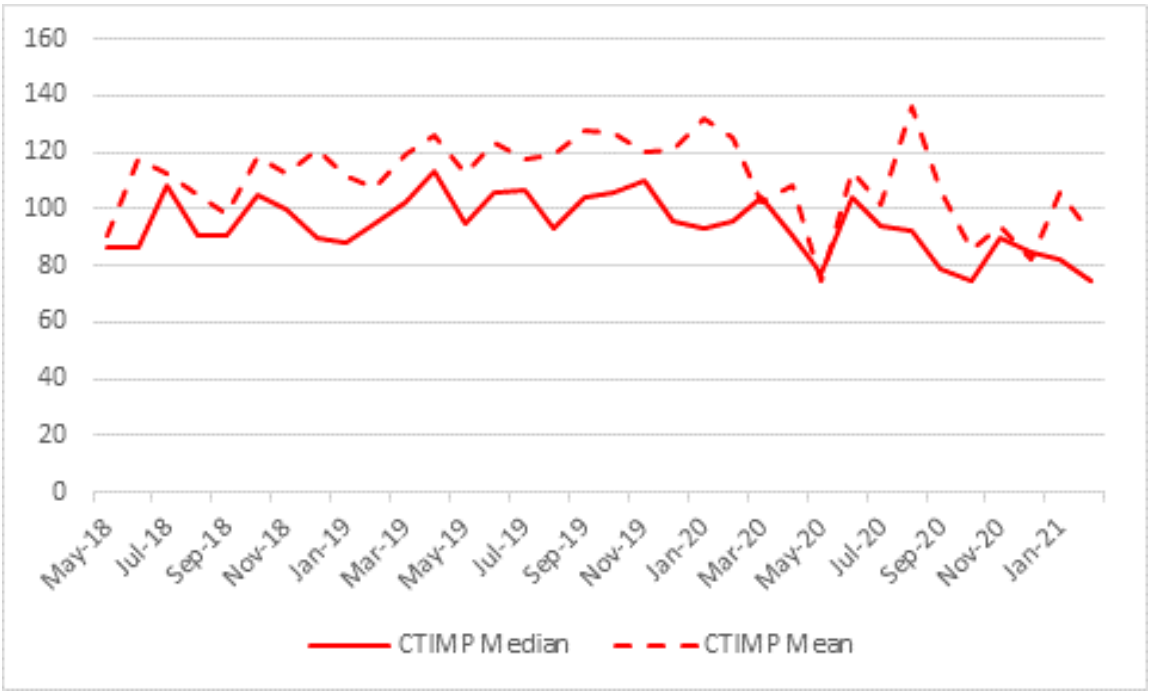
CWOW benefits

CWOW's 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.

CWOW timelines are not provided in this report as they are not directly comparable to non-CWOW applications. There is a key difference in the time that is the responsibility of the regulators. For non-CWOW studies we can measure the time from the first application (REC or MHRA) to the time we issue the REC's first decision. For CWOW 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 CWOW timeline for decision recorded by the HRA may often be longer than for non-CWOW studies. The total end to end timeline including response time from the applicant is, however, usually quicker for CWOW 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

The fast-track pilot for ethics review launched in January. 17 studies were reviewed in January and 2 received a final opinion in the month with median approval time of 13 days.

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
Full REC meeting (submission to approval)	7 days	11 days	19 days	27 days	34 days	36 days	22 days	34 days	28 days	28 days
Full REC numbers approved	57	79	74	56	29	43	35	27	17	17
24h turnaround submissions	20	8	4	2	2	5	6	2	2	0
36h – 72h turnaround submissions	83	72	36	12	6	9	18	12	13	13
1 – 2 weeks submissions	21	56	79	68	30	42	17	4	0	0

Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
September	44 days	17
October	35 days	14

November	40 days	16
December	29 days	11
January	41 days	7

Applications not approved but taking a long time:

2 applications are being processed with timelines exceeding our target of 35 or 60 days depending on the application type. Both applicants are responding to our queries and all efforts are being taken to chase for a speedy resolution.

RAG Status criteria

Staff engagement	green >76%, amber 68%-75%, red <68%
Staff satisfaction during Covid	tbc
Staff Capacity	green over 90%, amber 80%-90%, red <80%
REC membership vacancies	tbc
Customer satisfaction	green >76%, amber 68%-75%, red <68%
Ethical review of standard CTIMPs	green = 100%, amber 95%-99%, red <95%
Finance	Green +/- 4%, amber +/- 10%, red +/- 15%