Agenda item:	7
Attachment:	A

HRA Board paper

20 January 2021

Title of paper:	**Strategic performance report: April-November 2020**
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 five key areas: • Our people • Our customers and stakeholders • Our services • Finance • Programme delivery 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 to November 2020. 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 2020/1: April-November

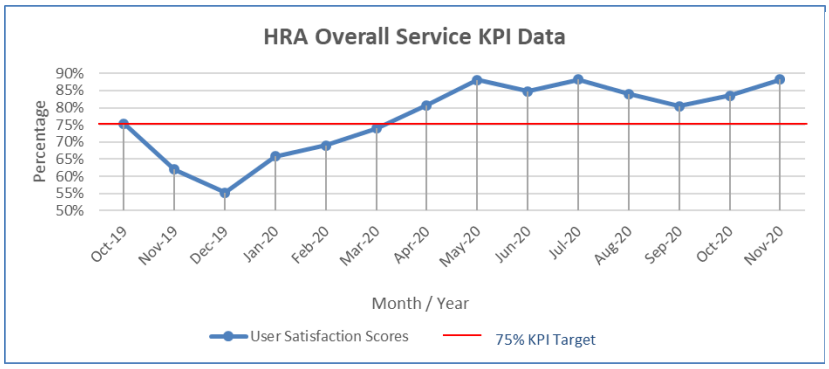
High level dashboard

Staff capacity ⇆

October/November 2020 89%

Maximum target: 96%. Target is based on number of staff funded minus 4% sick leave KPI. 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.

Customer satisfaction ⇆



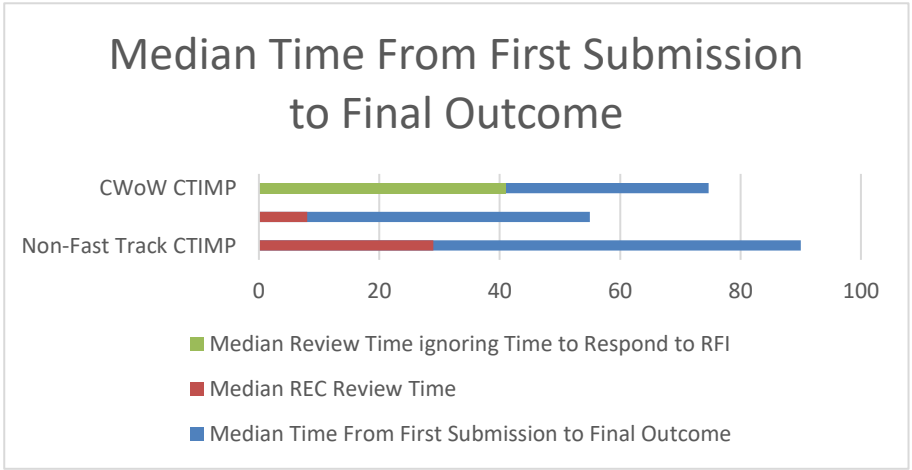
Customer satisfaction continues to outperform our target. The UK Customer Satisfaction Index for public sector organisations is 77%

Ethical review of standard CTIMPs (November 2020) ↑

Median time to complete full review 31.0 days

Proportion of full reviews completed in 60 days 93.8%

Approval of CTIMPs ⇆



Expenditure within 4% of funding (to November 2020) ⇆

Overall ✓

Research systems programme ✓

Commentary

This period has seen significant transformation programme activity, speeding up on recent months whilst at the same time as we have continued to deliver on our core services and support the national effort to enable COVID-19 research. The COVID-19 fast-track approval service continues to provide faster approvals, in line with agreed timelines and we are now looking to the future to see how this service might translate into a permanent service offering. During this period, we have:

- Appointed our new Chief Executive, Professor Matt Westmore who joins the HRA in February 2021 from his role as Director of the Wessex Institute at the University of Southampton. Matt's previous roles were with NIHR, including as Executive Director of the Evaluation Trials and Studies Coordinating Centre (NETSCC).
- Appointed Neelam Patel as a Non-Executive Board member to the HRA Board from April 2021. Neelam is also the Chief Executive of MedCity and has worked for the National Institute of Health Research (NIHR).
- Planned for and got ready to launch a pilot 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.
- Successfully delivered a streamlined approval module in partnership with MHRA to improve researcher experience for clinical trials
- Started work on options for registration of UK clinical trials with Deloitte
- Engaged with the research community to explore new ways of working to improve our research ethics review service
- Successfully gained approval from DHSC Investment Committee to fund an essential element of our transformation portfolio, research systems programme to 2027.
- Welcomed Kurt Weideling, Chief Digital Transformation Officer to the HRA, senior responsible officer for our digital strategy including our research systems programme
- Prepared and published 'public involvement in a pandemic report' – sharing lessons from our matching service
- Actively prepared for UK Transition out of the European Union.
- Launched our strategic planning process for 2021/22 informed by the comprehensive spending review outcome in November and our transformation programme
- Successfully closed our Bristol office and moved into the Bristol government hub
- Completed roll out of MS Teams to all staff and decommissioned skype for business

External environment

It's pleasing to see that external stakeholders remain supportive of the change we have achieved in response to COVID-19. We are now actively participating in the cross-sector Recovery, Resilience and Growth programme working with key stakeholders drawn from the research and health sector to meet current and future needs in this field.

We worked with the MHRA to prepare research sponsors for the end of the EU transition period, focussing on advice to sponsors around amendments and clinical trials registration. This has been well received by the sector.

Comment on performance (including areas of concern for KPIs)

As previously reported, the COVID-19 fast-track review service has seen a shift towards applications for projects aiming to understand the impact of COVID-19, rather than to develop therapies or diagnostics. These studies are being approved in 1-2 weeks in line with our agreed timelines. Earlier in the year our timelines were shorter as studies tended to be trials of diagnostics or therapies which are reviewed more quickly to meet urgent public health need.

Outlook for the next period

Protecting service quality in our core service delivery as well as driving forward on our transformation programme remain our focus for December and January. Implementation of our fast-track pilot service in January along with launching a new module to support improved researcher experience and streamlined processes for clinical trials approvals is also planned. We are also looking forward to reporting on progress made in considering future options for registration of UK clinical trials as well as outcome of our research review programme.

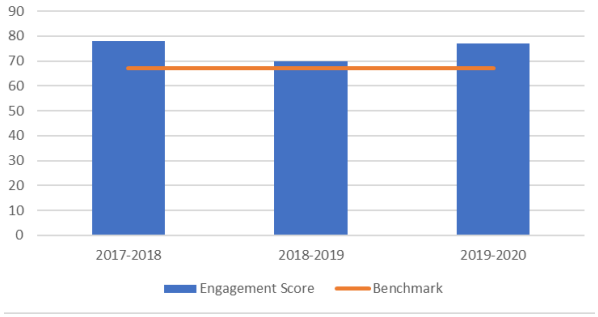
Strategic risk update

Risk ref	Risk title	Residual risk score	Tolerance threshold	Trend	Latest update
SR007	**Research Systems transformation**	**8**	**8**	Decreasing	Supplier identified. Full business case approved by DHSC Investment Committee on 21 December 2020.
SR002	**HRA long term financial resilience**	**8**	**8**	Decreasing	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**	Increasing	Limited capacity with other priorities recently identified 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	Publication of E, D & I strategy and implementation plan to follow

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

↑↓

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%

↑↓

Staff capacity

June/July 2020	91%
August/September 2020	90%
October/November 2020	89%

Maximum target: 96%

The staff capacity target is based on number of staff funded minus our maximum of 4% sick leave KPI. It is calculated based on figures of staff working against figures for staff funded and capacity is reduced for sickness rates above 4% and other types of leave.

↑↓

REC Membership Vacancies – Summary as of 11 December 2020 – England Only

No. RECS	64
Max. No. Volunteer Posts (based on 15 members per REC)	960

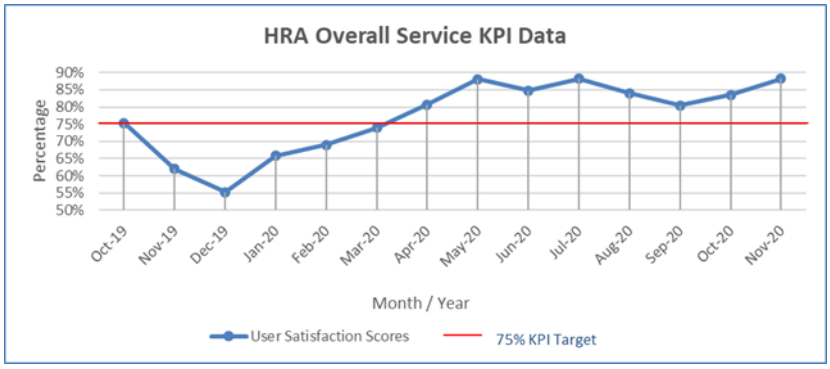
↑↓

Current vacancies – August / September (150), October / November (145)

Current members August / September (810), October / November 815

Member recruitment campaign launched in October 2020 has generated strong interest. This is currently being followed up with anticipated increase in membership in 2021.

Our customers and stakeholders



Customer satisfaction continues to outperform our target. The UK Customer Satisfaction Index for public sector organisations is 77%

↑↓

Visitors to the website

August 2020	34,588
September 2020	40,777
October 2020	27,978
November 2020	52,491

↑↓

Finance

Expenditure within 4% of funding

Overall	Research systems
✓	✓

To November 2020

↑↓

Approvals service

Number of applications for HRA Approval

April-Nov 2019:	3,269
April-Nov 2020:	2,604

This shows a 20% reduction in applications compared to the same period in 2019. This is primarily due to stopping student research, and the overall drop in research activity due to COVID-19. However, whilst the number of studies reduced, there was an increase in the complexity of the studies reviewed with fast-track studies and an increase in complex innovative designs for COVID-19 studies.

Number of applications for REC review only (i.e. phase I studies not requiring HRA Approval)

April-Nov 2019:	706
April-Nov 2020:	633

This shows a 10% reduction in applications compared to the same period in 2019. This is primarily due to the overall drop in research activity other than COVID-19. 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 standard CTIMPs to be reviewed by the REC within 60 days (where a statutory timeline is applicable). 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

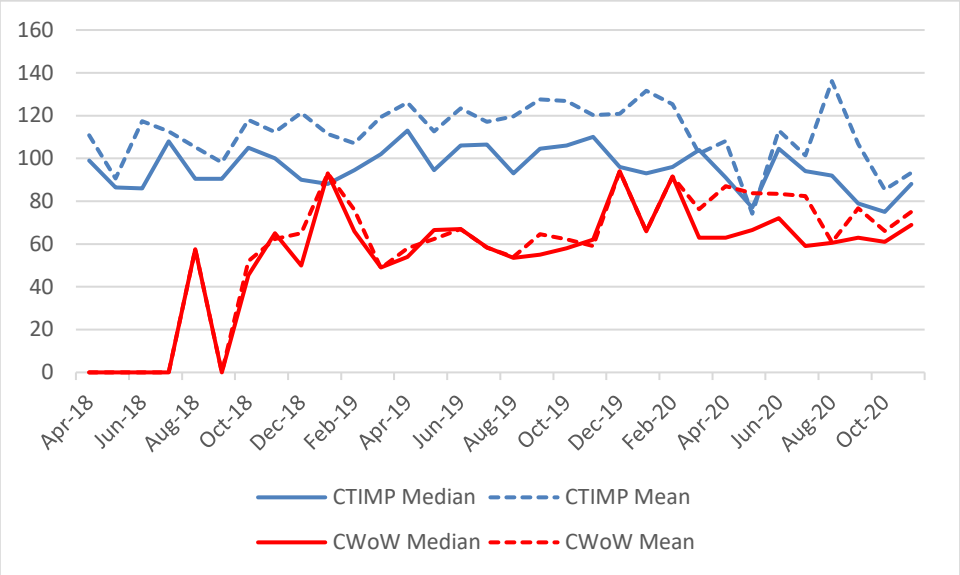
REC review of CTIMPS (England only)	**Jun-20**	**Jul-20**	**Aug-20**	**Sep-20**	**Oct-20**	**Nov-20**
Median time to complete full review	39.0	30.0	34.0	30.5	28.5	31.0
Proportion of full reviews completed in 60 days	89.4%	90.8%	93.9%	96.8%	94.1%	93.8%
Total completed	66	65	49	62	68	65
Total completed within 60 days	59	59	46	60	64	61

Reaching 100% is a key target for us, and significant work is underway to track the progress of studies as evidenced by the decreased median time of 31 days (well within limits). In the past two months most studies outside this target have been CWoW studies (5 out of 8). The small number of remaining trials that don't hit the timelines are primarily due to volunteer REC member or expert capacity to review responses to queries raised at the REC meeting. We are focussed on supporting our members to ensure the final decision is issued in a timely way.

HRA Approval

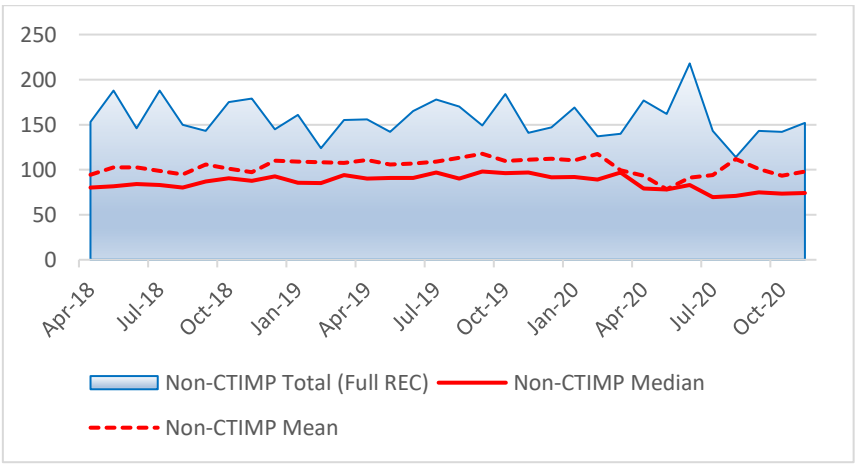
This section covers applications proceeding through to Approval in England and Wales. The graphs below show the median and mean elapsed timeline for applications from submission to approval (no clock stops). Applications withdrawn or invalid have been omitted from the data set.

CTIMP applications (excluding CWOW applications) compared to CWOW applications. (Where no CWOW applications have been approved the median/mean will dip to zero.)



Non-CTIMP applications requiring full REC review and Approval in England and Wales

The graph below shows the increased total number of non-CTIMP applications reviewed due to the large number of COVID-19 studies. The decrease in timelines during this period reflects the proportion of fast-track studies. The timeline shows full elapsed time, including time for applicant response. The fast-track COVID-19 studies have contributed to an overall decrease in timelines in this quarter. However, it should be noted that some non-COVID studies (particularly proportionate review) have been deprioritised and currently have longer timelines than usual.



Fast-track review of COVID-19 studies

Most applications are reviewed within 1-2 weeks of submission, as they relate to the impact of COVID-19 on other therapy areas rather than diagnostic or therapy studies. The table below shows the median timeline in days for studies considered at full REC meetings and the analysis of studies fast-tracked by timeline category. The increase in median timelines reflects the changing mix of studies. Urgent public health studies and other clinical trials and investigations continued to be reviewed within a few days during this time period.

	Apr 2020 days	**May 2020** days	**Jun 2020** days	**Jul 2020** days	**Aug 2020** days	**Sep 2020** days	**Oct 2020** days	**Nov 2020** days
Full REC meeting (submission to approval)	7	11	19	27	34	36	22	34
Full REC total numbers approved	57	79	74	56	29	43	35	27
24h turnaround submissions	20	8	4	2	2	5	6	2
36h – 72h turnaround submissions	83	72	36	12	6	9	18	12
1 – 2 weeks submissions	21	56	79	68	30	42	17	4

Median approval timeline for CAG research studies

Month	**Days from application to completion**	**Number of applications**
August	31 days	7
September	44 days	17
October	35 days	14
November	40 days	16