

Agenda item:	7
Attachment:	A

HRA Board paper

21 September 2022

Title of paper:	Strategic performance report: April 2022 – July 2022
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:	<p>The paper presents the performance of the HRA in delivering the strategy. It focuses on four key areas:</p> <ul style="list-style-type: none"> • Our people • Our customers and stakeholders • Our services • Finance <p>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 2022 to July 2022.</p> <p>This report provides a high-level strategic dashboard as well as a more detailed performance report to the Board.</p>
Budget / cost implication:	N/A
Dissemination:	Published on HRA website with Board papers
Time required:	10 minutes

Strategic performance report: Apr-Jul 2022

High level dashboard

<p>Staff capacity</p> <p>Apr/May: 92%; Jun/Jul: 85%</p> <p>Maximum target: 91%.</p> <p>Staff capacity has decreased in the last couple of months. This is being closely monitored to ensure HRA has capacity to deliver our strategy and statutory functions.</p>	⇕																																													
<p>Customer satisfaction</p> <div data-bbox="151 716 1324 1153"> <table border="1"> <caption>High levels of customer satisfaction maintained</caption> <thead> <tr> <th>Month / Year</th> <th>User Satisfaction Score (%)</th> <th>75% KPI Target (%)</th> </tr> </thead> <tbody> <tr><td>Jun-21</td><td>75</td><td>75</td></tr> <tr><td>Jul-21</td><td>80</td><td>75</td></tr> <tr><td>Aug-21</td><td>78</td><td>75</td></tr> <tr><td>Sep-21</td><td>82</td><td>75</td></tr> <tr><td>Oct-21</td><td>85</td><td>75</td></tr> <tr><td>Nov-21</td><td>78</td><td>75</td></tr> <tr><td>Dec-21</td><td>82</td><td>75</td></tr> <tr><td>Jan-22</td><td>78</td><td>75</td></tr> <tr><td>Feb-22</td><td>80</td><td>75</td></tr> <tr><td>Mar-22</td><td>85</td><td>75</td></tr> <tr><td>Apr-22</td><td>80</td><td>75</td></tr> <tr><td>May-22</td><td>80</td><td>75</td></tr> <tr><td>Jun-22</td><td>73</td><td>75</td></tr> <tr><td>Jul-22</td><td>85</td><td>75</td></tr> </tbody> </table> </div> <p>Customer satisfaction outperforms our target of 75% throughout the period except in June 22 where it fell to 73%. No root cause has been identified for this drop which reversed in July and August.</p>	Month / Year	User Satisfaction Score (%)	75% KPI Target (%)	Jun-21	75	75	Jul-21	80	75	Aug-21	78	75	Sep-21	82	75	Oct-21	85	75	Nov-21	78	75	Dec-21	82	75	Jan-22	78	75	Feb-22	80	75	Mar-22	85	75	Apr-22	80	75	May-22	80	75	Jun-22	73	75	Jul-22	85	75	⇕
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<p>Ethical review of CTIMPs (both the combined and non-combined processes)</p> <p>Median time to complete full review 36 days</p> <p>Proportion of full reviews completed in 60 days 95%</p> <p>96% (118 out of 123) combined review CTIMPs were reviewed within 60 days. 7 out of 8 standard process CTIMPs were reviewed within 60 days.</p>	⇕																																													
<p>Forecast expenditure within 4% of funding</p> <table border="0"> <tr> <td>Overall</td> <td>Research systems programme</td> </tr> <tr> <td style="text-align: center;">✓</td> <td style="text-align: center;">✓</td> </tr> </table> <p>Our forecast position (based on our revised estimates for research systems business case) is within 4% of funding allocated. £1m capital expenditure funding has been returned to DHSC following strategy refresh and deferral of some development work to 23/24.</p>	Overall	Research systems programme	✓	✓	⇕																																									
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Commentary

We launched our three-year strategy and our fast-track service has been embedded into our existing operating structure. In this period, we

- Launched our three-year strategy: making it easy to do research that people can trust, following extensive consultation with stakeholders including patients and the public
- Published our 2022-2023 business plan setting out year one delivery of our strategy
- Published Research Ethics Committees (RECs) service annual report, providing an extensive summary of the work done by the Committees in delivering our statutory services.
- Progressed our Think Ethics programme, putting people and ethics at the heart of health and social care research. This programme, working with partners in Northern Ireland, Scotland and Wales, aims to make ethics review more innovative and efficient. To assist with this, we will be holding a number of events in the coming months to hear about individuals' experiences and insights to inform the next stages of the programme.
- Made changes to the way we manage applications for fast-track ethics review, learning from our experiences delivering combined review and a dedicated committee in 21/22. We will still offer a fast-tracked service, with this now embedded into our existing REC committee structure creating a more resilience and efficient service.
- Published our 2022-25 People Strategy and appointed Becky Purvis as Interim Director of Policy and Partnerships and Julie Waters as Interim CDTO following a couple of resignations within the Executive Committee.

External environment

- Cabinet Office and DHSC have issued several commissions in preparation for parliament returning from recess and the new prime minister. HRA are working closely with our sponsor team to respond to these as they arise.
- The cost of living crisis, challenges within the NHS as well as other significant environmental factors will have an impact on public finances and potentially HRA future funding. Contingency options are being considered to manage any impact on our resources.

Outlook for the next period

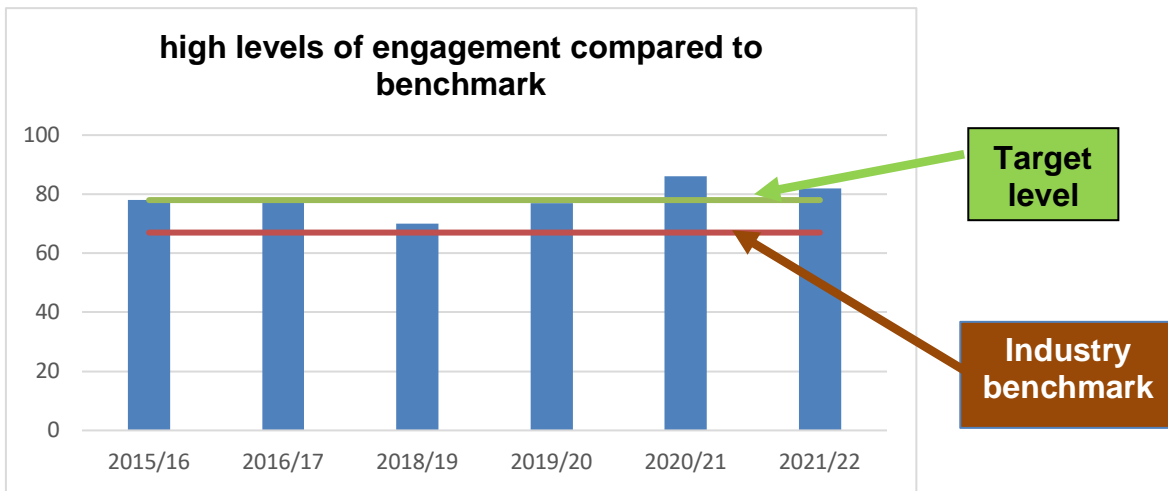
- The new prime minister will be announced together with a likely refresh of government priorities including a response to the cost of living crisis and energy prices

Strategic risk update

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.	16	8	↔	Recommendations for RSP reset approved at May HRA Board. Procurement process for new supplier underway, aiming to be appointed by October.
HRA3	Reputational - The HRA has very low representation from individuals with protected characteristics at Board and senior management 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 meeting its public sector equality duty.	9	6	↔	Community insight group to feed into HRA Board via paper and attendance at each meeting. Expertise in inclusive approach to recruitment practices a key requirement of senior posts.
HRA4	Reputational - The reputation of the HRA is adversely affected with fewer participants choosing to take part in research because of the HRA failing to perform its statutory functions, or an adverse event occurring resulting from the decision of a Research Ethics Committee, or poor research practice taking place or from lack of public involvement / influence within the HRA.	8	8	↔	Additional resources identified and posts to be recruited to support and strengthen assurance and third-party complaint handling.
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	↔	Business plan to support focus on being led by data to help prioritise and lead our overall approach to delivery, capturing learning to aid decision making.

HRA6	Information - Risk to the operational delivery of the HRA due to a successful and destructive cyber-attack causing loss of systems, loss of data, damage to reputation.	9	3	↔	Although good controls are in place risk escalated to Board due to growing international cyber activity.
HRA7	Regulatory – There is a risk the HRA could be closed or merged with another ALB impacting on the delivery of our strategic vision for high quality health and social care research today, which improves everyone’s health and wellbeing tomorrow.	4	4	New	Working with DHSC and other ALBs as part of DHSC ALB landscape review to look at opportunities for efficiencies across ALBs.

Our people



Staff engagement (based on annual staff survey) Industry benchmark

HRA staff 82% (target: 78%) (shown in green above)

Industry benchmark: 67% (shown in brown above)

March 2022

Staff capacity

Apr/May: 92%

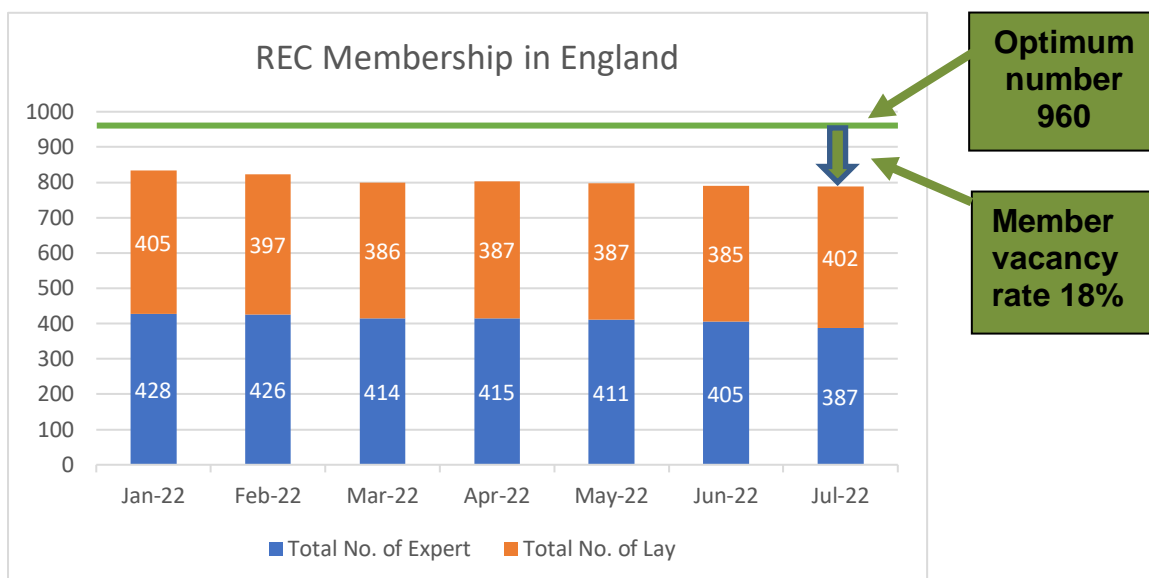
Jun/Jul: 85%

Target: 91%

Staff capacity has decreased in the last couple of months. This is being closely monitored to ensure HRA has capacity to deliver our strategy and statutory functions.



Research Ethics Committee (REC) members (England only)



Vacancies: the optimum number of REC members is 960. We currently have 789 members and are operating at a 18% REC member vacancy rate, compared to 13% at the beginning of the year.

Membership: Each REC has a mix of both expert and lay members. We monitor several key factors in REC membership including whether a REC has five or less experts. 30% of RECS meet this threshold.

Percentage of RECs with more than 6 experts: 72%

Percentage of RECs with between 1 and 5 experts: 28%

Number of RECs with 0 experts: 0%

Recruitment activities

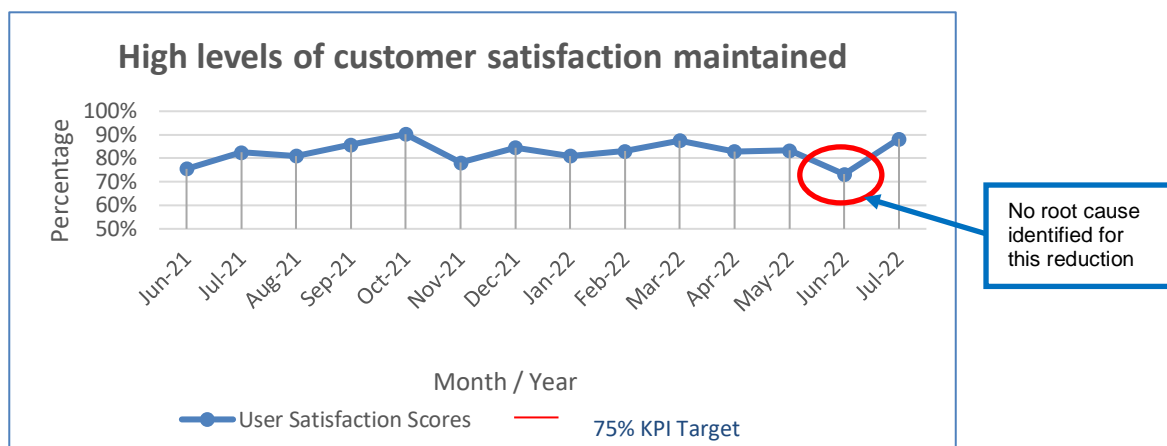
April 2022: NHS Pensions newsletter & University medical schools

Application packs requested at end of July: 645

Applications submitted at end of July: 68

Our customers and stakeholders

Customer satisfaction



Customer satisfaction outperforms our target of 75% throughout the period except in June 22 where it fell to 73%. No root cause has been identified for this drop which reversed in July and August.

Finance

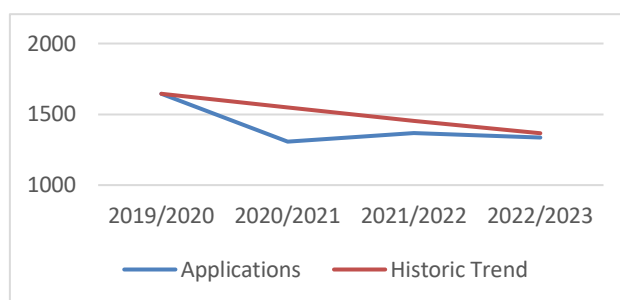
Forecast expenditure within 4% of funding

Overall	Research systems programme
✓	✓
<p>Our forecast position (based on our revised estimates for research systems business case) are within 4% of funding allocated. £1m capital expenditure funding has been returned to DHSC following strategy refresh and deferral of element of development work to 23/24.</p>	

Approvals service

Number of applications for HRA Approval

April 2019 - July 2019:	1645
April 2020 - July 2020:	1307
April 2021 - July 2021:	1368
April 2022 - July 2022:	1336



Application numbers reduced sharply during COVID-19 and have slowly increased since then. The overall picture is broadly in line with the long-term trend, around 6% reduction in applications each year. Whilst numbers have reduced, some applications are more complex, including innovative designs for COVID-19 studies.

Number of applications for REC review only

April 2019 - July 2019:	334
April 2020 - July 2020:	311
April 2021 - July 2021:	312
April 2022 - July 2022:	283

Long-term trends indicate new applications reduce by 6% each year. Application numbers dropped by more than this during COVID-19. In 2021/22 we received a surge in applications for REC review only. They are now back to the numbers we would expect. This is due to phase 1 healthy volunteer studies returning to pre-pandemic levels balanced by a greater reduction in student applications compared to long-term trends following changes we made to eligibility criteria.

Ethics review of clinical trials of investigational medicinal products (CTIMPs)

Our target is for 100% of applicable CTIMPs to be reviewed 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.

Ethics review of standard process CTIMPs (England only)

Standard review CTIMPS	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22
Median time to complete full review	30	28	37	45	54	44
Full reviews completed in 60 days	100%	93%	92%	80%	80%	100%
Full reviews completed within 60 days	23	15	13	5	5	3
Total completed	23	14	12	4	4	3

Ethics review of combined review CTIMPs (England only)

Combined review CTIMPS	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22
Median time to complete full review	39	33	36	39	35	37
Full reviews completed in 60 days	100%	98%	96%	98%	95%	97%
Full reviews completed within 60 days	32	50	45	65	60	58
Total completed	32	51	47	66	63	60

Combined review

For statutory timelines applicable to the HRA, 96% of applications are processed within 60 days in the two-month reporting period. One standard review CTIMP was not approved within 60 days – this was due to a delay with the chair reviewing a response to a provisional opinion.

Five combined review CTIMPs were not approved within 60 days during the reporting period – two applications were delayed as expert comments were needed after the REC review which took some time to obtain and the other three were delayed as the RFI took longer to review than normal.

Performance has been slightly lower than expected the last two months. The refreshed Approval Officer role will allow closer monitoring of timelines to prevent this re-occurring. Also, 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	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22
Median time to complete full review	n/a	13	n/a	16	n/a	n/a
Full reviews completed in 60 days	n/a	100%	n/a	100%	n/a	n/a
Total completed	0	1	0	1	0	0
Total completed within 60 days	0	1	0	1	0	0
Studies Submitted for Review	1	0	0	0	0	0

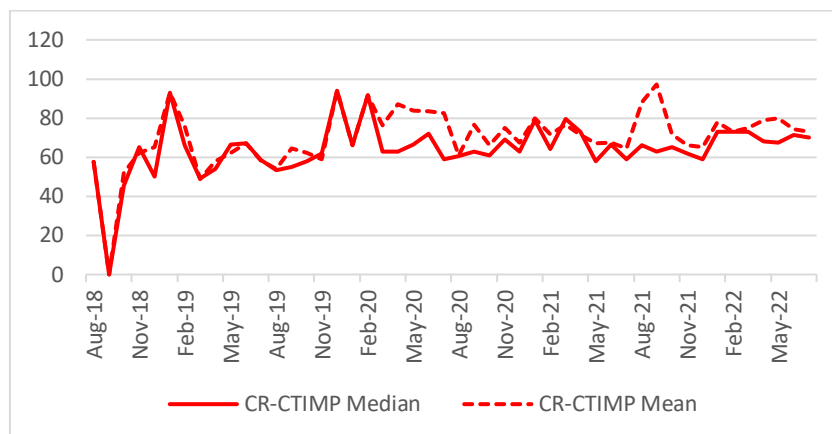
Fast-track REC (combined review, non-COVID-19 studies)

Fast Track REC	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22
Median time to complete full review*	10.5	12	15	16	12	15
Full reviews completed in 60 days	100%	100%	100%	100%	100%	100%
Total completed	6	13	17	9	11	8
Total completed within 60 days	6	13	17	9	11	8
Studies Submitted for Review	13	18	6	14	5	12

Fast-track combined review studies have comparable timelines to non-combined review studies when just the REC review aspect is considered. 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. From August 2022 fast-tracked applications will be reviewed as part of the existing REC structure.

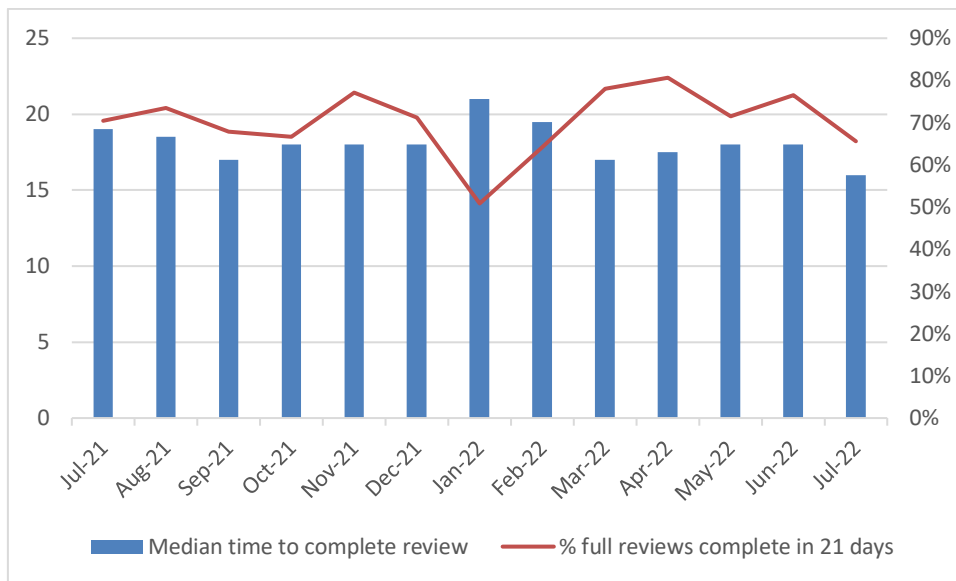
HRA Approval

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 summer 2021 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.



Proportionate Review

For applications suitable for proportionate review the final opinion from the REC should be issued within 21 days (minus any time the clock is paused for a provisional opinion). Performance at English RECs has been below the expected level for some time due to COVID 19 studies being prioritised. However, since March over 65% of applications have been reviewed within the expected timeframe, the best performance for some years. A number of factors have helped with this; changes to how Approval Specialists are assigned applications has smoothed their workflow allowing quicker validation, REC teams have a greater focus on timelines for this type of application, fully trained Approval Administrators are able to fulfil their part of the process with minimal supervision. Further projects are ongoing to increase performance further.



Median approval timeline for CAG research studies

Month	Days from application to completion	Number of applications
April	14 days	3
May	28 days	11
June	27 days	7
July	29 days	11

Applications in progress that have exceeded target times: 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%

Strategy delivery – interim report

Include: Health and social care research is done with and for everyone

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Include everyone in research:

We continue to work closely with MHRA developing resources to support greater diversity and inclusion of research participants. We are also working closely with them to propose changes to clinical trials legislation following a consultation on proposals requiring public involvement, transparency and diversity and inclusion – the government response to this consultation is expected to be published in autumn 2022.

The steering group to take forward the shared commitment to embed public involvement in health and social care research is reviewing an action plan, which includes individual projects to move issues forward and plans to mark the first anniversary of the commitment with a meeting and annual report demonstrating progress.

The Make it Public campaign continues to work to make transparency the norm with plans to hold the next virtual conference in March 2023.

Ask you what you want research to look like and act on this

Scoping work is underway to conduct a public dialogue to ask people what they want research to look like to earn their trust.

The steering group looking at how to do a better job of putting people first in research are developing plans and methods for rapid review and evidence gathering.

Involve you in the HRA

The HRA Community Insight Group meeting on 18 July informed the development of some proposals for how the Group might evolve to better represent and include the HRA Community (members of Research Ethics Committees, the Confidentiality Advisory Group and public contributors that are part of our public involvement network) within the HRA's governance and decision-making. We will consult on these proposals shortly.

We are working with a group of people involved in or impacted by research to develop some proposals for how we can do things differently to deliver our ambitions to include everyone in health and social care research at our September Board meeting. This builds on two workshops, one held as part of our strategy launch and a second workshop with the Board in July.

A Community Group is being established to help us deliver a more consistent, positive experience for everyone who works with us as a member of a Research Ethics Committee, the Confidentiality Advisory Group or as a public contributor. This will coordinate a number of workstreams to deliver on the Community Insight Group's action plan, which intends to ensure that working with the HRA is a positive experience that is open to everyone. This includes capturing more comprehensive EDI data about our Community safely and

securely so we can better understand how diverse and inclusive our Community is now and monitor our success as we work to make this open to everybody.

Procurement to redevelop the HRA website is continuing and recruitment for appropriate resourcing to support this is underway.

Accelerate: Research findings improve care faster because the UK is the easiest place in the world to do research that people can trust.

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Save money and time so that you can focus on doing good research

Following evaluation of the delivery of the Fast Track REC, HRA has completed the transition to a fast track REC service integrated into a pool of existing RECs. This will increase sustainability and creates the potential to increase the capacity and type of research that is offered the option of fast-track REC review.

Considerable activity has been progressed with IRAS partners to articulate question-sets and workflows that can be implemented in future development of IRAS, to streamline processes for applicants.

HRA is supporting a pilot of a revised Letter of Access for researchers working across NHS organisations.

The National Contract Value Review service programme has successfully collected data from the NHS on adherence to standard research tariffs. The change management plans to mandate the use of National Coordinators are progressing.

A revised model non-commercial agreement, a commercial hub and spoke agreement, and updates to the commercial non-interventional agreement have been agreed UK-wide.

HRA continues to support cross-sector actions to reset the national research portfolio. HRA is supporting communication with sponsors, and checks on accuracy of data held in NIHR systems.

Create a new online system to help you make research happen

Preparatory steps for the onboarding of the new development partner are underway, with new models for product management being implemented.

User research is underway on proposals for question-sets developed with IRAS partners.

Support new ways to do research

Preparations for the implementation of a new Clinical Trials Regulation are progressing with MHRA. The government response will be published once new ministerial arrangements are agreed. Joint work with MHRA is identifying the details of proposed

instructions to lawyers and requirements for guidance. Arrangements for co-production of guidance with the research community are being developed.

Mapping of existing initiatives to support decentralised and people-centred approaches to clinical research has been completed. A survey of issues around information governance in the NHS has been completed. Analysis will inform clarification of guidance.

HRA continues to support DHSC and NIHR with clarifying issues around the set-up of studies in non-NHS settings like care homes and schools.

A project to set out new quality standards, design principles and standardised ethics committee review framework for participant information and consent has completed preparatory work and is moving to drafting of standards and principles. The aim is make it easier for researchers to produce participant information that will be approved by RECs.

Digital: Use digital technology well to do our work

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User experience and engagement is at the heart of digital design.

We aim to design our digital systems in a human-centred way, i.e., place real emphasis on creating business processes that are informed by users' priorities and are acknowledged as not only being easy to use but also assists them in conducting their research.

To enable this approach, we are procuring delivery partner services. The specification for the services has been drafted, clearly articulating our proposed approach and the knowledge and experience to be shared with the HRA in new ways of working in this digital age. A new delivery dynamic is being sought, one that will cast new light on 'the art of the possible' and start to equip the HRA with the necessary skills and infrastructure to deliver for the long term.

To compliment this approach, plans are also being formulated to create strategic leadership teams that will provide crosscutting support and ensure all planned activities focus on strategic outcomes.

Process automation and integration improves our work

Head of Service Delivery has been appointed and is due to start with the HRA on 1 August 2022.

Users stories are being created following analytics discovery work to enable the implementation of a data warehouse solution to automate transformation and cleanse of research approval process data. First phase of work has been adapted following discovery. A foundation data layer will be built first following data migration healthcheck on legacy data.

Implemented several improvements to our cyber security policies and procedures as part of our response to the data security and protection annual audit. More work is planned to address the actions raised from cyber security audits and regular penetration tests.

Improve: Ensuring we have the right culture and capability to deliver our strategy

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Continuously learn, improve and innovate

We continue with our pilot of NIHR learning platform for members and staff and are implementing our new 70:20:10 blending learning approach, enabling staff to be responsible self-directed learners. Activities this period include providing dedicated training sessions, all staff VC presentation and targeted work with directorates and individuals focusing on our appraisal process.

We are also building organisational confidence to have inclusive conversations with sessions delivered this period on mental health and Pride. 29 equality impact assessments have been completed and reviewed this year.

Engagement work continues in developing our innovation and change delivery framework.

Be a great place to get involved and work

We have approved and published pay transparency guidance and revised our recruitment policy with a greater focus on equality, diversity and inclusion.

Our staff forum met in June and agreed a refreshed focus on wellbeing and innovation. The forum will be responsible for delivering actions in our staff survey action plan that relate to these areas. Terms of reference for the forum will be updated and agreed in September.

Social value has been built into the evaluation process for research systems delivery partner commercial exercise. We also took the decision to implement Artemis, contract management system, which will help improve consistency of our commercial processes and record keeping.

Be committed to environmental sustainability and achieving net zero.

We have agreed additional capacity to implement and monitor our sustainability strategy and the associated job description has been drafted. A green team member will participate in the recruitment process.

We continue to maintain our travel and accommodation at over 60% reduction at pre-pandemic levels and limited our domestic flights to essential travel only. We tested a new approach to deciding on whether a domestic flight is reasonable – assessing the travel across a number of environmental, cost and wellbeing measures to inform decision making. No domestic flights were taken during the period.