Agenda item:	**8**
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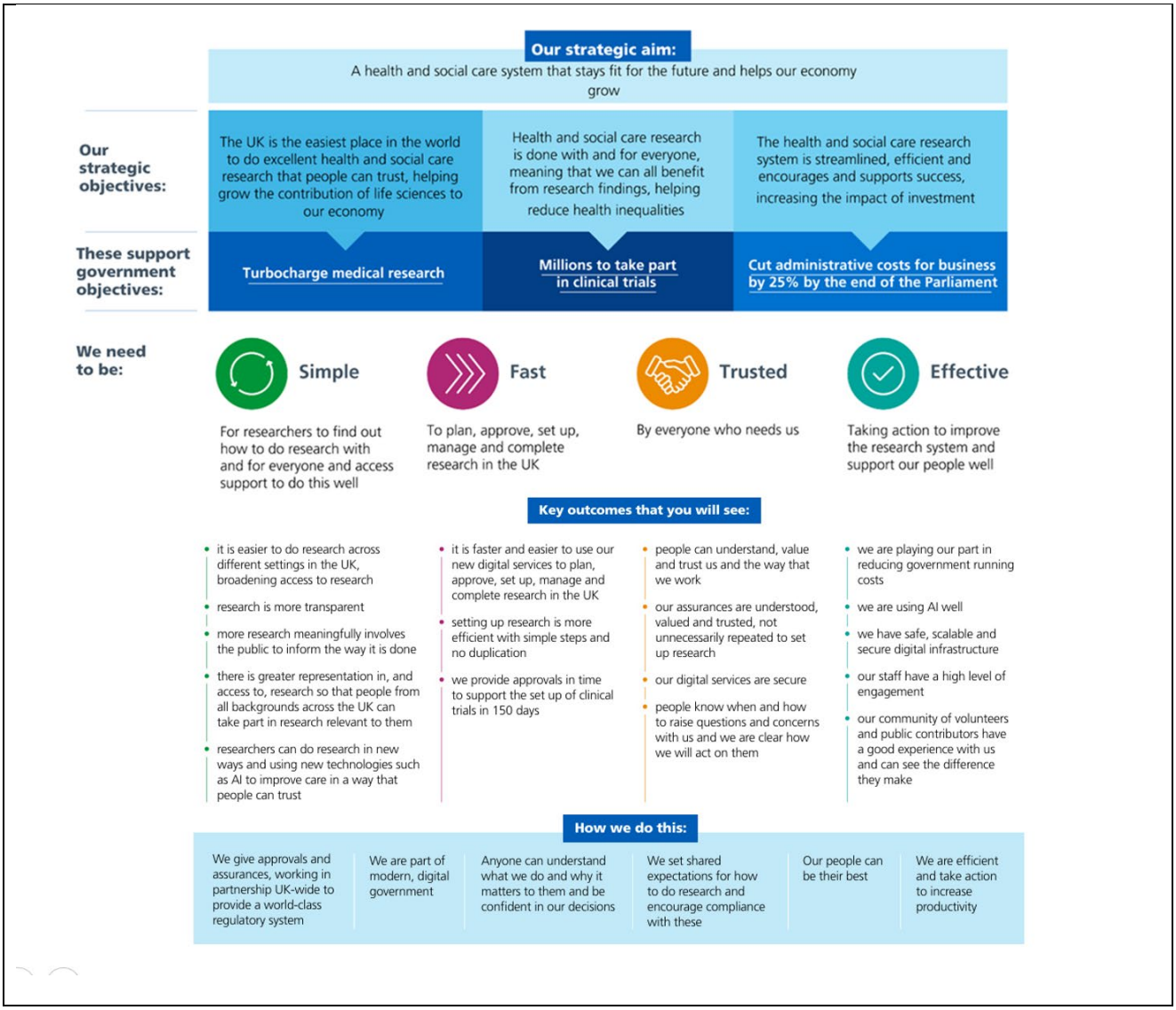
HRA Board

18 November 2026

Title of paper:	**Strategy Delivery Report: Quarter 2**
Submitted by:	Matt Westmore, Chief Executive Catherine McCarthy, Head of Corporate Portfolio Office
Summary of paper:	To provide the HRA Board with a review of progress with delivering the 2025-2028 strategy
Reason for submission:	For approval
Further information:	This report presents the strategy delivery performance at Q2 2026 2027. This is a new report designed around the delivery of outcomes grouped into four areas based on primary drivers: • Simple • Fast • Trusted • Effective It also presents key challenges: • Demonstrating Strategic Impact and Value • Research still does not feel sufficiently simple or efficient to users • Strong HRA approval performance is not yet consistently translating into faster end-to-end approvals and study set-up • The Research Systems Programme is making regular releases, but delivery remains challenging and confidence in adherence to the current roadmap is low. • Public involvement is widespread, but evidence of its quality and inclusivity is less mature.

	• Delivering increasing ambition within tighter resource constraints will require harder prioritisation and clearer evidence of benefits. • Delivery Capacity and Portfolio Prioritisation And potential areas for Board discussion: • The HRA's future role in the research system • Transforming research approvals across the system • The HRA's role in clinical trial recruitment
Budget / cost implication:	N/A
Dissemination:	Published on HRA website with Board papers
Time required:	10 minutes

1) HRA Strategy



2) Executive Summary

Progress

The Health Research Authority (HRA) remains on track to deliver its 2025-2028 strategy, with strong performance across regulatory delivery, digital transformation, stakeholder engagement, organisational effectiveness and public involvement. This report indicates that external developments continue to support the organisation's strategic priorities and that no significant changes to the strategy are currently required.

Progress is particularly evident in operational performance. Regulatory targets continue to be met, with 100% of CTIMP approvals issued within statutory timescales and applicant satisfaction reaching 87%, exceeding strategic targets. Digital transformation programmes are delivering benefits through increased platform adoption, reduced manual processing and 100% system availability. Cyber security performance has strengthened, Microsoft Copilot adoption has increased, and public involvement in research remains consistently high. Staff engagement and efficiency activities also show positive improvements, supporting organisational resilience and capability.

The external environment remains favourable for the HRA's objectives. National policy continues to focus on accelerating research delivery, improving the use of health data, strengthening the UK's life sciences sector and increasing evidence of research impact. However, wider concerns regarding public trust in science, data governance and equitable participation in research reinforce the importance of the HRA's ongoing leadership role in transparency, inclusion and representative research, public involvement and trustworthy regulation.

The strategic portfolio remains broadly on track, with governance arrangements providing assurance that delivery risks are being actively managed. The Research Systems Programme remains the organisation's largest and most significant investment, while projects and activities focused on study set-up, artificial intelligence, organisational design and research engagement continue to support delivery of strategic outcomes. Financial performance remains stable, with only a small forecast RDEL overspend that is expected to be managed within existing resources. Strategic risks are generally operating within agreed tolerances, although one risk remains above tolerance and is being reviewed by the senior team.

Challenges

Demonstrating Strategic Impact and Value: As national expectations increase around evidencing the health, societal and economic value of research, how should the HRA evolve its outcome measurement framework to better demonstrate its contribution to research system performance and UK economic growth?

Research still does not feel sufficiently simple or efficient to users: Only 20% of respondents currently describe study set-up as efficient, while 56% continue to report duplication. Measures of ease across different settings are also low, particularly for multi-site and multi-setting research. Changes to the survey methodology mean direct comparison with the previous baseline is difficult, and the full effect of current interventions is not expected

until later in the strategy period. This remains one of the clearest gaps between strong HRA operational performance and the experience of the wider research system.

Strong HRA approval performance is not yet consistently translating into faster end-to-end approvals and study set-up: CTIMP approvals continue to perform strongly, with 100% within 60 days and a median of 29 days. In contrast, only 47% of HRA and HCRW approvals are currently completed within 60 days. A significant proportion of elapsed time reflects responses awaited from sponsors or other regulatory dependencies, illustrating both the limits of the HRA's direct control and the need for stronger system-wide approaches.

The Research Systems Programme is making regular releases, but delivery remains challenging and confidence in adherence to the current roadmap is low: The programme continues to deliver incremental releases and is demonstrating benefits through increased use of Plan and Manage and reduced manual processing. However, the scale and complexity of the remaining transformation, transition from legacy systems, dependencies on partners and finite delivery capacity mean that the current roadmap is under pressure. Active re-estimation and prioritisation of the remaining features is underway. This will require difficult choices about scope, sequencing and capacity, alongside continued management of the workforce and cost implications of a longer transition.

Research transparency remains below our ambition: Clinical trial registration has improved to 94%, but remains below the 100% strategic ambition. More significantly, only 32% of the relevant completed trials in the available dataset had uploaded a summary of results to a registry. This remains an important gap between our commitment to transparency and observable behaviour across the research system. We are currently looking at a refresh of our research transparency strategy, Make it Public to identify future priorities.

Public involvement is widespread, but evidence of its quality and inclusivity is less mature: Public involvement in applications has plateaued at 84%. Of 416 studies analysed, only 115 provided sufficient information to determine whether involvement met best-practice principles, while 29 provided no information about involvement. Measures of diversity in participation and use of Inclusion and Diversity Plans are also not yet sufficiently mature to demonstrate progress against these strategic outcomes.

Delivering increasing ambition within tighter resource constraints will require harder prioritisation and clearer evidence of benefits: The HRA is committed to contributing to reductions in government running costs and has agreed a 3% capacity-releasing efficiency target, but the baseline and reporting methodology are still being established. At the same time, expectations of transformation, system leadership and improved research delivery remain high. This increases the importance of demonstrating benefits from investment and being explicit about what the organisation will prioritise, sequence differently or stop.

Delivery Capacity and Portfolio Prioritisation: PDG's routine assessment of available capacity and capability against baseline requirements is demonstrating a significant gap between the resources required to deliver the portfolio and those available. This pressure is increasingly reflected across the HRA's risk management system, from individual team and project risks through directorate and Executive-level risks. Expected downward pressure on headcount from DHSC is likely to exacerbate this position. The Board is invited to discuss whether it has sufficient assurance that the HRA is making the necessary choices about priorities, sequencing and what it will not deliver, given the capacity and capability available.

Suggested Areas for Board Discussion

The HRA's future role in the research system

Discussions with DHSC about the HRA's future role will help shape the next stage of the Target Operating Model, development of the next HRA strategy and preparations for the next Spending Review. The Board is invited to discuss:

- What role should the HRA seek to play in the future health and social care research system?
- Where should the HRA lead, where should it work through partnership, and where should it enable others?
- What capabilities and relationships will be needed to fulfil that role?

Transforming research approvals across the system

National expectations continue to increase around reducing study set-up times, simplifying the researcher experience and improving coordination between organisations. While the HRA continues to perform strongly against its own regulatory measures, there remains a wider challenge around translating this into improvements across the end-to-end research pathway.

The Board is invited to discuss:

- What further opportunities should be pursued through alignment with the MHRA, the devolved administrations and other research system partners.
- Where the Board would like to see greater pace, challenge or evidence of impact.

The HRA's role in clinical trial recruitment

The forthcoming Open Day and the HRA's work through UK Clinical Research Delivery provide opportunities to strengthen the organisation's leadership on participation and inclusion. The Board is invited to discuss:

- How the HRA can use its mandate, regulatory, convening and influencing roles to improve inclusive participation in research.

Data landscape

The changing health data landscape remains strategically important to the HRA, particularly in relation to public trust, governance and the development of new research models. As the Board has a dedicated seminar on this subject, we **not propose a substantive discussion under this item** but is noted here for completeness.

3) Key external developments

1. The UK is the easiest place in the world to do excellent health and social care research that people can trust, helping grow the contribution of life sciences to our economy

Over the past quarter there has been a consolidation of the 150-day target and an ongoing focus on system coordination and alignment. The HRA's work with MHRA on the Combined Review process has been a key contributor to meeting the 150-day target. There are opportunities for the HRA to ensure it is well-aligned and working in concert with existing partners UK-wide, including the administration in Northern Ireland, Scotland and Wales and the MHRA, as well as growing initiatives including the NIHR Life sciences industry hub and Health Data Research Service (HDRS), particularly as a number of areas of research data policy are being developed. Improving inclusive patient recruitment is an area highlighted as key for improvement – HRA activity with MHRA and as part of UKCRD is supporting this agenda.

- The government published a new progress report on delivering the Life Sciences Sector Plan, which was launched in July 2025. The update covers progress across 4 targets:
    - investment in commercial research and development
    - access to scale-up capital
    - patient access
    - foreign direct investment
- On 21 October the government announced that the average time to set-up a commercial clinical trial in the UK was down to just 100 days between January and March 2026. The Life Sciences Sector Plan, published in 2025, set a target for 95% of UK clinical trials to be set-up within 150 days by March 2026. 100% of the 24 commercially sponsored clinical trials set-up between January 2026 and March 2026 were set-up within the 150 days target.
- The August edition of the UK Clinical Research Delivery monthly update report highlights:
    - The process for adding Be Part of Research as a study recruitment route through IRAS has been simplified, including for studies already open to recruitment. The changes are intended to make it easier for researchers to access volunteer registries and support participant recruitment.
    - The introduction of the accelerated National Contract Value Review (NCVR) process across the UK, with work underway to eliminate parallel contracting processes and reduce escalation activity. This supports wider efforts to streamline study set-up and improve consistency across the research system.
- The **Association of the British Pharmaceutical Industry's** UK pharmaceutical investment competitiveness report 2026 identifies faster study set-up, more efficient regulation and improved patient recruitment as key factors in strengthening the UK's international competitiveness for commercial research and life sciences investment.
- **MHRA** has published its MHRA 2030 Strategy, setting out priorities to accelerate innovation, modernise regulation, increase the use of AI and real-world evidence, and improve the speed of clinical research and patient access to new treatments.
- HDRS has announced their first 43 funded Technical Transformation Projects. The aim is to build a portfolio of projects that work together, learning from what works well and has the potential to scale up.

- The Health Bill is progressing through the House of Lords, including proposals for a single patient record that have led to discussion about how these powers interact with existing safeguards for research.

2. **Health and social care research is done with and for everyone, meaning that we can all benefit from research findings, helping reduce health inequalities**

Insights into the basis of earning trust in health and social care research are valuable to inform the HRA's work, including acting on recommendations received following the infected blood inquiry Deciding whether to take part in research, and knowing what should happen if you do - Health Research Authority

- **Understanding Patient Data** has published its first State of the Nation report on public confidence in health data, finding that support for the use of health data remains high but is conditional on clear public benefit, transparency, robust governance and meaningful public involvement. The report highlights the importance of maintaining public confidence as health data becomes increasingly central to research, innovation and NHS reform.
- **Wellcome** has published its Global Monitor 2026, finding that global trust in science has declined since its pandemic peak and is now below 2018 levels. In the Wellcome Global Monitor report for 2026, it highlights the importance of demonstrating public benefit, relevance and trustworthiness to sustain confidence in science and research.
- **The Association of Medical Research Charities** (AMRC) has published a new genomics spotlight report highlighting the growing role of medical research charities in advancing genomics. The report finds that 71% of surveyed charities fund genomics-related research and identifies improving access to genomic services, strengthening data infrastructure and translating research into routine care as key priorities.

3. **The health and social care research system is streamlined, efficient and encourages and supports success, increasing the impact of investment**

Improved metrics are supporting activity to understand and take action to streamline the health and social care research system. The development of Plan and manage health and care research will support the collection of improved metrics and increasing coordination across the system.

- **NIHR** has published a new Gross Value Added (GVA) Model, estimating that research activity funded or enabled by the NIHR may contribute **£8.8 billion** to the UK economy in 2025/26. The model highlights the economic impact of both commercial and non-commercial research activity, reinforcing the growing emphasis across government and the life sciences sector on demonstrating the wider economic as well as health benefits of research investment.
- **NHS England** has published a new Framework for Integrated Care Boards (ICBs): monitoring research activity, setting out expectations for how NHS boards should oversee research activity and defining the characteristics of high-performing, research-active organisations. The framework reflects the increasing emphasis on embedding research within NHS performance, governance and accountability arrangements.

4) Outcome measurement

Overview

The Strategic Outcome Measurement Report demonstrates strong progress across the Health Research Authority's strategic objectives, particularly in regulatory performance, digital transformation, public involvement and organisational effectiveness. Operational measures continue to perform well, while several longer-term strategic outcomes remain in the early stages of implementation, with new baselines established to support future measurement. Overall, the organisation is delivering against its core responsibilities while building the foundations required to achieve its 2025-2028 strategic ambitions.

Key Achievements

- 100% of Clinical Trial Investigational Medicinal Product (CTIMP) approvals continued to be issued within the 60-day statutory target, with median approval times improving to 23 days in the latest reporting period.
- Confidentiality Advisory Group decision-making performance remains strong, achieving target timelines in the majority of cases.
- Applicant satisfaction increased significantly to 87%, exceeding the strategic target of 75%.
- Increased adoption of the new digital platforms, with modification volumes steadily increasing and significant reductions in manual processing achieved.
- Digital services maintained 100% system availability throughout the reporting period.
- Cyber security performance strengthened further, with security scores increasing to 88%, substantially above the minimum standard.
- Microsoft Copilot adoption increased from 62% to 72%, demonstrating growing confidence in AI-enabled productivity tools.
- Public involvement in research applications remained consistently high at 84%, significantly above the 2024 baseline of 74%.
- Public contributors continue to report a strong sense of influence over HRA activities, with 100% reporting that they had shaped and informed the work in the latest quarter.
- Positive stakeholder sentiment and trust continue to be monitored and maintained.
- Staff engagement increased to 76%, demonstrating continued progress toward the 2028 target of 80%.
- Efficiency activities moved from discovery into delivery, with reported efficiencies increasing from £67k to £107k.
- Collaborative working and shared service arrangements continued to expand while maintaining value for money.

Areas Requiring Continued Focus

- New survey methodologies have established refreshed baselines for measures assessing the ease and efficiency of research set-up. As a result, direct year-on-year comparison is not currently possible.
- A significant proportion of respondents remain undecided when assessing the ease and efficiency of study set-up, indicating further work is required to simplify the research environment.
- Reducing duplication in study set-up processes remains a strategic priority, with limited movement observed in current measures.

- Clinical trial registration rates remain high; however, only 32% of completed clinical trials are currently uploading summary results to registries, highlighting an important area for improvement.
- Delays in HRA and HCRW approvals continue to be driven primarily by sponsor responses to requests for information and dependencies on external regulatory approvals, limiting overall improvements in end-to-end timelines.

Strategic Progress Highlights

- Successful implementation of new clinical trials legislation, with formal reporting due in October 2026.
- Strengthened international engagement through collaboration with European partners, international conferences and knowledge-sharing activities.
- Progress in supporting new research models through engagement with the Health Data Research Service and development of guidance on data access, recruitment and governance.
- Initial work completed to incorporate sustainability considerations into future revisions of the UK Policy Framework for Health and Social Care Research.
- Continued development of policies and guidance supporting innovation, emerging technologies and AI-enabled research.

Overall Assessment

The HRA remains on track to deliver its 2025-2028 strategic objectives. Performance is particularly strong in regulatory delivery, digital resilience, stakeholder engagement and workforce effectiveness. While several system-wide outcome measures are at an early stage of maturity and have recently established new baselines, there is evidence that the organisation is creating the conditions necessary to achieve longer-term improvements in research efficiency, transparency, inclusion and innovation. Continued focus on reducing complexity, eliminating duplication and strengthening the end-to-end researcher experience will be critical to realising the full benefits of the strategy over the remaining implementation period.

5) Portfolio dashboard

The portfolio continues to support delivery of the organisation's strategic priorities, with overall performance remaining broadly on track. While a small number of initiatives are experiencing delivery pressures, governance, oversight and mitigating actions remain in place to maintain confidence in the achievement of planned outcomes.

The most significant area of investment continues to be the Research Systems Programme, which is delivering critical digital transformation and remains central to the organisation's long-term operating model. Progress has been maintained against key deliverables, although delivery remains dependent on effective management of resource capacity, external dependencies and evolving stakeholder requirements.

Across the remainder of the portfolio, projects are advancing as planned and contributing to strategic objectives through improvements in research set-up, digital capability, organisational effectiveness and stakeholder engagement. The Study Set-up Project continues to deliver tangible benefits to the research community, while the AI and Resources About Research initiatives are establishing the foundations for future service innovation and enhanced user experience. The Target Operating Model project is also progressing at pace and will be instrumental in strengthening organisational capability, resilience and future readiness.

Financial performance remains within acceptable tolerances and is being actively monitored through established controls. Portfolio risks are understood and managed, with particular focus on delivery dependencies, procurement timelines, resource availability and benefits realisation.

The portfolio is therefore delivering significant organisational change while maintaining strategic alignment and control. The Board can take assurance that appropriate governance arrangements are in place, delivery performance is being closely monitored, and corrective actions are being implemented where necessary. Continued focus on the successful execution of the largest and most complex initiatives will be critical to sustaining momentum and securing the planned benefits for patients, researchers and the wider health and social care system.

6) Strategic risks

The October 2026 Strategic Risk Register shows that five of the six strategic risks are operating at their stated tolerable levels: life sciences (9), health inequalities (6), impact of investment (12), digital (12) and resilience (12). Strategic risk 6.1 has been redrafted to place greater emphasis on cyber-attack, and its tolerable risk score has been increased to 12. Strategic risk 5.1 remains above tolerance, scoring 12 against a tolerable score of 8. A senior team is reviewing the residual score to understand why it remains above tolerance and how it can be aligned with the tolerable score of 8. The principal cross-cutting exposures are constrained financial and workforce capacity, prioritisation and strategic workforce planning, digital dependency and legacy-system resilience, and the ability to prevent, detect, respond to and recover from cyber incidents, including risks arising through suppliers.

7) Finance

Financial performance remains strong. There is some risk to our financial performance to remain within resources limits given that there are many competing priorities and external pressures, while maximising delivery within the resources available. Our assessment of this risk is low-medium likelihood.

Consequently we forecast a small RDEL overspend of £0.2m, which we expect to manage within the HRA portfolio. This reflects agreed changes to the RDEL/CDEL classification methodology with the NAO.

CDEL is forecast to underspend by £1.9m, driven partly by the same methodology and by shifts in RSP activity, including changes to data-related work and ongoing recruitment and retention challenges.

Core service delivery and continuous improvement activities remain within forecast and are being managed well. We remain compliant with the Better Payment Practice Code, with 99% of invoices paid within 30 days, and cash balances remain at acceptable levels.

8) Strategic communications and engagement

The Strategic Communications and Engagement update gives an overview of external activity happening across the HRA over Q2 and planned for Q3. This is broken down by our strategic drivers: simple, fast, trusted, and effective. The full report provides bulleted summaries of individual activities, with links where relevant. Highlights over this period include both national and international conferences on research transparency, publishing findings from the 2026 study set-up survey, and delivering a successful awareness campaign on contacting people about research that increased traffic to HRA guidance by 450%. A significant achievement has been the expanded adoption of the new Research Systems service from 10 to around 40 sponsor organisations. We also continued engagement with partners in the system to deliver national initiatives around AI, health data, public involvement, and in relation to the amended clinical trials legislation and guidance that was introduced in May 2026.