Academy of Medical Sciences' submission to the Department for Science, Innovation and Technology call for evidence on data regulation in the age of AI and other data-intensive technologies

September 2026

Introduction

The Academy of Medical Sciences is one of the UK's four National Academies, and is the independent, expert voice of biomedical and health research. The Academy welcomes this consultation as timely and necessary for ensuring AI and data-based technologies are leveraged to their full potential. This response draws on the experience of our Fellowship of leading researchers, and relevant recent Academy outputs.

The Academy is developing a longer-term programme of work on the responsible, effective and equitable use of AI and data across the biomedical sciences. The scope of this response is therefore limited to findings from existing reports and consultations, and recent engagement with a small group of Fellows with relevant expertise. Our work will evolve into a more comprehensive set of policy positions over the course of the programme.

Opinions expressed in this report do not necessarily represent the views of all Fellows.

Theme 1 – Accessing and using data

Prompt 1

What are the challenges you face, or can foresee emerging, when accessing and using personal and non-personal data when developing or using AI and data-intensive technologies?

The UK has rich health data assets, including strengths in longitudinal data linkage and large genomic programmes, but their value is limited by infrastructure and access, procurement, workforce, legal and governance barriers that limit responsible data sharing and reuse.

Access and infrastructure

1. Access to and linkage of high-quality, representative datasets is vital for developing and deploying AI models, but health data remains difficult to access because of fragmented systems, complex processes and siloed datasets. Where datasets do exist, gaining access permissions can be laborious and cause delays.
2. Basic NHS digital infrastructure remains a significant challenge, with some healthcare settings still lacking the high-quality electronic health records necessary for an increasing number of AI tools, including many clinical decision support tools. Additionally this may limit the NHS's ability to build high-quality, diverse datasets which is an essential prerequisite for developing inclusive data-driven technologies.
3. Digital systems are often not interoperable, limiting data transfer and increasing the cost and effort of scaling AI-based innovations. This can also exacerbate existing disconnects between the NHS and technology developers. Standardising digital

systems, data collection, data quality, metadata and interoperability requirements would support the development and scale-up of technologies across different healthcare settings. Linking datasets will need to go hand in hand with a more streamlined system for gaining permission to use them.

4. Not all NHS trusts need to be involved at every stage of AI development. A tiered approach could be adopted based on digital maturity and readiness. Larger, research-active trusts could lead the development and training of AI tools, while other trusts could focus on validating algorithms or supporting real-world deployment and evaluation. This would allow organisations to contribute according to their capabilities.

5. Producing high-quality health data requires investment. Clinical trials devote substantial time and resources to data collection, validation and cleaning, which generally results in datasets of much higher quality. Incentives could be introduced to encourage the collection and maintenance of high-quality routine health data. AI technologies could support this by identifying inconsistencies, missing information and potential errors within electronic health records. Licensing access to high-quality datasets could provide a mechanism for trusts to recover some of the costs associated with data curation and reinvest in future data quality improvements. The OPTIMAM Mammography Image Database is a one example of a data set generating revenue through this method.

Workforce and skills

6. Better access to and linkage of data needs to be supported by capacity building in the skills required to manage and analyse large datasets. Cultural, workforce and financial barriers in the NHS can prevent promising AI-based health technologies from being adopted or scaled, even where there is a strong underlying data or technology opportunity.

7. NHS Trusts can struggle to implement digital innovation because of limited capacity, lengthy local IT prioritisation processes with competing pressures, and the cost and complexity of infrastructure investment.

8. Frontline pressure, risk-averse cultures and limited AI literacy can reduce uptake of AI and other data-intensive technologies. Clinicians need protected time, skills and support to innovate and use data-intensive technologies effectively. This includes support staff for IT and research and development with the appropriate skills for AI deployment.

Procurement

9. Demand signalling from the healthcare system at local, regional and national levels would help developers design technologies that address priority NHS challenges. One approach could be to conduct a Delphi exercise to identify and prioritise the AI tools with the greatest potential to meet healthcare needs and therefore warrant national investment and support.

10. Interoperability and sustainability should be used as key procurement criteria to support standardisation and make future adoption easier across the NHS.

11. A consistent commercial architecture could support smarter commissioning and reduce duplicative commissioning of AI-based health technologies across NHS bodies. This would require a centralised or more coordinated NHS innovation procurement process, potentially a “single front door”.

Time, capacity and the cost of delay

12. Time to adoption is currently unmeasured and therefore unmanaged. There are no published service standards for the cumulative journey a technology must complete across research approval, regulatory assessment, data protection and information governance review, clinical safety assurance and local deployment sign-off.

13. Information governance decisions are made locally and inconsistently, so that a nationally agreed governance position is renegotiated many times over and the same request may be assessed differently by each participating organisation. Nationally issued, adoptable governance templates and model data sharing agreements, with a clear presumption in favour of the national position, could reduce duplication without weakening protection.

14. Regulatory cost is largely fixed and therefore falls disproportionately on smaller organisations. The quality management, clinical evaluation and post-market obligations attaching to a given risk classification are broadly the same for a small company as for a multinational. Fellows have observed that proportionality is presently defined against risk class alone; without also accounting for organisational capacity, the framework selects for incumbents, and UK-originated innovation is acquired, relocated or abandoned before reaching patients. Shared quality management infrastructure, reference datasets and subsidised assurance routes should be treated as national infrastructure rather than as individual company overhead.

15. Privacy-enhancing technologies, federated analytics and high-fidelity synthetic data offer routes to model development that reduce reliance on the movement of identifiable data. Clear regulatory recognition of these approaches, including what constitutes acceptable evidence of privacy preservation and when federated or synthetic approaches are sufficient for regulatory purposes, would address several of the access barriers described above.

Assessing the costs of inaction

16. More broadly, we have heard that a significant risk to public benefit in this area is not necessarily that these technologies are adopted badly, but that they are not adopted at all. Deployment of these technologies must be safe, evaluated and equitable, but a comprehensive assessment should consider a balance both of the risks of adopting AI and data-intensive technologies in health, but also the risks of not adopting them.

17. Harms arising from the use of a technology are visible, attributable and subject to investigation and redress. Harms arising from non-use are unattributed and absorbed

into ordinary service pressure. As a result, decision-making processes may place greater weight on the risks of adoption than on the potential benefits that may be forgone.

18. Fellows have indicated that making this trade-off explicit could allow for better evaluation of the risks of adoption versus non-adoption. Where a data-driven or AI-based technology is refused, delayed or withdrawn, recording the expected outcome under continued standard care could ensure that the benefits and risks of adoption vs non-adoption decisions are properly evidenced. This approach could identify where regulatory and governance processes and timelines inadvertently delay patient access to new innovations, and build a more accurate picture of the costs associated with these delays.

19. This equally applies where UK innovators seek market authorisation in other jurisdictions first because those pathways are faster or more predictable and as a result UK patients receive those technologies last. The competitiveness of the UK regulatory environment is therefore a matter of population health as well as industrial strategy.

Theme 2 – Data quality, accuracy and downstream impacts

Prompt 2

How do you assess and manage fairness and impacts on individuals when using AI or other data-intensive technologies?

The principal challenges in assessing and managing fairness are ensuring that data is representative, diverse and of high quality, and that appropriate evaluation mechanisms are in place to identify and mitigate impacts on individuals over time.

Quality and representation

20. AI systems depend best on data that is similar to the data on which they are trained; If some people (e.g., ethnic minorities) are not represented in that data, then it is likely to perform less well when used in that group, leading to bias, and potential exacerbation of health inequalities. Efforts to improve the awareness of this, and transparency of reporting of data diversity in datasets include the UK-led international STANDING Together programme.

21. Inclusion and exclusion criteria in clinical trials can also introduce bias into datasets, which may affect the performance of AI tools trained on those data.

22. Where electronic health record data does exist, it is often inconsistent, incomplete, or contains errors. Before focusing on more advanced uses of the data, we should prioritise improving data quality and cleaning the underlying records.

23. Representativeness should be treated as a continuing obligation of market access rather than as a pre-market gate. A requirement for complete representativeness before any deployment has a predictable distributional consequence: the populations for whom least data exists wait longest for benefit, so a mechanism intended to advance equity delays it.

Validation and evaluation

24. Health technologies require robust validation and independent evaluation, including clear expectations about how models should be assessed and how their limitations should be understood. Technologies should be evaluated not only on their overall performance, but on how they perform across different population groups. This includes assessing whether they deliver equitable outcomes for individuals of different ages, sexes, ethnicities and other relevant characteristics. This will allow assessment of whether tools perform safely and effectively across different populations and clinical settings.

25. The performance of AI-based health technologies may change over time as target populations, clinical environments or data inputs change, so post-market surveillance (again looking at overall performance and subgroup performance) and clear procedures for responding to underperformance are essential. This should include mechanisms for improving, maintaining or potentially withdrawing AI-based health technologies if they are no longer performing as intended.

26. Post-market surveillance is at present an unfunded expectation. Continuous real-world performance monitoring requires access to outcome data, linkage and analytic capability that few developers can build independently, with the result that surveillance is either not performed or is performed only by the largest organisations. National federated post-market monitoring infrastructure, available to developers on common terms, would make the expectation deliverable and would generate comparable evidence across technologies.

27. Economic models are needed to capture and quantify the system-wide value of AI-based health technologies, so commissioners and central government can understand their broader impact.

28. Health technology assessment methods assume a stable intervention and a fixed comparator and are poorly suited to software that is updated frequently and improves over its lifetime. Evaluation approaches that accommodate iterative change, including conditional or staged recommendation linked to real-world performance, are needed. Otherwise, assessment methodology becomes a barrier to precisely the improvement cycle that makes these technologies valuable.

Theme 4 – Transparency and rights in complex data environments

Prompt 1

What approaches have you found effective for providing transparency and enabling individuals to exercise their data protection rights?

Use of data-driven technologies should be guided by clear principles that ensure they deliver public benefit while protecting privacy and individual choice. To support informed decision-making and public trust, these technologies should be sufficiently transparent and explainable, with patients and the public meaningfully involved in decisions about data use and governance.

Guiding principles

29. Data-driven technologies should be designed and used for clearly defined purposes that uphold the social value of the NHS and benefit individuals, the NHS or society. This means that they should by default be designed and used in ways and settings that respect and protect the privacy and choices of patients and the public. Responsible stewardship of patient data and data-driven technologies is key to building trust.

30. An accreditation mark from an independent board could help signal good practice and high standards in the use of AI-based health technologies, making it easy for patients and the public to see where guiding principles have been followed.

Transparency and proportionate explainability

31. Transparency and explainability are important for building confidence in AI-based health technologies, particularly given concerns about "black box" systems and the difficulty of understanding how decisions or outputs are generated. Clear, accessible communication about how AI-based health technologies function, and about the evidence of their effectiveness in real-world settings, can improve confidence among end-users. This information should include how datasets are representative of the population and should be accessible and understandable to the clinicians that deploy AI technologies.

32. Open communication, improved AI literacy and engagement with trusted voices, such as charities, Understanding Patient Data and Health Data Research UK, could help improve public understanding and confidence. It is important that the NHS adopts a clear and consistent communication strategy on AI. Patients should be reassured that AI technologies will be used responsibly, just as healthcare professionals are expected to deliver care safely and responsibly. A unified national communications campaign co-developed with end-users, early adopters and trusted organisations could help build public trust.

Public and patient involvement

33. Public and patient involvement should be embedded in decisions about data use, including through meaningful and early engagement in the development and governance of data-driven technologies. This could help foster a community of early adopters who can act as ambassadors within the healthcare workforce.

34. Government, health data groups and patient groups such as citizens' panels are key enablers for patient and public involvement in decisions about data use.

35. Public and patient involvement is currently framed principally around consent, transparency and trust. It should also address risk appetite. Fellows noted that patients living with poor outcomes are frequently more willing to accept uncertainty in exchange for earlier access than the systems acting on their behalf assume, particularly in oncology and rare disease. Asking patients and the public what balance of risk and delay they consider acceptable would give decision-makers a legitimate basis for proportionate risk-taking, rather than defaulting to caution in the absence of a mandate.

Theme 5 – Effectiveness of data frameworks in regulating AI

Prompt 1

Overall, what is working well, where have you observed disproportionate or unintended barriers in practice, and where have risks to data protection arisen?

Strengths

36. The UK has significant strengths in health data, including longitudinal linkage from exposure to outcome and large genomic programmes that can link genetic characteristics to future health outcomes at scale.

37. MHRA scientific advice meetings, the AI Airlock and the Innovative Devices Access Pathway provide useful mechanisms for testing and refining approaches to data-driven and AI-based health technologies. This allows innovators to clarify ethical and regulatory expectations early.

38. The AI & Digital Regulations Service provides a valuable service as a single point of access to guidance on AI development and adoption, bringing together resources from the MHRA, NICE, CQC and the HRA; in addition the UK AI Standards Hub is a sector-agnostic resource, that can promote standards relating to AI, including in healthcare.

Barriers

1. Accountability and liability for harms caused by a process or decision involving an AI-based health technology are still somewhat uncertain and generate anxiety amongst health professionals. There has also been uncertainty about the routes to contestability and redress for AI-related harms. Clinicians are asked to accept personal accountability for outputs they cannot inspect, and indemnity and insurance arrangements have not kept pace. In addition to clarifying the allocation of liability between manufacturer, deploying organisation and clinician, government should examine whether a backstop indemnity or no-fault compensation route is required for AI used in clinical care, drawing on the precedent of existing statutory compensation schemes.

2. A lack of confidence among end-users, including healthcare practitioners and patients, is a barrier to adoption and may be driven by perceived risk, concerns about privacy and cyber security. Initiatives to improve digital literacy, data skills and understanding of the benefits and limitations of data-driven technologies and AI among the NHS workforce and the public is essential for adoption.

3. Cultural barriers in the NHS, including risk aversion and concerns that innovations must deliver equal benefit everywhere before adoption, can prevent useful technologies from being adopted.

4. Procurement processes are difficult to navigate and may discourage technology companies from operating in the UK. Lengthy and duplicative documentation creates additional burdens for individual healthcare providers.

5. One respondent reported that approval processes are often slowed by risk aversion and limited familiarity with AI among IT teams. They suggested that a standardised set of deployment documentation for each AI product, including a common hazard log and core assurance materials (such as DCB0129 and DCB0160 documentation), could be developed and shared to streamline local assessments and reduce duplication.

6. Fragmentation in the healthcare system can create inefficiencies and makes coordination and cross-sector collaboration essential for safe and effective AI adoption.

7. A vast amount of AI-mediated health interaction now occurs outside the regulated perimeter. General-purpose conversational systems and consumer wellness applications can provide health information and advice at a very large scale with no classification, no post-market surveillance and no adverse incident reporting route. A framework that concentrates on technologies deployed within the health service while leaving this larger exposure unaddressed is leaving this risk unaddressed, and Fellows proposed that the boundary between wellness and medical purpose requires clarification.

Prompt 2

Are the existing data frameworks sufficiently adaptable to future developments in AI?

Existing frameworks will need to remain agile, risk-proportionate and adaptable to keep pace with AI and other data-intensive technologies, particularly in higher-risk areas such as healthcare (including) clinical trials.

Regulatory frameworks

8. Regulators should establish core principles for AI regulation, balancing the need for international harmonisation to reduce regulatory burdens with flexibility to diverge where this supports UK competitiveness and innovation for patient benefit**.** Examples of harmonisation include the use of standard definitions of AI and medical device

functions (such as through the IMDRF), a shared commitment to the Principles of GMLP and common approaches to managing model updating such as through predetermined change control plans. Alignment with international data quality standards, including standards developed by the ISO, could further support confidence and consistency in AI development and regulation.

9. Regulatory frameworks should provide clear expectations on validation, and the level of evidence required before market approval, including for devices based on generative AI.

10. Standards for AI use in healthcare should be developed with all relevant stakeholders, including patients and the public. Independent audit may be needed to ensure compliance. This could help ensure consistency of performance across the healthcare system.

Guidance

11. Regulators should provide more detailed guidance on when an AI health technology qualifies as a medical device and its risk categorisation, with examples. They should also provide guidance on the levels of evidence required for validation in silico and in clinical. Case studies of successful AI adoption in healthcare, including collaborations with developers, would be particularly useful for emerging businesses who are trying to navigate regulatory expectations.

12. The regulatory framework should continue to support confidential early dialogue between innovators and regulators through schemes such as the MHRA scientific advice meetings, the AI Airlock and the Innovative Devices Access Pathway noted above, enabling ethical and regulatory expectations to be clarified before technologies are deployed. Raising awareness of the AI and Digital Regulations Service guidance for developers and adopters could further support more confident innovation.

13. In order to build and develop complex regulatory frameworks, regulatory bodies need sufficient capacity and technical expertise to evaluate AI models and respond to growing demand. Capacity and expertise need to grow continuously so regulators can evaluate increasingly complex AI and computational models. Skills assessments could help identify regulatory workforce gaps and support continuous workforce planning.

Concluding remarks

14. A systems approach is needed because AI-based health technologies can have wide-ranging effects across healthcare, and frameworks should be able to account for system-level benefits and risks. Data and AI strategy should therefore be developed with partners across the healthcare system to ensure frameworks remain aligned with infrastructure, workforce, governance and adoption needs. An example of this is the National Commission into the Regulation of AI in Healthcare – due to report in September 2026 – which is addressing many of these issues and will

provide recommendations to the UK Government regarding a future regulatory framework for AI in healthcare, including the regulation of AI health technologies.