

Introduction & summary

The Academy's mission is to help create an open and progressive biomedical and health research sector to improve the health of people everywhere. In this response, we will comment specifically on **the regulation and governance of artificial intelligence (AI) used in healthcare and medical research.**

Our response to this call for evidence is based on our previous policy work on AI and health and other relevant topics (e.g. health data), as well as evidence from members of our elected Fellowship and leadership programme, which include some of the UK's foremost experts in clinical and academic medical research. To aid navigation around this response, we have used the survey block headings as subheadings. Due to the nature of our evidence gathering we have not always been able to answer the Likert-scale questions. We have, however, provided written responses to all the questions.

Overall, we welcome the white paper on 'a pro-innovation approach to AI regulation', and its intention to support innovation while providing a framework to ensure risks are identified and addressed.¹ This is particularly important in the healthcare space, where there may be serious implications for health. An important consideration is public and patient involvement in the development and evaluation of AI-based health technologies, which is particularly relevant in the healthcare sector. We have also heard concerns about existing regulator capacity, in particular at the Medicines and Healthcare products Regulatory Agency (MHRA); as the number of algorithms grows, this will have an increasing impact on regulators, so support to increase the capacity of regulators will be necessary. We also heard that it will be important for the framework to be implemented in a flexible and iterative manner, so that it can be adapted to the rapidly changing landscape of AI. We discuss these and other reflections on the white paper in our answers below.

The revised cross-sector AI principles

1. Do you agree that requiring organisations to make it clear when they are using AI would improve transparency?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

To achieve a valuable level of transparency about AI for end-users, information needs to be clear, accessible, and usable, without being overwhelming (in length or complexity). All information should allow scrutiny by the end-user, to inform their decisions. Therefore,

¹ Department for Science, Innovation and Technology (2023). *A pro-innovation approach to AI regulation* (Cm 815). <https://www.gov.uk/government/publications/ai-regulation-a-pro-innovation-approach/white-paper>

while making it clear when AI is being used is a necessary step towards transparency, it is not sufficient – information about how AI is being used is also important.

2. Are there other measures we could require of organisations to improve transparency for AI?

Provision of meaningful, actionable information about how AI is used is necessary. This could include how datasets used to train an AI algorithm are representative of the population. This information should be conveyed in an accessible, understandable and usable format for the intended audience, in such a way that can be acted upon.² One idea we have heard to enable this could be the introduction of an accreditation mark, from an independent board, that signals good practice and high standards in the development and use of AI technology. Then additional supporting information about the AI-based technology could also be made available to end-users should they wish to access it.

3. Do you agree that current routes to contest or get redress for AI-related harms are adequate?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

We have heard that it is difficult to ascertain the effectiveness of current routes to contestability and redress for AI-related harms in healthcare, as only a few AI algorithms have been implemented in the healthcare system. However, questions were raised about their adequacy for the following reasons:

- Accountability is currently poorly defined, particularly if harm is caused due to a process or decision that involved an AI-based health technology.
- A mechanism to report adverse incidents is lacking.

4. How could current routes to contest or seek redress for AI-related harms be improved, if at all?

There are some governance mechanisms that could be useful to improve current routes to contestability or redress for AI harms, including:

- Standards for AI use in the healthcare context should be devised in collaboration with all relevant stakeholders and co-developed with patient and public representatives. The Academy recognises the importance of organisations such as the UK AI Standards Hub who do vital work in developing technical standards.³
- We have heard from some experts that independent audit to ensure organisations are adhering to these standards will also be important.

² Academy of Medical Sciences (2017). *Enhancing the use of scientific evidence to judge the potential benefits and harms of medicines*. <https://acmedsci.ac.uk/file-download/44970096>

³ <https://aistandardshub.org/>

5. Do you agree that, when implemented effectively, the revised cross-sectoral principles will cover the risks posed by AI technologies?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

The principles cover the main risks and could address the risk profile posed by AI technologies. However, the success of these principles will be dependent on effective implementation. Careful consideration of what effective implementation looks like and of sector-specific risks and needs will be needed to ensure the principles are applied in practice in healthcare and health research, and more broadly.

6. What, if anything, is missing from the revised principles?

The Academy has previously developed a set of principles to guide development, evaluation and deployment of data-driven technologies (including those using AI) in health and social care, reflecting the values and expectations of patients, the public and healthcare professionals.⁴ These principles are as follows:

- A. **Purpose, value and benefits:** Data-driven technologies should be designed and used for clearly defined purposes that uphold the social values of the NHS and benefit individuals, the NHS, or society.
- B. **Privacy and rights:** Data-driven technologies should be designed and used in ways and settings that respect and protect the privacy, rights and choices of patients and the public.
- C. **Public engagement and partnership:** Those determining the purpose and uses of data-driven technologies should include patients and the public as active partners.
- D. **NHS data stewardship and responsibilities:** The NHS, and those acting on its behalf, should demonstrate their continued trustworthiness by ensuring responsible and effective stewardship of patient data and data-driven technologies in the NHS.
- E. **Evaluation and regulation:** Data-driven technologies should be evaluated and regulated in ways that build understanding, confidence and trust, and guide their use in the NHS.

While many of these principles for the use of data-driven technologies in healthcare are reflected in those in the white paper, it would be useful to include those that are not currently covered. Notably, patient and public involvement is a key value that should be included in the AI principles, particularly for health and healthcare. Patients and members of the public are key stakeholders – both as end-users of the AI-based health technologies and providers of the health data used to train them. Therefore, it is of utmost importance that patients (in the context of healthcare and health research) and the public should be included as active partners in determining the purpose and uses of data-driven technologies, including AI-based technologies.

⁴ Academy of Medical Sciences (2018). *Our data-driven future in healthcare*. <https://acmedsci.ac.uk/file-download/74634438>

A statutory duty to regard

7. Do you agree that introducing a statutory duty on regulators to have due regard to the principles would clarify and strengthen regulators' mandates to implement our principles while retaining a flexible approach to implementation?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

We agree that a statutory duty on regulators to have due regard to the principles is necessary for the use of AI in health and health research. However, we have heard concerns about a current lack of capacity and technical capability of regulators, including the MHRA, which would impact their ability to effectively enact this statutory duty.

8. Is there an alternative statutory intervention that would be more effective? Please limit your response to 1-2 sentences.

We are not aware of an alternative statutory intervention that would be more effective.

New central functions

9. Do you agree that the functions outlined in section 3.3.1 would benefit our AI regulation framework if delivered centrally?

We support the proposed new central functions to support the framework and believe these could improve coherence of AI regulation between sectors.

10. What, if anything, is missing from the central functions?

Ensuring that consumers and end users are informed about the principles set out in this white paper will be important and should be a central function.

11. Do you know of any existing organisations who should deliver one or more of our proposed central functions?

We are unable to recommend any existing organisations who could deliver on one or more of the proposed central functions.

12. Are there additional activities that would help businesses confidently innovate and use AI technologies?

Yes.

We have received the following suggestions from our experts:

- The central body should consider harmonisation with international regulations where appropriate to reduce regulatory burdens and maintain the UK's competitiveness and strong international partnerships.
- Access to high quality, representative health datasets is also important for developers, as it underpins the successful research, development, and downstream deployment of AI-based technologies in the healthcare system.
- Case studies of well-documented examples of AI adoption in healthcare would be useful for emerging businesses. These case studies should also highlight examples of successful collaborations between developers, end-users and other stakeholders during the development and adoption of AI-based health technologies.⁵
- An adequate Intellectual Property (IP) and legal framework that enables collaboration while respecting IPs to create a sustainable competitive edge within the international market.
- There should be further work to explore what standards could be useful to accelerate the adoption of AI-based health technologies in the healthcare system.

13. Are there additional activities that would help individuals and consumers confidently use AI technologies?

Yes.

Our experts have suggested several activities that could be useful to achieve this:

- Building a robust system for the evaluation of and communication about the effectiveness of AI-based health technologies will be important to build the confidence and trust needed to encourage adoption and scale-up of these technologies within the healthcare system. This should include mechanisms for post-marketing surveillance to evaluate impact and ongoing effectiveness.⁶
- The Academy champions meaningful involvement of patients, carers and the public in research, including in the development of AI-based health technologies.^{7,8,9} Building understanding of AI in the wider public, by improving health and digital literacy, will be important, and education about the potential benefits and limitations of AI in healthcare will help build trust in these tools. This could include a national forum and/or other mechanisms such as citizens' panels.¹⁰ Early and continued

⁵ Participants at the Academy of Medical Sciences' FORUM workshop on '[accelerating safe and effective adoption of artificial intelligence in the healthcare system: learning by doing](#)', March 2023. The workshop report will likely be published in July 2023.

⁶ Participants at the Academy of Medical Sciences' FORUM workshop on '[accelerating safe and effective adoption of artificial intelligence in the healthcare system: learning by doing](#)', March 2023. The workshop report will likely be published in July 2023.

⁷ Academy of Medical Sciences (2019). *Artificial intelligence and health*. <https://acmedsci.ac.uk/file-download/77652269>

⁸ Academy of Medical Sciences (2017). *Response to the House of Lords' Artificial Intelligence Committee call for evidence*. <https://acmedsci.ac.uk/file-download/47067991>

⁹ Academy of Medical Sciences (2021). *Response to the MHRA consultation on the future regulation of medical devices in the United Kingdom*. <https://acmedsci.ac.uk/file-download/34065057>

¹⁰ Participants at the Academy of Medical Sciences' FORUM workshop on '[accelerating safe and effective adoption of artificial intelligence in the healthcare system: learning by doing](#)', March 2023. The workshop report will likely be published in July 2023.

engagement with end-users will help ensure the AI-based health technologies developed are useful, relevant and effective.¹¹

- Training and capacity-building of the healthcare workforce will be crucial to enable them to confidently adopt and use AI-based health technologies.^{12,13}
- There needs to be more clarity about where accountability and liability lie when AI-related harm occurs. The current lack of case law reinforces this uncertainty.¹⁴ Furthermore, a mechanism to report 'adverse incidents' for AI-based health technologies should be included.

14. How can we avoid overlapping, duplicative or contradictory guidance on AI issued by different regulators?

Avoiding overlapping, duplicative or contradictory guidance between regulators is important and likely to be challenging within the proposed framework. However, the proposed central oversight function would be best placed to identify duplications and resolve these issues.

Monitoring and evaluation of the framework

15. Do you agree with our overall approach to monitoring and evaluation?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

The report acknowledges the need for regulators to be involved in the monitoring and evaluation process. However, as the number of algorithms grows, this will have an increasing impact on regulators, so support to increase the capacity of regulators will be necessary.

16. What is the best way to measure the impact of our framework?

We have heard that it will be important to agree clear and measurable definitions of each proposed principle and function, and to build mechanisms to measure the success of principles in advance of the implementation of the framework.

We have also heard that evaluation might be difficult due to the distributed nature of the regulators that will be implementing the framework.

¹¹ Participants at the Academy of Medical Sciences' FORUM workshop on '[accelerating safe and effective adoption of artificial intelligence in the healthcare system: learning by doing](#)', March 2023. The workshop report will likely be published in July 2023.

¹² Participants at the Academy of Medical Sciences' FORUM workshop on '[accelerating safe and effective adoption of artificial intelligence in the healthcare system: learning by doing](#)', March 2023. The workshop report will likely be published in July 2023.

¹³ Academy of Medical Sciences (2018). *Our data-driven future in healthcare*. <https://acmedsci.ac.uk/file-download/74634438>

¹⁴ Participants at the Academy of Medical Sciences' FORUM workshop on '[accelerating safe and effective adoption of artificial intelligence in the healthcare system: learning by doing](#)', March 2023. The workshop report will likely be published in July 2023.

To measure how well the framework promotes the innovation of AI in the UK, there are multiple metrics that could be collected. Examples of high-level indicators could include:

- The number and proportion of AI algorithms developed within the UK.
- Import and export metrics for AI algorithms.
- Value added – in healthcare this could include the impact on health outcomes and/or on the healthcare system (e.g. efficiency or cost savings).

17. Do you agree that our approach strikes the right balance between supporting AI innovation; addressing known, prioritised risks; and future-proofing the AI regulation framework?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

It will be difficult to judge this until the approach has been implemented – feedback loops of different timeframes should be incorporated to allow for iteration of the framework, in collaboration with relevant stakeholders in each sector.

18. Do you agree that regulators are best placed to apply the principles and government is best placed to provide oversight and deliver central functions?

Yes.

In the case of healthcare and health research, this would include the MHRA and Health Research Authority.

Regulator Capability

19. As a regulator, what support would you need in order to apply the principles in a proportionate and pro-innovation way?

The Academy of Medical Sciences is not a regulator. However, we have heard from our Fellows and other experts involved in previous Academy work that there are concerns about the capacity of regulatory systems in the UK, including the MHRA (and a lack of Approved Bodies supporting the MHRA in the evaluation of medical devices). The need to increase capacity to meet regulatory demands was highlighted in the 2021 Regulatory Horizons Council Report on Medical Devices and the Government Chief Scientific Advisor’s recent pro-innovation regulation review of the life sciences.^{15,16} Sufficient resourcing is essential for governing bodies to meet increasing regulatory demand, including of AI, in an effective, timely manner, and we encourage the Department of Science, Innovation & Technology and the Office for AI to assure themselves that this is provided.

To allow regulators to apply these principles, it will be important that regulatory bodies have access to the relevant technical expertise in AI. We have also heard that regulation should be proportionate to the level of risk to health of the patient and that the risk to health of not

¹⁵ Regulatory Horizons Council (2021). *Regulatory Horizons Council report on medical devices regulation*. <https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-medical-devices-regulation>

¹⁶ Government Chief Scientific Advisor, Professor Dame Angela McLean (2023). *Pro-innovation Regulation of Technologies Review: Life Sciences and the government response*. <https://www.gov.uk/government/publications/pro-innovation-regulation-of-technologies-review-life-sciences>

implementing an AI-based health technology should be taken into account too. There is a need for a clear pathway for regulatory approval. We welcome the introduction of the AI and Digital Regulations Service to provide clearer guidance to developers, and to analyse and improve the pathway of AI-based health technologies through the regulatory system.¹⁷

20. Do you agree that a pooled team of AI experts would be the most effective way to address capability gaps and help regulators apply the principles?

	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree	Don't know
Please answer:	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

AI experts should be included as their technical skills and the scientific community they represent will be important. However, to ensure there is full consideration of the impact of these principles in 'real-world' settings across sectors, including in industry, a cross-sector team with a range of relevant skills and including patient and public contributors would be required. Skills including law, ethics, humanities, regulatory science, economics, and social science would also be important. To be effective, it is important that the team has a breadth of expertise across the domains where AI will operate.

Assurance and standards

21. Which non-regulatory tools for trustworthy AI would most help organisations to embed the AI regulation principles into existing business processes?

Engaging the public in dialogue about AI and ensuring that consumers and end users are informed about the principles set out in this white paper would be helpful, as mentioned in the answer to question 10. The broad principles could be used to raise consumer awareness of what represents 'good AI', helping them to identify which companies and which tools they want to use or are comfortable to be in use. As discussed above, case studies of successful AI adoption in healthcare following the principles will help. The consequent public scrutiny and expectation could then incentivise organisations to embed the AI regulation principles into existing business processes surrounding the development and use of AI algorithms.

Final thoughts on the framework

22. Do you have any other thoughts on our overall approach? Please include any missed opportunities, flaws, and gaps in our framework.

From the perspective of healthcare and health research, the approach set out in the white paper appears to be a good starting point. Gaps may become apparent after implementation, so the approach should remain flexible to allow for iteration and change. The Government should be prepared to modify the approach if it proves to be insufficiently agile, proportionate, or helpful.

¹⁷ Participants at the Academy of Medical Sciences' FORUM workshop on '[accelerating safe and effective adoption of artificial intelligence in the healthcare system: learning by doing](#)', March 2023. The workshop report will likely be published in July 2023.

This response was prepared by Martha Roberts, Policy Intern, and Dr Anna Hands, Policy Manager, and informed by members of the Academy's Fellowship and previous policy work in this area. For further information, please contact Dr Anna Hands, Policy Manager (anna.hands@acmedsci.ac.uk).