The Royal College of Pathologists
Pathology: the science behind the cure

The Royal College of Pathologists' response to the National Commission into the Regulation of AI in Healthcare: Call for Evidence

February 2026

Introduction

The Royal College of Pathologists (RCPath) welcomed the opportunity to respond to the Medicines and Healthcare products Regulatory Agency (MHRA) call for evidence to guide the work of the National Commission on the Regulation of AI in Healthcare.

Response to call for evidence questions

Question 1: Which of the following best describes your view about the need to change the UK's framework for regulating AI in healthcare?

☐ No change: The framework should be maintained as it is

☐ Minor adjustments: The current framework works but requries small changes

☒ Significant reform: The current framework requires substantial changes

☐ Complete overhaul: The overall framework should be replaced entirely

☐ Unsure

Question 2.1: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Safety and Performance Standards

☐ Strongly disagree

☒ Disagree

☐ Neither agree or disagree

☐ Agree

☐ Strongly agree

Question 2.2: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Data Privacy and Data Governance

☐ Strongly disagree

☒ Disagree

☐ Neither agree or disagree

☐ Agree

☐ Strongly agree

Question 2.3: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Transparency

☐ Strongly disagree

☒ Disagree

☐ Neither agree or disagree

☐ Agree

☐ Strongly agree

Question 2.4: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Requirements for clinical evidence

☐ Strongly disagree

☒ Disagree

☐ Neither agree or disagree

☐ Agree

☐ Strongly agree

Question 2.5: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains: Post Market Survillience

☐ Strongly disagree

☒ Disagree

☐ Neither agree or disagree

☐ Agree

☐ Strongly agree

Question 3: How would you rate the current framework's impact on innovation?

☐ Too restrictive [stifles innovation]

☒ Somewhat restrictive [creates some barriers]

☐ About right [balances safety and innovation]

☐ Somewhat loose [lacks necessary controls]

☐ Too loose [risks patient safety]

Question 4: How might the UK's framework for regulation of AI in healthcare be improved to ensure the NHS has fast access to safe and effective AI health technology?

The RCPath approach to AI is outlined in its position statement on artificial intelligence (2023).[1] In relation to the regulatory framework specifically, a key improvement would be establishing clear, pathology-specific regulatory pathways that recognise the unique validation needs of digital diagnostics, including requirements for demonstrating performance across diverse laboratory settings, instruments and population groups.

To support approvals, the UK could expand adaptive regulatory mechanisms – such as conditional authorisations or sandbox environments specifically for pathology (e.g. MHRA's AI Airlock pilot) – allowing promising pathology AI tools to be used in real-world NHS settings while ongoing evidence is gathered. This would help regulators, developers and pathology teams jointly identify risks, monitor model drift and ensure the technology performs reliably in routine practice.

Currently, pathologists are presented with manufacturers claims about a device and find it challenging to access vendor-independent information about the performance of AI. It is very challenging or impossible to see what evidence was submitted in order to obtain approval for devices. As a result, pathologists and pathology departments are making decisions about adoption based on partial or limited evidence.

The published evidence for AI devices could be better quality[2] and many devices on the market either lack transparent data about their evaluation or have not been evaluated on NHS data at all.[3] MHRA could review this publication and its recommendations but ensuring there is robust verification on local NHS data prior to deployment of AI is key.

A register of AI devices in the UK has been developed.[4] MHRA could recommend adoption and maintenance of this register to help inform pathologists about the evidence for new products.

There is also a lack of data comparing how different AI devices perform on the same clinical problems, datasets or real-world conditions such as varied populations, scanners or staining methods. We recommend generating this evidence using diverse NHS datasets across multiple sites to test real-world performance. More broadly, assessment is hampered by limited sharing of sufficient technical detail between vendors. Validation processes like CE kitemarking that allow self-verification make comparisons difficult. Robust, standardised and anonymised datasets are essential to enable consistent, independent benchmarking of AI tools and comparatively test algorithms.

The role of pathologists in early stage evaluations of devices could be clearer. For example, the use of devices in 'shadow mode' or NHS-led evaluations are often complex to navigate in terms of ethical and regulatory guidelines. This complexity makes it hard to perform NHS-led evaluations in the real world.

Question 5: How should the regulatory framework manage post-market surveillance for AI health technologies?

Effective post-market surveillance for AI technologies requires continuous oversight to ensure that systems remain safe, reliable and clinically appropriate. Surveillance should allow real-world data to emerge through routine use – supported by strong safety measures – and include comparisons of outcomes with and without AI to understand true clinical impact.

To minimise the burden on innovators and NHS users, regulators could work with the professions and vendors to provide standardised templates for clinical evidence generation, bias assessment and post-market monitoring. This would reduce complexity while maintaining safety. National reference datasets and testing environments would further support comparability across products, enabling consistent validation and early detection of model drift or performance degradation.

Rapid incident-reporting mechanisms are essential to identify and address evolving risks promptly. Most digital pathology and AI systems do not easily support ongoing monitoring/quality control (QC) of AI (e.g. monitoring daily performance or errors, or more broadly evaluating data drift). As a result, laboratories have to develop QC and monitoring systems in-house. Guidance from MHRA or centralised QC/reporting tools might be useful here.

The current lock-in on the AI solution makes it difficult to develop self-learning and self-adjusting algorithms. Regulation of this aspect is also important.

Transparency about intended use, performance limitations and known risks is also critical for maintaining public trust. Sharing learning across NHS organisations – supported by open reporting dashboards and common quality indicators – will strengthen system-wide safety while accelerating responsible adoption.

Question 6: Which statement best reflects your view on the current legal framework for establishing liability in healthcare AI tools?

☐ Sufficient: existing laws (e.g. medical legligence, product liability, etc.) can adequately handled AI-related disuptes

☒ Gaps exist: existing laws work for most cases but leave uncertainty in some scenarios

☐ Insufficient: existing laws are unfit for AI

☐ Unsure

Question 7: How could manufacturers of AI health technologies, healthcare provider organisations, healthcare professionals and other parties best share responsibility for ensuring AI is used safely and responsibly?

In general, ensuring the safe and responsible use of AI in healthcare requires clearer distribution of responsibility across manufacturers, healthcare providers and clinicians. At present, most histopathology AI devices are a 'second read', so liability sits with healthcare providers and pathologists for appropriate use of the systems, and with manufacturers for appropriate design and performance.

Manufacturers should be responsible for transparent model documentation, clear intended-use statements and ongoing performance monitoring. They must provide robust evidence of validation across diverse datasets and laboratory settings and communicate limitations or risks promptly.

Healthcare provider organisations should ensure safe local deployment through appropriate governance structures, integration testing and processes for monitoring real-world performance. Healthcare providers also need to ensure that clinicians have access to appropriate training, equipment and protected time to learn how to use AI systems safely. It is not clear yet that providers are entirely ready for AI adoption.

Pathologists and other clinicians play a critical role in evaluation and safe implementation. They must be equipped to ensure there is a rigorous evaluation of AI devices prior to deployment or purchase. After AI go-live, pathologists need to interpret AI-generated outputs, understand model limitations and recognise when results are plausible – or when further investigation is needed. Training must evolve alongside technology, to ensure that consultants and pathologists in training develop the skills to work in digital environments. This includes maintaining competence with traditional microscopy, understanding validation principles, and being able to collaborate effectively with informaticians and data scientists.

There is a mismatch between the current training in pathology and the skills required in fully digital laboratories. Embedding AI literacy into curricula and training is necessary.

AI may unintentionally reduce experiential learning opportunities by automating straightforward cases often used in early training.

From a regulatory perspective, manufacturers should be required to provide clear documentation about device performance and the requirements for ongoing monitoring.

It may be worth considering a risk sharing approach to liability. We understand that there are AI devices in other domains that come with a vendor-provided insurance in the case of errors. Of course, avoiding or minimising errors in the first place is preferable.

Question 8: In the event of an adverse patient outcome where an adverse patient outcome involved an AI tool, where do you think liability should lie?

This is a complex area as adverse outcomes can be due to multiple factors, and these factors may not always be fully understood or measurable. More work is needed to clarify this.

Liability must be allocated based on the specific circumstances of the incident and the degree of clinician involvement.

In the event of an adverse patient outcome involving an AI tool, liability should be considered according to several factors including the design and intended use of the system and how it was employed in the real world. Clinical-led oversight remains, and pathologists retain responsibility for interpreting results and ensuring that AI outputs are used appropriately within clinical context. AI should be treated as one of the tools pathologists can use. Currently, no AI is allowed to diagnose on its own. Pathologists, who are making the diagnosis, should be able to make it without pressure from AI and with clear statement on what AI was used and in what context. Where a clinician makes the final judgement, an appropriate level of professional accountability remains.

There is a risk that individual pathologists become liable for adverse outcomes in all cases (the 'liability sink'), which could lead to a reluctance to use AI and get the benefits of the system for patients. The role of automation bias and reduction in clinical experience in evaluating input data will also add complexity to this situation.

If harm results directly from a flaw in the AI system – such as a software error, inadequate instructions for use or an autonomous function that bypasses clinician review – liability should shift towards the manufacturer or system provider.

To some extent, liability issues with AI are similar to those of other laboratory instruments and procedures. However, AI differs in that there may be accuracy issues relating to data or unpredictable model outputs – for example, data drift or shift – that may be outside of the field of view of the pathologist responsible for the case. In this case, liability is unclear – while it is likely that the department should be responsible for the overall safe operation of AI systems, it is not clear that laboratories are currently capable of monitoring AI systems to this degree.

Establishing clear boundaries for liability will require national leadership across regulators, the NHS and professional bodies, to support safe adoption, maintain public trust and ensure that supporting innovation does not expose patients to unmanaged risk.

Question 9: Do you have any other evidence to contribute? Note: please confirm that you have the necessary permissions prior to sharing any documents in this way.

As a technology-centric specialty, pathology has significant potential to use AI to enhance diagnostic accuracy and efficiency, reducing bottlenecks and improving patient outcomes. Effective regulation is essential to ensure this potential is realised in a way that balances innovation with patient safety.

RCPath supports the use of AI to improve laboratory workflow and assist pathologists to enhance accuracy, speed or consistency of diagnosis. Improvements to the UK's regulatory framework for AI in healthcare are welcome. To support delivery, the profession needs to have direct influence in the regulation of AI. There is also an important role for the College in the regulation and standardisation of AI, and this role should be recognised by the MHRA and other organisations and form part of the regulatory process.

While there has been a significant investment in digitisation, pathology labs have some way to go before all are fully equipped to support AI.

Pathologists remain fundamental to safe laboratory practice. AI can enhance efficiency and diagnostic quality, but it does not replace clinical expertise. Addressing workforce shortages and investing in training, infrastructure and protected time is essential to enable pathologists to adopt AI safely and responsibly within routine diagnostic workflows.

Perhaps more important than the technical ability to install AI, there is a major gap in the readiness of laboratories to provide the operational and clinical oversight of AI tools once

they are deployed. Even installing or monitoring a single AI tool can be a substantial undertaking for a laboratory – yet there are dozens on the market. Consolidation or centralisation of the technical and operational sides of AI could help here, and would increase the quality of AI oversight nationally.

While pathologists may not lead AI development, they should be equipped to engage in informed dialogue and guide its clinical application. Ensuring pathologists are involved in design, validation, procurement and governance will protect patient safety and build trust in AI-enabled diagnostic services. Strong coordination between pathologists, computer scientists, universities, regulatory bodies and industry is essential.

Question 10: You can upload documents to be considered as part of this call for evidence.

- The Royal College of Pathologists. *Position statement on digital pathology and artificial intelligence (AI).* Published February 2023.
- The Royal College of Pathologists and the Royal College of Radiologists. *Embracing AI to support the NHS in delivering early diagnoses*. Report from a meeting at 10 Downing Street. Published 30 October 2023.

References

1. The Royal College of Pathologists. *Position statement from the Royal College of Pathologists (RCPath) on digital pathology and artificial intelligence (AI)*. Published February 2023. Available at: www.rcpath.org/static/90e5e248-4ad3-4d61-8247223f9faffc80/RCPath-AI-position-statement-2022.pdf
2. McGenity C, Clarke EL, Jennings C, Matthews G, Cartlidge C, Stocken DD, Treanor D. Artificial intelligence in digital pathology: a systematic review and meta-analysis of diagnostic test accuracy. *NPJ Digit Med* 2024;7:114.
3. Matthews GA, McGenity C, Bansal D, Treanor D. Public evidence on AI products for digital pathology. *NPJ Digit Med* 2024;7:300.
4. The Royal College of Pathologists. *First of its kind central register of AI-based pathology tools*. Published 27 February 2025. Available at: www.rcpath.org/discover-pathology/news/firstofitskindcentralresourceofaibasedpathologytoolslaunched.html

Contact details

This response was collated by the Workforce and Engagement team within the Professional Practice Directorate of the College, informed by feedback from expert members.

Please contact the College if you have any questions: consultations@rcpath.org.

About the Royal College of Pathologists

The Royal College of Pathologists is a professional membership organisation with more than 11,000 fellows, affiliates and trainees, of which 23% are based outside of the UK. We are committed to setting and maintaining professional standards and promoting excellence in the teaching and practice of pathology, for the benefit of patients.

Our members include medically, dentally and veterinary qualified pathologists and clinical scientists in 17 different specialties, including cellular pathology, haematology, clinical biochemistry, medical microbiology and veterinary pathology.

The College works with pathologists at every stage of their career. We set curricula, organise training and run exams, publish clinical guidelines and best practice recommendations, and provide continuing professional development. We engage a wide range of stakeholders to improve awareness and understanding of pathology and the vital role it plays in everybody's healthcare. Working with members, we run programmes to inspire the next generation to study science and join the profession