Medicines & Healthcare products Regulatory Agency

Call for Evidence: National Commission into the Regulation of AI in Healthcare

Published 18 December 2025

National Commission into the Regulation of AI in Healthcare

Introduction to the National Commission

The 10 Year Health Plan for England and the Life Sciences Sector Plan commit to the NHS becoming the most AI-enabled healthcare system in the world, supported by the delivery of a new regulatory framework for medical devices including AI.

While AI stands to have a transformational positive impact on health and healthcare, the technology presents several new regulatory challenges. If addressed properly, AI could transform patient care to be safer, faster and more personalised; it could improve productivity in the NHS and wider health and care sector; and it could accelerate a thriving health technology sector that supports UK growth.

The UK's expertise in healthcare research, AI and regulatory science afford it the opportunity to become a world-leading authority in the regulation of AI in healthcare. The National Commission on the Regulation of AI in Healthcare is designed to help us realise this mission. The Commission brings together diverse expert voices representing technology, health, legal, patients and public, and relevant government, NHS and arm's length bodies.

This group of thought leaders will tackle some of the most pressing challenges on the regulation of AI and advise the MHRA on the development of a new regulatory framework for AI in healthcare that is safe, fast, and trusted. The National Commission's recommendations will be published by the MHRA in 2026.

Commission Membership

The Commission is chaired on behalf of the MHRA by Professor Alastair Denniston, head of the UK's Centre of Excellence in Regulatory Science in AI & Digital Health (CERSI-AI). Its Deputy Chair is the Patient Safety Commissioner Professor Henrietta Hughes.

Together with the Commissioners, they will make recommendations to guide how cutting-edge AI technologies can be responsibly integrated into everyday healthcare**.** The Commission's membership list is set out on the MHRA's website.

The Commission is supported by four working groups. These include experts who have worked with global tech companies, leading clinicians, regulators and global AI experts. These groups support the Commission with expert advice, evidence, and practical recommendations. In addition, a research and engagement programme supported by the

Health Foundation will provide evidence throughout the timeframe of the Commission, so the views and voices of patients and service users remain central to the commission's work.

About the call for evidence

To ensure the National Commission's work reflects the full breadth of perspectives, this call for evidence invites contributions from across the UK and internationally. Information gathered via the call for evidence will help to shape the Commission's recommendations and address the most pressing challenges in AI regulation.

Audience

The call for evidence forms part of the Commission's research and engagement programme. It is open to any interested individual or organisation. However, the MHRA is particularly interested in hearing from:

- Public: Patients, members of the public, and charities representing healthcare service users.
- Industry: AI health tech companies (any size, and both specialist health tech, and general tech with a health interest), trade associations, approved bodies, and notified bodies.
- Healthcare leaders and health professionals: NHS and independent sector leadership, health professionals, and professionals in supporting roles (for example, procurement, practice managers).
- Healthcare provider organisations.
- Healthcare professional bodies.
- Regulators: UK healthcare regulators, and international medical device regulators

Scope

The Commission is tasked with making recommendations about the regulatory framework for AI health technologies. The MHRA is seeking evidence and views on the following areas:

- Requirements of the existing regulatory framework for AI in healthcare, and changes that are required to make it safe, fast, and trusted.
- Monitoring how AI is being used in healthcare, including specific products and whether they are used according to their intended purpose.

- Approaches to ensure that AI health technologies operate safely and perform as expected in both pre-market and post-market phases.

- How to manage the overlap between multiple sources of assurance, including regulation of medical devices, oversight of trained healthcare professionals, and regulation of health and care services.

- How liability and responsibility is managed within the regulatory system, and distributed across the AI supply chain.

Issue date and duration

The call of evidence was issued on Thursday 18 December 2025

This call for evidence will close on 23.59 pm (UK time) on Monday 2nd February 2026.

Respond online

To help us analyse the responses please use the online system wherever possible. Please note that you don't have to answer every question, only the questions which are relevant to you. Visit **the MHRA website to** submit your response. The survey can be found at https://www.surveys.mhra.gov.uk/6939648ad7139569e30a4579.

Other ways to respond

If you need an alternative format for accessibility reasons and are unable to use the online system, for example because you use specialist accessibility software that is not compatible with the system, you may request the form in an alternative format.

By email

Engagement@mhra.gov.uk using the subject line *National Commission into the Regulation of AI in Healthcare*

By post

National Commission into the Regulation of AI in Healthcare
C/o PPSE Team
MHRA
10 South Colonnade
Canary Wharf
London E14 4PU

Confidentiality and data protection

Disclosing your data to a third party

The MHRA will be working with a research partner to analyse responses to this call for evidence. The MHRA contract with the research partner will stipulate that personal data will only be used by research partners under MHRA's direct instruction, as set out in the contract. The research partner will not share your personal data with any organisation apart from the MHRA. They will hold your personal data securely and retain the responses to the call for evidence until work on developing the regulatory framework has been completed by the MHRA.

Personal data

If you are responding as an individual rather than on behalf of an organisation, the MHRA will ask if you are willing to provide personal data – your sex as registered at birth, your ethnic group, and your email address or other contact information. **All of these are optional, and you can choose not to provide these if you prefer**.

Your personal data will be processed for the purposes of summarising who responded to this call for evidence – for example reporting the percentage of people in each ethnic group. **In addition, the MHRA may use any contact information you provide to invite you to contribute further evidence.**

Our legal basis for processing this data is 'consent' and 'public task' [UK GDPR Article 6(1)(a and e)]. For processing special category data, we rely on 'Substantial Public Interest' for the purpose of 'Equality of Opportunity or Treatment' [UK GDPR Article 9(2)(a and g); and Data Protection Act 2018 Schedule 1, Part 2, paragraph 8]. Your data will be stored securely.

Where the processing of your personal data is based on consent, you can withdraw your consent, and have personal data removed. You can do this by emailing engagement@mhra.gov.uk **If you withdraw your consent, the MHRA will discontinue processing any identifiable personal information that relates to you.**

For more information, about your rights and how MHRA manages your personal data please see MHRA Privacy Notice.

We will summarise all responses and publish this summary on GOV.UK. The summary will include a list of names or organisations that responded, but not individual peoples' names, addresses or other contact details.

Enquiries

If you have an enquiry relating to the policy content of the call for evidence, you can contact the MHRA by email at info@mhra.gov.uk with the subject line "*National Commission into the Regulation of AI in Healthcare"*

The response

The results of the Call for Evidence and the department's response will be published on GOV.UK following analysis of the responses.

Section 1 – Respondent information

By telling us about yourself, your position, and where you work, we can better understand your responses and your perspective.

Question 1: Are you responding as an individual or on behalf of an organisation?

a) In a personal capacity
b) Organisation

If you selected 'In a personal capacity', please answer the following questions:

Question 2.1: Which of the following best describes you or your role:

- Patient, carer and/or a member of the public
- UK Industry worker – you work for health technology companies, trade associations, approved bodies
- Non-UK Industry worker
- Healthcare professional
- Healthcare manager
- Regulatory professional
- Scientist or academic researcher
- Other (limit 100 characters)

Question 2.2: What is your current gender?

- Female
- Male
- Non-Binary
- Prefer not to say

Question 2.3: What is your ethnic group?

(Choose one option that best describes your ethnic group or background)

- Asian or Asian British
    - Indian
    - Pakistani
    - Bangladeshi
    - Chinese
    - Any other Asian background
    - Prefer not to say
- Black, African, Caribbean or Black British
    - Caribbean

    - African
    - Any other Black, Black British, or Caribbean background
    - Prefer not to say
- Mixed or multiple ethnic groups
    - White and Black Caribbean
    - White and Black African
    - White and Asian
    - Any other Mixed or multiple ethnic background
    - Prefer not to say
- White
    - including English, Welsh, Scottish, Northern Irish or British
    - Irish
    - Gypsy or Irish Traveller
    - White - Roma
    - Any other White background
    - Prefer not to say
- Other ethnic group
    - Arab
    - African
    - American
    - Australian
    - Chinese
    - European
    - Japanese
    - Any other ethnic group
    - Prefer not to say
- Prefer not to say

If you selected ‘On behalf of an organisation’, please answer following questions

Q3.1: What is the name of the organisation you are representing?

Q3.2: What type of organisation is this?

- Industry: software and AI developers, trade associations, approved bodies, and notified bodies
- Healthcare leaders and professionals: NHS and independent sector leadership, healthcare professional, and professionals in supporting roles (eg, procurement, practice managers).

- Healthcare provider organisations (for example, primary care (such as GP practices), secondary or tertiary care (hospitals), regional care (such as regional boards) or NHS Commissioners
- Regulators and government bodies: UK health regulators, international medical device regulators, UK or international government departments or other bodies
- Charities or public bodies
- Other (limit 100 characters)

Question 3.2.1: Which of the following best describes your organisation:

- My organisation does not develop healthcare AI products
- My organisation has one or more healthcare AI products currently on the market
- My organisation is developing one or more healthcare AI products, but they are not yet on the market

Q3.3 The MHRA intends to list the names of organisations which respond to this call for evidence in the report to be published on GOV.UK. Can the report identify your organisation as contributing in this way?

A) Yes
B) No

Q4: We may want to follow up with you - if you are happy to be contacted, please provide us with a contact name, organisation (if relevant) and email address. Please note, this question is optional.

Section 2 – Information on how AI is used in Health and the Current Regulatory Frameworks

This section contains information which may be helpful background when considering your responses to this Call for Evidence. It contains technical information for people familiar with medical device regulation. We have also produced a summary of this information with less technical language, which can be found in the next section.

How AI is being used in healthcare

Healthcare artificial intelligence (AI) covers a large range of products, used in a broad range of contexts, with the level of risk and the sources of assurance varying across them.

Starting outside formal healthcare services, a recent survey estimated that just under 1 in 10 people use large language mode (LLM)-based chatbots as the source of information they 'most often' use for health and care purposes. Health and wellbeing apps have provided citizens with the AI generated analyses of health data from personal devices for many more years.

Moving into administrative uses in formal care settings, some health providers are using automated systems with conversational interfaces to invite patients to screening appointments and schedule appointments via messaging.

Ambient Voice Technologies are used to summarise consultations. AI-enabled AVTs can record and summarise consultations, reducing the amount of note-taking that health professionals need to do. A newer class of patient assistant services have been emerging, providing patients with their own record of a conversation and advice based on it.

Other AI health technologies may be useful in screening (for example, in detection of cancer), in diagnosis, in supporting treatment decisions and in helping deliver therapies. Some AI technologies have relatively 'narrow' tasks (for example, screening for one condition) and others have broader applications (for example those that are based on newer forms of AI such as large language models). Additionally, AI can now be designed to coordinate multiple specialist AI systems to undertake more complex tasks (known as 'agentic AI').

The existing regulatory framework

Device regulation

Regulation provides the most formal source of assurance for AI in healthcare. Processes are designed to ensure products placed on the market meet the performance and safety requirements as claimed by the manufacturer and required by the regulations. When regulations are effectively implemented, they should give healthcare professionals and patients confidence the product is safe and effective. Products are medical devices when they meet the definition of a medical device as set out in the Medical Devices Regulations 2002. AI and other forms of software which have a medical purpose and fall within the definition will currently qualify as medical devices.

Pre-market assessment

The Medical Devices Regulations 2002 define classes of risk for medical devices (including software and AI), and the requirements against them. For low-risk devices, manufacturers must self-declare conformity with the requirements of the regulations. For medium-risk and high-risk medical devices, assessment processes apply scrutiny to a product and manufacturer to ensure it meets the relevant regulatory requirements. In Great Britain, Approved Bodies carry out independent assessment of conformity of medium and high-risk medical devices, reviewing for example the clinical evidence and risk management, manufacturing and quality systems, and labelling and instructions for use. Once this is complete, the manufacturer must register the device with the MHRA before placing it on the Great Britain market. Due to its unique access to both the UK Internal Market and EU Single Market, Northern Ireland follows EU regulations for medical devices and a CE certificate and marking is required.

Data privacy and security

When accessing and using and managing patient data, all parties involved need to ensure this data is used in a secure way, which does not compromise the safety of the patient. The process for doing this is set out in several pieces of legislation.

- This includes the:
- Public Records Act 1958 which sets out the responsibilities placed on officials when they access data,
- Freedom of Information Act 2000 which outlines how the public can access data held by public institutions,
- Health and Social Care Act 2008 which requires healthcare providers to maintain safe, accurate and complete patient records,

- Data Protection Act 2018 which sets out how personal information can be processed,
- Data Use and Access Act 2025, which introduces changes to GDPR, specifically around the use of data for scientific purposes.

When looking to access data, all parties should work together to complete a data sharing agreement and a data protection impact assessment to ensure there are clear, agreed responsibilities between parties and mitigations are in place to ensure patient data is not compromised or accessed in an unlawful way.

Post-market surveillance and vigilance

The manufacturer is required to conduct post-market surveillance (PMS) of their medical device, assessing the device's safety and performance in the market.

In June 2025, the MHRA introduced new regulations covering requirements for post-market surveillance in Great Britian. The regulations reinforced existing requirements and introduced new requirements for manufacturers of medical devices to:

(1) Have a post-market surveillance system in place
(2) Produce a post-market surveillance plan and undertake PMS in accordance with the plan
(3) Report serious incidents to MHRA
(4) Investigate serious incidents and report to MHRA on the conclusions
(5) Undertake preventative and corrective actions as required
(6) Undertake field safety corrective actions and issue field safety notices to affected customers
(7) Conduct trend reporting of significant increases in incidents that do not require reporting
(8) Produce a post-market surveillance safety report or periodic safety update report against the PMS plan depending on the device risk class
(9) Meet documentation and information provision requirements to support the processes

Software and AI as a Medical Device Change Programme

The MHRA published the Software and AI as a Medical Device Change Programme in 2023. The Change Programme aims to provide a regulatory framework that provides a high degree of protection for patients and public, but also makes sure that the UK is recognised globally as a home of responsible innovation for medical device software looking towards a global market.

Non-technical summary: Section 2 – Information on how AI is used in Health and the Current Regulatory Frameworks

How AI is being used in healthcare

Artificial intelligence (AI) is being used in many ways to help health providers and to assist people with their health. Some examples include:

- **Chatbots and Apps:** Nearly 1 in 10 people now use AI-powered chatbots to get health advice. Many apps use AI to analyse health data from devices like smartwatches.

- **Admin Support:** Some hospitals use automated systems to invite patients to appointments or screenings.

- **Voice Technology:** AI can record and summarise doctor-patient conversations, helping doctors spend less time taking notes. Some services even give patients a summary of their visit and advice based on it.

- **Screening and Diagnosis:** AI can help spot diseases (like cancer), support doctors in making treatment decisions, and assist with therapies. Some AI tools focus on specific tasks, while others have a broader range of applications

How AI in healthcare is regulated now

To keep people safe, there are existing rules for how AI can be used in healthcare:

- **Medical Device Rules:** If an AI tool is used for medical purposes, it is treated as a medical device and must meet strict safety and performance standards.
- **Approval Process:** Low-risk devices can be certified by the manufacturer. Medium-risk and high-risk devices are checked by independent bodies before they are allowed on the market. In Great Britain, the MHRA oversees this process. Northern Ireland follows EU rules.
- **Data Privacy:** Patient data must be kept safe and used properly. There are laws to protect personal information and make sure everyone involved agrees on how data is shared and protected.

Checking safety after devices are used

Once an AI medical device is being used, the manufacturer must keep checking that it is safe and working well.

New rules from June 2025 mean manufacturers must:

- Have a plan for monitoring their devices
- Report and investigate serious problems
- Take action to fix issues and inform customers
- Regularly review and report on device safety

How new technologies are evaluated

The National Institute for Health and Care Excellence (NICE) looks at new digital health technologies, including AI, to see if they are useful for the NHS. If NICE recommends a technology, it can be funded and used across the country.

Improving regulations for AI in healthcare

The MHRA has a programme to make sure the UK is a safe and innovative place for medical AI. The aim is to protect patients and encourage responsible development of new technologies.

AI tools which do not qualify as a medical advice

Not all healthcare AI tools qualify as medical devices. A future regulatory framework should also consider these tools.

Section 3 – Questions

The MHRA is seeking views through a Call for Evidence to help shape how artificial intelligence is regulated in healthcare. Your input will guide the work of the National Commission on the Regulation of AI in Healthcare and support the UK Government's ambition to make the NHS the world's most AI-enabled healthcare system.

Please do not share any personal information or information about a third party when responding to the call for evidence.

Everyone is welcome to respond. You don't need technical knowledge to take part. Questions are not mandatory. If you prefer, you can focus on questions 7, 8, and 9, which are designed for broader perspectives.

Q1: Which of the following best describes your view about the need to change the UK's framework for regulating AI in healthcare?

a) No change: The current framework should be maintained as is.
b) Minor adjustments: The current framework works but requires small changes.
c) Significant reform: The current framework requires substantial changes.
d) Complete overhaul: The current framework should be replaced entirely.
e) Unsure

Q2.1 - Q2.5: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains:

a) Safety & performance standards
b) Data privacy & data governance
c) Transparency
d) Requirements for clinical evidence
e) Post-market surveillance

For each, select from:

- Strongly disagree
- Disagree
- Neither agree nor disagree
- Agree
- Strongly agree

Q3: How would you rate the current framework's impact on innovation?

a) Too restrictive [stifles innovation]
b) Somewhat restrictive [creates some barriers]

c) About right [balances safety and innovation]
d) Somewhat loose [lacks necessary controls]
e) Too loose [risks patient safety]

Q4: 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? Word limit: 500 words

You may wish to consider some or all of the following in your response:

- Gaps and other limitations of the existing regulatory framework

- Innovative and effective approaches to AI regulation used in other sectors, and other jurisdictions

- Ensuring public and patient safety whilst minimising the cost of complying with regulations (in terms of time and resource)

- The boundaries of regulation, including the ways AI can qualify as a 'medical device', and how such devices are classified according to risk.

Q5: How should the regulatory framework manage post-market surveillance for AI health technologies? Word limit: 500 words

You may wish to consider some or all of the following in your response:

- The challenges posed by novel and emerging types of AI, including foundation models and highly capable agentic AI

- AI systems which are capable of continuous learning and/or updating

- AI systems that are used for other purposes beyond the original intended use

- AI systems which are developed by a single institution for in-house use only

- Information sharing between healthcare provider organisations and manufacturers for the purposes of post-market surveillance

Q6: Which statement best reflects your view on the current legal framework for establishing liability in healthcare AI tools?

a) Sufficient: existing laws (eg. Medical negligence, product liability, etc) can adequately handle AI-related disputes

b) Gaps exist: existing laws work for most cases, but leave uncertainty in some scenarios
c) Insufficient: existing laws are unfit for AI
d) I am unsure

Q7: 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? Word limit: 500 words

You may wish to consider some or all of the following in your response:

- The specific duties for each party, and any duties which are shared

Q8: In the event of an adverse patient outcome where an adverse patient outcome involved an AI tool, where do you think liability should lie? Word limit: 500 words

You may wish to first consider the following scenarios:

- When the AI tool gives the correct answer, but is incorrectly overridden by the healthcare professional

- When the AI tool gives the incorrect answer and the healthcare professional follows it (i.e. they incorrectly choose to trust the AI)

Q9: Do you have any other evidence to contribute? You can submit written evidence in the comment box. Note: please confirm that you have the necessary permissions prior to sharing any documents in this way.

Question 10: You can upload documents to be considered as part of this call for evidence. Note: please confirm that you have the necessary permissions prior to sharing any documents in this way.

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