techUK response to MHRA's Call for Evidence on AI Regulation

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

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: To what extent do you agree or disagree that the current regulatory framework is sufficient in the following domains (multiple-choice question, rating system)

a. Safety & performance standards – **neither agree nor disagree**
b. Data privacy & data governance – **disagree**
c. Transparency – **strongly disagree**
d. Requirements for clinical evidence – **strongly disagree**
e. Post-market surveillance – **disagree**

Q3: How would you rate the current framework's impact on innovation? (multiple-choice question)

a. Too restrictive; it stifles innovation.
b. **Somewhat restrictive; it creates some barriers.**
c. About right; it balances safety and innovation.
d. Somewhat loose; it lacks necessary controls.
e. Too loose; it 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?

techUK members believe faster NHS access to safe and effective AI requires significant reform, centred on proportionate regulation, reusability of assurance, and clearer coordination across the regulatory and NHS landscape.

Industry leaders consistently reported that existing assurance and approval processes are misaligned with the pace of AI development, particularly for iterative updates and low-risk applications. Additionally, current approaches place disproportionate emphasis on large, upfront evidence packages and lengthy conformity assessments, which are better suited to static technologies and risk delaying the deployment of beneficial AI. This challenge is compounded by ongoing uncertainty and inconsistency in the classification of what constitutes a medical device, creating avoidable delay, cost, and risk aversion.

techUK members emphasised that an effective framework should rebalance regulatory scrutiny across the product lifecycle. Pre-market requirements should remain focused on baseline safety, performance, privacy, security, and governance, with evidentiary expectations proportionate to the intended use and risk profile. At the same time, the framework should place greater weight on post-market surveillance, real-world performance monitoring, and iterative evaluation to reflect the dynamic nature of AI systems. This approach would allow the NHS to adopt proven tools more quickly while maintaining robust safeguards over time.

Members cautioned that overly burdensome regulatory routes for low-risk AI tools may have unintended consequences, including the increased use of "Shadow AI" general-purpose or consumer AI systems in pressured clinical environments without appropriate safeguards. A more proportionate and agile regulatory cadence would reduce these risks by providing credible, compliant pathways for adoption.

At the same time, even where regulatory requirements are met, suppliers face substantial post-regulatory friction due to duplicative NHS procurement and assurance processes across trusts and ICBs. This duplication is often driven by liability concerns and the absence of mechanisms that allow local organisations to rely on central endorsement.

To address these challenges, techUK members recommended a more proportionate, risk-based framework, including a dual-lane approach for lower- and higher-risk use cases, clearer classification guidance, and faster pathways for low-risk updates within intended use.

Industry leaders also highlighted the importance of reusability of approvals and of assessed components. Industry highlighted the potential value of a single assessment or "innovator passport" model to enable wider NHS access once core requirements are met, similar to the ongoing DHSC's plans around the ***MedTech Compass***. Crucially, members stressed that any streamlined framework will depend on MHRA having sufficient capability and clarity to provide consistent, timely, AI-informed guidance, alongside clearer navigation of how MHRA requirements interact with wider regulatory and assurance regimes. Additionally, members welcomed the direction of travel represented by initiatives such as the AI Airlock but noted that its impact would be strengthened if participation provided a clearer pathway towards compliance on exit. Enabling outputs from sandbox environments to meaningfully reduce subsequent regulatory and assurance duplication would accelerate deployment and incentivise early, proactive engagement.

Q5: How should the regulatory framework manage Post-Market Surveillance for AI health technologies?

techUK members argued that Post-Market Surveillance (PMS) for AI health technologies must be designed to reflect the dynamic and adaptive nature of AI systems, rather than being treated as a direct extension of traditional, static medical device monitoring.

Industry leaders caution MHRA stakeholders to consider how AI performance may evolve over time due to model drift, data shifts, or changes in deployment context. PMS frameworks must therefore explicitly account for evolving system behaviour if they are to remain effective over the full lifecycle of an AI product.

A central theme from industry discussion was the need for proportionate, risk-based monitoring, aligned to the clinical impact and intended use. Higher-risk applications should be subject to more robust and continuous oversight, while lower-risk tools should not face disproportionate monitoring obligations that deter adoption without improving patient safety. Members also noted that AI systems may be used in practice in ways that differ from their original intended use, reinforcing the importance of ongoing surveillance rather than one-off assurance.

Stakeholders further emphasised that PMS should move beyond predominantly manual or reactive reporting models. Greater use of software-enabled, continuous monitoring of performance, adverse events, and emerging risks would support earlier detection and more timely intervention. This includes meaningful evaluation of model drift and algorithmic bias as substantive safety activities, rather than procedural formalities.

Industry stakeholders also stressed the importance of clear escalation and intervention mechanisms within Post-Market Surveillance frameworks. This includes defining thresholds that trigger review or action, and ensuring appropriate human oversight is available when safety concerns arise. techUK members cautioned that without clearer guidance on Post-Market Surveillance expectations, there is a risk of inconsistent implementation, either leaving safety gaps or imposing unnecessary burdens on manufacturers and NHS organisations. A proportionate, clearly articulated Post-Market Surveillance framework is therefore critical to supporting both patient safety and timely, sustainable adoption of AI health technologies.

Q6: Which statement best reflects your view on the current legal framework for establishing liability in healthcare AI tools? (multiple-choice question)

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?

techUK members highlighted that safe and responsible use of AI health technologies depends on clear and shared responsibility across the full lifecycle of AI systems, rather than focusing primarily on development and pre-market validation. Given the potential for model drift and for AI tools to be used differently in real-world settings than originally intended, industry leaders stressed that responsibility must extend into deployment, ongoing monitoring, and change management.

In practice, this requires role-specific duties that connect end-to-end. Manufacturers should adopt a safety-first approach throughout design and development, including proportionate post-market surveillance to monitor real-world performance and identify emerging risks early. Where “human in the loop” oversight is required, products should be designed so the user interface enforces meaningful review (for example, by requiring an explicit clinical sign-off step before an AI output can be acted on). Manufacturers should also maintain established system safety and IT safeguards (including

cybersecurity, patching and update controls) and keep clear documentation of how the AI is intended to be used and how it should be monitored.

Industry leaders cautioned that in the absence of clarity around responsibility and liability, local healthcare organisations may respond by creating additional assurance and governance steps, particularly when AI tools are deployed across multiple trusts or care pathways. This fragmentation can slow adoption and undermine consistency. Members therefore emphasised the value of a more centralised assessment framework that enables local actors to rely on shared assurance, reducing unnecessary duplication while maintaining safety.

Some techUK members also described the current liability landscape as fragmented and unclear in practice, contributing to hesitancy among both suppliers and deployers. It is unclear how existing liability mechanisms apply to generative AI tools. Traditional insurance routes may be difficult to access or assess due to limited precedent and the pace of technological change. techUK members recommended the development of consolidated, practical guidance that maps liability considerations across the lifecycle and clarifies what sits within MHRA's remit versus wider legal reform. In parallel, industry suggested exploring insurance and risk-transfer approaches as part of a broader effort to build confidence and enable responsible adoption of AI in healthcare.

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?

Allocating liability for adverse outcomes involving AI tools is inherently complex, because safe AI adoption spans development, deployment and professional oversight, often across multiple organisations within a single care pathway. Industry stakeholders emphasised that any future approach to liability should therefore recognise shared and differentiated responsibilities across the AI lifecycle. This includes responsibility for the design and validation of AI tools, decisions about their deployment and suitability for specific clinical contexts, and the way tools are monitored and overseen in real-world use. Where multiple organisations and professionals are involved, liability frameworks should reflect this complexity rather than assuming a single point of failure.

Manufacturers should remain responsible for safety and performance within the claimed intended purpose, including design controls, validation, change management and PMS. PMS expectations should mirror a risk-based approach: for systems with relatively stable architecture, manufacturers could periodically repeat the validation tests used at approval to confirm outputs have not drifted; for systems more prone to

unpredictability (including continuously adapting or generative approaches), manufacturers should monitor real-world performance signals (for example false positives, false negatives and emerging failure modes) with clear escalation thresholds.

Deploying organisations and commissioners should be responsible for contextual suitability, local configuration and ensuring governance is in place, including role-appropriate training, clear incident reporting routes and local monitoring arrangements.

Given current uncertainty, clearer system-level guidance is needed so responsibility does not fall disproportionately on individual clinicians or practices. Standardised contractual and clinical protection arrangements, covering monitoring responsibilities, update obligations, reporting routes and remediation, would support clearer allocation of responsibilities across manufacturers, commissioners and providers and enable safer adoption.