MHRA expands AI Airlock programme with a £3.6 million funding boost over three years

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The MHRA continues to be at the forefront of innovation and secures multi-year funding to expand its pioneering AI Airlock programme.

The Medicines and Healthcare products Regulatory Agency (MHRA) has secured a major funding uplift to expand its pioneering AI Airlock programme, the UK's first regulatory sandbox for Artificial Intelligence as a Medical Device (AIaMD).

Following a successful second phase, the Department of Health and Social Care (DHSC) has allocated £1.2 million per year for the next three years (2026–2029) to the programme.

The newly approved multi-year funding will enable the AI Airlock programme to scale beyond the constraints of yearly financial cycles. This will support more ambitious, longer-term testing models while helping to create a more sustainable regulatory pathway for future AI medical technologies.

AI Airlock is led by the MHRA in partnership with DHSC, NHS AI Team, and Team AB (the consortium of UK Approved Bodies).

The programme is a key enabler of wider AI regulatory reform and aligns with Government priorities across the AI Opportunities Action Plan, the Regulatory Action Plan, and long-term strategic programmes including the 10-Year Health Plan and the Life Sciences Sector Plan.

James Pound, Executive Director, Innovation and Compliance, said:

> Securing this multi-year funding boost marks a pivotal moment for AI Airlock and for the safe and responsible advancement of AI in healthcare.
>
> The programme has already shown how collaborative, real-world testing can uncover regulatory challenges early and help innovators bring high-quality, safe technologies to patients faster.
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> This additional investment will allow us to scale up and ultimately strengthen our ability to ensure that AI-powered medical devices can reach patients safely, efficiently and with the confidence of robust regulatory oversight.

Dr Dom Pimenta, CEO and Co-founder, TORTUS AI, said:

> The AI Airlock programme represents a unique and critical opportunity to bring together stakeholders around high-priority areas in clinical AI, helping to chart a clear and actionable path forward. At TORTUS, we've found the cross-educational aspect of the programme particularly valuable—both in deepening our understanding of regulatory objectives and in sharing industry expertise at a time when AI is advancing at an unprecedented pace.

> The extension of this initiative is fantastic news, as it has the potential to set a global benchmark for safe, effective, and rapid deployment of clinical AI solutions.

AI Airlock has continued to grow since the launch and early pilot phase in 2024, with a second round of projects opening in 2025. The pilot highlighted several areas where AI medical devices raise new regulatory challenges. It showed that risk management must consider issues specific to AI, such as reducing errors and inaccuracies by using techniques that ground model responses in verified clinical information. It also found that improving how AI systems explain their recommendations is crucial for supporting clinician confidence. The pilot underlined the need for ongoing monitoring once products reach the market, to identify changes in performance or over-reliance by users.

Phase two of the programme builds on this work and includes specific regulatory challenges for AI-powered diagnostic tools, pre-determined change control plans (PCCPs), and how AI devices may expand in scope or intended use. The phase has explored a diverse range of technologies, including large language models, voice tools, and specialised diagnostics for cancer and rare diseases. So far, AI Airlock has produced a series of reports and case studies to support learning across the sector.

Reporting for phase two is expected to be published in Summer 2026. Together with the pilot findings they will inform the design of phase three and continue to shape the MHRA's broader approach to AI regulation.

Insights from the AI Airlock are contributing to the National AI Commission's work on the future regulation of AI in healthcare

The AI Airlock strengthens the healthcare system by helping industry and regulators to work together on real-world challenges. This supports safe innovation and a more coordinated approach to regulating AI medical devices.

AI Airlock remains central to the MHRA's wider programme of work to develop a robust, futureproof regulatory framework for medical devices. The MHRA remains committed to prioritising patient safety, enabling responsible AI innovation, and ensuring the UK remains an attractive market for medical technology innovators.

Notes to editors:

- The programme was launched in Spring 2024 and is the MHRA's first regulatory sandbox for AI as a Medical Device (AIaMD) products.

- Further details regarding the AI Airlock phase three design and call for applications will be made available later in the year.

- The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

- The MHRA is an executive agency of the Department of Health and Social Care.

- For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

https://www.gov.uk/government/news/mhra-expands-ai-airlock-programme-with-a-36-million-funding-boost-over-three-years