Blog post

Building on the Spirit of Exploration – Phase 2 of the MHRA's AI Airlock

AI Airlock is the MHRA's first regulatory sandbox for AI as a Medical Device (AIaMD), providing a safe space for regulators and innovators to test, learn and adapt approaches to AI regulation in healthcare. The pilot offered valuable insights into responsible AI regulation and highlighted where frameworks must evolve. With AI Airlock Phase 2, we are building on that learning - scaling up, deepening our exploration and broadening the conversation.

From Discovery to Design

Building on the discoveries from the pilot, Phase 2 while exploring deeper, aims to collaboratively design potential regulatory solutions.

Our AI Airlock Kick-off Connect event in October, brought together the Phase 2 Cohort and expert stakeholders, offering early insights into each technology and sparking important discussions.

Key Questions and Early Insights

The discussions helped us identify and refine the key regulatory questions across three core challenge areas:

1. **AI-Powered In-Vitro Diagnostics (IVDs)**
   We're exploring how to define robust, standardised performance metrics for AI-driven diagnostic tools by testing how performance parameters can be measured and aligned with international standards to ensure that the AI technologies remain both adaptable and trustworthy.
2. **Scope of Intended Use and Validation**
   We're examining what constitutes a "significant change" for evolving AI products looking at how new functionalities, adaptive learning, and data updates may affect classification, risk, and revalidation to inform clearer guidance for managing boundary changes responsibly.
3. **Post-Market Surveillance (PMS) and Predetermined Change Control Plans (PCCPs)**
   We're exploring how AI devices can be safely monitored over time, focusing on challenges such as data scarcity, multi-site deployment, and automation bias, and how strong post-market surveillance frameworks can support continuous real-world improvement.

Looking Ahead

With each of the manufacturer we've been intensively co-developing a refined test plan, outlining key questions, testing methodologies and evidence-collection strategies.

Next is **Sandbox testing,** to explore regulatory questions, performance and safety of AI technologies across one or more controlled environments without impacting patients.

Simulation environment offers a structured, discussion-based workshop session where experts work through realistic case studies to generate insights that inform future regulatory guidance.

A **virtual test environment** allows candidates to evaluate their AI medical device using retrospective de-identified patient data, synthetic or simulated data to safely assess and monitor system performance and regulatory compliance without impacting clinical care.

A **real-world test environment** follows the same process as the virtual environment and uses similar types of data but applies testing in clinical settings under controlled oversight to assess practical performance and risks without impacting the clinical care.

In spring 2026, the programme aims to produce a range of evidence-based outputs that will inform National Commission into the Regulation of AI in Healthcare, as well as other cross-government and international initiatives to harmonise standards.

The Airlock reflects its namesake: a place to pause, test, and adapt before advancing. Phase 2 builds on that mission, creating a safe and transparent space for shared learning and shaping the future of AI regulation in healthcare.