Medicines & Healthcare products Regulatory Agency

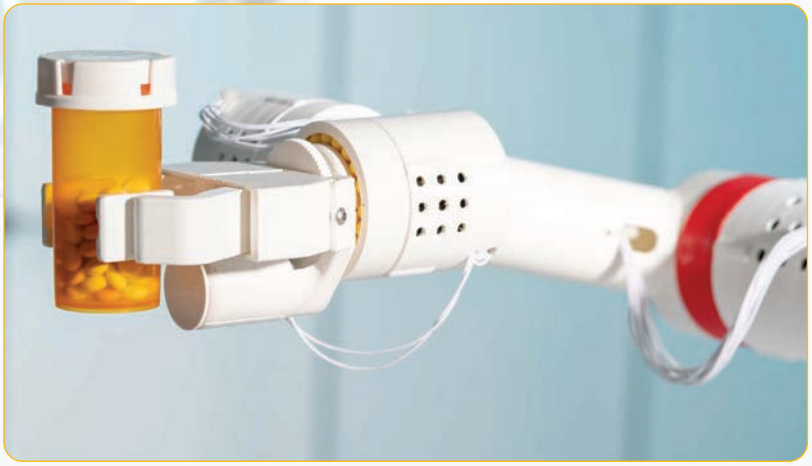
The Medicines and Healthcare products Regulatory Agency (MHRA) has announced it is taking forward its new 'regulatory sandbox', the AI-Airlock, which will provide a regulator-monitored virtual area for developers to generate robust evidence for their advanced technologies.

Artificial intelligence in healthcare represents the exciting potential to improve patient outcomes in many ways, for example through improving diagnoses and treatment selections, optimising medication dosages, and providing enhanced personalised care for patients.

Technologies like these can sometimes be challenging to test using traditional trial techniques and would therefore benefit from the AI-Airlock project's collaborative approach to identifying and managing evidence requirements.

This means patients could benefit from faster access to developing technologies, such as improved diagnostics or precision medicine, in light of this recent announcement.

This world-leading partnership between government, regulators and industry will see advanced AI technology used in NHS settings, with strict safety controls, ahead of navigating regulatory approval. Where successful, the AI-Airlock will help NHS patients to benefit earlier from emerging technologies before they are available anywhere else in the world.



This will support innovators to work within the current regulatory system, identify where their products need to build more evidence needed for a safety and efficacy assessment, and help resolve issues.

It follows a robust process, so manufacturers of software and AI medical devices understand and deliver what is required to ensure the real-world viability of these devices. The process, following the 'regulatory sandbox' model, is a world-leading mechanism to assist in the safe development and deployment of software and AI medical devices.

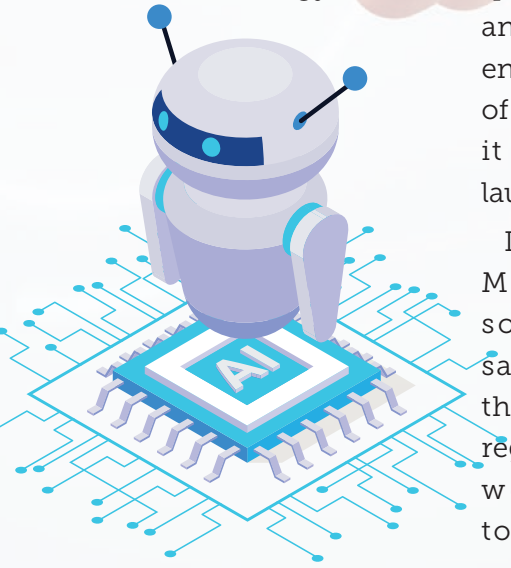
This learning can then be shared, helping to provide an evidence base that promotes a wider understanding of the challenges and potential solutions that are available.

This initiative demonstrates the MHRA's commitment to building on its existing capabilities and investing its regulatory expertise to enable highly innovative areas of medical product development, bringing cutting-

edge products to UK patients faster, without compromising on its robust standards of safety and performance.

The AI-Airlock is designed to be a collaborative space, bringing together expertise from innovators, regulatory organisations including approved bodies, government, the NHS and academia.

The announcement of government funding from the Department of Science, Innovation and Technology and the Department of Health and Social Care will enable development of the service so that it will be ready to launch in April 2024.



Dr Paul Campbell, MHRA head of software and AI, said: "Building on the success of the regulatory sandbox, we are excited to deliver a new, world-leading methodology to support safe early access to AI for patients and healthcare.

"We need to ensure that AI is safe and properly regulated, but in a way that doesn't stifle innovation and access to the latest of medical technologies to improve patient care.

"The deployment of AI and machine learning enabled med-tech devices is challenging, given the level of complexity of these products.

"However, by moving beyond conventional product concepts and associated regulations, sandboxes like the AI-Airlock offer a unique and safe learning space for manufacturers to work with regulators and other parties to explore new, cutting-edge solutions to help resolve these challenges.

"The new AI-Airlock scheme run by the MHRA will give us answers about how best to provide safe and effective products, such as AI-driven medical devices, to the NHS and patients."

Dominic Cushnan, NHS England AI, imaging & deployment director, said: "The NHS is already a leader in the testing of new AI technologies, and I am proud that we are now funding and collaborating on this new initiative with the MHRA to help move the dial even further, to bring the latest state-of-the-art AI and its benefits to the NHS and patients faster."

About the MHRA:

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. Its 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.

Source:
MHRA media release