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# Key events since Washington DC



**UK General Election**

**Engagement with new Government**

*Updated Medical Device Framework 2024/25 milestones*

April | May | June | July | Aug | Sep

*Pilots with 18 volunteer devices for International Reliance*

AI Airlock launch

Policy intention for International Reliance published

Common Specifications consultation launched

IMDRF Clinical Evaluation Working Group of IVDs launch

# Innovative Devices Access Pathway (IDAP)

## For developers of new and innovative products

**IDAP Pathway**
To enable and improve patient access to innovative and transformative medical devices by providing an integrated and enhanced regulatory and access support and advice package to developers.

**IDAP Pilot**
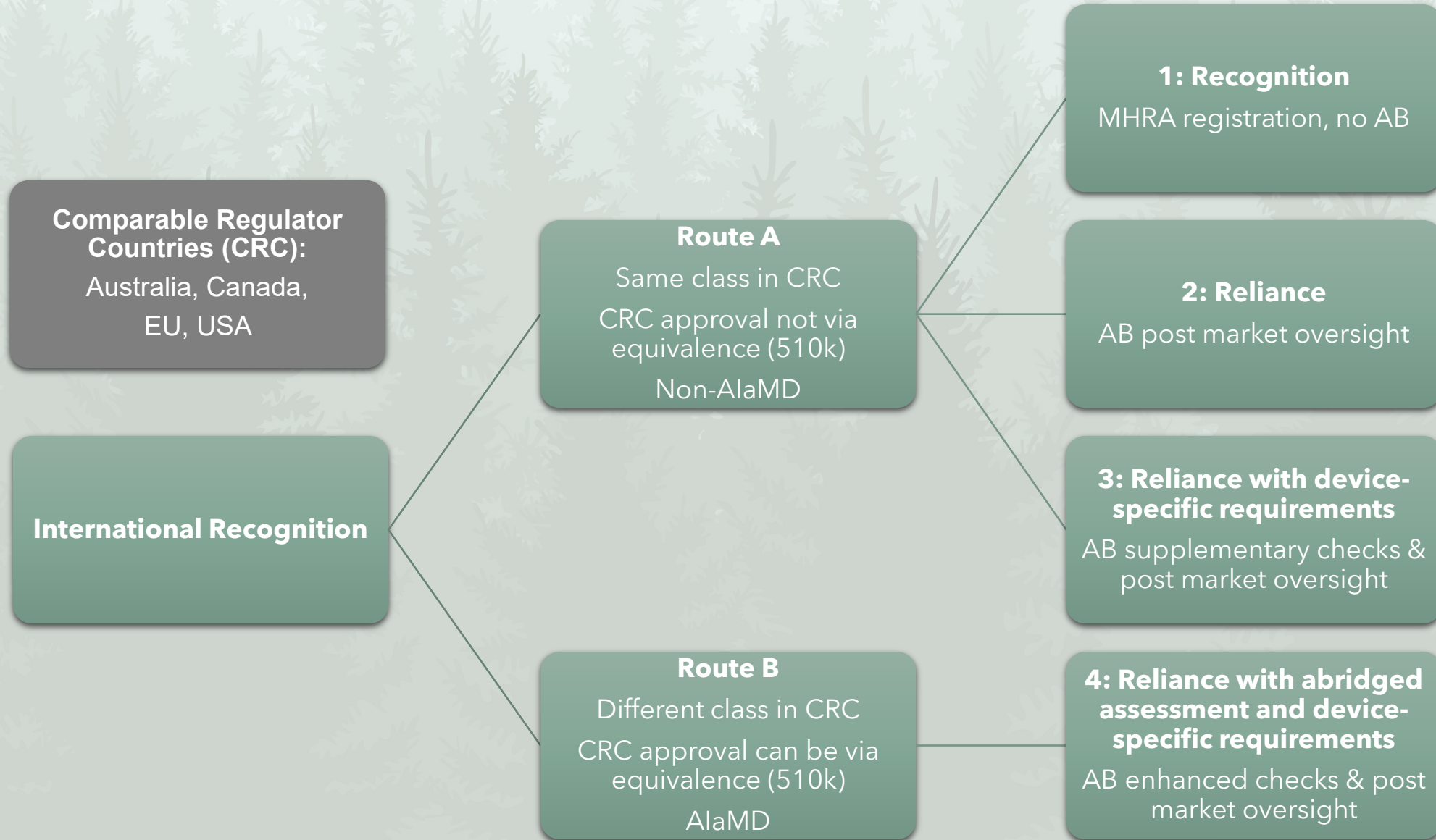To test, develop and refine the tools, processes and systems for a full IDAP pathway.

*IDAP Pilot*

# Innovative Devices Access Pathway (IDAP)

| Pilot Products | Technology-type |
|---|---|
| Liver cancer treatment using focused ultrasound | Medical Device |
| Pulse oximeter which accurately measures blood oxygen irrespective of skin pigmentation | Medical Device |
| Blood-based biomarker test for Alzheimer's Disease | IVD (blood test, lab-based assay) |
| Algorithm-based infection predictor | IVD (blood test, rapid) |
| Portable diagnostic device for stroke identification | IVD (point-of-care) |
| Self-test diagnostic device for neutropenia | IVD & SaMD (self-test) |
| Multiple Sclerosis fatigue app | SaMD (app) |
| Artificial intelligence  to predict at risk COPD patients | SaMD/AI |

# International reliance routes

**Comparable Regulator Countries (CRC):**
Australia, Canada, EU, USA

**International Recognition**

**Route A**
Same class in CRC
CRC approval not via equivalence (510k)
Non-AIaMD

**Route B**
Different class in CRC
CRC approval can be via equivalence (510k)
AIaMD

**1: Recognition**
MHRA registration, no AB

**2: Reliance**
AB post market oversight

**3: Reliance with device-specific requirements**
AB supplementary checks & post market oversight

**4: Reliance with abridged assessment and device-specific requirements**
AB enhanced checks & post market oversight

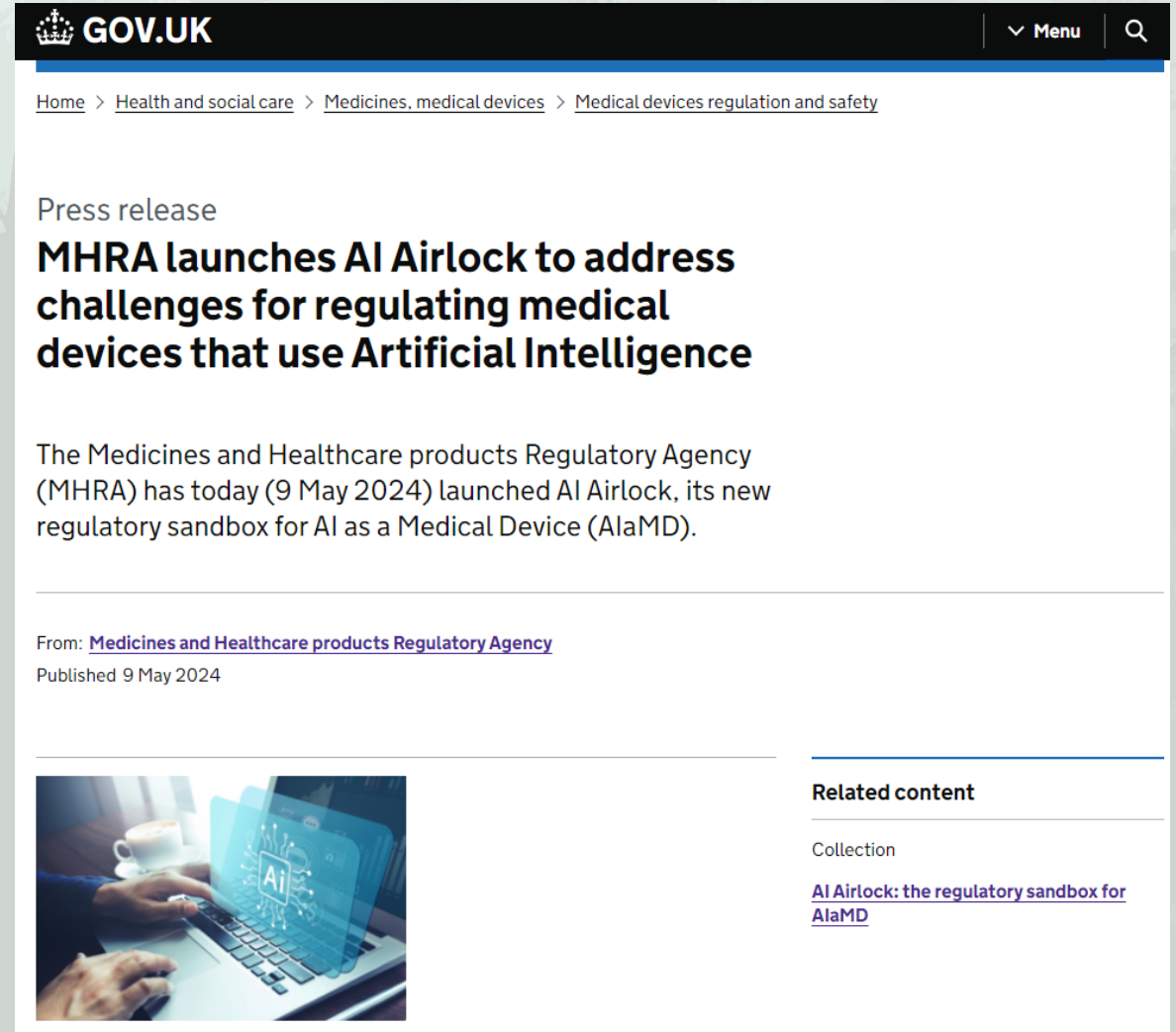*The policy intent is published on the MHRA webpage.*

# Artificial Intelligence (AI) airlock

**AI Airlock Regulatory Sandbox:**
a **safe space** to gain further understanding of **targeted challenges** and **regulatory consequences** on the current medical device regulatory pathway, using **real world products and prototypes** of innovative AI medical devices

*AI Airlock Regulatory Sandbox*



GOV.UK

Home > Health and social care > Medicines, medical devices > Medical devices regulation and safety

Press release

## MHRA launches AI Airlock to address challenges for regulating medical devices that use Artificial Intelligence

The Medicines and Healthcare products Regulatory Agency (MHRA) has today (9 May 2024) launched AI Airlock, its new regulatory sandbox for AI as a Medical Device (AIaMD).

From: Medicines and Healthcare products Regulatory Agency

Published 9 May 2024

Related content

Collection

AI Airlock: the regulatory sandbox for AIaMD

# Artificial Intelligence (AI) airlock



**Application and Review** → **Testing Design** → **Test Implementation** → **Exit and Review** → **Documentation and publication**

# What's coming next?

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