



Medicines & Healthcare products  
Regulatory Agency

# MHRA and Artificial Intelligence

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**24<sup>th</sup> January 2025**



# MHRA – Who we are

**We are the Medicines and Healthcare products Regulatory Agency (MHRA).**

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We improve and protect the health of millions of people every day by making sure healthcare products in the UK **meet the highest standards** and are safe to use.

We are the UK regulator of medicines, medical devices and blood components for transfusion. We are responsible for making sure these products meet set standards for safety, quality and efficacy.



# AI in Healthcare

- AI for improving MHRA processes
- AI as a Medical Device (AIaMD)
- AI to meet MHRA regulatory requirements

# AI for improving MHRA processes

Approach and Use Cases

# Strategic Themes

The MHRA Digital and Technology Group have updated our 12-month technology roadmap with emphasis on three strategic themes:

- **Innovation**
- **Technology Remediation**
- **Cybersecurity**

We also have a refreshed plan for information governance and data protection policies as well as for new ways of working.

All of which are fundamental to the successful deployment of AI

# Approach to AI through Innovation

We have set up an Innovation team to accelerate the prototyping of AI use cases to better understand the technology and to 'test and learn'

As a first step we introduced Microsoft Copilot to a cohort of users across the Agency as this is a packaged solution that allowed early visibility of an AI solution using a Large Language Model

We have since identified 17 use cases for prototyping with different technologies and different AI paradigms

We are also developing our internal AI guiding principles and governance structures to be able to safely deploy AI tools into the Agency



# Spectrum of capabilities

The use cases range from **productivity** improvements and **decision support** through to **decision making** across all areas of the business including, communications, customer service and Helpdesk, as well as across the regulatory activities for the whole product lifecycle



We selected a number of use cases to progress to prototypes which are now being further developed into live services that will be used within the business

# Use Case: GMP compliance validation tool

**Problem:** The current process for certifying Good Manufacturing Practices (GMPs) is time-consuming, where assessors must manually locate information in documents within the submission and then cross-reference this across multiple sources to validate the details in the submission

**Solution:** Decision Support Tool

We are streamlining the verification process, using AI tools to automatically process documents to identify key information that is then used to cross-check and retrieve data from a range of sources.

This is presented to the assessor along with a confidence rating of the match across the submitted and retrieved information.

The assessor then makes the decision



# Use case: Protecting consumers from fraudulent medical products

**Problem:** There is a proliferation of websites selling counterfeit medicines and devices or illegally selling drugs without prescriptions. The Criminal Enforcement Unit manually identify web-sites through e.g. Internet searching which are then analysed. This is time consuming and often leads to negative results i.e. the web site is not unsafe.

**Solution:** Decision Support Tool

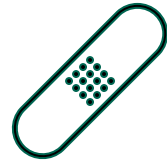
We are streamlining the process of identifying candidate websites for investigation. We are using web scraping technology and Natural Language Processing to analyse websites across a range of factors that are 'scored' and an overall risk rating then calculated for each website to indicate the potential level of risk. This allows the high priority web sites to be allocated for investigation

# Regulation of AlaMD

# What does the MHRA do for AI and digital health?



**Patient  
Safety  
Regulator**



**Medical Products**  
(Medicines,  
Devices and Blood  
Products)



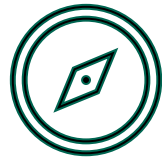
**Including  
Software and AI  
products**



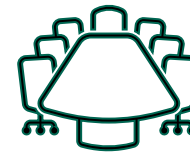
**Across the whole  
product lifecycle**  
(Design, Use, Updating  
and Decommissioning)



**Write and  
enforce  
legislation**



**Create  
regulatory  
guidance &  
alignment**



**Contribute to projects,  
investigations and  
standards development**



**Run projects to inform  
policy and improve  
regulations**

# In-flight work for *AlaMD*

Domestic framework updates

# AI in Healthcare



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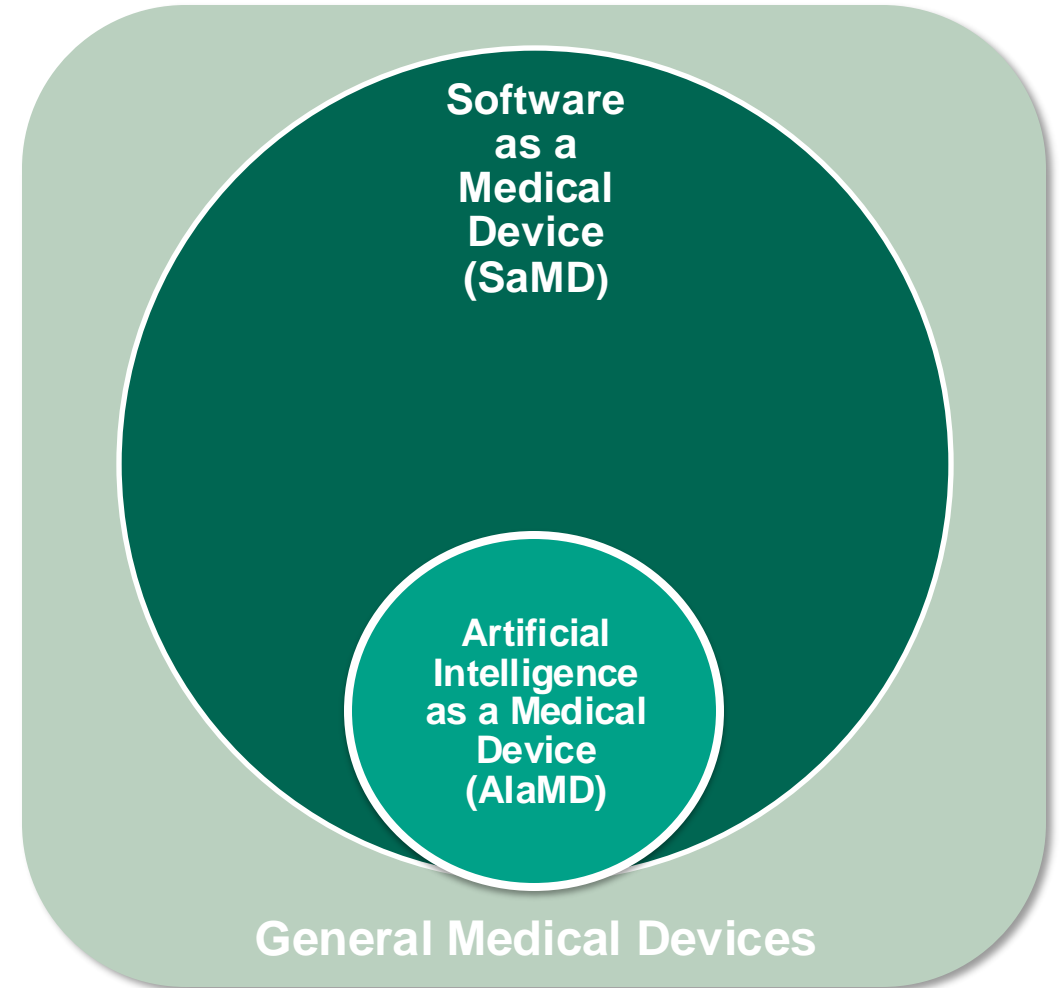
## Impact of AI on the regulation of medical products

Implementing the AI White Paper principles

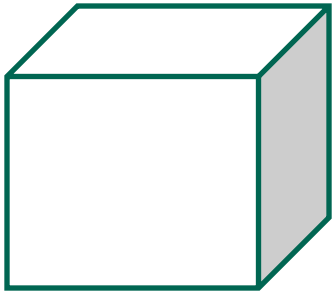
Published April 2024

**MHRA as a regulator of Artificial  
Intelligence products intended for a  
medical purpose.**

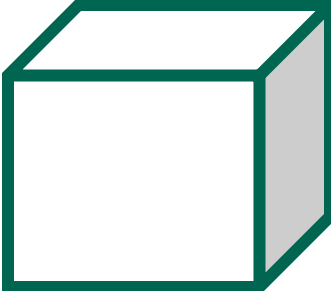
AI Medical Devices = Software Medical Devices = General  
Medical Devices (UK MDR 2002)



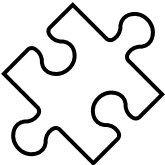
# Medical Device Regulatory Reform



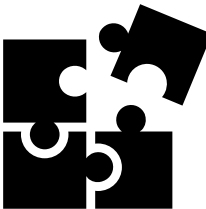
**Updated Legal Framework**



**New Guidance**



**Link to Standards**

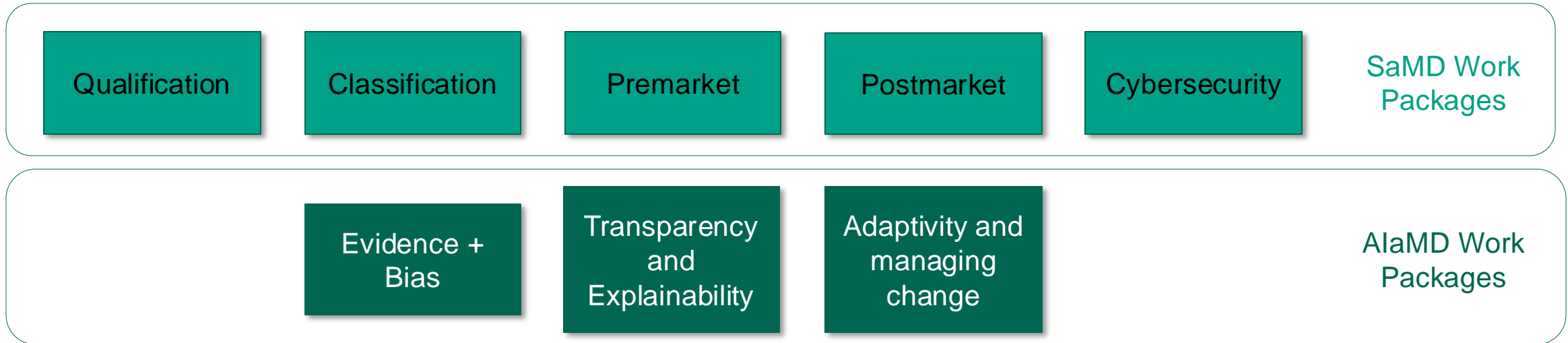




# Legal Framework

- MedTech Regulatory Reform (MTRR) project is updating the UK Medical Device Regulations 2002 to improve patient safety and provide clear pathways for innovation.
- Recently updated requirements for postmarket surveillance in the UK
- Future regulations cover a range of updates, specifically for software and AI:
  - Definition of software
  - Alignment of risk classification with international position
  - Addition of cybersecurity requirements into law (previously mostly in guidance)
  - Adding in the legal foothold for Pre-Determined Change Control Plans for adaptive software and AI products.

# Software and AI Change Programme - Guidance



A programme of regulatory and best practice guidance building on legal changes is being implemented.

Guidance  
**Crafting an intended purpose in the context of Software as a Medical Device (SaMD)**

Guidance on defining intended purpose for Software as a Medical Device (SaMD), to help SaMD manufacturers in meeting their statutory obligations.

From: [Medicines and Healthcare products Regulatory Agency](#)  
Published 22 March 2023

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**Documents**

[HTML](#) [Crafting an intended purpose in the context of software as a medical device \(SaMD\)](#)  
HTML

Guidance  
**Reporting adverse incidents involving software as a medical device under the vigilance system**

Information for manufacturers of software as a medical device, detailing events that may cause indirect harm and are therefore reportable.

From: [Medicines and Healthcare products Regulatory Agency](#)  
Published 15 May 2023  
Last updated 15 January 2025 — [See all updates](#)

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**Documents**

[HTML](#) [Guidance for manufacturers on reporting adverse incidents involving software as a medical device under the vigilance system](#)  
HTML

Guidance  
**Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles**

Guiding principles for the use of Predetermined Change Control Plans (PCCPs) for managing rapid product changes.

From: [Medicines and Healthcare products Regulatory Agency](#)  
Published 24 October 2023

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**Documents**

[HTML](#) [Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles](#)  
HTML

Guidance  
**Machine learning medical devices: transparency principles**

Guidelines for communicating clear and relevant information about machine learning-enabled medical devices.

From: [Medicines and Healthcare products Regulatory Agency](#)  
Published 13 June 2024

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**Documents**

[HTML](#) [Transparency for machine learning-enabled medical devices: guiding principles](#)  
HTML

[Medicines & Healthcare products Regulatory Agency](#)

Guidance  
**Good Machine Learning Practice for Medical Device Development: Guiding Principles**

Published 27 October 2021

# Standards

- Rapid growth area for AI
- Recognition of standards
- Move toward designation and presumptive conformity.



# In-flight work for *AlaMD*

International Collaboration and Alignment

# International Medical Device Regulators Forum (IMDRF)

The screenshot shows the IMDRF website's 'Working groups' page. The header includes the IMDRF logo and a search bar. The main content area lists several working groups, each with a representative image and a brief description. The 'Artificial Intelligence/Machine Learning-enabled' group is highlighted with a red circle. Below the grid is a link to 'View closed working groups'.

**Working groups**

- Adverse Event Terminology**  
Harmonize terminology for reporting adverse events related to medical devices, and further harmonize adverse event reporting datasets to improve signal detection.
- Artificial Intelligence/Machine Learning-enabled**  
Seeking to harmonize internationally, principles to help promote the development of safe and effective AI/ML enabled medical devices
- Good Regulatory Review Practices**  
Develop good review practices for pre-market reviews and evaluations.
- Personalized Medical Devices (PMD)**  
Harmonize the regulatory requirements for medical devices that are intended for a particular individual, considering unique characteristics and risks associated with each type of device.
- Quality Management Systems**  
Ensure alignment of IMDRF QMS and risk management documents with current international standards
- Regulated Product Submission**  
Harmonize the format and content of regulatory submissions.
- Software as a Medical Device**  
Promote consistency in regulatory assessment for Software as a Medical Device to reach patients more efficiently.

[View closed working groups >](#)

The screenshot shows the 'Member sites' and 'Regional harmonization initiatives' sections of the IMDRF website. The 'Member sites' section lists various countries and regions with dropdown arrows. The 'Regional harmonization initiatives' section lists several international organizations.

**Member sites**

- Australia
- Brazil
- Canada
- China
- European Union
- Japan
- Russia
- Singapore
- South Korea
- United Kingdom
- United States of America

**Regional harmonization initiatives**

- [APEC LSIF Regulatory Harmonization Steering Committee](#)
- [Global Harmonization Working Party \(GHWP\)](#)
- [Pan American Health Organization \(PAHO\)](#)
- [African Medical Devices Forum \(AMDF\)](#)

**Official observers**

- [Argentina National Administration of Drugs, Food and Medical Devices](#)
- [World Health Organization \(WHO\)](#)
- [Swissmedic](#)

**Global initiative to produce regulatory guidance promoting alignment between jurisdictions**

**IMDRF and predecessor (GHTF) have been promoting alignment since 1992**

# International Medical Device Regulators Forum (IMDRF)

- Core Working Groups for AI Regulation:
  - Software as a Medical Device (Chaired by Canada and US FDA)
  - Artificial Intelligence/Machine Learning Enabled Medical Device (Chaired by UK and US FDA)
- Proposed software and AI guidance work:
  - **Software Risk Classification**
  - Software Clinical Evaluation
  - Key Definitions
  - Quality Management Systems
  - **Good Machine Learning Practice (GMLP) Principles**
  - **AI Lifecycle Management**
  - **Pre-determined Change Control Plans**



# In-flight work for AlaMD

Projects for supporting innovation and education

# AI Airlock – A proactive approach

- Launched the 12-month pilot in Spring 2024
- Testing has started on 4 challenges areas:
  - Monitoring of AI
  - Management of hallucinations
  - Explainability vs clinical utility
  - Validation of LLMs and Synthetic Data
- Initial findings expected mid-February

## AI Airlock: the regulatory sandbox for AIaMD

A proactive, collaborative, agile and the first of its kind approach to identifying and addressing the challenges faced by AI as a Medical Device (AIaMD).

From: [Medicines and Healthcare products Regulatory Agency](#)

Published 9 May 2024

Last updated 23 September 2024 — [See all updates](#)



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**NHS**  
England



Artificial Intelligence and  
Digital Regulations Service

# AI and Digital Regulations Service for health and social care

[www.digitalregulations.innovation.nhs.uk](http://www.digitalregulations.innovation.nhs.uk)

A collaboration between:

**NICE**  
National Institute  
for Health and  
Care Excellence

  
Medicines &  
Healthcare products  
Regulatory Agency

  
Care Quality  
Commission

  
Health Research  
Authority



# Regulatory Science Innovation Networks

- Launching soon!
- Will be linking up for collaboration on a range of new and in-flight activities
- Watch this space



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