Medicines & Healthcare products Regulatory Agency

MHRA and Artificial Intelligence

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MHRA – Who we are

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

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 though 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.

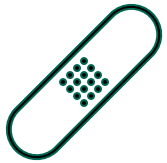
Solution: Decision Support Tool

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 AIaMD

What does the MHRA do for AI and digital health?

Patient Safety Regulator

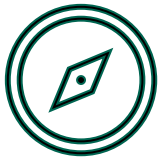


Medical Products (Medicines, Devices and Blood Products)

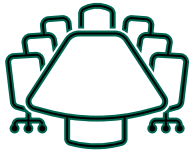
Including Software and AI products

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 AIaMD

Domestic framework updates

AI in Healthcare

Medicines & Healthcare products Regulatory Agency

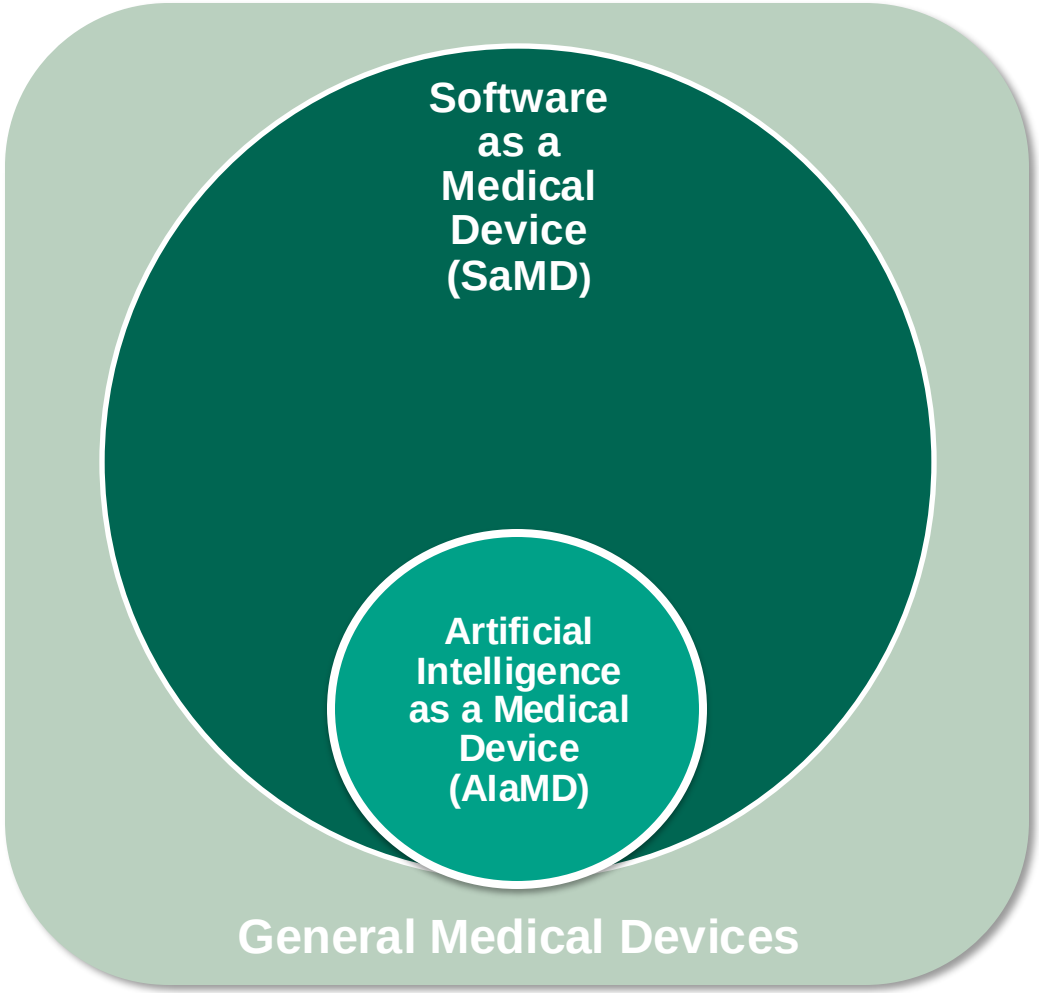
Impact of AI on the regulation of medical products

Implementing the AI White Paper principles

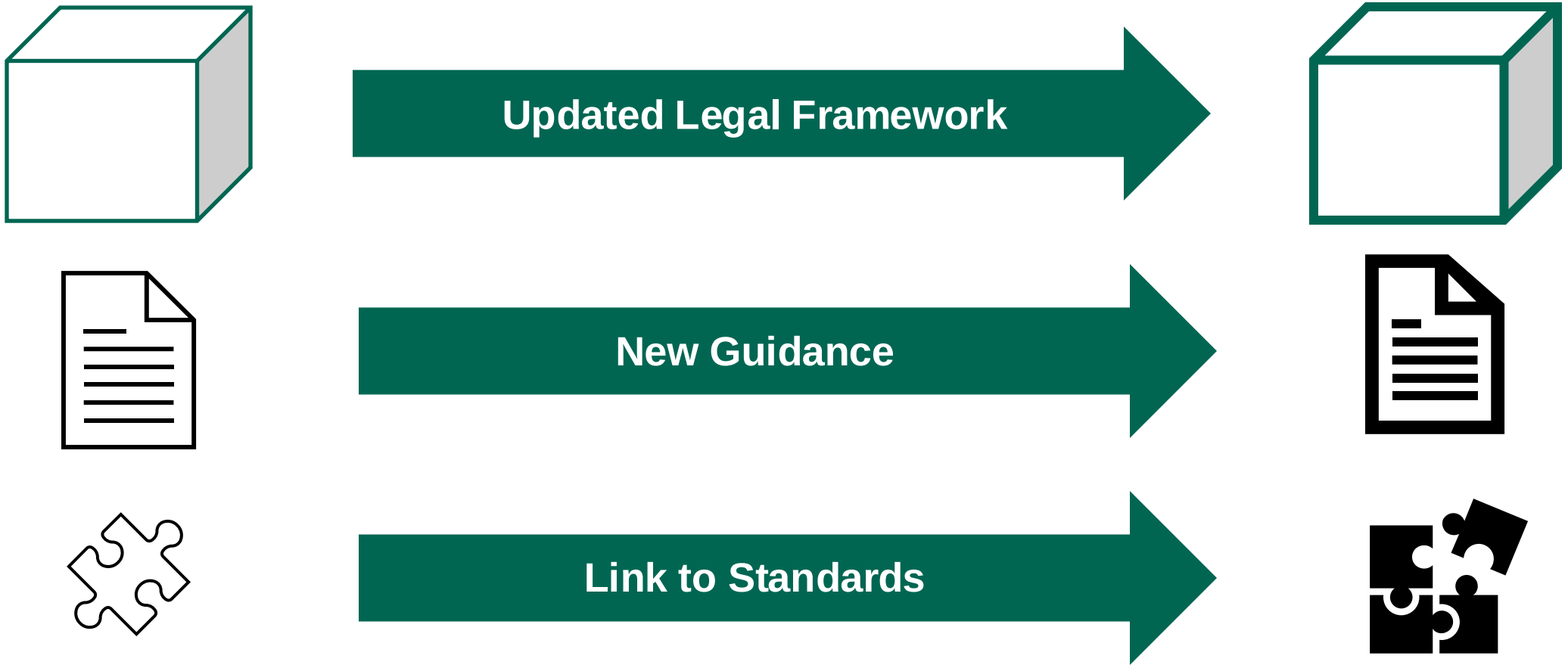
Published April 2024

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



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

Qualification | Classification | Premarket | Postmarket | Cybersecurity — SaMD Work Packages

Evidence + Bias | Transparency and Explainability | Adaptivity and managing change — AIaMD Work Packages

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
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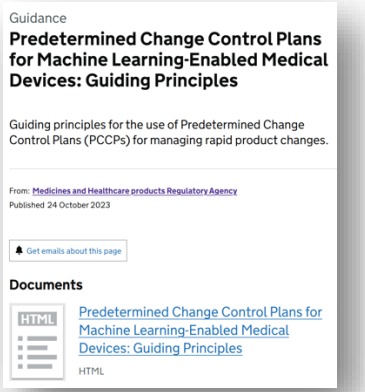
Guidance

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
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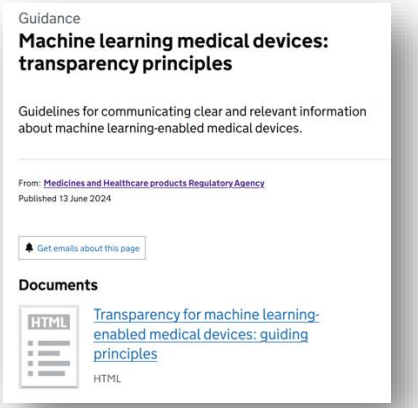
Guidance

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
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Medicines & Healthcare products Regulatory Agency

Guidance

Good Machine Learning Practice for Medical Device Development: Guiding Principles

Published 27 October 2021

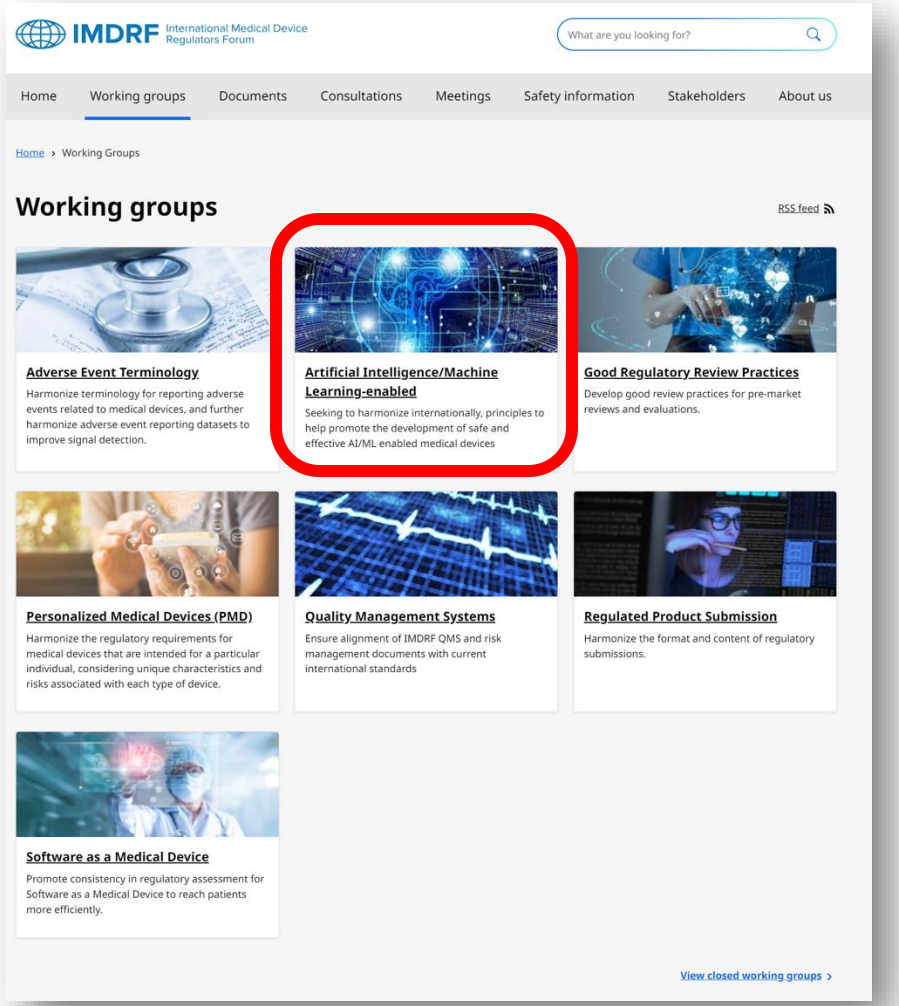
Standards

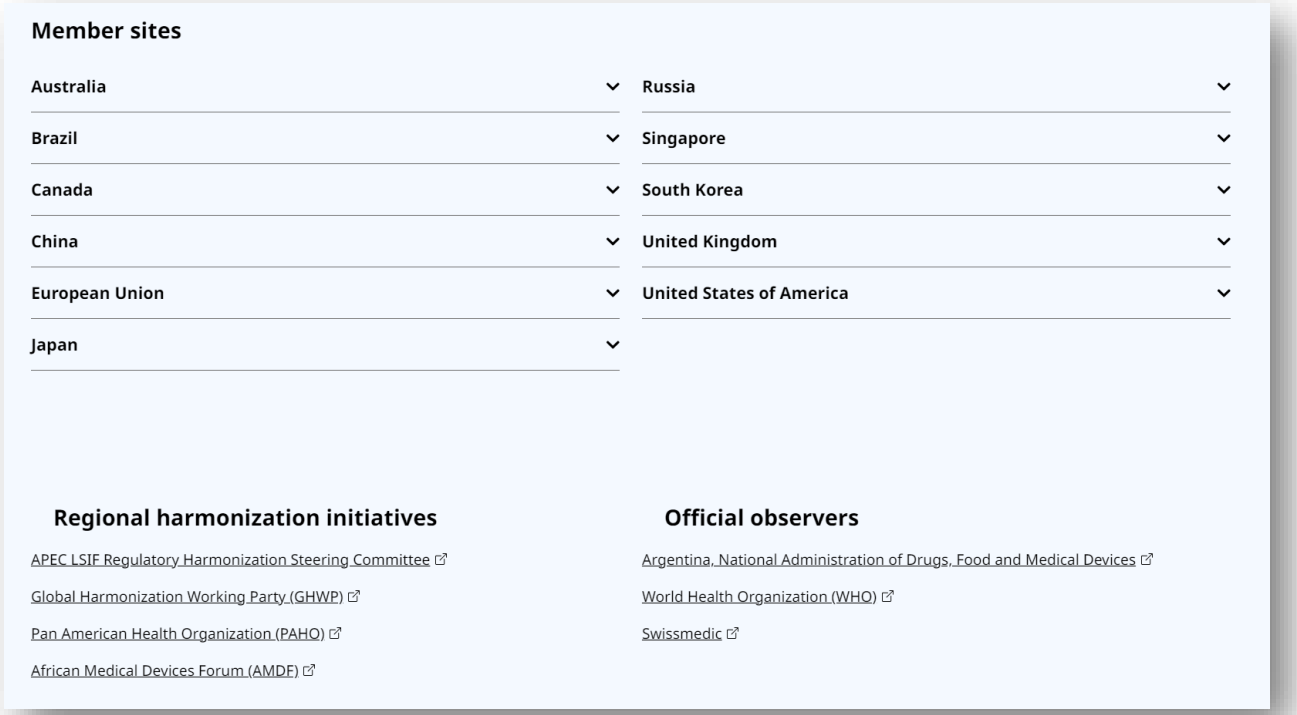
- Rapid growth area for AI
- Recognition of standards
- Move toward designation and presumptive conformity.

In-flight work for AIaMD

International Collaboration and Alignment

International Medical Device Regulators Forum (IMDRF)





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 AIaMD

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

Medicines & Healthcare products Regulatory Agency

TEAM AB

NHS England

NHS
Artificial Intelligence and Digital Regulations Service

AI and Digital Regulations Service for health and social care

www.digitalregulations.innovation.nhs.uk

A collaboration between:

NICE National Institute for Health and Care Excellence

Medicines & Healthcare products Regulatory Agency

CareQuality Commission

NHS 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