# Regulatory Update for MHRA – United Kingdom

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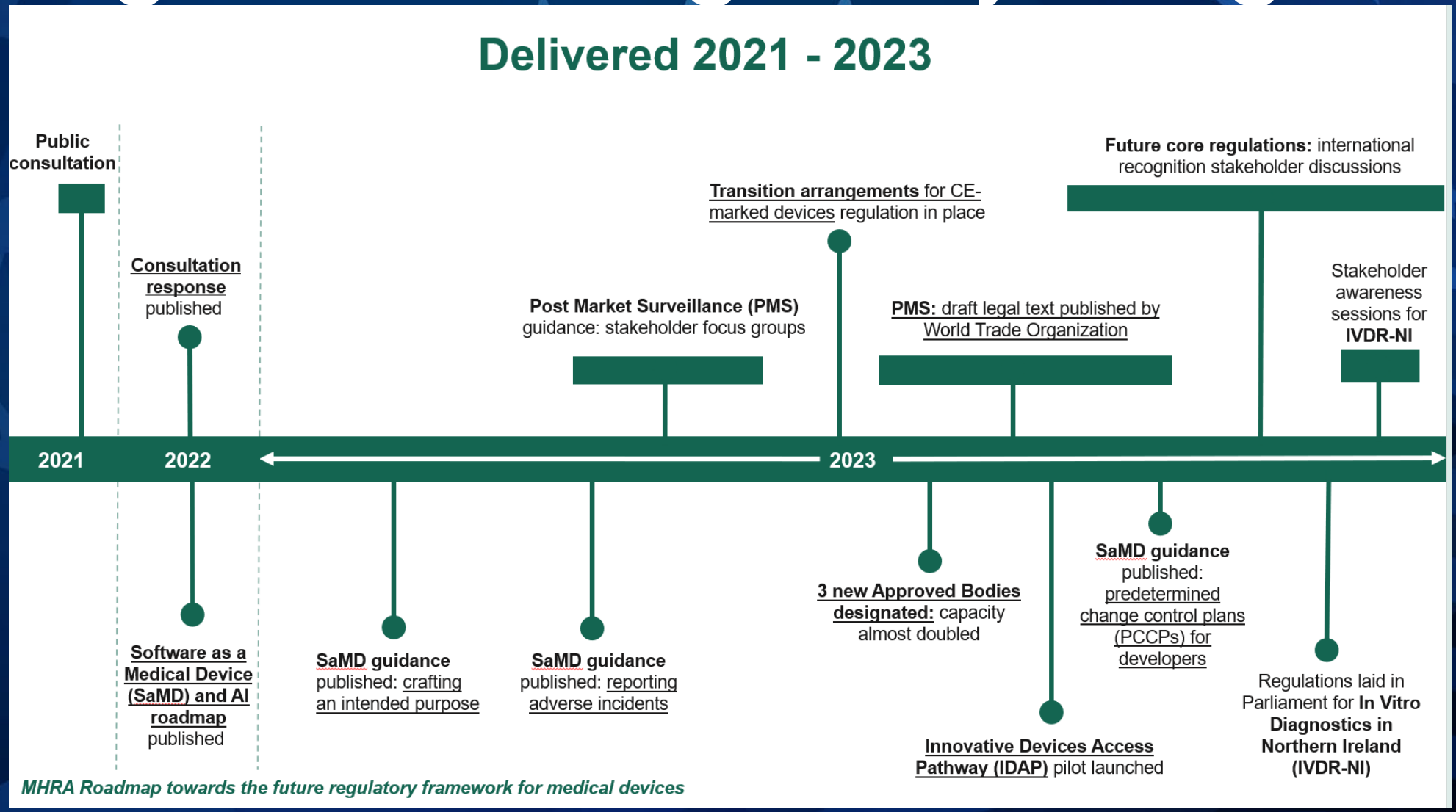
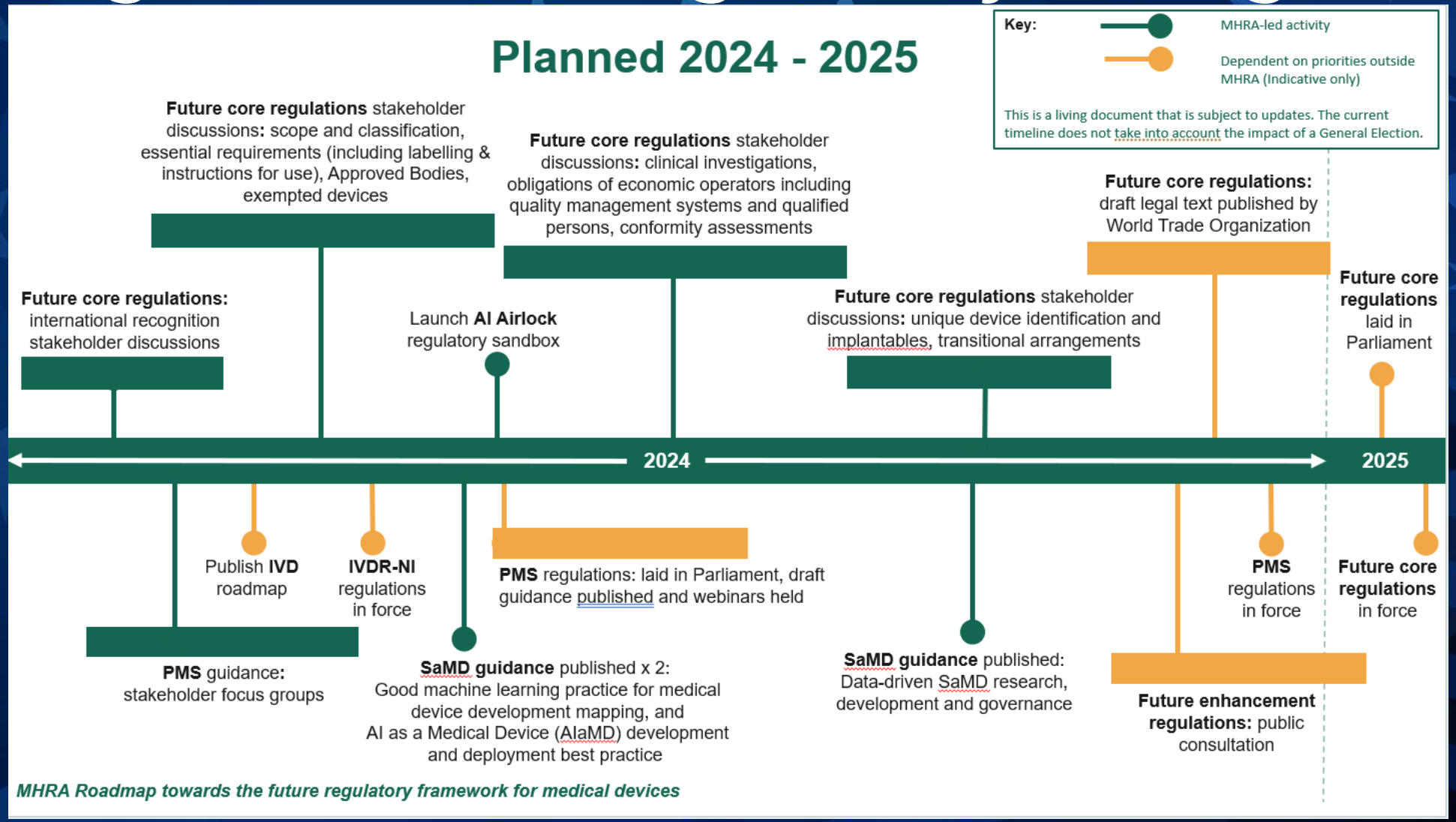
IMDRF International Medical Device Regulators Forum

# Progress on UK regulatory changes



# Progress on UK regulatory changes



# Support for Innovators - AI Airlock

- In October 2023, the MHRA announced the government funding by DHSC for the launch of a new regulatory sandbox for AI developers, launching in April 2024.
- The AI Airlock facilitates the development and deployment of AI medical devices (AIaMD), to provide patients earlier access to cutting-edge innovations whilst prioritizing safety in care improvements.
- AI Airlock, is a multi-partner regulatory sandbox pilot that aids stakeholders (from innovators and developers to healthcare providers and regulators) to better understand and manage the challenges of regulating and implementing AIaMDs.
- This pioneering partnership among government, regulators, and industry will introduce advanced AI technology in healthcare with stringent safety controls, allowing patients to benefit sooner from emerging technologies ahead of global availability.

# Support for Innovators - Innovative Devices Access Pathway

A partnership which aims to bring medical technologies to market that address unmet clinical needs in the NHS


- The program will create a roadmap to support innovators in generating the evidence required for regulatory approval and health technology assessment and facilitate patient access in the NHS.
- Pilot scheme funded by DHSC has selected 8 devices to test and refine a series of support tools.
- Aligns with the UK's MedTech Strategy and the ambitions outlined in the Life Sciences Vision.

# Support for Innovators - Innovative Devices Access Pathway – 8 devices in pilot

| Disease area | Technology |
|---|---|
| Alzheimer's | IVD (blood test, lab-based assay) |
| Sepsis/Infection/ AMR | IVD (blood test, rapid) |
| Primary and secondary liver cancer | Medical Device |
| Hypoxaemia | Medical Device |
| Fatigue due to Multiple Sclerosis | SaMD (app) |
| Stroke | IVD (point-of-care) |
| Neutropenic sepsis in chemotherapy patients/AMR | IVD & SaMD (self-test) |
| COPD | SaMD/AI |

# Support for Innovators – UK Regulatory Science and Innovation Networks (RSINs)

- The development of proposals for virtual networks of expertise in regulatory science that generate research-based evidence and insights.
- The science of developing new tools and approaches that enhance regulatory decision making across product lifecycles (such as approvals, ongoing safety and performance monitoring), and support policymaking that enables agile and proportionate regulation in response to innovation.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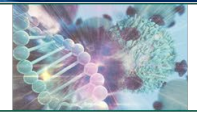
# RSINs: Collaborators and themes for Human Health

- **1st phase, Discovery Phase, about to be launched (March 2024 – August 2024)**

£50K will be awarded to each and up to 40 collaborations for building virtual relationships, gather data and information, perform regulatory research for upcoming innovation in their area of expertise

| | | | |
|---|---|---|---|
| Artificial Intelligence (AI) and Software as a Medical Device |  |  | Biotherapeutics, Cell and Gene Therapies |
| Data Science |  |  | Diagnostics and Genomics |
| Genomics and Synthetic Human Biology |  |  | International Recognition |
| In Vitro Diagnostic (IVD) Regulation |  |  | Medical Technologies |
| Neurotechnology |  |  | Vaccines and Immunotherapies |

**Lead Organisation**

- UK registered
- Business of any size
- Academic Institution
- Independent research and technology organisation (RTO) or Catapult centre eligible for UKRI funding
- Charity
- Not for profit

**Collaborators**

- UK registered
- Business of any size
- Academic Institution
- public sector research establishment (PSRE) eligible for UKRI funding
- Independent RTO or Catapult centre eligible for UKRI funding
- Charity
- Not for profit
- Regulator
- Other public sector organisation

- **2nd phase, Implementation Phase, (September 2024 – December 2025)**

Identified partners from the Discovery Phase will be invited to apply for a bigger pot of money that will allow to establish their RSINs

# AI/ML – enabled Working Group

**Laura Squire, Medicines and Healthcare Products Regulatory Agency**

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# AI Working Group:

- **Current work item: Good Machine Learning Practice (GMLP)**
  - GMLP provides fundamental principles to promote the development of safe, effective, and high-quality AI-enabled medical devices
  - AIWG is drafting Guiding Principles for GMLP based on earlier trilateral GMLP document, including updates reflecting recent advancements in AI
  - Two focus areas being addressed by subgroups are:
    (1) Addressing needs of Generative AI/ Large Language Models (LLMs); and
    (2) Ensuring alignment with and referencing of other IMDRF documents
  - Target for public consultation of the GMLP document is Summer-Fall 2024
- **Future work:**
  - Deeper dive into GMLP for Pre-determined Change Control Plans
  - AI Lifecycle Management proposed as NWIP to MC

# Adverse Event Terminology – Maintenance Working Group

**Laura Squire, Medicines and Healthcare Products Regulatory Agency**

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# Adverse Event Terminology – Maintenance Working Group

- **Finalizing maintenance for 2023-24**
  - Working with webmaster to prepare final documents for publication
  - Reviewing and updating maintenance SOP in partnership with IMDRF webmaster and MedDRA Maintenance & Support Services Organization
  - Looking forward to the second round of maintenance as chair
    - Deadline for submission of change requests is 1st September 2024


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