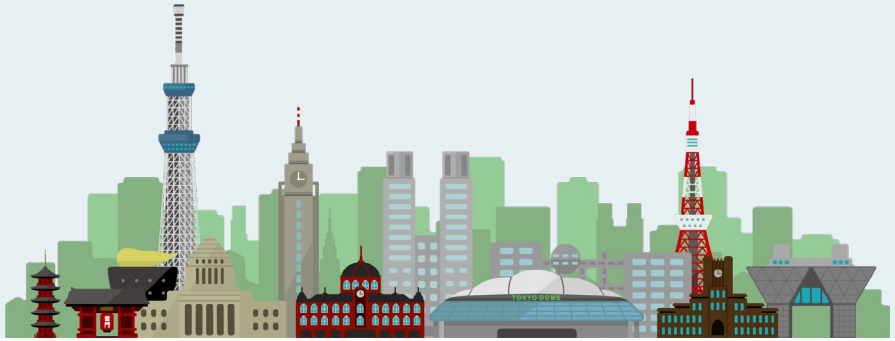
IMDRF International Medical Device Regulators Forum



United Kingdom Country Update

Clare Thompson, PhD
Medical Devices Regulatory Specialist







Medicines & Healthcare products Regulatory Agency

Overview

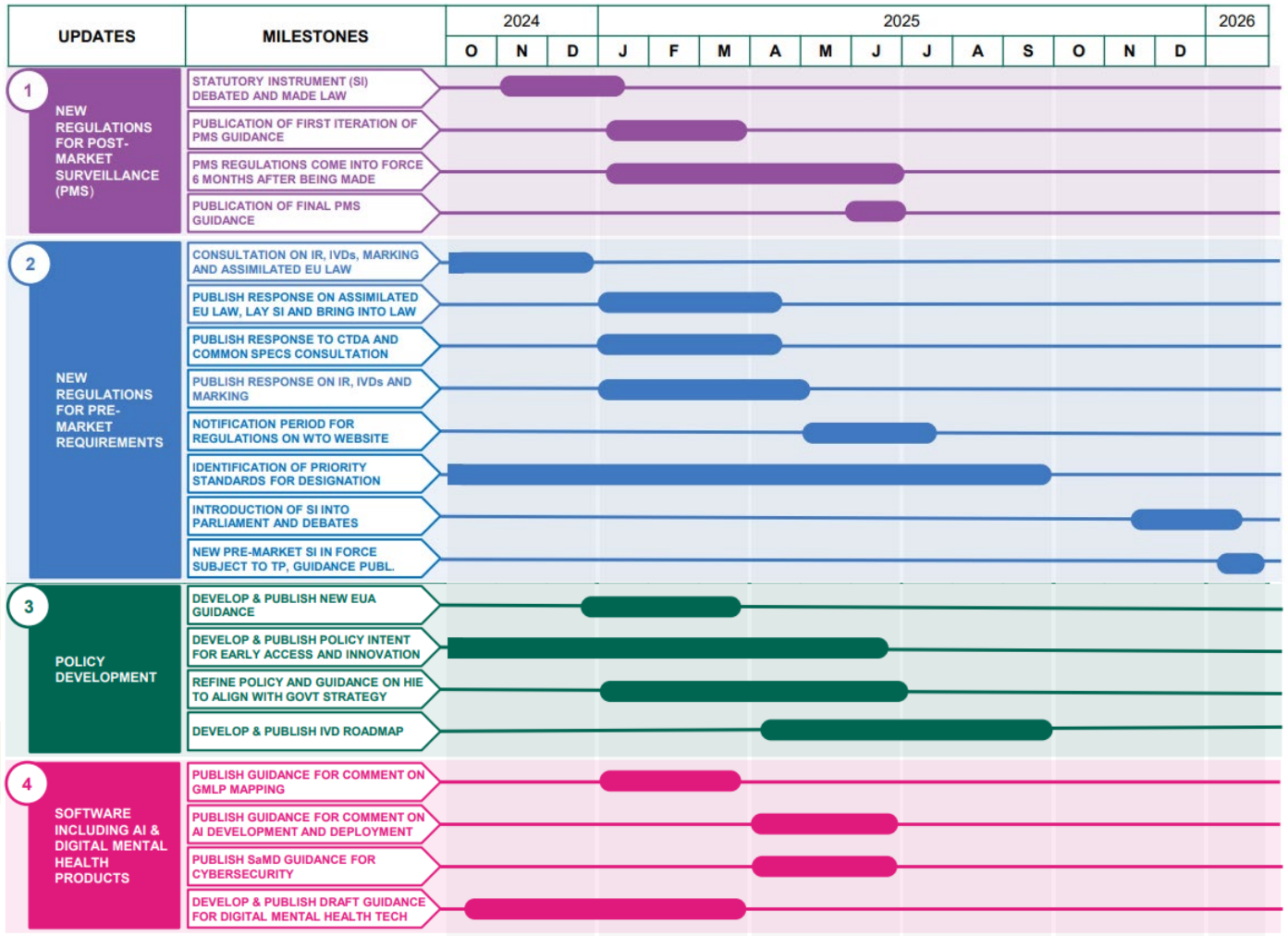
The UK is a hub for MedTech innovation…

- Medical Devices Regulatory Reform Roadmap
- Post-Market Surveillance legislation
- Pre-market Regulations legislation
- Pathway to the patient

A clear direction for the future

- Protect and improve public health
- Risk-proportionate regulation of medical products
- Use of scientific expertise to support innovation
- Predictable and timely outcomes

Medical Devices Regulatory Reform Roadmap

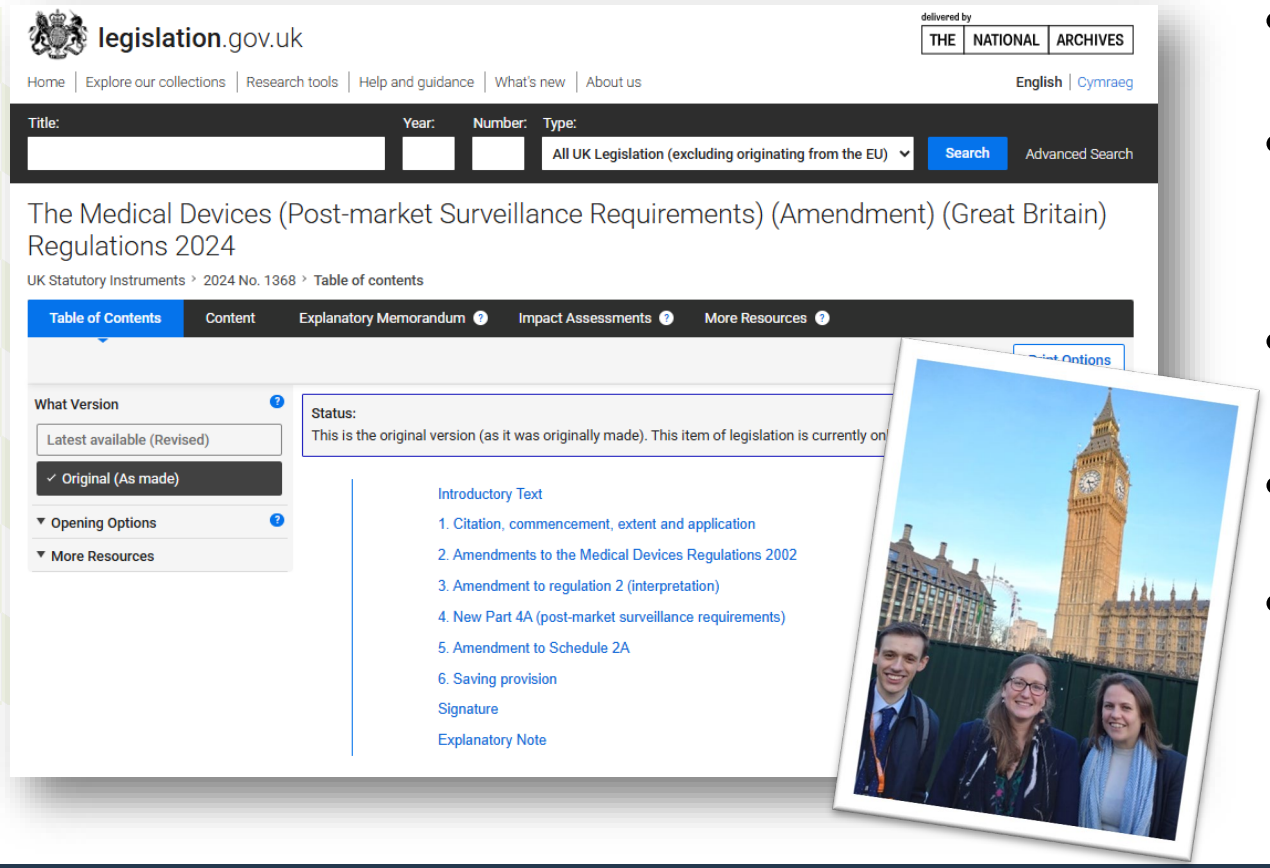


- Upcoming legislation
- Develop policy for early access and innovation
- Publish IVD roadmap

Regulatory Roadmap (Dec 2024)

New Post-market surveillance legislation for Great Britain

Coming into force from 16 Jun 2025



- 3.2m medical device registrations
- Risk proportionate requirements for devices in use in Great Britain
- Safeguarding patient health
- Harmonisation across industry
- Support plans for new routes to market and improved access to devices

Guidance to support implementation

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

Collection

Medical devices: post-market surveillance

Information for manufacturers of medical devices on post-market surveillance, reporting adverse incidents and field safety corrective actions to the MHRA.

From: Medicines and Healthcare products Regulatory Agency

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Post-Market Surveillance Guidance (Jan 2025)

- Detailed requirements
- Improved patient and public engagement
- Expanded scope for incident reporting
- Shortened timelines for reports
- Comprehensive trend reporting
- Pragmatic approach to custom-made devices

Upcoming changes to Pre-market regulations

Risk based classification for medical device and IVDs

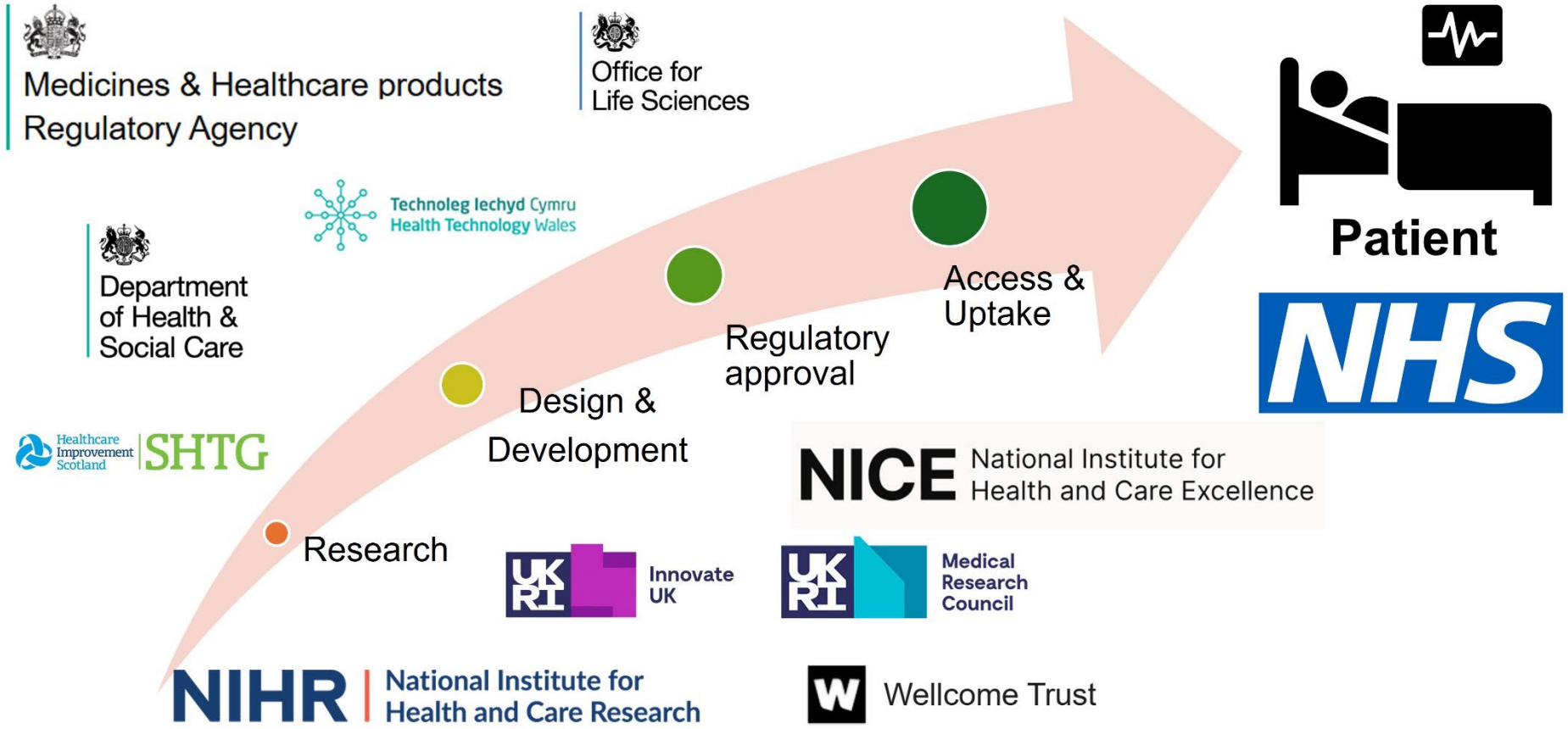
Enhanced requirements for implantables supporting safe innovation

Harmonisation to international requirements for safety and performance

Improved traceability through mandated use of UDI

New routes to market including international reliance pathways

A connected network of expertise supporting innovative MedTech



The UK: The place for medical device innovators

- Facilitating scientific research and innovation
- Risk proportionate regulations that promote patient safety
- Enabling patient access
- Strong support from an interconnected healthcare network
- Open for adoption of new technologies

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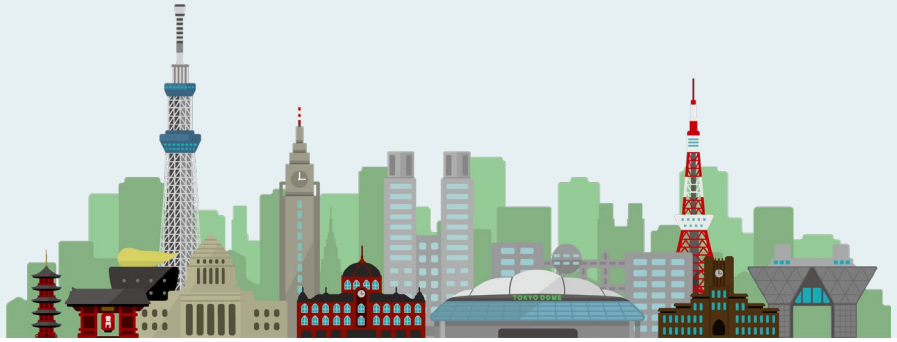

Thank you

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