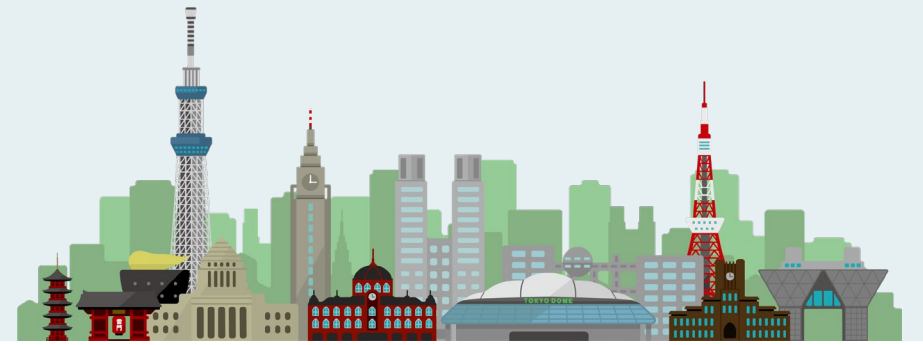




IMDRF International Medical Device
Regulators Forum



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...

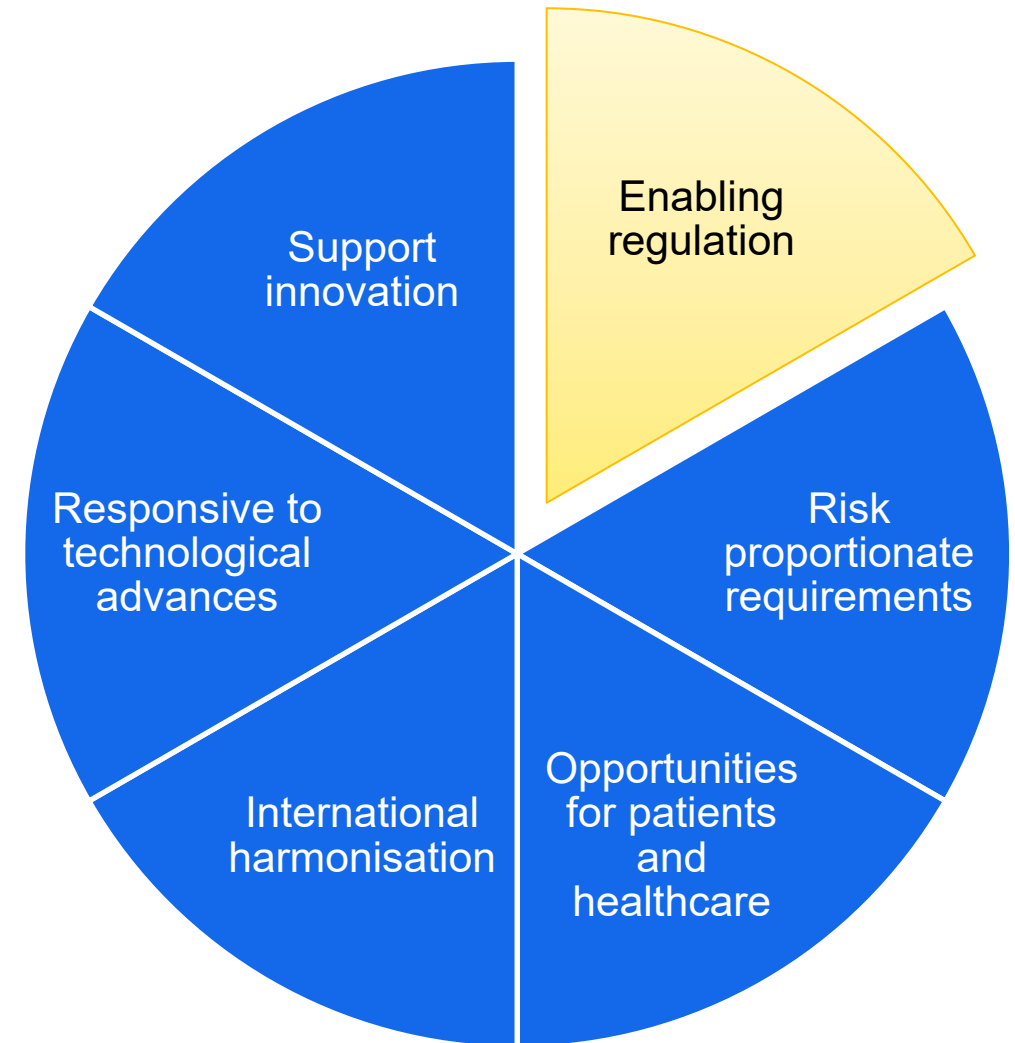
- Medical Devices Regulatory Reform Roadmap
- Post-Market Surveillance legislation
- Pre-market Regulations legislation
- Pathway to the patient





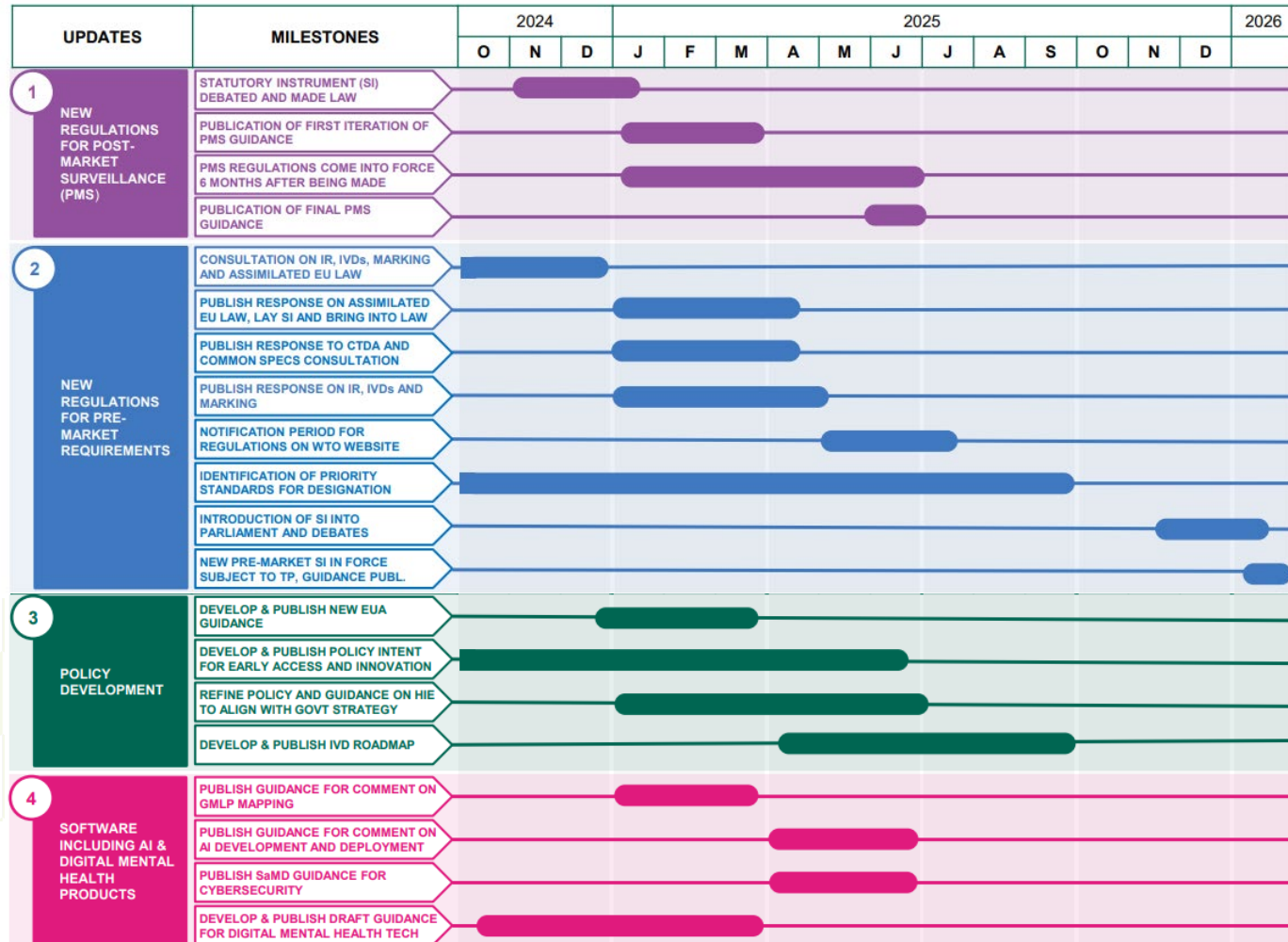
A clear direction for the future

- 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

legislation.gov.uk

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English | Cymraeg

Title: Year: Number: Type: All UK Legislation (excluding originating from the EU) Search Advanced Search

The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024

UK Statutory Instruments > 2024 No. 1368 > Table of contents

Table of Contents Content Explanatory Memorandum Impact Assessments More Resources

What Version

Latest available (Revised)

Original (As made)

Opening Options

More Resources

Status: This is the original version (as it was originally made). This item of legislation is currently on the statute book.

Introductory Text

1. Citation, commencement, extent and application
2. Amendments to the Medical Devices Regulations 2002
3. Amendment to regulation 2 (interpretation)
4. New Part 4A (post-market surveillance requirements)
5. Amendment to Schedule 2A
6. Saving provision

Signature

Explanatory Note

- 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](#)

Published 26 January 2015

Last updated 15 January 2025 — [See all updates](#)



*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



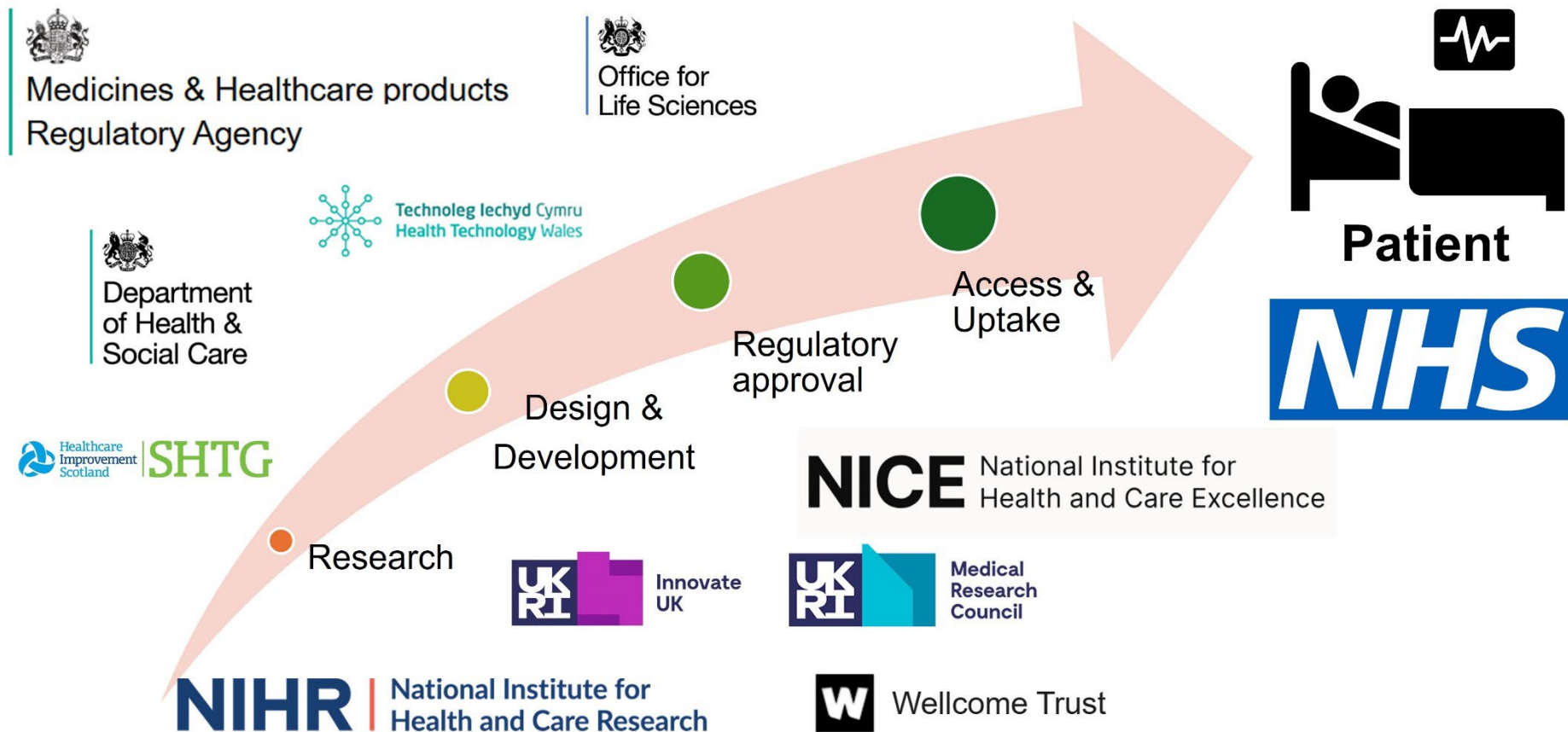
Improved
traceability
through
mandated
use of UDI



New routes to
market including
international
reliance pathways



A connected network of expertise supporting innovative MedTech

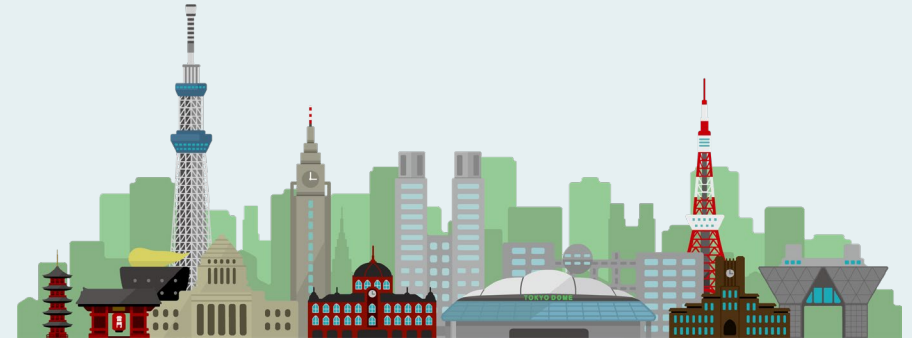




The UK: The place for medical device innovators



- 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



Thank you

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