Roadmap towards the future regulatory framework for medical devices

9th January 2024
Delivered 2021 - 2023

Software as a Medical Device (SaMD) and AI roadmap published

Public consultation

Consultation response published

Post Market Surveillance (PMS) guidance: stakeholder focus groups

Transition arrangements for CE-marked devices regulation in place

PMS: draft legal text published by World Trade Organization

Future core regulations: international recognition stakeholder discussions

Stakeholder awareness sessions for IVDR-NI

3 new Approved Bodies designated: capacity almost doubled

SaMD guidance published: predeteremined change control plans (PCCPs) for developers

Innovative Devices Access Pathway (IDAP) pilot launched

MHRA Roadmap towards the future regulatory framework for medical devices

Regulations laid in Parliament for In Vitro Diagnostics in Northern Ireland (IVDR-NI)
Planned 2024 - 2025

Future core regulations: stakeholder discussions: scope and classification, essential requirements (including labelling & instructions for use), Approved Bodies, exempted devices

Future core regulations: stakeholder discussions: clinical investigations, obligations of economic operators including quality management systems and qualified persons, conformity assessments

Future core regulations: stakeholder discussions: unique device identification and implantables, transitional arrangements

Future core regulations: international recognition stakeholder discussions

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Future core regulations: stakeholder discussions: unique device identification and implantables, transitional arrangements

Future core regulations: international recognition stakeholder discussions

SaMD guidance published x 2: Good machine learning practice for medical device development mapping, and AI as a Medical Device (AIaMD) development and deployment best practice

SaMD guidance published: Data-driven SaMD research, development and governance

PMS regulations: laid in Parliament, draft guidance published and webinars held

Future core regulations: draft legal text published by World Trade Organization

MHRA Roadmap towards the future regulatory framework for medical devices

Future core regulations: international recognition stakeholder discussions

Publish IVD roadmap

IVDR-NI regulations in force

Future core regulations laid in Parliament

Future core regulations laid in Parliament

Future core regulations: public consultation

This is a living document that is subject to updates. The current timeline does not take into account the impact of a General Election.

Key:
- MHRA-led activity
- Dependent on priorities outside MHRA (Indicative only)