IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority (HSA), Singapore

Ms Low Lai Peng

Acting Director, Therapeutic Devices Branch, Medical Devices Cluster

HSA, Singapore

IMDRF International Medical Device Regulators Forum

Medical Device Regulatory Reliance Programme

MALAYSIA MEDICAL DEVICE AUTHORITY (MDA)
– SINGAPORE HSA

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Overview

- 6-month pilot from **1 Sep 2025**
- The programme enables mutual regulatory reliance for **Class B, C and D** medical devices (MDs) registered in either country
- This initiative marks an important step forward in strengthening regional regulatory partnerships

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Medical Device AUTHORITY MALAYSIA

HSA Health Sciences Authority

MALAYSIA

Verification Route for MDs registered on Singapore Medical Devices Register (SMDR)

Reciprocal Regulatory Reliance

SINGAPORE

Abridged Route for MDs registered on Malaysia Medical Device Authority Register (MDAR)

30 working days (WDs) vs. 60WDs under full conformity assessment route through MDA's Conformity Assessment Body (CAB). Device will then be registered within 30WDs

~ 30% reduction in review time compared to Full route

Devices can now go through pathways with Shorter timeline & Lower cost

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Documentary Requirements

As specified in '*GN-15: Guidance on Medical Device Product Registration*' for **Abridged Route**

+

[NEW] **Letter requesting participation**, signed by local applicant (Registrant)

Scan for more information

Application to Participate in Singapore- Malaysia Medical Device Regulatory Reliance Programme

(completed by local applicant)

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

Date:.....Month:.....Year:.....

Subject: Application for Medical Device Registration via Abridged Route (Class B/C/D)

Dear Sir/Madam,

I, [*Company Name*], the Applicant for registration, hereby request to participate in Singapore – Malaysia Medical Device Regulatory Reliance Programme for the registration of medical device with the following details:

1. Name of Device (on Medical Device Authority Register (MDAR)):
2. Identifier (e.g. Model Number, Product Code, Reference Number):
3. Brand Name:
4. MDAR Registration number:
5. Information on Medical Device Registration Certificate Holder (in Malaysia):
   a. Company Name:
   b. Address:
   c. Name of Authorized Representative:
   d. Contact Email:

The required registration documents will be based on the Abridged evaluation route as specified in GN-15: Guidance on Medical Device Product Registration.

I, the undersigned, hereby attest that the information provided is/are accurate, correct, complete and current to this date.

I respectfully submit this application for your kind consideration.

Yours sincerely,

[Signature]

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Application Process

Application of device registration to be submitted through our online platform, *Singapore Health Product Access and Regulatory E-System (SHARE)*

Interim steps before system enhancement to include the **Regulatory Reliance Program** option

- Post-submission, email HSA with the SHARE application number
- HSA will adjust and apply Abridged route fees & turnaround time (TAT)

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Updates from meeting of the ASEAN Medical Device Committee (AMDC)

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ASEAN Medical Device Committee (AMDC)

- Responsible for harmonising medical device regulations across ASEAN member states through the **ASEAN Medical Device Directive (AMDD)**
- Facilitating trade by streamlining market entry processes to and enabling faster access to healthcare technologies throughout the region
- **Recent Activities**: The 14th AMDC meeting was recently held in Siem Reap, Cambodia, continuing the committee's ongoing work in regional regulatory harmonisation

10 Member States

- Brunei Darussalam
- Cambodia
- Indonesia
- Laos PDR
- Malaysia
- Myanmar
- Philippines
- Singapore
- Thailand
- Vietnam

asean

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AMDC Work Plan 2026 – 2030

- Setting a 5-year roadmap to work towards the objective of ***"Advance the harmonisation of standards, technical regulations, and conformity assessment procedures"***
- The meeting discussed priority areas for each strategic measure
- The workplan is scheduled for finalisation by 1H 2026

Advance the harmonisation of standards, technical regulations, and conformity assessment procedures
STRATEGIC MEASURE
Strengthen mutual recognition of conformity assessment results in ASEAN
Strengthen joint ASEAN approaches on issues related to standards and conformance for effective representation and participation in international and regional bodies and associated recognition arrangements
Enhance standard harmonization efforts towards alignment with international standards
Expand standards and conformance initiatives to facilitate development in nascent sectors aiming to reinforce connectivity and integration through technological advancement and sustainable development

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Join Us: IMDRF 2026 in Singapore!

29th IMDRF Meeting

9-13 March 2026

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Thank you/Questions

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Regulatory Update on Medical Devices in the Republic of Korea

KIM, Hyun-Soo
Assistant Director
Medical Device Evaluation Department
Ministry of Food and Drug Safety (MFDS)
Republic of Korea

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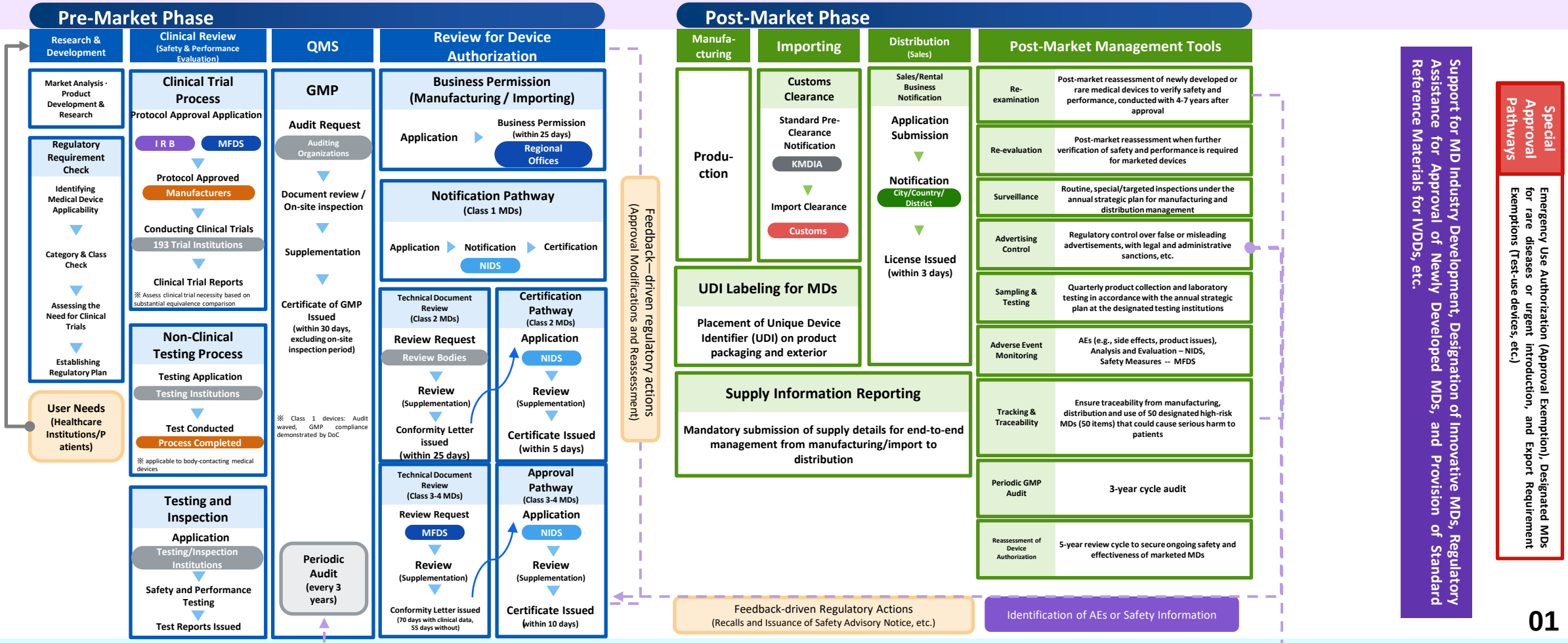
Korean Medical Devices Regulatory Framework

: Medical Devices Lifecycle Safety Management



Support for MD Industry Development, Designation of Innovative MDs, Regulatory Assistance for Approval of Newly Developed MDs, and Provision of Standard Reference Materials for IVDs, etc.

Special Approval Pathways

Emergency Use Authorization (Approval Exemption), Designated MDs for rare diseases or urgent introduction, and Export Requirement Exemptions (Test-use devices, etc.)

Legal Framework for Medical Devices in Korea

Pharmaceutical Affairs Act
(since 1953)

Medical Devices Act
(May 2004)
(applies to general medical devices and IVDDs)

* Including Software (SW)

In Vitro Diagnostic Medical Devices Act
(May 2020)

Digital Medical Products Act
(January 2025)

Act on the Nurturing of the Medical Device Industry and Support for Innovative Medical Devices
(May 2020)

Special Act on the Promotion of Development and Emergency Supply of Medical Products for Public Health Crisis
(March 2021)

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(March 2021)

Key Updates

▣ Medical Devices Act and Regulations

❖ Strengthening Post-Market Surveillance: Long-term Follow-up of Implantable Medical Devices

- **Legal basis**: effective Jan 31, 2025
- Decision Criteria

  1) Whether adverse events during use of the device occurred at least once a year

  2) Whether the device may cause death or serious incurable adverse effects after implantation

- **Amendments to subordinate regulations**: **Processing sensitive information**

  ✓ **legal basis**: effective Aug 1, 2025

  ✓ collection & analysis of **real-world data**

Key Updates

▣ QMS Regulations

❖ Introduction of KGMP & MDSAP Combined Audits (April 7, 2025)

- **(As-Is) Separate audits** for KGMP and MDSAP
- **(To-Be) Combined audits** for export-oriented manufacturers
  - ✓ to reduce audit burden and encourage broader use of MDSAP
  - ✓ to provide incentives to MDSAP AOs in Korea

KGMP Certification Bodies & MDSAP AOs in Korea (2)

- **TÜV SÜD Korea (TSK)**
- **TÜV Rheinland Korea (TRK)**

Key Updates

▣ Use of MDSAP

❖ Status of MDSAP-Certified Manufacturers located in the Republic of Korea

Year	2021	2022	2023	2024	July 2025
Site	161	169	213	241	265

❖ Use of MDSAP in the Republic of Korea

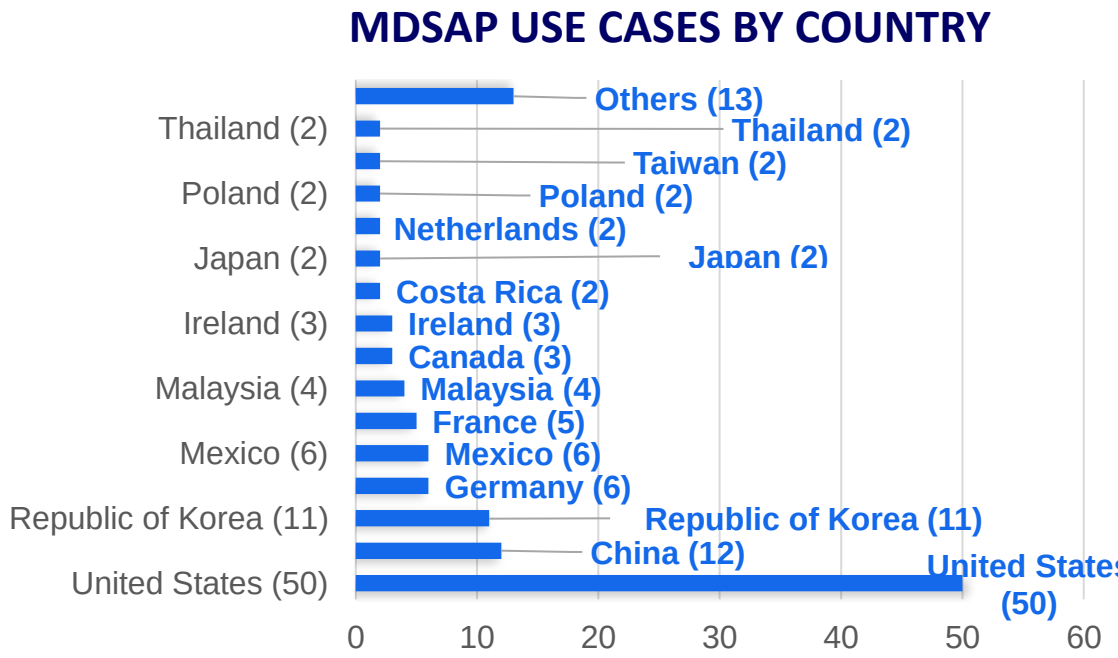
- 106 MDSAP reports (2024) and/or certificates were submitted as part of GMP inspection applications

  → Accepted as **mandatory documentation**

- **44** sites (as of August 2025) submitted valid MDSAP report

  → Qualified for **document review only**

  * 19 Sites in 2024



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(March 2021)

Key Updates

▣ Digital Medical Products Act and Regulations (effective Jan 24, 2025 / Jan 24, 2026)

Digital Medical Products Act

- Decree of the Digital Medical Products Act
- Rule of the Digital Medical Products Act

Guidelines

Subordinate Regulations (6)

① **(Classification)** Regulation on Classification and Designation of Digital Medical Products

② **(Authorization)** Regulation on Approval/Certification/Notification/Evaluation of Digital Medical Products

③ **(QMS)** Good Manufacturing Practice for Digital Medical Devices

④ **(Clinical Investigation)** Regulation on Protocol Approval & Conduct & Management of Clinical Trials for Digital Medical Devices

⑤ **(Cyber Security)** Regulation on Cybersecurity for Digital Medical Devices

⑥ **(Special Provisions)** Regulation on Certification Criteria for Excellent Governance Systems

Guidelines (New / Revised) (6)

① **(New)** Guideline on Authorization Review of Digital Medical Devices Software

② **(Revised)** Guideline on Clinical Trial Design Methods for Digital Medical Devices Applying AI Technology

③ **(Revised)** Guideline on Authorization Review of Medical Devices Software

④ **(Revised)** Guideline on Authorization Review of Digital Medical Devices Applying AI Technology

⑤ **(Revised)** Guideline on Authorization Review of Digital Medical Devices Applying Virtual Convergence Technology

⑥ **(Revised)** Guideline on Authorization Review of Digital Therapeutics

Key Updates

▣ Digital Medical Products Act and Regulations (effective Jan 24, 2025)

① (Classification) Regulation on Classification and Designation of Digital Medical Products

- Classification system reflecting the development and risk considerations of AI/SW-based products
  - ✓ Aligned with IMDRF /SaMD WG/ N12, N81

② (Authorization) Regulation on Approval/Certification/Notification/Review and Evaluation of Digital Medical Products

- Introduction of software usability evaluation and Pre-determined Change Control Plan (PCCP)
- Exemption conditions established for certain Clinical Decision Support System (CDSS)
- Enhanced disclosure requirements to improve transparency of AI medical devices (SW-Labeling with AI related information)
- Established evaluation framework for Digital Health Technologies (DHTs) combined with pharmaceuticals and devices
  - ✓ Aligned with IMDRF /AIML WG/ N67, N88
  - ✓ Aligned with IMDRF /SaMD WG/ N41

③ (QMS) Good Manufacturing Practice (GMP) for Digital Medical Devices

- Based on ISO 13485, reflecting characteristics of SW (IEC 62304) and AI-specific Control Measures

Key Updates

▣ Digital Medical Products Act and Regulations (effective Jan 24, 2025 / Jan 24, 2026)

④ **(Clinical Investigation) Regulation on Protocol Approval & Conduct & Management of Clinical Trials for Digital MDs**

- Simplified procedures for data-driven trials
- Facilitated Decentralized Clinical Trials (DCT) and use of real-world evidence

⑤ **(Cybersecurity) Regulation on Cybersecurity for Digital Medical Devices**

- Cybersecurity requirements covering AI/SW lifecycle
  - ✓ Aligned with IMDRF /CYBER WG/ N60, N70, and N73

⑥ **(Special Provisions) Regulation on Certification Criteria for Excellent Governance Systems**

- Designating firms with proven AI governance & AI cybersecurity capacity
- Allows “use first, evaluate later” for AI products difficult to assess individually
  - ✓similar to a conditional regulatory sandbox

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Special Act on the Promotion of Development and Emergency Supply of Medical Products for Public Health Crisis
(March 2021)

Digital Medical Products Act Updates

AI Act
(January 2026)

Key Updates

▣ Digital Medical Products Act & AI Act in Korea

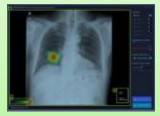
Medical Devices Act

In Vitro Diagnostic Medical Devices Act

AI MD / SaMD

"Digital Health"

Digital Medical Products Act



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Digital(AI·SW) Pharmaceuticals / Digital(AI·SW) Health Technology

AI Act

High-impact(High-Risk) AI based MD

DMP Act + AI Act

Overlapping Requirements are deemed fulfilled when compliance with the DMP Act is demonstrated

AI Act (Basic Act)

Digital Medical Products Act

Key Updates

▣ Act on the Nurturing of MD Industry & Support for Innovative MDs (established Apr 30, 2019)

➢ **To support rapid productization and promote public health**

✓ designation of "**Innovative Medical Devices**"

✓ applying to technologies significantly improving safety and performance

❖ **Special authorization pathways** applied to designated innovative devices

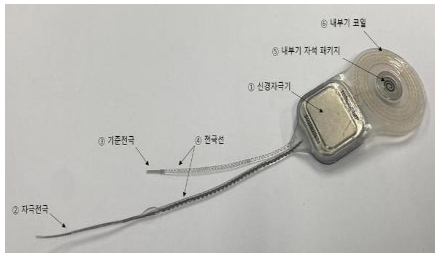
- Priority review, Stepwise review, etc.
- To support timely market entry and patient access
- 111 innovative medical devices designated (as of Aug 2025)

❖ **Ongoing activities:**

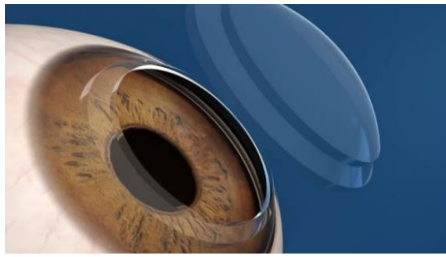
- Training specialized personnel
- Full lifecycle technical support
- Collecting & Providing R&D information domestically/internationally

Fundus Image Reading Solution

Electrosurgical System for Hypertension



Implantable Cochlear Hearing Device



Corneal Prosthesis

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Thank you/Questions

Email: policymfds@korea.kr

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IMDRF Stakeholder Forum
Regulatory Update, Switzerland

Mr. Markus Wälti,
Head of Division Medical Devices Vigilance, Swissmedic

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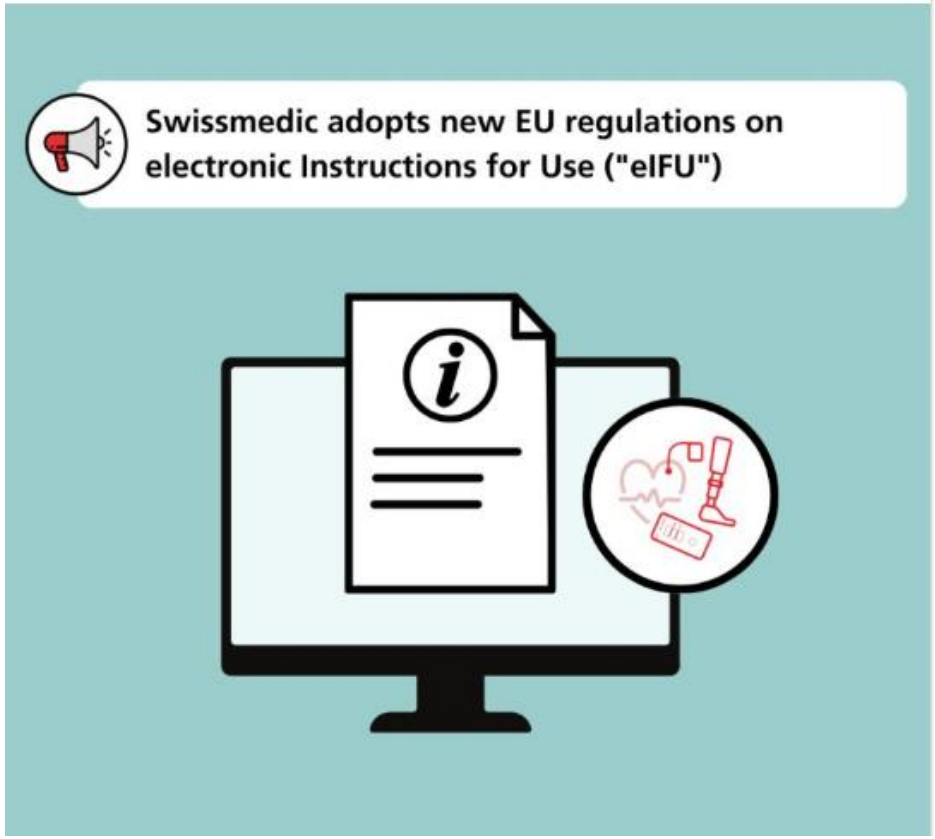
Key changes to regulatory framework

Following the entry into force of the EU's new Implementing Regulation (EU) 2025/1234 on 16 July 2025, Swissmedic is adopting the updated provisions on electronic Instructions for Use (eIFUs).

The regulation extends the scope of electronic IFUs to all medical devices (not IVDs), including legacy devices, their accessories, and products without a medical purpose intended for professional users.



Learn more: [Announcement] / [Website]

Key changes to regulatory framework

Go Live of the UDI Devices Module in swissdamed – a milestone for greater transparency in the Swiss medical device market!

August 2025
Voluntary registration of devices, systems and procedure packs begins

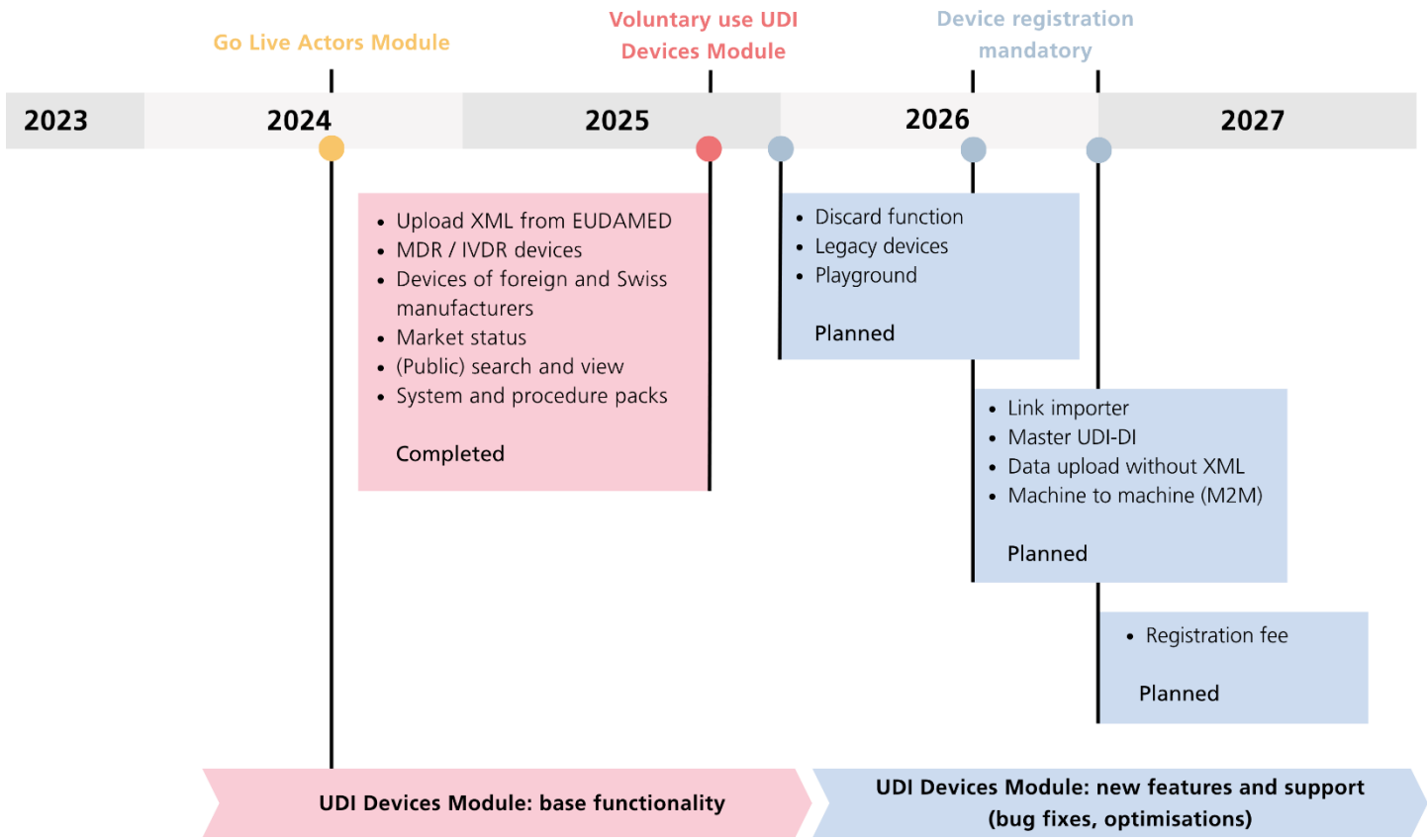
End of 2025
Playground for testing device data available

1 July 2026
Mandatory registration begins, immediate registration for devices with serious incidents

31 December 2026
End of transition period

Learn more: Announcement / Website

swissdamed: roadmap



Learn more: [Announcement](#) / [Website](#) / [technical documentation](#)

IMDRF International Medical Device Regulators Forum

swissdamed: UDI Devices Module: Data Elements

Learn more: [technical docs]

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Outlook on the future regulatory framework

Press release | Published on 30 April 2025

The Federal Council defines guidelines for expanding the supply of medical devices

Bern, 30.04.2025 — At its meeting on 30 April 2025, the Federal Council noted the ongoing efforts to implement Motion 20.3211, which aims to open the possibility for medical devices from non-European regulatory systems to be placed on the Swiss market. In order to ensure adequate supplies of medical devices and to guarantee patient safety, the Federal Council defined guidelines and will assign responsibility for controls to private bodies.

In November 2022, the National Council referred to the Federal Council the motion (20.3211) brought by Damian Müller, a member of the Council of States, calling for measures to enable medical devices from non-European regulatory systems to be placed on the market in Switzerland. The aim of this motion is to expand sources of medical device supplies beyond the European Union (EU), including in particular devices authorised by the US Food and Drug Administration (FDA).

Learn more: Press release / Medical devices legislation

Controls by private bodies

An impartial assessment and effective controls are necessary to ensure the safety of the medical devices concerned. The Federal Council intends to assign responsibility for reviewing the conditions for devices already authorised by the FDA in the US to private bodies. These bodies will review the relevant conditions under a simplified conformity assessment procedure, taking into account elements already performed by the FDA.

Next steps

The Federal Council has therefore requested the Federal Department of Home Affairs (FDHA), in collaboration with the Federal Department of Economic Affairs, Education and Research (EAER) and the Federal Department of Foreign Affairs (FDFA), to explore this approach in more detail.

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Hospital Inspection - Annual Report 2024 - Scope: reprocessing units for MD & endoscopy, maintenance, vigilance

Key weaknesses identified in the areas of:

- **Reprocessing**: understaffed and undertrained teams → infection risk (flexible endoscopes sensitive to heat).
- **Documentation**: inadequate and partly not established lifecycle processes (inventory, preventive maintenance) → device failure risk.
- **Vigilance**: gaps in training and process quality
- Unresolved **cybersecurity** risks in >40% of cases.

Take aways:

- No direct patient harm identified
- Immediate action was taken to guarantee safety and functionality of devices
- Many hospitals still fall short of legal requirements
- Report emphasises root-cause analysis and targeted recommendations

Learn more: Report 2024

Key changes to guidance documents & forms

swissdamed

- Handbook swissdamed User Guide Actors (revised, 15.08.2025)
- Business Rules (initial, 15.08.2025)
- Quick Guides: Public search & UDI Registration & User Guide UDI Devices Module (initial, 15.08.2025)
- Privacy Notice and Terms of Use (revised, 05.08.2025) & Service Agreement (revised, 15.08.2025)

Healthcare institutions*

- Information sheet on In-house Medical Devices (initial, 01.05.2025)

Materiovigilance / Post-Market Surveillance

- Guidance document Incident economic operators (revised, 20.05.2025) – use of EU-MIR form 7.3.1 mandatory from Nov. 2025

Clinical Trials

- FO Application simplified review MD & FO Application simplified review IVD (revised, 09.05.2025)
- FO Form Modifications, notifications, reports MD IVD (revised, 23.05.2025)

Economic Operators

- Information Sheet Systems and procedure packs (initial, 04.08.2025)
- Information sheet derogation MD (revised, 26.03.2025)

Other Guidance

- Products without an intended medical purpose (revised, 30.05.2025)
- Injectable products for wrinkle treatment (revised, 25.06.2025)

*Good practice documents are available only in our national languages: German, French, and Italian.

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Meetings, Workshops and Training (Link) – since the last IMDRF MC

Date	Organizer	Event, Location
14 Mar	Higher Technical School of Medical Technology, Sarnen	Guidelines for the Maintenance of Medical Devices
18 Mar	DIA Europe 2025, Basel	Session 1: How Swissmedic Implements AI Internally Session 2: TRICIA – Using NLP to Enhance Risk Assessment of Incoming Incident Reports Session 3: Panel Discussion
16 Apr, 04 Sep	H+ Education & Swiss Society for Sterile Goods Supply (SGSV)	Reprocessing of Endoscopes – STE Endo
08 May	Swiss Society for Sterile Goods Supply (SGSV)	News from Swissmedic: Findings from Hospital Inspections and Swissmedic's Topic-Specific Expectations for AEMPs Regarding Validation of Packaging Processes
09 May	HF Medi, Training Course "Operating Technique: Assistance, Positioning & Suturing in the OR"	Vigilance Concerning Medical Devices – What It Means for Operating-Room Staff
02-06 Jun	Swissmedic	14th Swissmedic Regulatory Training
06 Jun	Swiss Association of Infrastructure Hospitals (IHS)	Guidelines for the Maintenance of Medical Devices
12 Jun	Swiss Society for Microbiology (SGM)	Requirements for In-house IVDs According to the IvDV and IVDR
16-20 Jun	Informaconnect for MedTech Summit	Combined Studies: The Swiss Approach
18 Jun	SGSV-SSSH, Swiss Society for Sterile Goods Supply	Good Practice for Maintenance in AEMPs
18 Jun	Swissmedic	Guidelines for the Maintenance of Medical Devices
18 Jun	SSSH/SGSV – Swiss Society for Sterile Goods Supply	News from Swissmedic: Reprocessing of Flexible Endoscopes
23 Jun	Swissmedic	Roundtable on Medical Technology (RTMT)
25 Jun	Insel Group	Cyber-security of Medical Devices – What Swissmedic Expects from Hospitals

IMDRF International Medical Device Regulators Forum

Meetings, Workshops and Training (Link) – since the last IMDRF MC

Date	Organizer	Event, Location
27 Jun	University Hospital Zurich	Laboratory Medicine – More Than Machines and Data
25-27 Aug	Interest Group – Re-use in Healthcare	Hospital Inspections by Swissmedic
26 Aug	HF Medi, Training Course “Operating Technique: Assistance, Positioning & Suturing in the OR”	Vigilance Concerning Medical Devices – What It Means for Operating-Room Staff
26 Aug	Swiss Society for Clinical Chemistry (SGKC)	Requirements for In-house IVDs According to the IvDV and IVDR
04 Sep	Swiss Society for Endocrinology and Diabetology (SGED)	Regulatory Framework When Technology Fails
09 Sep	Federal Office of Public Health (FOPH), Department of Communicable Diseases	Requirements for In-house IVDs According to the IvDV and IVDR
10 Sep	Centre for Health Law and Management, University of Bern	Current Medical-Device Regulation: Developments and Insights from Enforcement
11 Sep	MedTech Pharma Platform	Participation in Panel Discussion
20 Sep	H+ Education & Swiss Society for Sterile Goods Supply (SGSV)	News from Swissmedic: Inspection Results in AEMPs
30 Sep	Higher Technical School of Medical Technology, Sarnen	Implementation of the New GPI

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Marketing Authorisation for Global Health Products (MAGHP) in 2025

Visiclor Eye Gel – ophthalmic anesthetic

- Submitted Q1 2024
- Assessment completed
- Active participation of South African Authority SAHPRA
- Product approved by Swissmedic on 21 February 2025
- Approval in South Africa on 13 May 2025

Riamet/Coartem Baby – antimalarial for infants

- Submitted Q1 2024
- Assessment completed
- Close collaboration with authorities from Burkina Faso, Côte d'Ivoire, Kenya, Malawi, Mozambique, Nigeria, Uganda and Tanzania
- Product approved in Switzerland on 3 July 2025
- Submission/national decision phase in targeted countries ongoing

Learn more: Announcement / Website

Thank you/Questions

Swissmedic,
Swiss Agency for Therapeutic Products
Markus Wälti
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Hallerstrasse 7
3012 Berne, Switzerland
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Stay connected: join our community on social media
and sign-up for our newsletter,
or send us your questions to questions.devices@swissmedic.ch.

Do you know the Swissmedic magazine ‘Visible’?
Find out more: Visible | Swissmedic

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Medicines & Healthcare products Regulatory Agency

United Kingdom Country Update

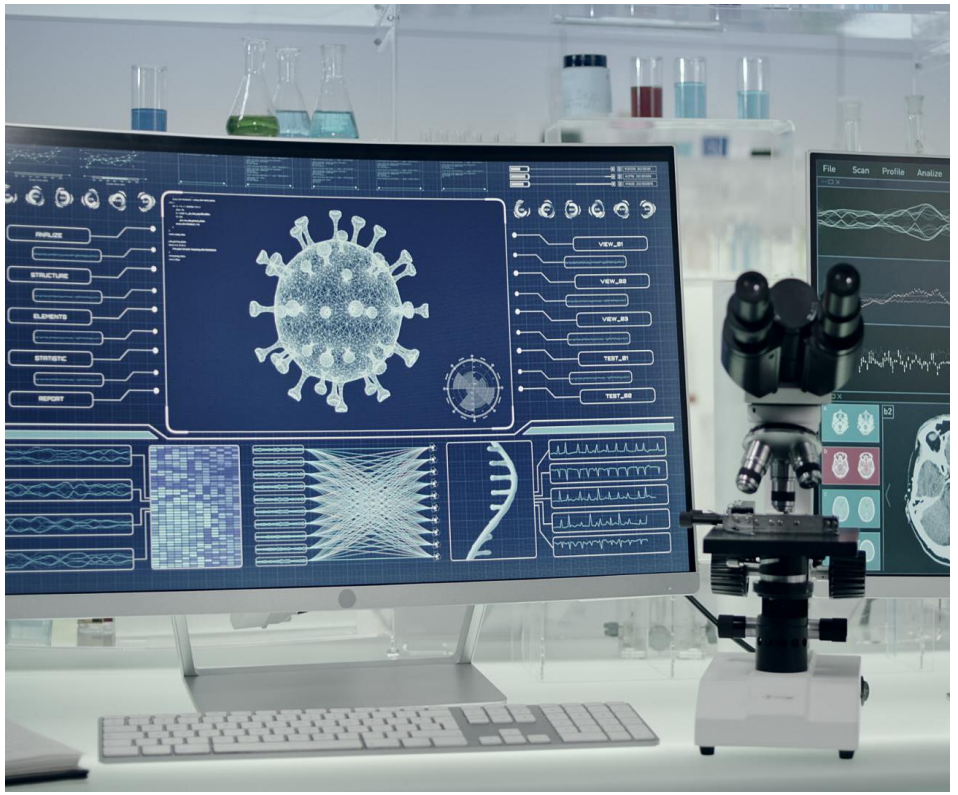
Holly Coole – Senior Manager, Digital Mental Health Software Team

IMDRF International Medical Device Regulators Forum

Overview

Safe, rapid access and a hub for innovation

- Policy context
- Medical Devices Regulatory Reform Roadmap
- Post-Market Surveillance legislation
- Pre-market Regulations legislation
- Driving innovation

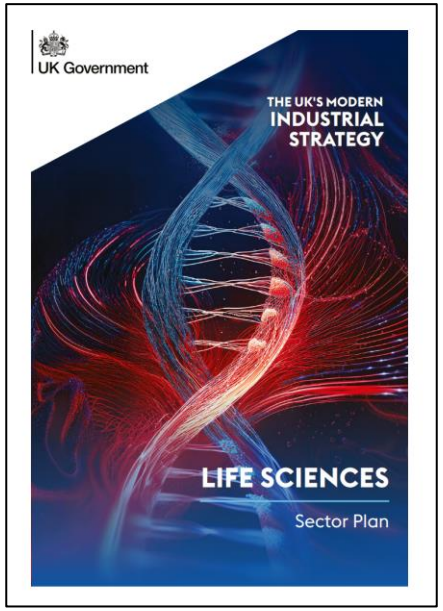


15 September 2025

A clear direction for the future

A regulatory framework for:

- Safe and rapid access to devices through:
  - Risk proportionate and predictable routes to market
  - New international reliance routes
  - UKCA focused on innovation e.g. AIaMD
  - Aligns with international standards to facilitate collaboration



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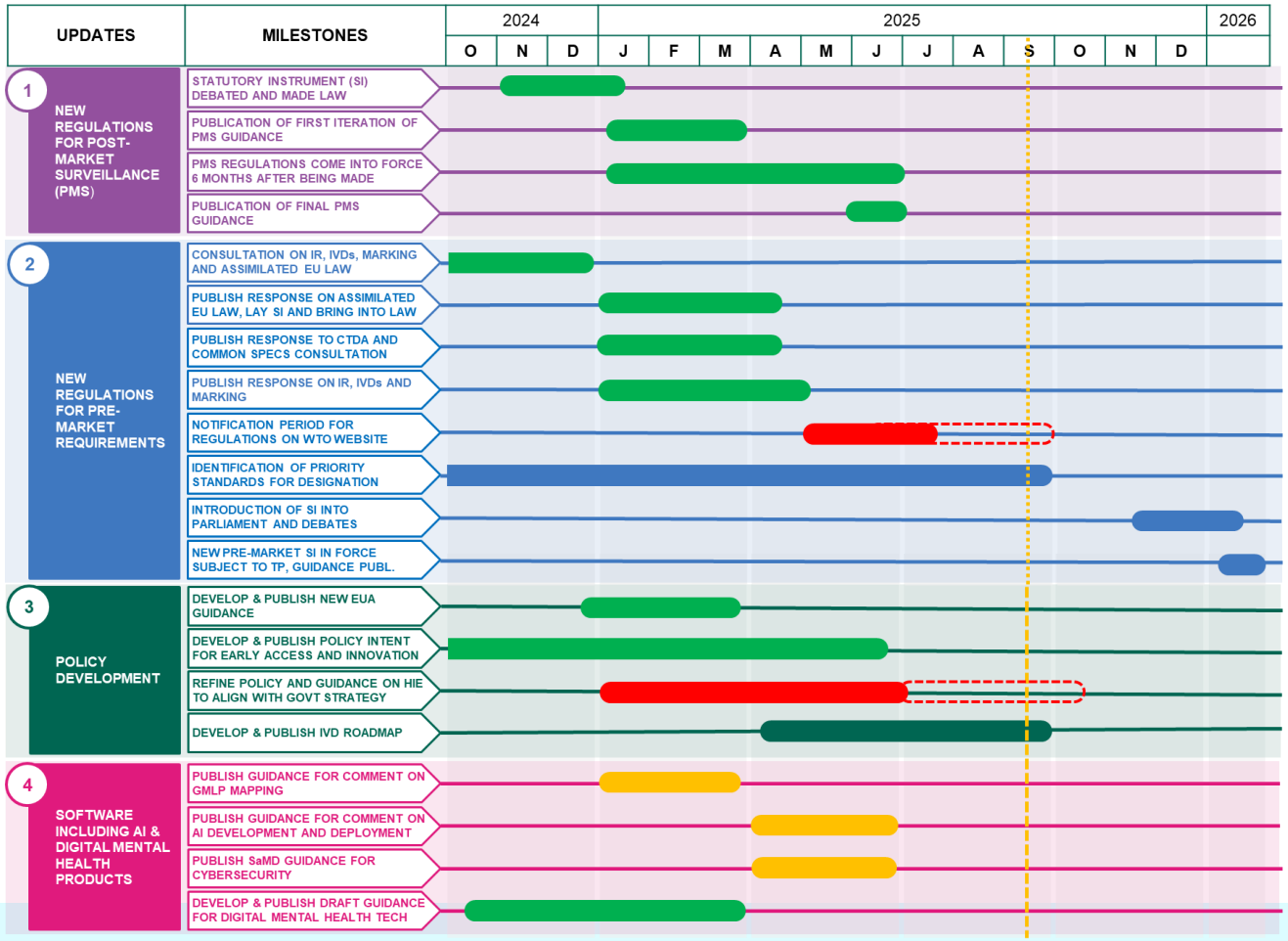
Medical Devices Regulatory Reform Roadmap



Delivered:

- PMS Regulations
- **Consultation on future routes to market**
- New Exceptional Use Authorisation guidance
- **Statement of policy intent for early access**

Pending:

- **Notification of Pre-market to WTO website**
- Priority designated standards
- Refined policy and guidance on HIE
- **Consultation on indefinite recognition**

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Post-market Regulations

STATUTORY INSTRUMENTS

2024 No. 1368

MEDICAL DEVICES

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

Made *16th December 2024*

Coming into force in accordance with regulation 1(2)

- Robust PMS requirements reflective of device risk classification
- Increased scrutiny and regulatory oversight
- Enhanced reporting obligations for manufacturers supporting early detection of safety issues
- Better harmonisation across industry and internationally
- Improved coordination and collaboration with other regulators
- In force since 16 June 2025
- Month on month increase in adverse incident reporting

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Pre-market Regulations

Our objectives are **patient safety, access to medical devices, supporting innovation and growth**

Risk based classification for medical device and IVDs

Enhanced requirements for implantables supporting safe innovation

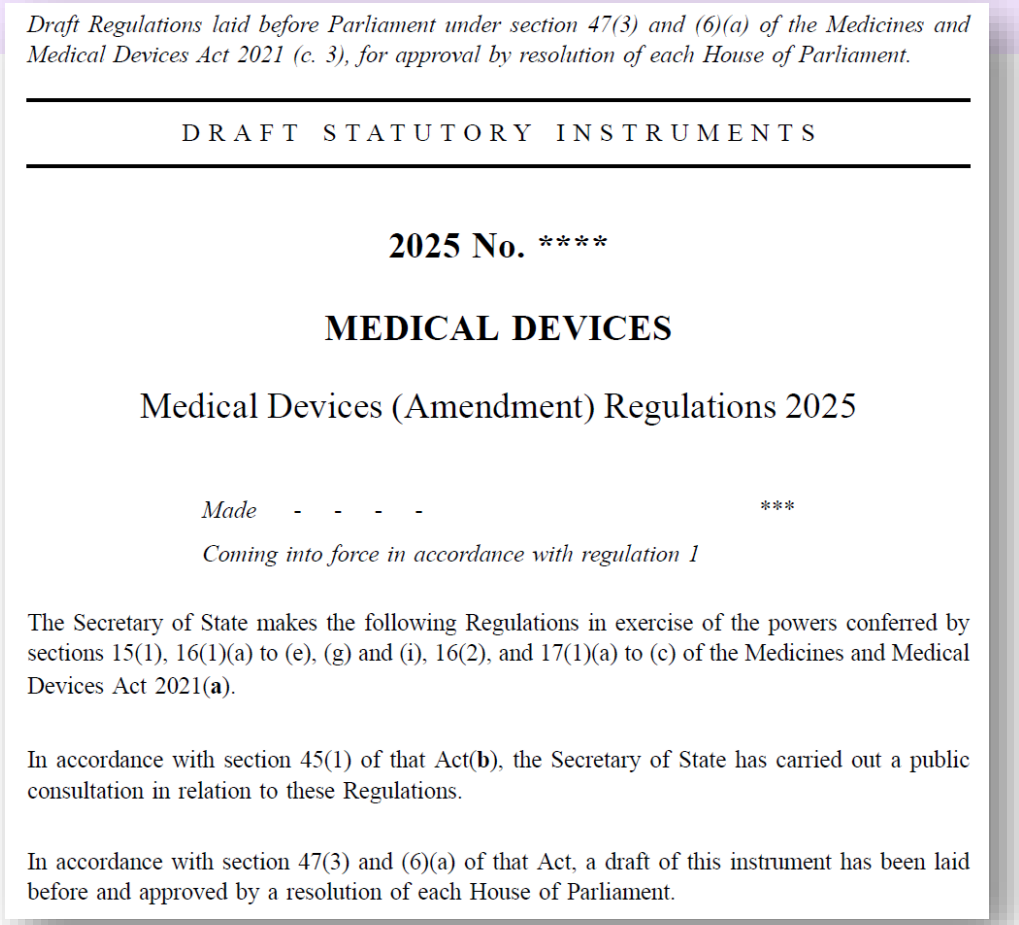
Pre-determined change control plans for software as a medical device

Improved traceability through mandated use of UDI

New routes to market including international reliance pathways

Pre-market Regulations progress

- Finalising drafting with government legal
- Routes to Market consultation now completed
- Short delay in notification to World Trade Organisation to around Oct 2025
- Plan to lay in Parliament end of 2025
- Debates in Q1 2026 – depending on parliamentary timetables
- Coming into force starting in 2026



Draft Regulations laid before Parliament under section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021 (c. 3), for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2025 No. **

MEDICAL DEVICES

Medical Devices (Amendment) Regulations 2025

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 15(1), 16(1)(a) to (e), (g) and (i), 16(2), and 17(1)(a) to (c) of the Medicines and Medical Devices Act 2021(**a**).

In accordance with section 45(1) of that Act(**b**), the Secretary of State has carried out a public consultation in relation to these Regulations.

In accordance with section 47(3) and (6)(a) of that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

IMDRF International Medical Device Regulators Forum

Supporting innovation

- **AI Airlock**
- UK CERSIs
- IDAP and innovation pathways
- **Early access to devices**
- Scientific and Regulatory Advice

IMDRF International Medical Device Regulators Forum

AI Airlock

A safe space to test medical device regulatory pathways with innovative AI products, to gain further understanding of targeted challenges and identify and influence regulatory consequences.

Airlock Objectives

Unlock

1.share pilot insights and learnings publicly, across the MHRA and **influence** the **Software Change Programme** Roadmap

2.to **transition future Airlock phases** into business operations including building team capacity and capability and a secured funding baseline

Expand

3. **Phase 2.0** – to work with a **new cohort** of applicants to investigate **further regulatory challenges** and recommendations for change

4. Partner Sandboxes to **increase scope and expertise** of the regulatory sandbox programme

Key partners

- DHSC
- NHS AI Team
- Team AB

Department of Health & Social Care

TEAM AB

Key outputs

- Influencing the Software Change Programme with outputs from the pilot.
- Pilot 2.0 - Evidence of further challenges in regulating AIaMD and Airlock recommendations for change
- Secured funding baseline and programme team

IMDRF International Medical Device Regulators Forum

Early Access to Devices

The statement of policy intent outlining initial plans to launch an Early Access service for innovative medical technologies.

Building on UCNA and IDAP pilot

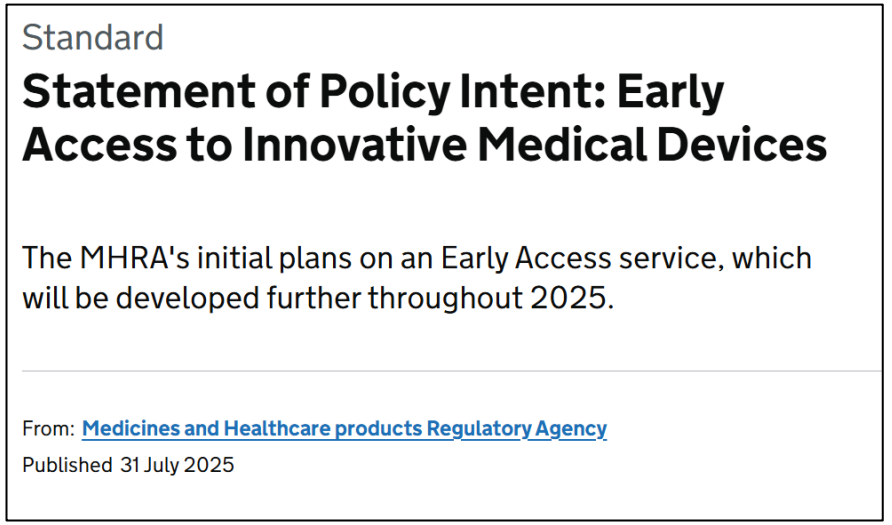
The service builds on the UCNA tool piloted in IDAP and incorporating partners' feedback.

Expanding Access for Innovators

The service will support more innovators to meet demands in the NHS or to develop innovations incubated within the NHS.

Risk-Proportionate Regulation

The service emphasises risk-proportionate regulation and oversight as well as ongoing support to ensure patients receive safe medical devices.


Standard

Statement of Policy Intent: Early Access to Innovative Medical Devices

The MHRA's initial plans on an Early Access service, which will be developed further throughout 2025.

From: Medicines and Healthcare products Regulatory Agency

Published 31 July 2025

IMDRF International Medical Device Regulators Forum

Thank you!

Holly Coole
Senior Manager – Digital Mental Health
Software team

Info@MHRA.gov.uk
gov.uk/mhra
Follow us on social media

Medicines & Healthcare products Regulatory Agency

US FDA Update

Michelle Tarver, MD, PhD
Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration

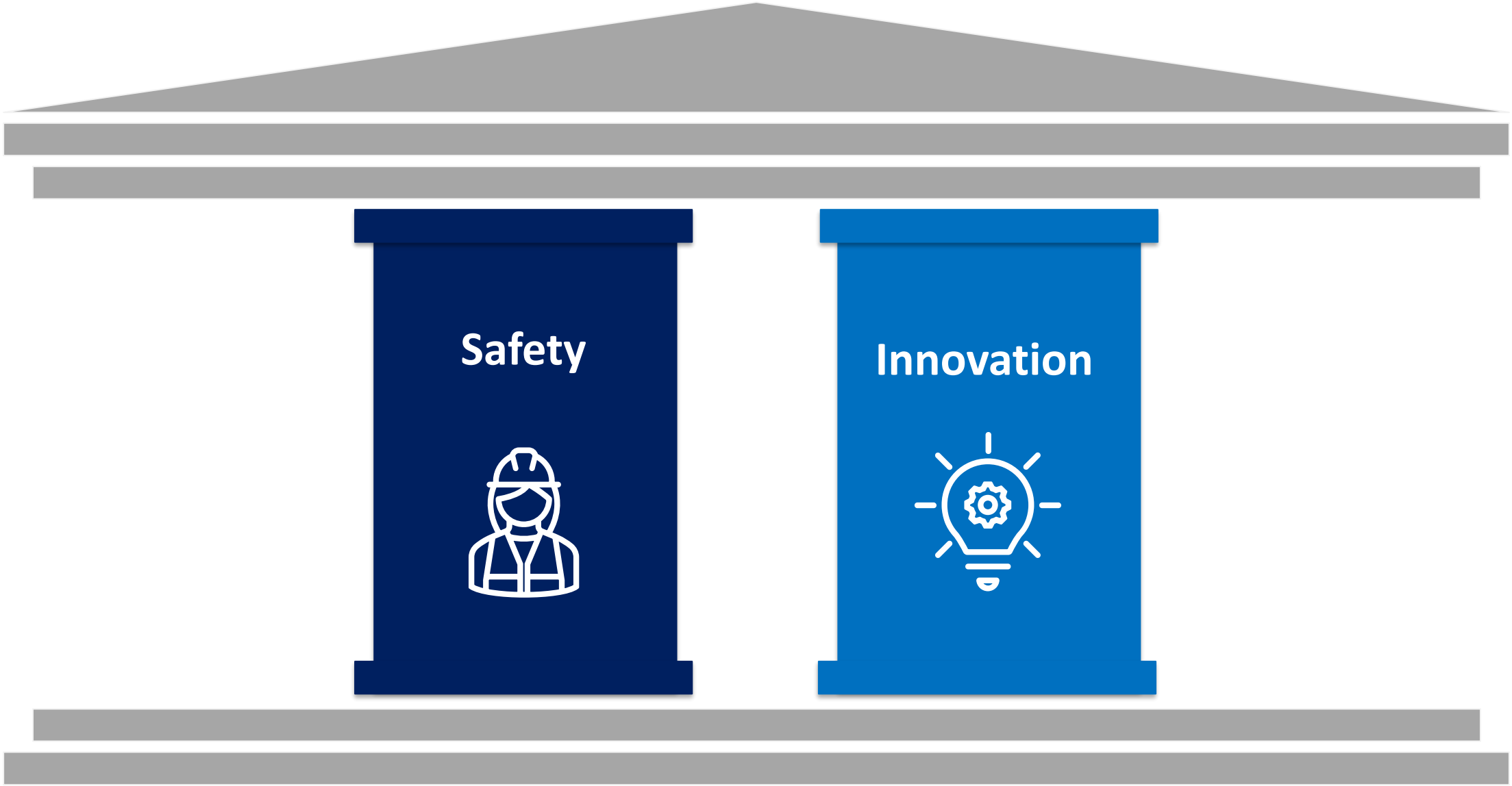
September 16, 2025

Patients are at the Heart of What We Do

Center for Devices and Radiological Health (CDRH) Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance

CDRH Core Pillars



Patient-Centered Development & Evaluation

Development

Identify unmet medical needs & **clarify** what matters most to patients

Clinical Trial Design

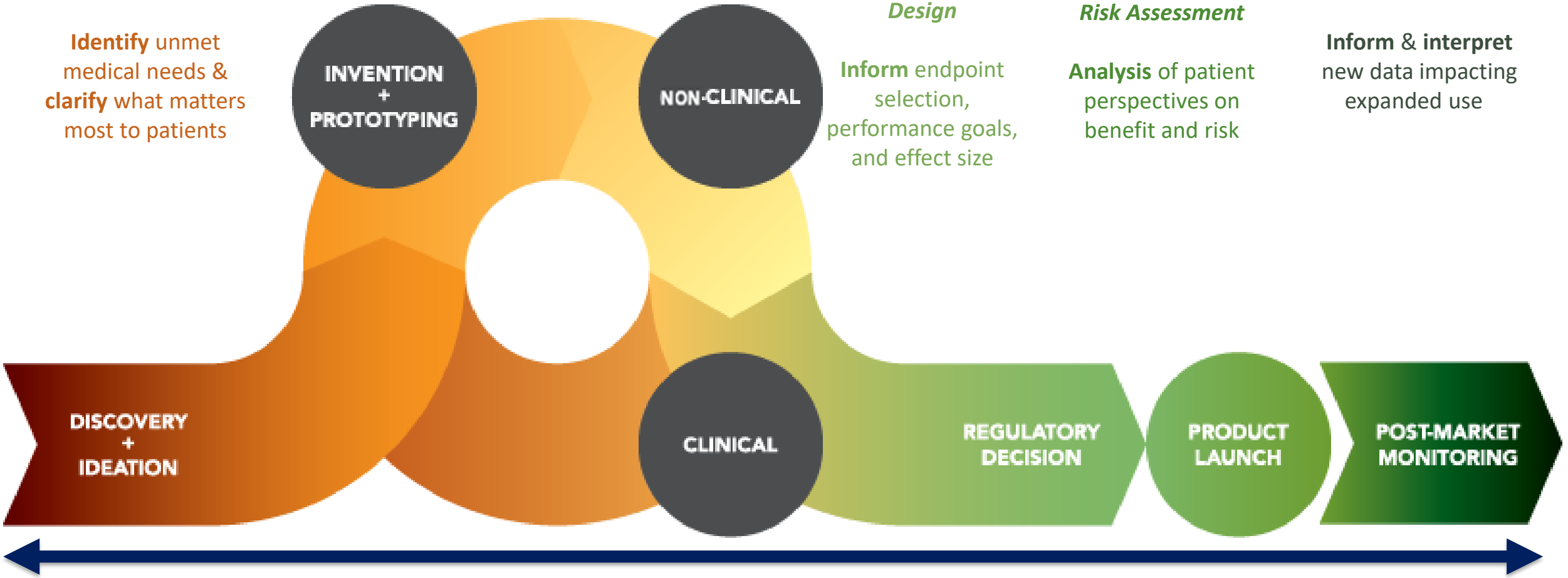
Inform endpoint selection, performance goals, and effect size

Premarket Benefit-Risk Assessment

Analysis of patient perspectives on benefit and risk

Post-Market

Inform & **interpret** new data impacting expanded use



Real-World Evidence Program

Use of Real-World Data & Evidence in place of conventional clinical trial data to reduce time to answer device questions

Regulatory Decision-Making

180+ devices authorized using RWE

Collaboration

Engaged with 100 national or regional registries from 45 countries

Transparency

Updated webpage with reporting adverse events & more for medical devices from RWD sources

Knowledge Management

2023 daft guidance including new appendices of examples and recommended elements

Total Product Life Cycle Advisory Program (TAP) Pilot Update

93 enrolled

Engage in a teleconference within 14 days for 90% of requests for interaction

Written feedback on all other requested topics within 40 days for 90% of requests

100% of key quantitative performance metrics met

CDRH data as of 9/1/2025

Digital Health Innovation

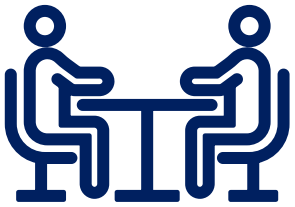
New!

Regulatory Accelerator – Curated resources to support development of medical device software

Resource Index

Visual guide to FDA tools and resources available throughout the process of bringing a device to market

Early Orientation



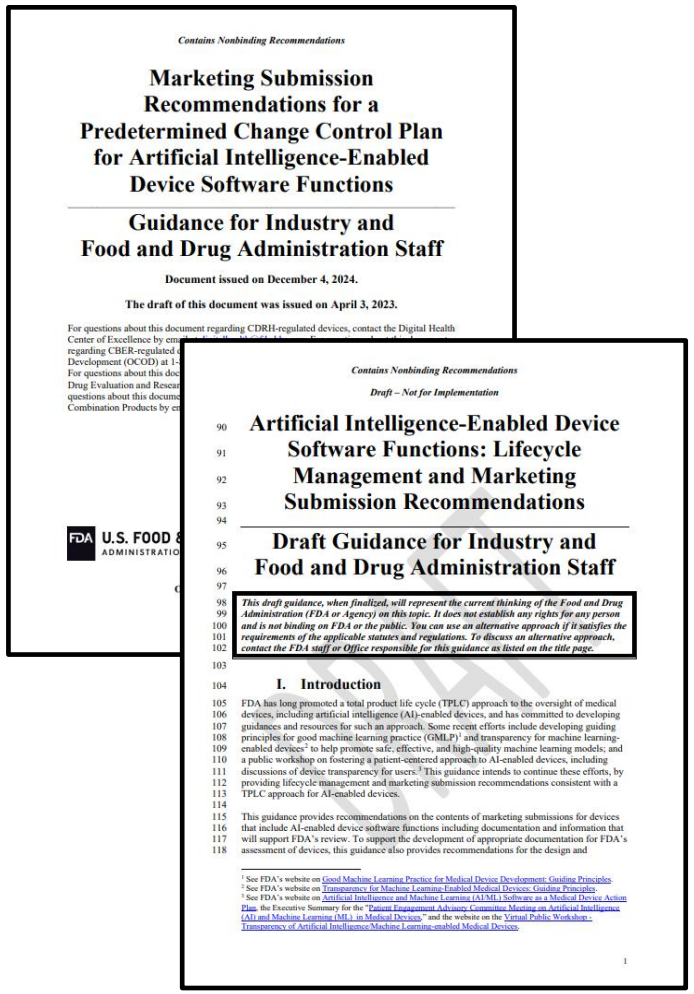
Best practices for engaging early with the FDA on marketing submissions on medical device software

Guidance Navigator

Resource for identifying guidances that may be applicable to a device across the development life cycle

www.fda.gov/medical-devices/digital-health-center-excellence/regulatory-accelerator

AI in Medical Devices



Contains Nonbinding Recommendations

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 4, 2024.

The draft of this document was issued on April 3, 2023.

For questions about this document regarding CDRH-regulated devices, contact the Digital Health Center of Excellence by email at [illegible]
regarding CBER-regulated d
Development (OCOD) at 1-
For questions about this doc
Drug Evaluation and Resear
questions about this docum
Combination Products by em

FDA U.S. FOOD &
ADMINISTRATIO

Contains Nonbinding Recommendations

Draft – Not for Implementation

Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA has long promoted a total product life cycle (TPLC) approach to the oversight of medical devices, including artificial intelligence (AI)-enabled devices, and has committed to developing guidances and resources for such an approach. Some recent efforts include developing guiding principles for good machine learning practice (GMLP)[1] and transparency for machine learning-enabled devices[2] to help promote safe, effective, and high-quality machine learning models; and a public workshop on fostering a patient-centered approach to AI-enabled devices, including discussions of device transparency for users.[3] This guidance intends to continue these efforts, by providing lifecycle management and marketing submission recommendations consistent with a TPLC approach for AI-enabled devices.

This guidance provides recommendations on the contents of marketing submissions for devices that include AI-enabled device software functions including documentation and information that will support FDA's review. To support the development of appropriate documentation for FDA's assessment of devices, this guidance also provides recommendations for the design and

[1] See FDA's website on Good Machine Learning Practice for Medical Device Development: Guiding Principles.
[2] See FDA's website on Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles.
[3] See FDA's website on Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device Action Plan, the Executive Summary for the "Patient Engagement Advisory Committee Meeting on Artificial Intelligence (AI) and Machine Learning (ML) in Medical Devices," and the website on the Virtual Public Workshop - Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices.

1

Authorized AI/ML-Enabled Medical Devices*

Over 1,200 AI-enabled devices have been authorized by FDA

Search: Show 50 entries

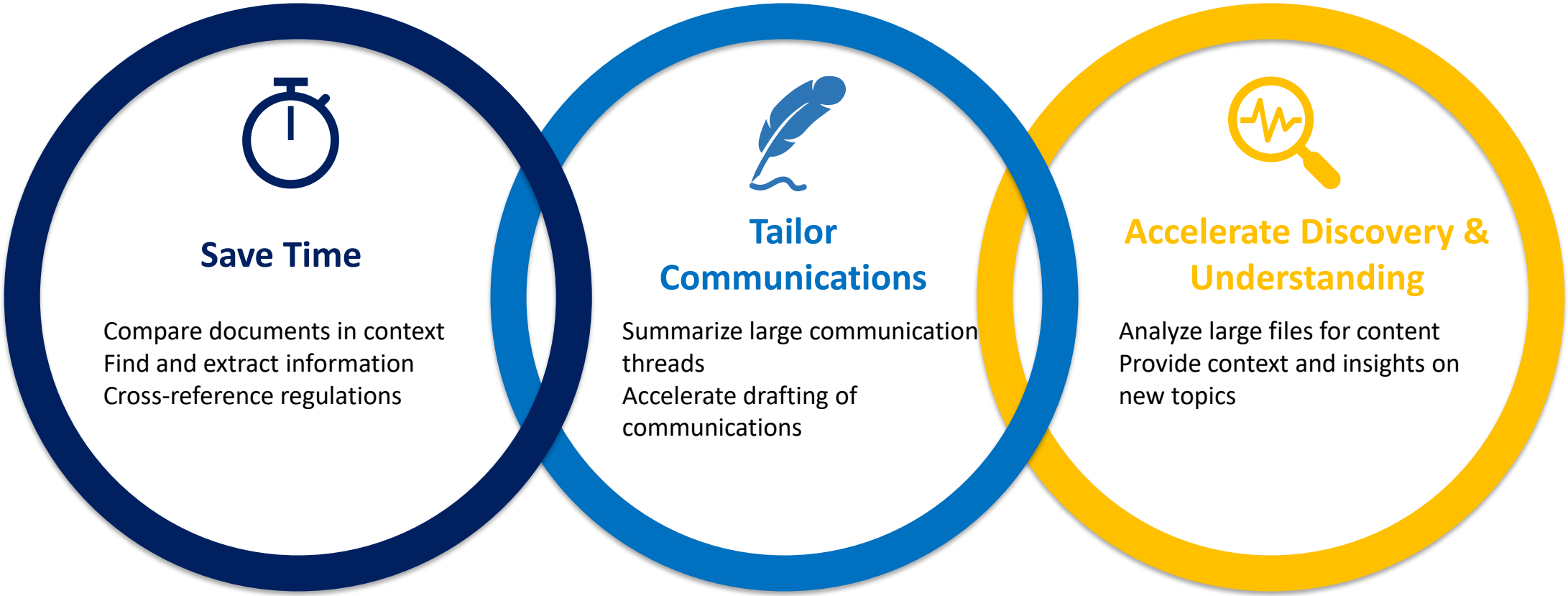
Date of Final Decision	Submission Number	Device	Company	Panel (lead)	Primary Product Code
05/30/2025	K251406	BriefCase-Triage	Aidoc Medical, Ltd.	Radiology	QAS
05/30/2025	K250236	Swoop® Portable MR Imaging® System (V2)	Hyperfine, Inc.	Radiology	LNH
05/30/2025	K243863	Opulus™ Lymphoma Precision	Roche Molecular System	Radiology	QIH
05/30/2025	K243005	AudaxCeph Cephalogram Analysis Software	Audax d.o.o.	Radiology	QIH
05/30/2025	K242830	LensHooke X3 PRO Semen Quality Analyzer; LensHooke X3 PRO SE Semen Quality Analyzer	Bonraybio Co., LTD.	Hematology	POV
05/30/2025	DEN240047	Allix5	Clairity, Inc.	Radiology	SEZ
05/29/2025	K250543	Voluson™ Performance 16; Voluson™ Performance 18	GE Medical Systems Ultr	Radiology	IYN
05/28/2025	K243378	Rapid MLS	iSchemaview Inc.	Radiology	QIH

*Updated July 2025

AI Use in CDRH's Work

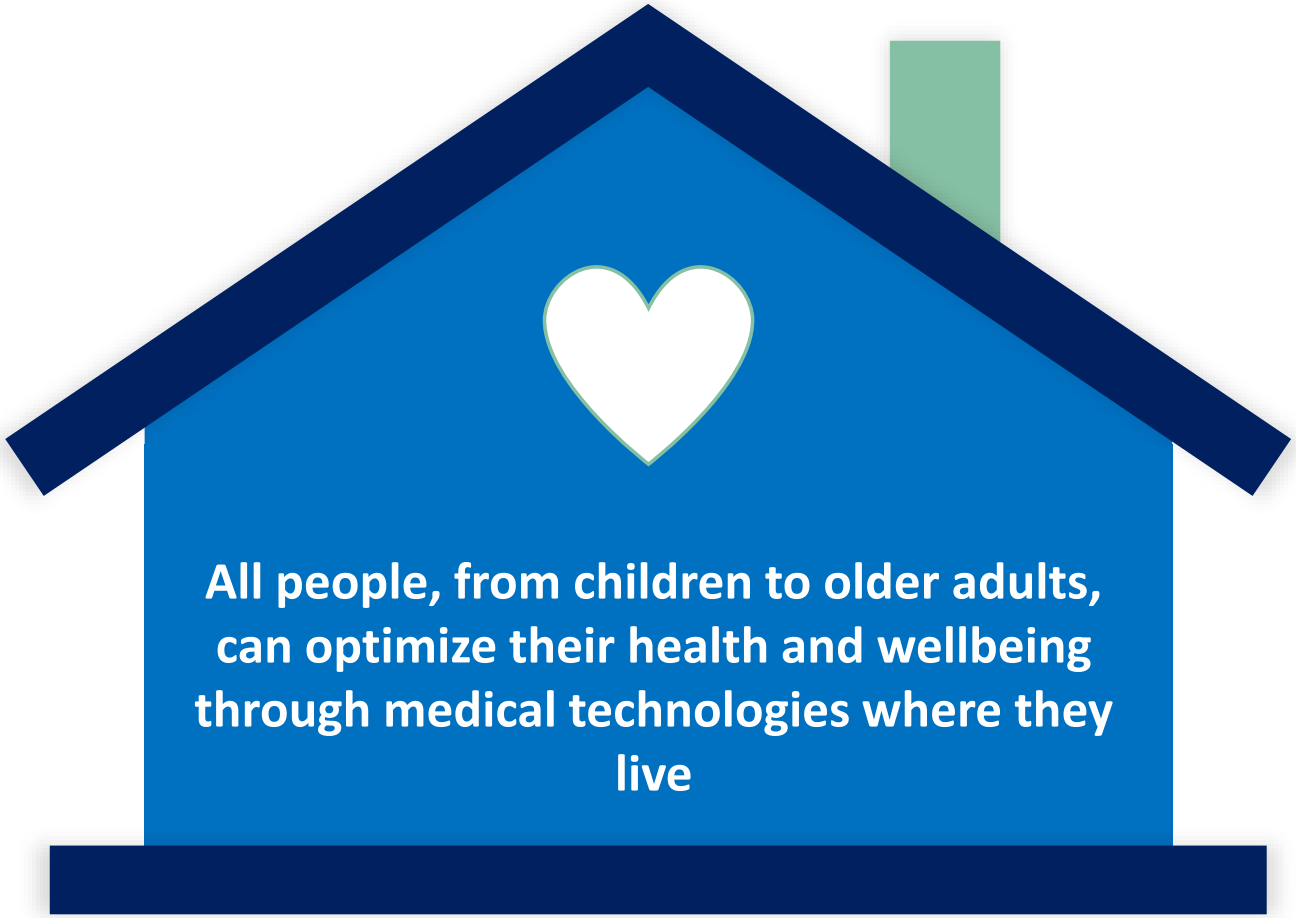
Meet Elsa: Your AI Assistant

An AI assistant designed by FDA employees for FDA employees



Home as a Health Care Hub Initiative

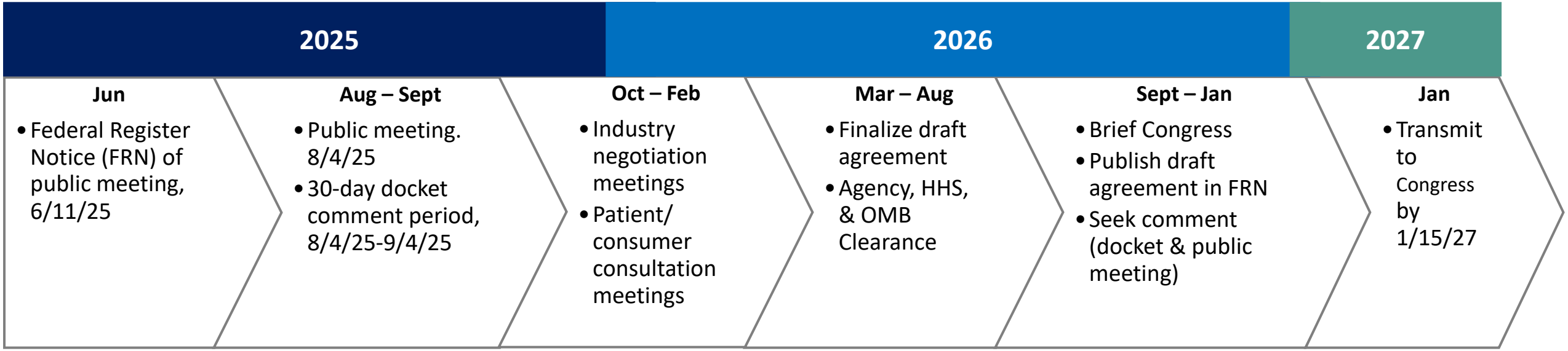
Reimagine the home environment as an integral part of the health care system, with the goal of advancing access to better health outcomes for all people in the U.S.



The Idea Lab

Fueling innovation in home use of medical devices through person-centered design

MDUFA VI Reauthorization Timeline



CDRH Vision

Patients in the U.S. have high-quality, safe, and effective medical devices of public health importance


FDA
U.S. FOOD & DRUG
ADMINISTRATION