US FDA
CDRH Update

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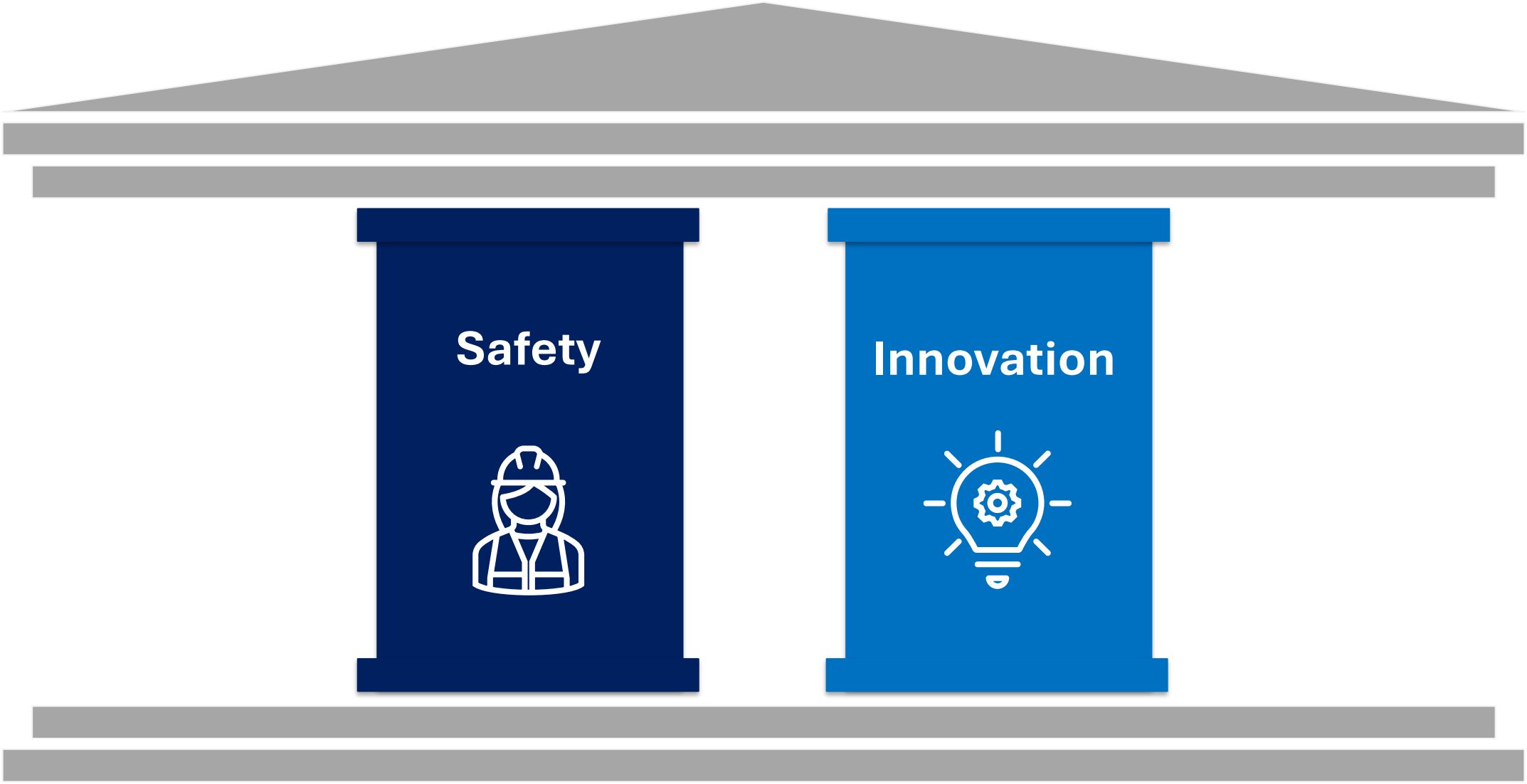
Patients are at the Heart of What We Do

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

*Our vision does not signal a competition with other countries - but rather provides a metric for timely patient access to devices that meet FDA's standards.

CDRH's Core Pillars



MDUFA V Review Performance

Submission Type	Action	Review-Time Goal	FY23 Current Performance	FY24 Current Performance	FY25 Current Performance
Original PMAs, PDPs, Panel-Track PMA Supplements, and Premarket Reports	Substantive Interaction	95% in 90 calendar days			
	Decision with No Advisory Committee Input	90% in 180 FDA days			
180-Day PMA Supplements	Substantive Interaction	95% in 90 calendar days			
	Decision	95% in 180 FDA days			
Real-Time PMA Supplements	Decision	95% in 90 FDA days			
De Novo Classification Requests	Decision	70-90% in 150 FDA days			
510(k) Premarket Notifications	Substantive Interaction	95% in 60 calendar days			
	Decision	95% in 90 FDA days			
Pre-Submissions	Provide Written Feedback	75-90% in 70 calendar days (or 5 days prior to meeting)			

Goal met

Currently meeting goal; final performance TBD

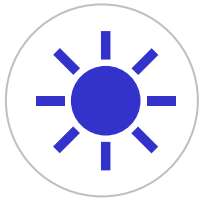
CDRH data as of 12/31/2025

MDUFA VI Proposed Committment

Advancing Regulatory Excellence through a proven Total Product Life Cycle approach to safety and innovation for medical devices.

Strengthen Core Review Fundamentals

Elevate the Quality of the Journey



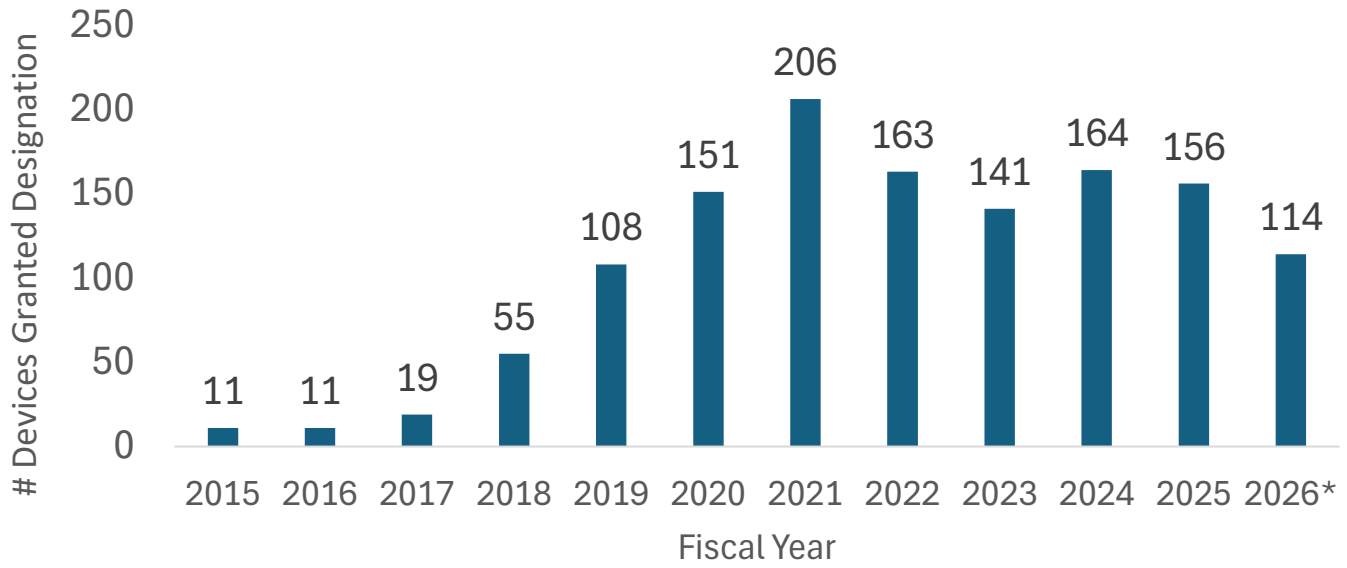
Optimize Transparency & Accountability

Breakthrough Devices Program (BDP)

1299 Designated Devices

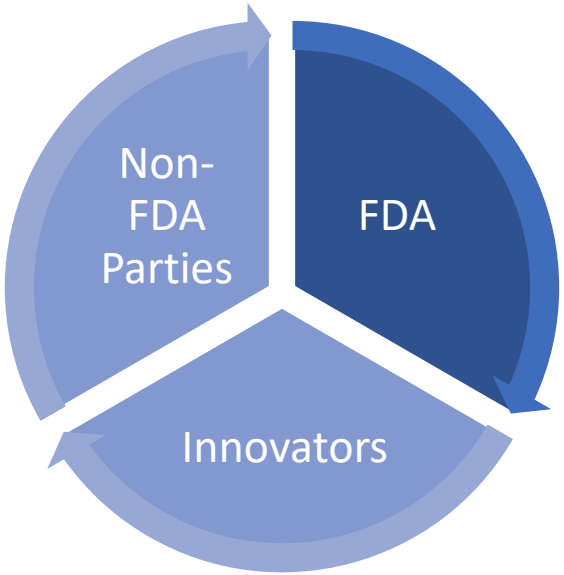
205 Marketing Authorizations

- **63** PMAs
- **91** 510(k)s
- **51** De Novos



*CDRH data as of 6/30/2026

Total Product Life Cycle (TPLC) Advisory Program (TAP)



Facilitates engagement for developers with other key parties of breakthrough devices

- More than 130 devices enrolled in TAP
- TAP expanded to all OHTs
- TAP is using lessons learned in MDUFA V to make program enhancements for MDUFA VI
  - The pilot independent assessment report is available online and indicates exceptionally high satisfaction and strong innovator endorsement.
- TAP continues to have a strong focus on engagement and collaboration between FDA and CMS and will continue to build out the relationship

CDRH data as of 7/1/2026

Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage

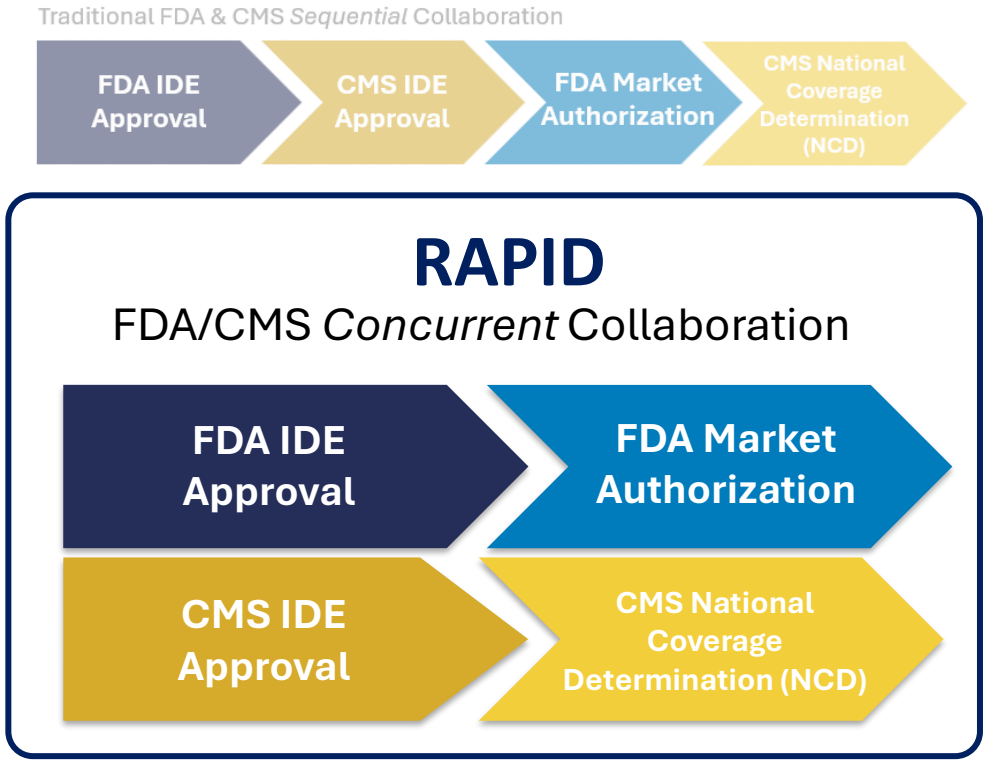
On April 23, 2026, CMS announced RAPID, a new Medicare coverage pathway

Proposed notice issued 8/7/2026; Comment period closes 10/13/2026

RAPID **accelerates beneficiary access** to eligible Class II and III FDA-designated Breakthrough Devices facilitated via FDA's TAP program

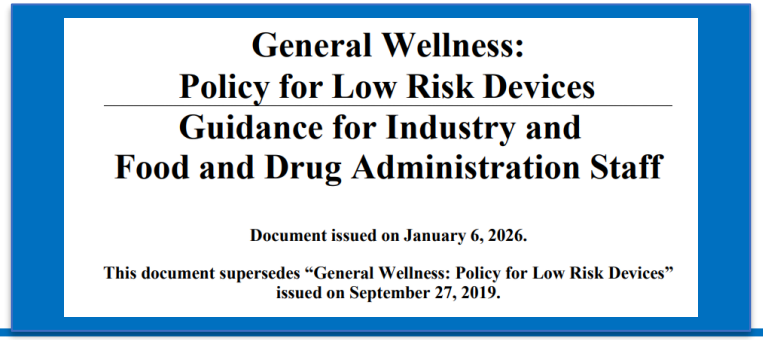
CMS and FDA align premarket review and coverage processes to provide **predictable and timely Medicare coverage**

Under RAPID, NCD **coverage** could begin **as soon as 60 days** after FDA Market Authorization



Under RAPID, CMS and FDA collaborate concurrently, so beneficiaries can have faster access to new technologies

Updated Digital Health Guidances

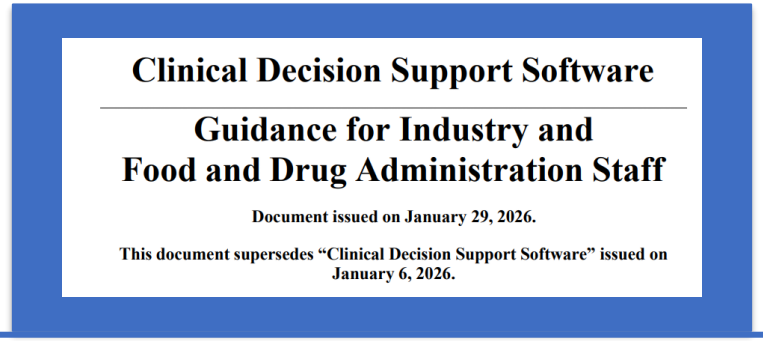

General Wellness:
Policy for Low Risk Devices
Guidance for Industry and
Food and Drug Administration Staff

Document issued on January 6, 2026.

This document supersedes "General Wellness: Policy for Low Risk Devices" issued on September 27, 2019.

General Wellness Guidance

- Clarifies FDA's policy toward low-risk general wellness products
- Supports innovation in lifestyle and wellness technologies
- Focuses FDA oversight on higher-risk products that impact diagnosis or treatment


Clinical Decision Support Software

Guidance for Industry and
Food and Drug Administration Staff

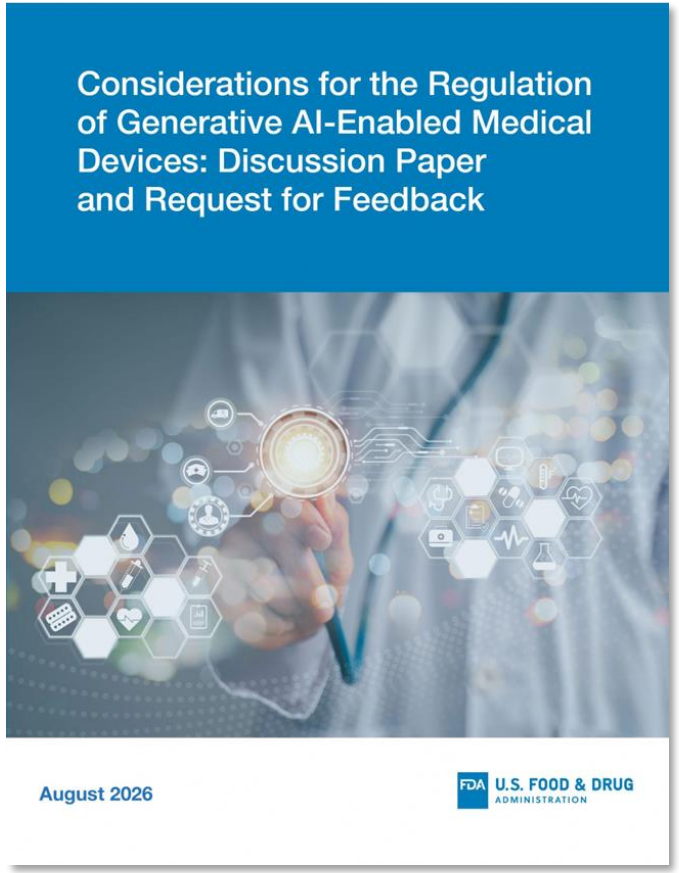
Document issued on January 29, 2026.

This document supersedes "Clinical Decision Support Software" issued on January 6, 2026.

CDS Guidance

- Clarifies scope of FDA oversight for software supporting clinical decisions
- Has a policy for clinical decision support software to output one recommendation if clinically appropriate
- Provides updated examples to support safe integration of AI-enabled tools

New Releases for Digital Health and AI



AI-Enabled Medical Devices List

Over 1,500 AI-enabled medical devices have been authorized by FDA

Date of Final Decision	Submission Number	Device	Company	Panel (Lead)	Primary Product Code
03/30/2026	K254207	AiORTA - Plan v2.0	ViTAA Medical Solutions, Inc.	Radiology	QIH
03/28/2026	K252360	ECG-AI Pulmonary Hypertension (PH) 12-Lead algorithm (1020)	Anumana, Inc.	Cardiovascular	SAT
03/27/2026	K253649	Spectral CT Verida Family	Philips Medical Systems Technologies , Ltd.	Radiology	JAK
03/27/2026	K252148	Butterfly Gestational Age Tool	Butterfly Network, Inc.	Radiology	IYN
03/27/2026	K254161	Automated Aortic Stenosis	GE Medical Systems	Radiology	POK

Data as of 9/1/2026

Technology-Enabled Meaningful Patient Outcomes (TEMPO) for Digital Health Devices Pilot

Announced on **December 8, 2025**

The pilot is intended to:

Promote access to certain digital health devices while safeguarding patient safety.

Evaluate a risk-based enforcement approach that supports digital health devices intended to improve patient outcomes in certain conditions.

Responsibly encourage innovation while collecting real-world evidence to better understand how these devices perform in real-life settings.

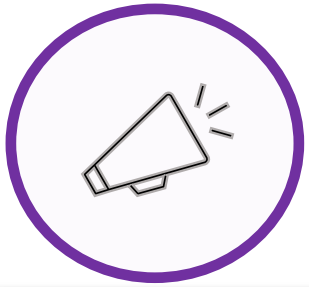
The TEMPO Pilot supports patient-centered innovation by facilitating earlier access to promising digital health devices while generating real-world evidence to inform future oversight.

4 participants selected to date

Data as of 9/1/2026

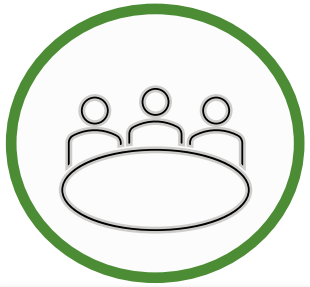
Home as a Health Care Hub

Encouraging the development of technologies that bring high quality care into the home and supporting access to health care and new models of care delivery



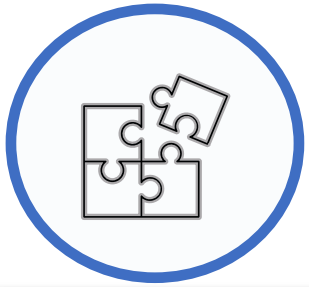
Recent News

Advancing innovation through new clearances and approvals, digital health pilot and updated public list, and new draft guidance



Insights and Engagement

Expanding Stakeholder Engagement to identify barriers and co-develop solutions



Challenging Innovators

Inviting innovators to pursue solutions for medical device technologies to be used in the home setting aimed at reducing hospital readmissions

Resources for Innovators

Developing clear pathways to demonstrate safety and effectiveness across the continuum of care, including a focus on safe, connected device ecosystems

Innovation Challenge Goal: Accelerate patient access to medical device technologies aimed at reducing hospital readmissions

FDA invites innovators to pursue potential participation in the Innovation Challenge by providing proposed solutions for medical device technologies to be used in the home setting

Submission period closes September 30, 2026

https://www.fda.gov/medical-devices/home-health-care-hub/fda-readi-home-innovation-challenge-reducing-readmissions-through-device-innovation-home

2 participants selected to date

Data as of 9/1/2026

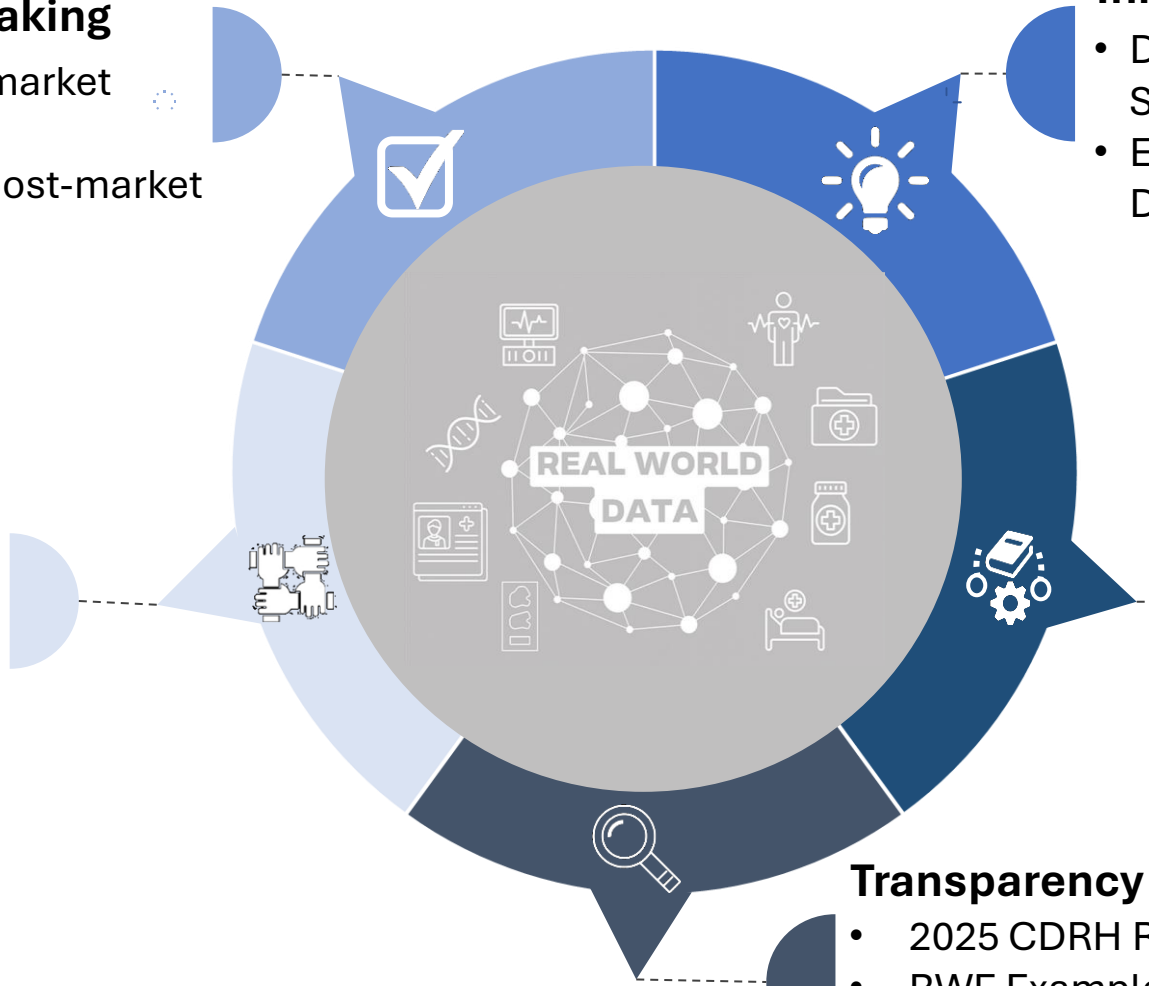
Real-World Evidence Activities

Regulatory Decision Making

- Supported over 150 premarket authorizations
- RWE used to meet >50 post-market study commitments

Innovation

- Device Identification (UDI & SHIELD)
- External Evidence Methods Development



Collaborations

- FDA Sentinel 3.0
- MDIC

Knowledge Management

- Training (e.g., SME, Focal Points)
- RWD Source Catalog

Transparency

- 2025 CDRH RWE Guidance
- RWE Examples
- Industry RWE Meetings

Quality Management System Regulation (QMSR)

Final QMSR rule published on February 2, 2024

*QMSR became effective on **February 2, 2026** (two-year transition)*

QMSR Core Actions

- Replaces the long- standing CGMP regulation: Quality System regulation
- Directly incorporates requirements from international quality management system standards (ISO 13485:2016 and ISO 9001:2015 Clause 3)
- Embeds risk-based quality requirements and globally harmonizes device quality expectations

QMSR Major Impacts

- Aligns FDA expectations more closely with international practice and risk-based lifecycle approach
- Harmonization that can simplify global quality system management expectations

Medical Device Single Audit Program

Chair & Secretariat
2026-2027

MDSAP
Medical Device Single Audit Program

7,500
MANUFACTURING SITES

81
COUNTRIES

30K+
Audits

2026 MDSAP FORUM

KYOTO, JAPAN
JUNE 15-19, 2026

MDSAP.RAC.SECRETARIAT@FDA.HHS.GOV
mdsapforum2026_secretariat@pmda.go.jp

CDRH Regulatory Reliance Portal

Resources and information to support the development of regulatory reliance programs that use CDRH as a reference regulatory authority

https://www.fda.gov/medical-devices/cdrh-international-affairs/cdrh-regulatory-reliance-portal-medical-devices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