2024 CDRH Innovation Report

CDRH is committed to advancing the core pillars of medical device safety and innovation to protect, promote, and encourage public health for all.

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

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Introduction

Medical device use has transformed over the last 50 years with tremendous advances in science and the onset of the digital age. In the past, many developers of innovative medical devices chose not to come to the U.S market first, if at all, in part due to CDRH programs, policies, and processes that lagged behind the innovation and were not fit for purpose.

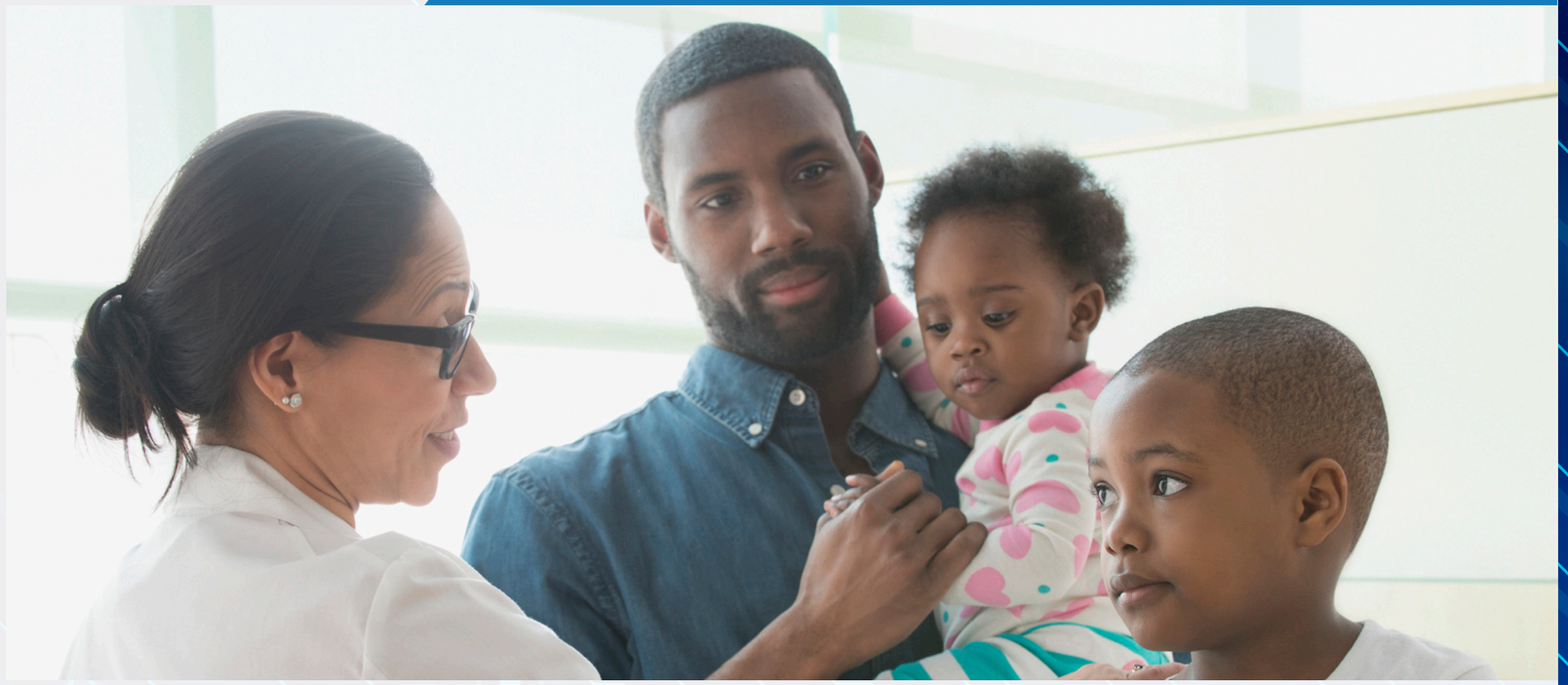
In 2009, CDRH committed to change that dynamic. As noted in our **companion report on medical device safety,** over a decade ago, CDRH established a new vision for the Center based on our two pillars of safety and innovation. This included a focus on promoting innovation, while continuing to prioritize safety, so that patients in the U.S. have timely access to high-quality, safe, and effective medical devices that have the potential to make a difference in people's lives.

Since 2009, the number of innovative medical devices we authorized annually in the U.S. increased five-fold, in no small part due to a series of actions taken by CDRH, often in collaboration with our customers and other partners.

CDRH Vision

Patients in the U.S. have access to 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 the FDA's standards.



Encouraging Innovation

We enhanced our existing premarket review programs, such as **510(k)** and **De Novo**, through new policies and more efficient processes that streamlined our review, while requiring more data to support authorizations as medical technologies became more complex. In parallel, we created new programs and structures to advance innovation, such as the Breakthrough Devices Program that grew out of our 2011 Innovation Pathway pilot, the Safety and Performance Based Pathway, the Safer Technologies Program, and our Digital Health Center of Excellence.

The **Breakthrough Devices Program** and **Safer Technologies Program (STeP)** facilitate timely access to life-saving devices by expediting regulatory review.

Interactive and timely communication.

Qualify for prioritized review.

Active engagement of senior management.

100+ Devices authorized through the Breakthrough Devices Program since program launch in 2015.

2 Devices authorized through the STeP Program since program launch in 2021.

The **Safety and Performance Based Pathway Program** ensures better quality devices on the market by allowing innovators to assess devices against performance criteria.

Enables proactive application of regulatory science.

Promotes the use of modern predicate devices.

Eliminates need to procure predicate devices.

10 Published guidances.

The **Digital Health Center of Excellence** empowers stakeholders to advance health care by fostering responsible and high-quality digital health innovation.

Strategically advancing digital health science and evidence.

Reimagining medical device regulatory paradigm tailored for digital health technologies.

Harmonizing international regulatory expectations and industry standards.

~700 AI/ML-enabled devices authorized.

Increasing Regulatory Flexibility

CDRH has updated key frameworks and policies to increase flexibility. We strengthened and streamlined the clinical trial enterprise, including through significantly reducing the time to authorize well-designed clinical trials, establishing new policies for early feasibility studies, and working with partners to create clinical trial networks. We helped establish new mechanisms to collect real-world data and to use real-world evidence to support our marketing authorization decisions and postmarket monitoring capabilities.

Reformed **Clinical Trial Program** to make it more attractive for industry to perform studies in the U.S. and patients can have earlier access to innovative technologies.

Decreased median time to clinical trial authorization by 90 percent.

Use of updated, flexible framework for **Benefit-Risk Decision-Making** to align with regulatory standard of reasonable assurance.

6 Guidances Issued.

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

100+ Devices Authorized using RWE.

Creation of National Evaluation System for health Technology (NEST).

Engaged with 100 national or regional registries from 45 countries.

Partnering with Patients and Stakeholders

Medical devices provide an opportunity to improve health equity – better health care, quality of life, and wellness for all, regardless of demographic or geographic location. We made patients our partners and incorporated their voices in the work we did across the Total Product Life Cycle, including the establishment of our Patient Science and Engagement Program. We focused our decision-making on what mattered most, implementing a modern, flexible approach to benefit-risk determinations.

We put an emphasis on providing excellent customer service, and we made a commitment to accomplish our work through collaboration with other members in the medical device ecosystem, including co-founding the Medical Device Innovation Consortium (MDIC) to advance the development of medical device regulatory science as well as establishing a qualification program for and developing a catalog of regulatory science tools. We also co-founded the International Medical Device Regulators Forum (IMDRF) to advance global harmonization so that all people have timely access to the devices they need, and facilitated the establishment of Collaborative Communities.

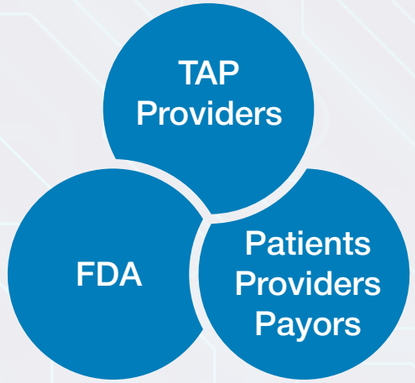
CDRH **proactively integrates patient perspectives** into the Total Product Life Cycle of medical devices to consistently place the patient at the center of what we do.	The use of peer-reviewed **Regulatory Science Tools (RSTs)** allows innovators to efficiently navigate the design and redesign loop, and expedite medical device innovation.	**The International Medical Device Regulators Forum (IMDRF)** is a group of medical device regulators from around the world that have voluntarily come together to harmonize the regulatory requirements for medical products.	**Collaborative Communities** bring stakeholders together to address health care challenges.
Patient-Reported Outcomes (PROs) included in 52% of authorizations with clinical studies, with 34% using PROs as primary and secondary endpoints. Patient-centered research projects in diverse populations across 18+ disease/condition areas. Patient engagement network with 20+ partner organizations.	Tools include methods, models, datasets, clinical outcome assessments, and more. More than 150 tools in catalog. 20+ new tools added every year. 900+ Premarket submissions cited use of RSTs.	11 Management Committee Members. 3 Official Observers. 14 Affiliate Members.	Participation in 16 Collaborative Communities.

Collaborating with Innovators

We have long recognized that making our regulatory programs more effective, efficient, and predictable is only part of the puzzle, as innovators face a variety of challenges, including payor coverage and reimbursement. The road from concept to commercialization is fraught with obstacles, which is why it has often been called the "Valley of Death."

Over the years, we have increasingly taken actions to help innovators navigate various aspects of this challenging process that impact people's access to important medical devices. In early 2023, we launched a pilot of our **Total Product Life Cycle Advisory Program (TAP)** to proactively help innovators navigate the journey from concept to commercialization, making it more predictable, efficient, and timely. We expanded the program in the fall of 2023 and plan to continue enrolling more innovators and their devices into TAP, with a goal of enrolling up to 325 by 2027.

43
TAP devices and counting



- **Better Evidence Strategy for Faster Commercialization.**
- **Accepted Devices Qualify for Priority Review.**
- **Enables Strategic Relationship Building throughout the Device Ecosystem.**
- **Expedites Innovation.**
- **Facilitates High-speed FDA Interactions.**

Looking Forward

We continue to build on these efforts. This year, we plan to take three actions to help further ensure important, innovative, high-quality, safe, and effective devices are developed and marketed to U.S. patients.

Modernize Premarket Review

Reimagine premarket review to drive innovative change.

- Communicate clear and reasonable expectations.
- Facilitate high-quality submissions and first-cycle authorizations.
- Enable agile review and decision-making.

Bring FDA to Innovators

Co-locate TAP Advisors in Innovation Geographic Hubs to support early-stage innovators in navigating the path to patient access.

- Enable early dialogue with FDA to increase transparency and predictability.
- Utilize FDA expertise as thought partners to catalyze innovation; increase efficiency and reduce risk, costs, and time.

Launch Home as a Health Care Hub

Focus prevention, wellness and health care on the person right where they live.

- Develop a prototype home model to facilitate innovation of integrated, consumer-friendly, medical-grade technology to deliver and expand access to first-class care at home.
- Expand opportunities for all people to contribute to the evidence generation process for medical devices.
- Work with developers, providers, and patients to facilitate innovation of new home-use devices.

As a result of our efforts and other actions by our collaborators, the U.S. marketplace has and continues to become more attractive for the early launch of innovative medical devices that make a meaningful difference in people's lives.

ADDITIONAL INFORMATION

U.S. FOOD & DRUG ADMINISTRATION

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