IMDRF International Medical Device Regulators Forum | 26th Session

# US FDA Update

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US Food and Drug Administration

# Overview

- Digital Health Center of Excellence
- Advancing Health Equity
- 2024 CDRH Innovation and Safety Reports

# Digital Health Center of Excellence Updates


U.S. FOOD & DRUG ADMINISTRATION

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International Medical Device Regulators Forum

# Continuing our Collaborative Approach to AI

## 2019

- Published AI/ML-SaMD Discussion Paper
- First joined Collaborative Community related to AI/ML

## 2020

- Public Workshop on AI/ML in Radiological Imaging
- Patient Engagement Advisory Committee Meeting on Patient Trust in AI/ML Devices

## 2021

- Posted List of Currently Marketed AI/ML Devices
- Published AI/ML Medical Device Software Action Plan
- Public Workshop on Transparency of AI/ML Devices
- Published Good Machine Learning Practice Principles

## 2022

**List Updated**

- Contributed to IMDRF's Key Terms & Definitions: Machine Learning Enabled Medical Devices
- Published Clinical Decision Support (CDS) Final Guidance
- Recognized new Consensus Standard on AI/ML

## 2023

**List Updated**

- Published Predetermined Change Control Plan for AI/ML Devices Draft Guidance
- Announced formation of Digital Health Advisory Committee
- Published PCCP Guiding Principles

## 2024 (so far)

**List Updated**

- Published AI & Medical Products paper on how FDA Centers are working together
- Developed AI and Medical Products page centralizing AI resources
- NPJ journal article on Transparency in AI/ML-enabled devices
- Published Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles

## Coming Soon

- Final guidance on PCCP for AI-enabled devices
- Draft guidance for Content and Lifecycle of AI-enabled devices
- First Digital Health Advisory Committee meeting – Generative AI and Medical Devices
- IMDRF Good Machine Learning Principles

## Future Plans

*AI/ML Medical Device Software Action Plan*

- ❑ Develop AI quality assurance plan and infrastructure needs
- ❑ Strengthen FDA's role in harmonizing GMLP
- ❑ Foster a patient-centered approach
- ❑ Support development of regulatory science methods
- ❑ Advance real-world performance pilots

# International Collaboration on Guiding Principles for Artificial Intelligence Support Harmonization

U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

**Good Machine Learning Practice for Medical Device Development: Guiding Principles**

October 2021

The U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) have jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). These guiding principles will help promote safe,

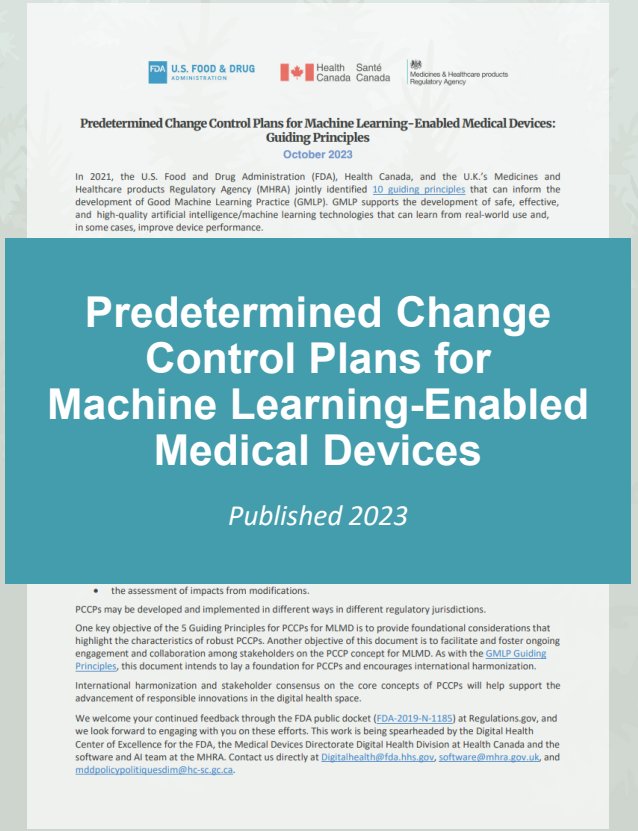
- Tailor practices from other sectors so they are applicable to medical technology and the health care sector
- Create new practices specific for medical technology and the health care sector

As the AI/ML medical device field evolves, so too must GMLP best practice and consensus standards. Strong partnerships with our international public health partners will be crucial if we are to empower stakeholders to advance responsible innovations in this area. Thus, we expect this initial collaborative work can inform our broader international engagements, including with the IMDRF.

We welcome your continued feedback through the public docket (FDA-2019-N-1185) at Regulations.gov, and we look forward to engaging with you on these efforts. The Digital Health Center of Excellence is spearheading this work for the FDA. Contact us directly at Digitalhealth@fda.hhs.gov, software@mhra.gov.uk, and mddpolicy-politiquesdim@hc-sc.gc.ca.

**Good Machine Learning Practice for Medical Device Development**

*Published 2021*



U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

**Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles**

October 2023

In 2021, the U.S. Food and Drug Administration (FDA), Health Canada, and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). GMLP supports the development of safe, effective, and high-quality artificial intelligence/machine learning technologies that can learn from real-world use and, in some cases, improve device performance.

- the assessment of impacts from modifications.

PCCPs may be developed and implemented in different ways in different regulatory jurisdictions.

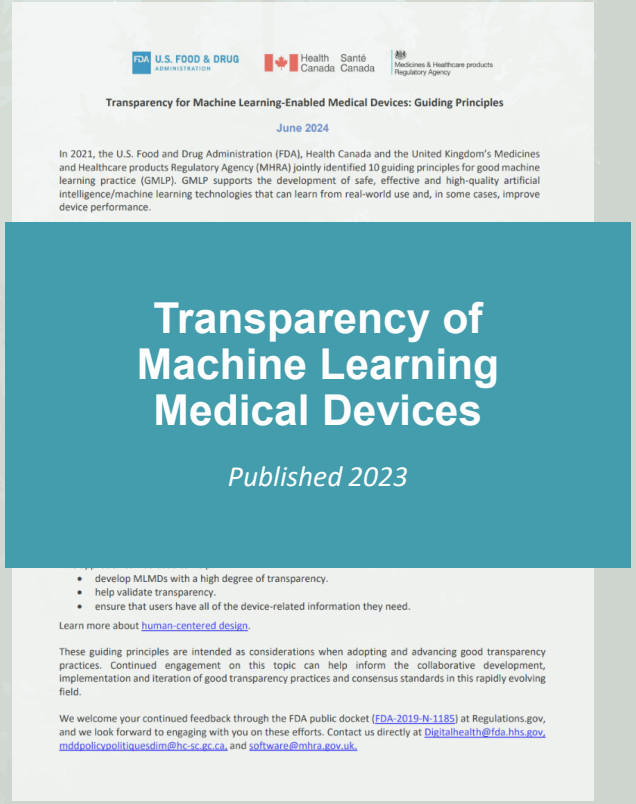
One key objective of the 5 Guiding Principles for PCCPs for MLMD is to provide foundational considerations that highlight the characteristics of robust PCCPs. Another objective of this document is to facilitate and foster ongoing engagement and collaboration among stakeholders on the PCCP concept for MLMD. As with the GMLP Guiding Principles, this document intends to lay a foundation for PCCPs and encourages international harmonization.

International harmonization and stakeholder consensus on the core concepts of PCCPs will help support the advancement of responsible innovations in the digital health space.

We welcome your continued feedback through the FDA public docket (FDA-2019-N-1185) at Regulations.gov, and we look forward to engaging with you on these efforts. This work is being spearheaded by the Digital Health Center of Excellence for the FDA, the Medical Devices Directorate Digital Health Division at Health Canada and the software and AI team at the MHRA. Contact us directly at Digitalhealth@fda.hhs.gov, software@mhra.gov.uk, and mddpolicypolitiquesdim@hc-sc.gc.ca.

**Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices**

*Published 2023*



U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

**Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles**

June 2024

In 2021, the U.S. Food and Drug Administration (FDA), Health Canada and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) jointly identified 10 guiding principles for good machine learning practice (GMLP). GMLP supports the development of safe, effective and high-quality artificial intelligence/machine learning technologies that can learn from real-world use and, in some cases, improve device performance.

- develop MLMDs with a high degree of transparency.
- help validate transparency.
- ensure that users have all of the device-related information they need.

Learn more about human-centered design.

These guiding principles are intended as considerations when adopting and advancing good transparency practices. Continued engagement on this topic can help inform the collaborative development, implementation and iteration of good transparency practices and consensus standards in this rapidly evolving field.

We welcome your continued feedback through the FDA public docket (FDA-2019-N-1185) at Regulations.gov, and we look forward to engaging with you on these efforts. Contact us directly at Digitalhealth@fda.hhs.gov, mddpolicypolitiquesdim@hc-sc.gc.ca, and software@mhra.gov.uk.

**Transparency of Machine Learning Medical Devices**

*Published 2023*

# Predetermined Change Control Plans

## 2022 Omnibus Appropriations Bill

Added section 515C to the FD&C Act so that changes to a device consistent with an approved predetermined change control plan do not require a supplemental application.

## Scope

This provision applies to all devices—it is not specific to software or AI/ML-enabled devices. It applies to both premarket approvals and 510(k) applications.

## Predetermined Change Control Plans

PCCPs are planned changes that may be made to the device (and that would otherwise require a supplemental application) if the device remains safe and effective without any change.

*Recent Guidance*

GUIDANCE DOCUMENT

**Predetermined Change Control Plans for Medical Devices**

*Draft Guidance for Industry and FDA Staff*

AUGUST 2024

GUIDANCE DOCUMENT

**Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions**

*Draft Guidance for Industry and Food and Drug Administration Staff*

APRIL 2023

# Digital Health Advisory Committee (DHAC)

**Purpose:** Solicit views from technical and scientific subject matter experts to improve the FDA's understanding of the Digital Health Technologies (DHT's) that supports safe and effective regulation while encouraging innovation.

## Charter

- **Topics**
  - AI, digital diagnostics, digital therapeutics, AR/VR, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, cybersecurity, others.

- **Duties**
  - Advise the FDA on issues related to Digital Health Technologies (DHTs). Provide expertise and perspective to improve Agency understanding of the benefits & risks,
  - New approaches to develop and evaluate DHTs.
  - Promote innovation, identifying barriers.
  - Consider unintended consequences from policy or regulation.

## Committee

- **Standing members**
  - *(8) Academic/practitioners*
  - *(1) Consumer representative (nominated by consumer orgs.)*

- **Industry representative**
  - *Non-voting; (1) nominated by industry per meeting/topic*

- **Temporary members**
  - Qualified pool of scientific and technical experts.
  - The number of temporary members selected for a particular meeting will depend on the meeting topic.

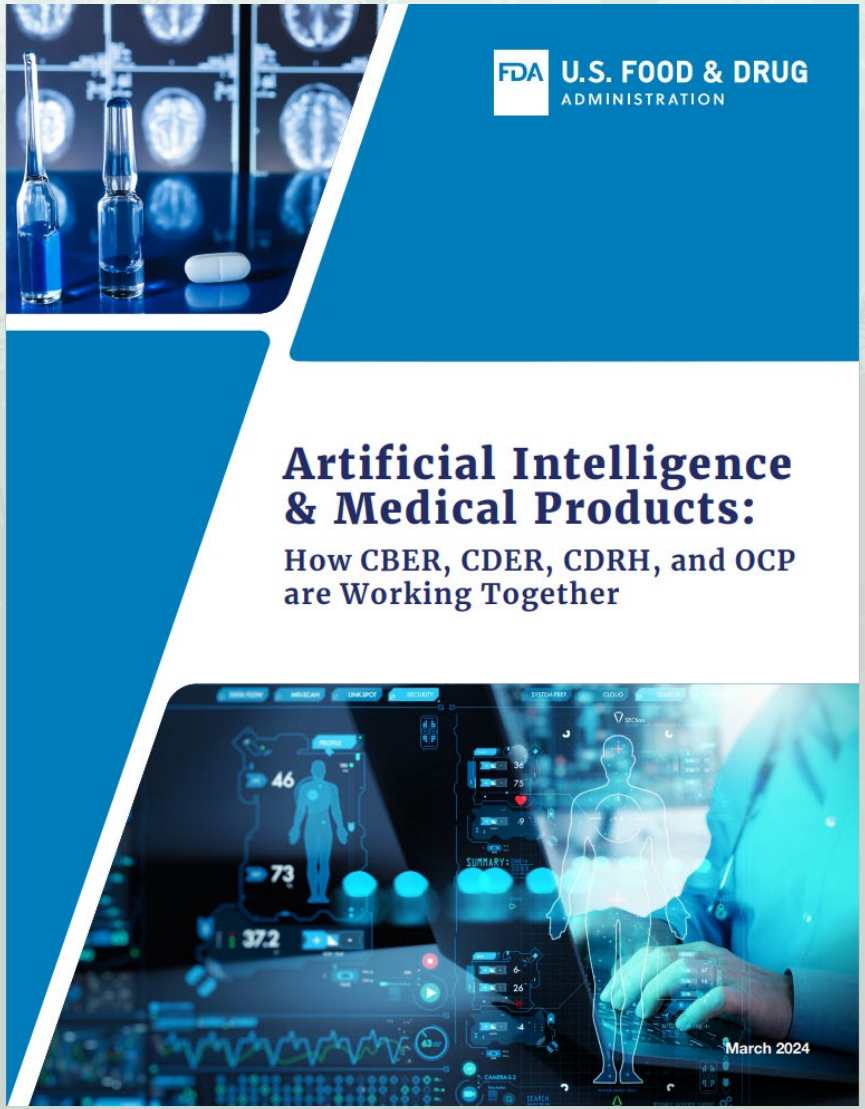
# FDA Digital Health Advisory Committee Provides Our Commissioner with Expertise on Digital Health Issues


**Save the Date:**

November 20-21, 2024: FDA will hold its inaugural Digital Health Advisory Committee meeting in person in Gaithersburg, MD, with simultaneous webcast.

# Artificial Intelligence Paper Outlines FDA's Approach to Protect Public Health and Promote Ethical Innovation

*Published March 2024*



# Advancing Health Equity

SEATTLE WASHINGTON
SEA KING COUNTY "The Emerald City" The City of Flowers

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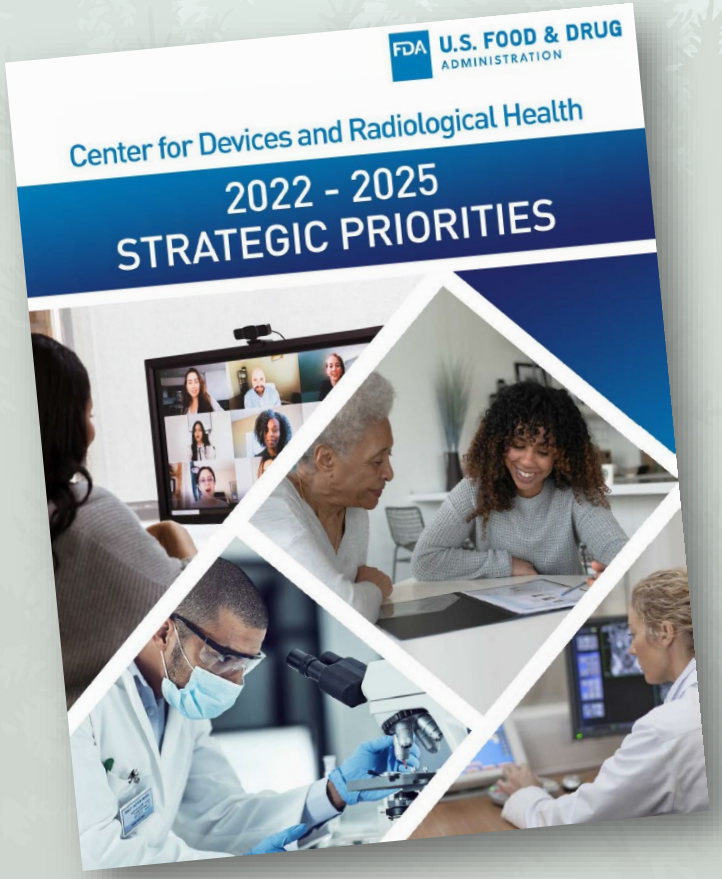
# CDRH 2022–2025 Strategic Priorities




1. PROMOTE A MODERN AND DIVERSE WORKFORCE
2. ENHANCE ORGANIZATIONAL AGILITY AND RESILIENCE
3. ADVANCE HEALTH EQUITY

# CDRH 2022-2025 Strategic Priority
# Advancing Health Equity

## Empower People
to make informed decisions regarding their healthcare

## Facilitate Availability
of and access to medical technologies for all populations

## Reduce Barriers
and increase opportunities for participation by diverse populations in evidence generation

## Support Innovation
of technologies that address health disparities

# Transforming the Healthcare System

- No person should be left behind in healthcare
- Clinical care and evidence generation centered on the person not the system
- Health and wellness delivered at home and uniquely shaped experientially for the occupant
- Integrative medical devices and technology that are not interruptive, distracting and counter to the home experience are the way of the future
- Home is the frontier often neglected in device development and conceptualization but critical to their success

# Home as a Healthcare Hub

CDRH is launching the co-creation of virtual-reality **prototypes of homes**

- To facilitate innovation of integrated, consumer-friendly, medical-grade technology to deliver and expand access to first-class care at home
- In collaboration with an architectural firm, patient groups, healthcare providers, and medical device industry

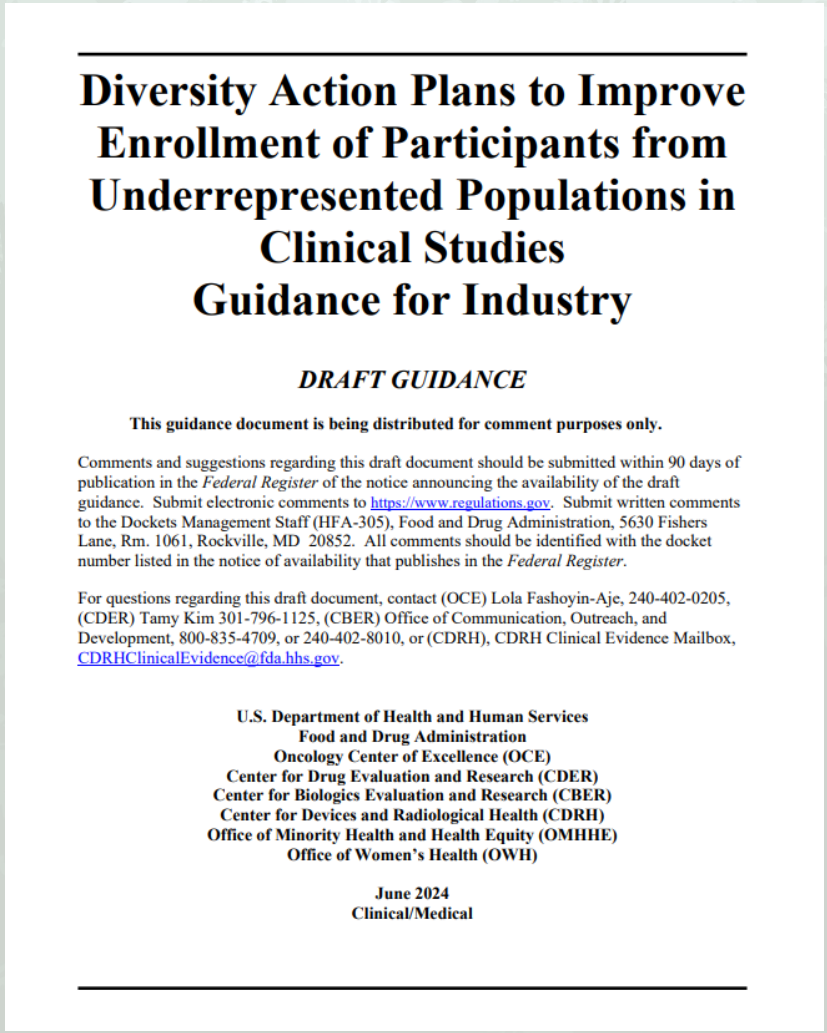
**Home as a Healthcare Hub**

Facilitate adaptation of existing devices and development of innovative new devices to nestle unobtrusively in the home environment

Foster the discussion of frameworks and identification of missing critical elements in a precompetitive space

Pilot effort in the clinical area of diabetes given marked racial, ethnic, and geographic disparities in prevalence and burden of disease

# Diversity Action Plan Draft Guidance



**Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies**
**Guidance for Industry**

***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE) Lola Fashoyin-Aje, 240-402-0205, (CDER) Tamy Kim 301-796-1125, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or (CDRH), CDRH Clinical Evidence Mailbox, CDRHClinicalEvidence@fda.hhs.gov.

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Oncology Center of Excellence (OCE)**
**Center for Drug Evaluation and Research (CDER)**
**Center for Biologics Evaluation and Research (CBER)**
**Center for Devices and Radiological Health (CDRH)**
**Office of Minority Health and Health Equity (OMHHE)**
**Office of Women's Health (OWH)**

**June 2024**
**Clinical/Medical**

- Issued in June 2024
- Intended to increase clinical study enrollment of participants of historically underrepresented populations
- Enhances understanding of the disease or medical product under study
- Outlines the
  - Format and content required for diversity action plans
  - When a plan is required
  - Timing and Process for submitting plans
  - Criteria and process for evaluating waiver requests

# CDRH Innovation and Safety Reports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# CDRH Innovation Report

- Encouraging Innovation
  - Breakthrough devices program
  - Safer Technologies Program (STeP)
  - Safety and Performance Based Pathway
  - Digital Health Center of Excellence
- Increasing Regulatory Flexibility
  - Reformed the clinical trial program
  - Benefit-Risk Decision Making
  - Use of Real-World Data and Evidence
- Partnering with Patients and Stakeholders
  - Integrating patient perspectives
  - Use of Regulatory Science Tools
  - IMDRF
  - Collaborative Communities
- Collaborating with Innovators
  - Total Product Lifecycle Advisory Program (TAP)

# CDRH Safety Report

- Enhancing Manufacturing Quality
  - Case for Quality Program
  - Medical Device Single Audit Program (MDSAP)
  - Medical Device Innovation Consortium (MDIC)
  - Quality Management System Regulation (QMSR)
- Strengthening Postmarket Surveillance
  - National Evaluation System for Health Technology (NEST)
  - Unique Device Identifier (UDI) System
  - Medical Data Enterprise Initiative
- Increasing Data Transparency, Communication, and Collaboration
  - IMDRF
  - Emerging Signals Guidance
  - Improvements to Manufacturer and User Facility Device Experience (MAUDE)
  - Launched Customer Collaboration Portal
- Strengthening Medical Device Recall Program
- Executing the Medical Device Safety Action Plan


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# THANK YOU