Digital Health Regulatory Update: United States

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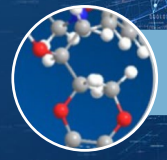
What is digital health technology?

"A system that uses computing platforms, connectivity, software, and sensors for healthcare and related uses"

Used as a medical product

Incorporated into a medical product

Used as a wellness product



Used to develop or study a medical product

Used as a companion or adjunct to a medical product, including diagnostics and therapeutics

Source: BEST (Biomarkers, EndpointS, and other Tools) Resource, 2016 (www.ncbi.nlm.nih.gov/books/NBK338448/)

Digital health technologies function across the healthcare continuum

Healthy Living | Prevention | Diagnosis | Treatment | Rehabilitation | Home Care | Management

Moving healthcare from the clinic to the patient

Understanding physiology and behavior in the real world

Leveraging, sensors, connectivity, and software

Digital Health & AI

1200+ FDA authorized AI/ML-enabled medical devices

Milestones

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 Authorized 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
- Published Digital Health Policy Navigator

2023

List Updated

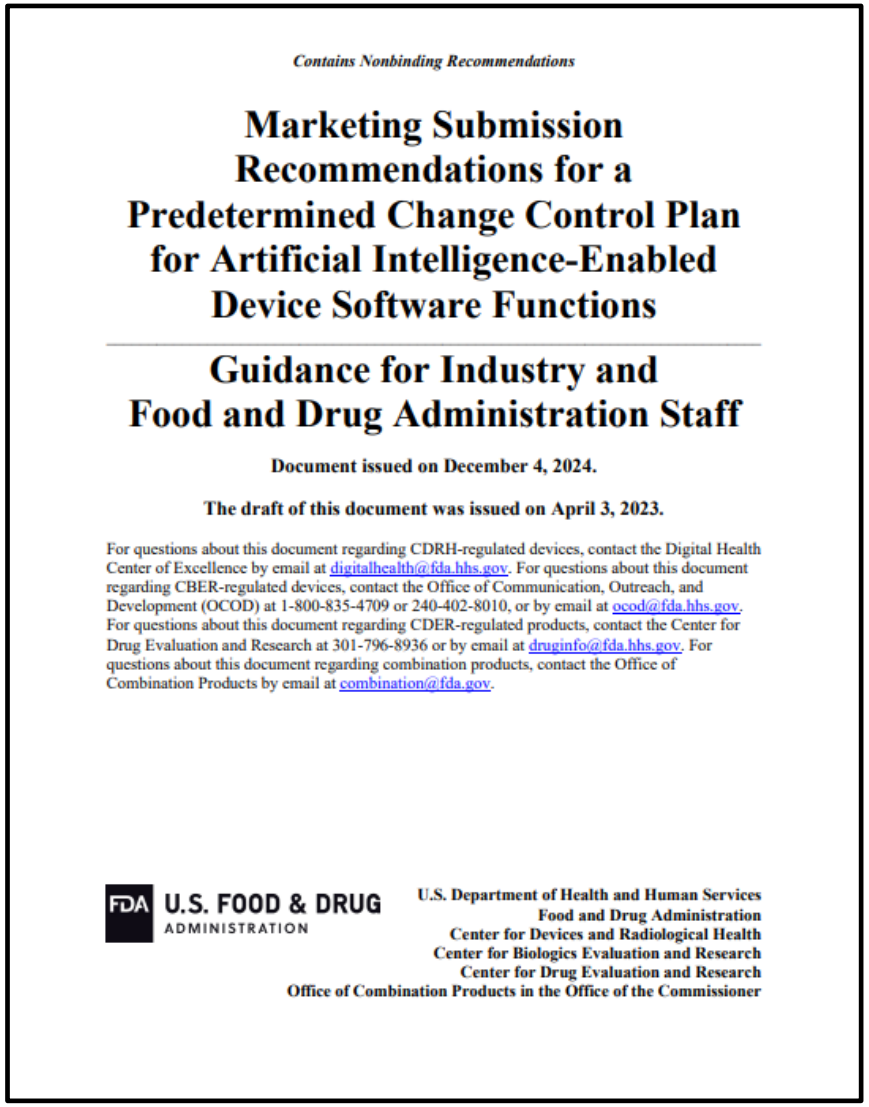
- Published Predetermined Change Control Plan for AI/ML Devices Draft Guidance
- Announced formation of Digital Health Advisory Committee
- Published PCCP Guiding Principles

2024 / 2025

List Updated

- Published AI & Medical Products paper on how CBER, CDER, CDRH, and OCP are working together
- Developed AI and Medical Products page centralizing AI resources across FDA.gov
- NPJ journal article on Transparency in AI/ML-enabled devices
- Published AI Glossary
- Published w/MHRA & HC ML Transparency Principles Document
- Published PCCP for AI-enabled devices final guidance
- Held first Digital Health Advisory Committee meeting (GenAI)
- Published Content and Lifecycle of AI-enabled devices draft guidance (2025)
- Co-led development of IMDRF Good ML Principles Document (2025)

Digital Health & AI Guidance



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 digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact the Center for Drug Evaluation and Research at 301-796-8936 or by email at druginfo@fda.hhs.gov. For questions about this document regarding combination products, contact the Office of Combination Products by email at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

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Center for Biologics Evaluation and Research
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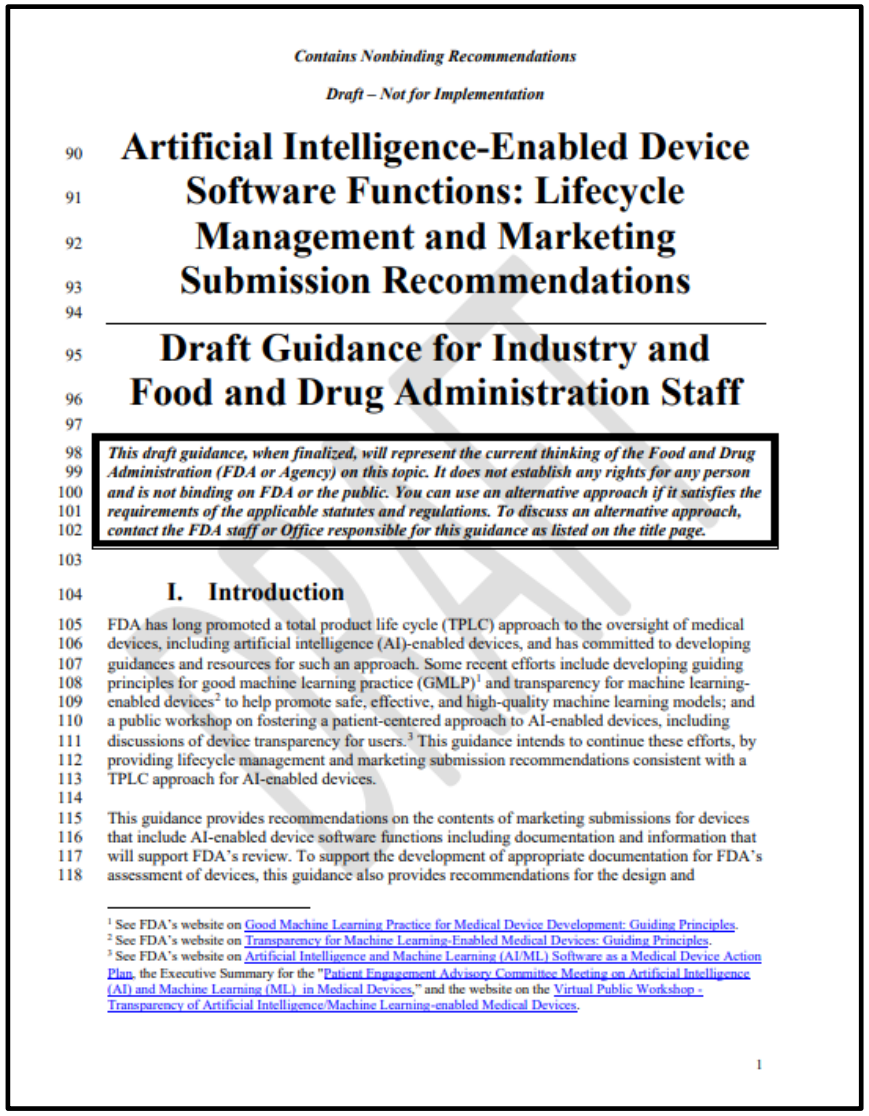
Office of Combination Products in the Office of the Commissioner



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.

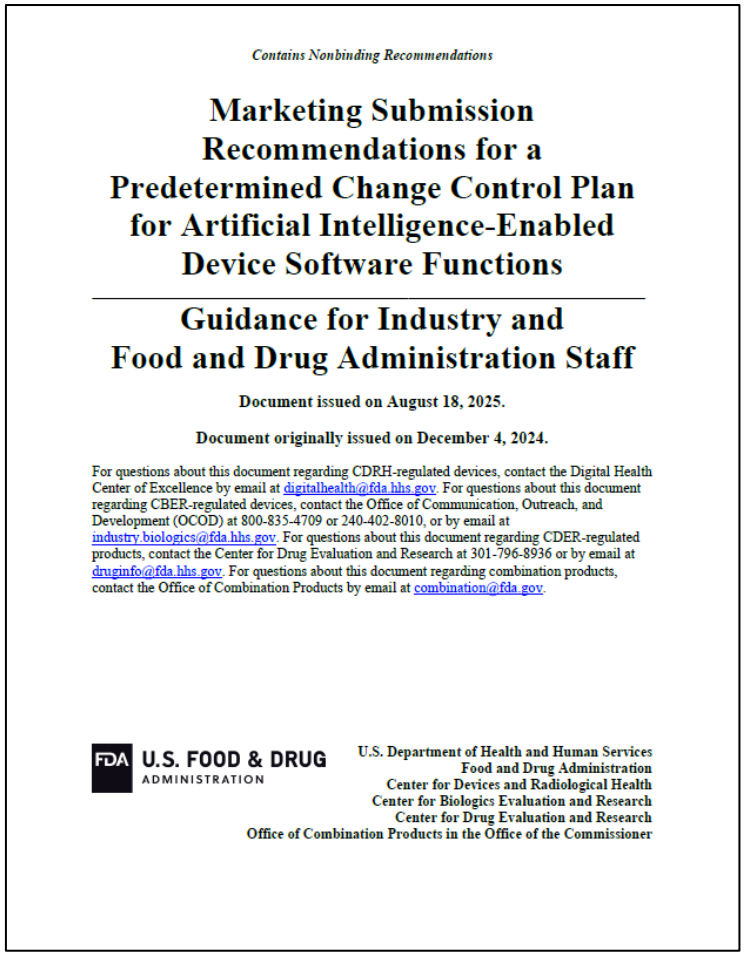
This guidance provides recommendations on the contents of marketing submissions for devices that include AI-enabled device software functions including documentation and information that will support FDA's review. To support the development of appropriate documentation for FDA's assessment of devices,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

Pre-Determined Change Control Plan (PCCP)

- Allows for certain iterative changes without further FDA review after devices receive marketing authorization
  - Not limited to digital health technologies…
  - … but can be especially beneficial for them



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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

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The Digital Health Center of Excellence (DHCoE)

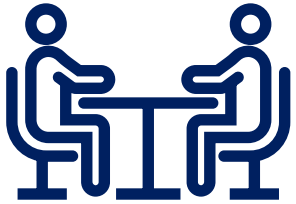
DHCoE encourages the development of innovative, safe, and effective medical devices, including devices that incorporate sensor-based digital health technology.

Regulatory Accelerator: curated resources to support the 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



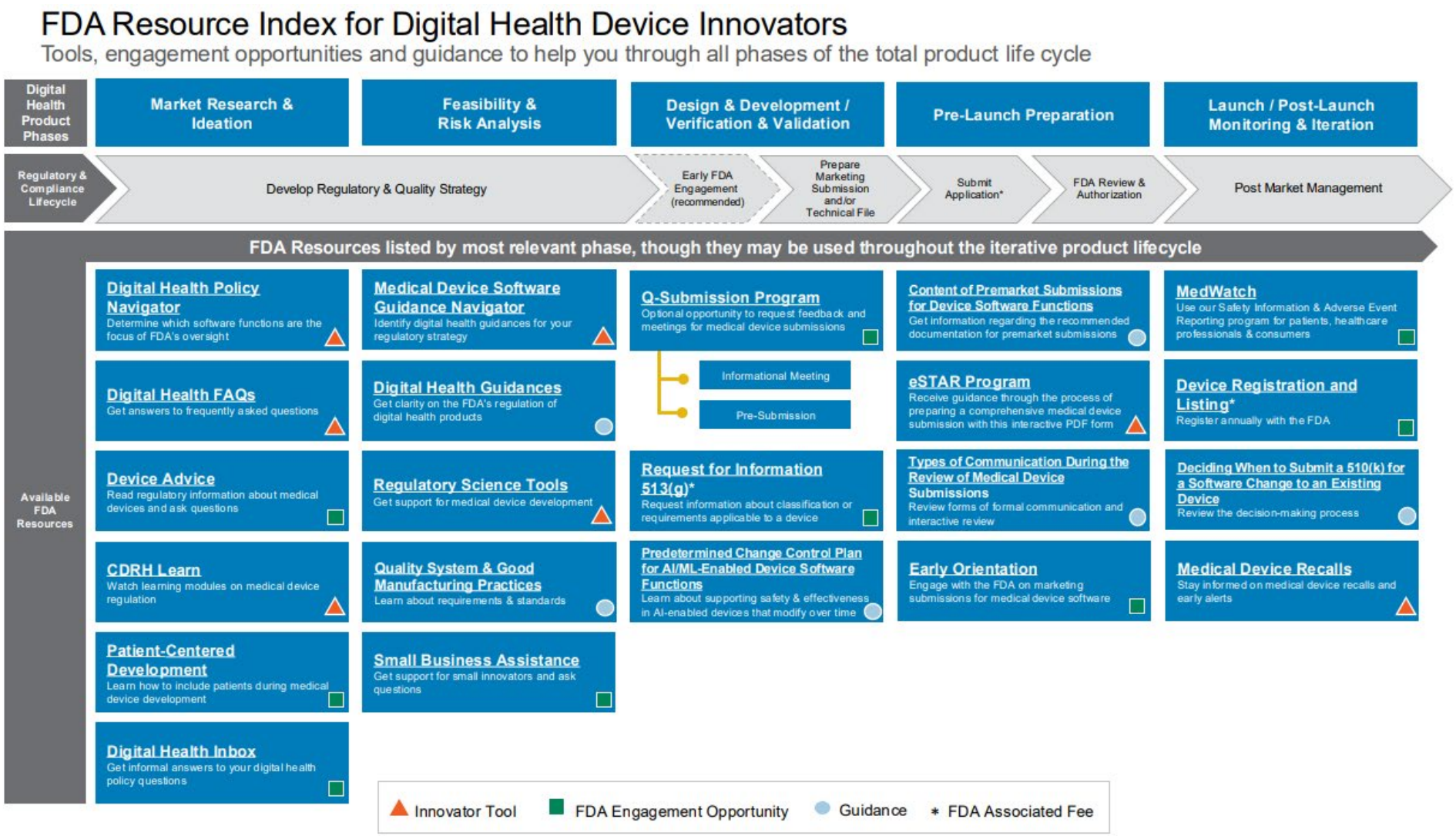
Best practices for engaging early with the FDA on marketing submissions on medical device software

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

Resource Index for DH Device Innovators



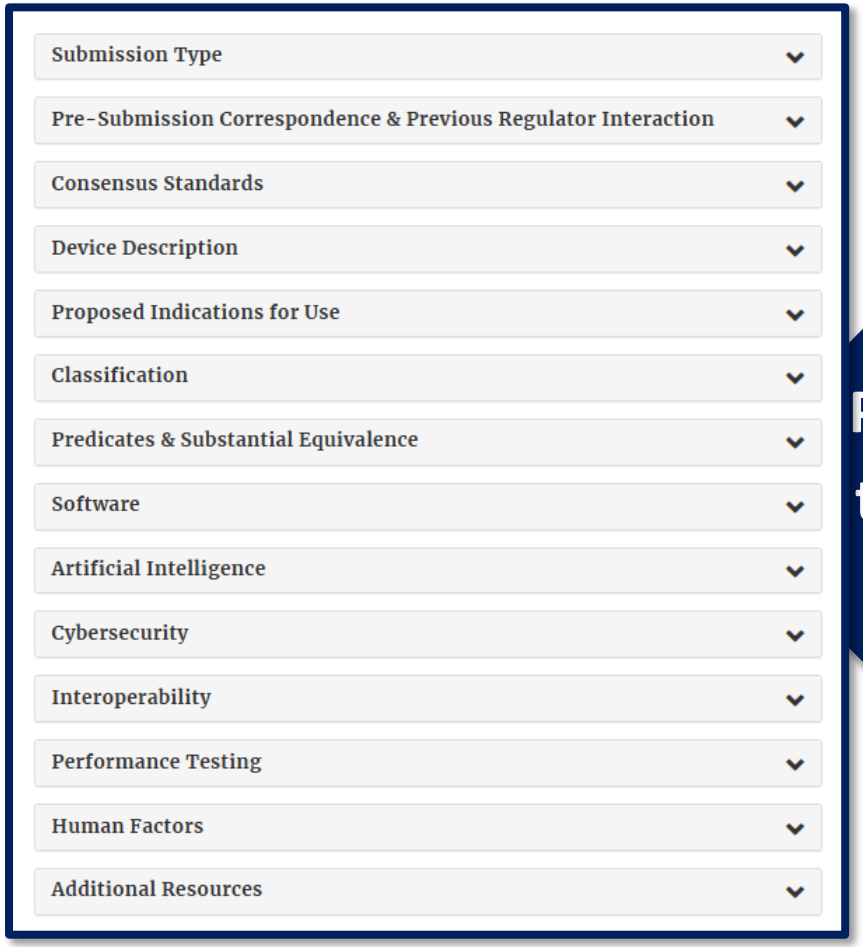
Early Orientation Meetings for Marketing Submissions with Medical Device Software

Optional, interactive review mechanism for sponsors to provide an overview and device demonstration to the FDA review team to facilitate understanding of a device under review

Best Practices

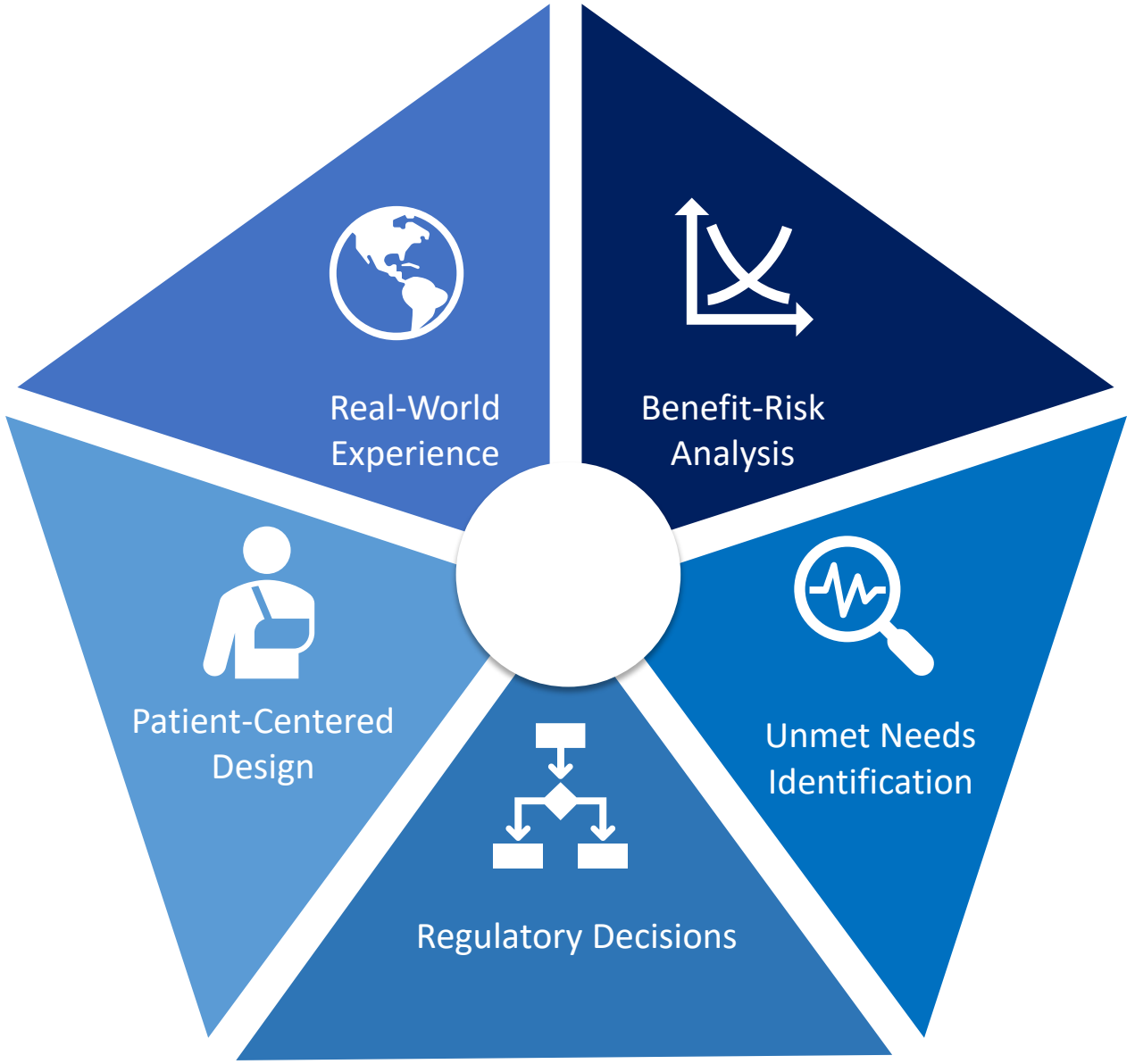
- ✓ When to Consider a Meeting
- ✓ Requesting a Meeting
- ✓ Scheduling the Meeting
- ✓ Preparing for the Meeting
- ✓ Interacting with the FDA During the Meeting

Medical Device Software Guidance Navigator



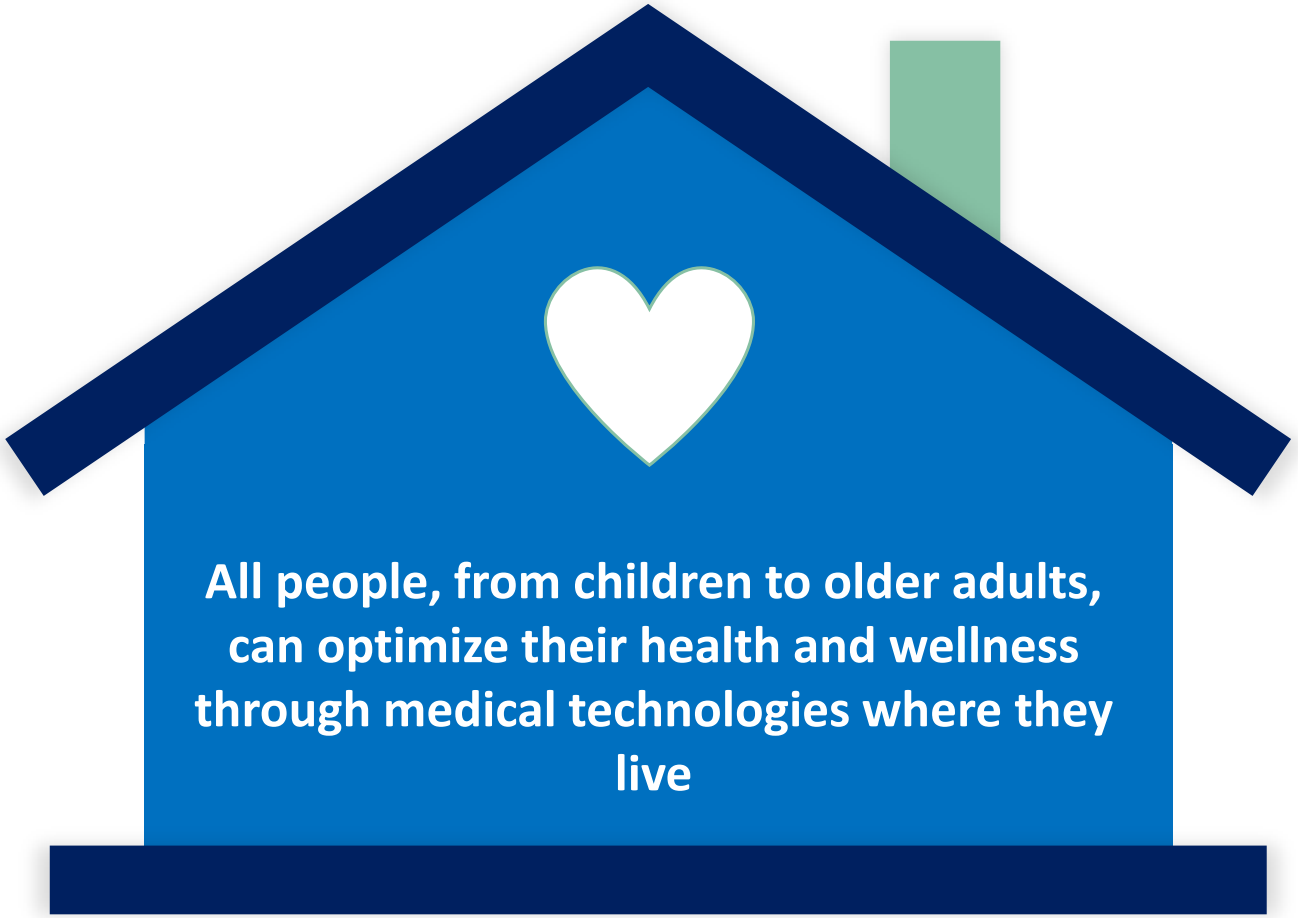
Provides a streamlined approach for innovators to identify guidances that may be applicable to their device across the development life cycle

The value of the patient voice



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.

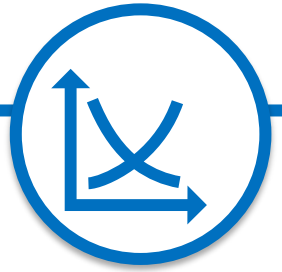


Methods to measure the patient's experience

Clinical Outcome Assessments

Measures that reflect how a patient feels & functions

e.g., PROs



Patient Preference Information

Captures how patients value benefits and risks

e.g., survey-based methods

Patient-Generated Health Data

Health related data recorded by patients

e.g., wearables

How are we building global collaborations in digital health?

Guiding Principles for Artificial Intelligence

Good Machine Learning Practice for Medical Device Development

Published 2021

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, effective, and high-quality medical devices that use artificial intelligence and machine learning (AI/ML).

Artificial intelligence and machine learning technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. They use software algorithms to learn from real-world use and in some situations may use this information to improve the product's performance. But they also present unique considerations due to their complexity and the iterative and data-driven nature of their development.

These 10 guiding principles are intended to lay the foundation for developing Good Machine Learning Practice that addresses the unique nature of these products. They will also help cultivate future growth in this rapidly progressing field.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Security Practices Are Implemented
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Training Data Sets Are Independent of Test Sets
Selected Reference Datasets Are Based Upon Best Available Methods	Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
Focus Is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Users Are Provided Clear, Essential Information	Deployed Models Are Monitored for Performance and Re-training Risks are Managed

The 10 guiding principles identify areas where the International Medical Device Regulators Forum (IMDRF), international standards organizations, and other collaborative bodies could work to advance GMLP. Areas of collaboration include research, creating educational tools and resources, international harmonization, and consensus standards, which may help inform regulatory policies and regulatory guidelines.

We envision these guiding principles may be used to:

- Adopt good practices that have been proven in other sectors
- 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.

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

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.

In this document, FDA, Health Canada, and MHRA jointly identified 5 guiding principles for predetermined change control plans. These principles draw upon the overarching GMLP guiding principles, in particular principle 10, which states that deployed models are monitored for performance and re-training risks are managed.

Advancements in digital health technologies include artificial intelligence/machine learning-enabled medical devices (MLMD). Regulatory expectations that are aligned with best practices for development and change management, such as those described in the GMLP Guiding Principles, can help to support the quality of such devices. Ultimately, this can lead to patient benefits such as earlier access to innovative technologies or more accurate diagnoses.

The change management process helps to ensure the ongoing safety and effectiveness of devices in the face of change throughout the device's total product lifecycle (TPLC). However, certain changes to MLMDs, such as changes to a model or algorithm, may be substantive or significant. For this reason, they can require regulatory oversight, such as additional premarket review. Such regulatory expectations may not always coincide with the rapid pace of MLMD development.

Internationally, the medical device community is discussing the use of predetermined change control plans (PCCPs) as a way of managing certain device changes where regulatory authorization before marketing is typically required. PCCPs can be used to help:

- align regulatory processes with the rapid and ongoing approach to change management in MLMDs
- manage risks in a timely and ongoing fashion through monitoring, maintenance, and/or improving device performance
- uphold high regulatory standards to ensure device safety and effectiveness.

For this document, the term PCCP describes a plan, proposed by a manufacturer, that specifies:

- certain planned modifications to a device
- the protocol for implementing and controlling those modifications and
- 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.

Transparency of Machine Learning 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.

Learn more: Good machine learning practice for medical device development: Guiding principles

The FDA, Health Canada and MHRA have further identified guiding principles for transparency for machine learning-enabled medical devices (MLMDs). These principles build upon the GMLP principles, especially:

- principle 7: Focus is placed on the performance of the human-AI team.
- principle 9: Users are provided clear, essential information.

While the guiding principles presented here promote transparency for MLMDs, transparency is a good practice to consider for all medical devices.

In this document, "transparency" describes the degree to which appropriate information about a MLMD (including its intended use, development, performance and, when available, logic) is clearly communicated to relevant audiences. "Logic" refers to information about how an output or result was reached or the basis for a decision or action. The degree to which this logic can be explained in a way that a person can understand is known as "explainability". Logic and explainability are aspects of transparency.

Effective transparency:

- ensures that information that could impact risks and patient outcomes is communicated.
- considers the information that the intended user or audience needs and the context in which it's used.
- uses the best media, timing and strategies for successful communication.
- relies on a holistic understanding of users, environments and workflows.

Another important concept related to transparency is "human-centered design". This is an iterative process that addresses the whole user experience and involves relevant parties throughout design and development. This approach can be used to help:

- 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.

IMDRF and Digital Health

- **AI/ML-Enabled Devices**
  - Key definitions
  - Good machine learning practices
- **Software as a Medical Device**
  - Key definitions
  - Risk categorization
  - Application of quality management system
  - Clinical evaluation
  - Characterization considerations

IMDRF
International Medical Device Regulators Forum

US - Japanese Partnerships: Next Steps?

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U.S.-Japan Regulatory Collaboration

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U.S.-Japan Regulatory Collaboration

The FDA's Center for Devices and Radiological Health (CDRH) recognizes the importance of globally harmonized medical device regulatory policy and practices. This page explains how the FDA collaborates with stakeholders in Japan through the Harmonization by Doing (HBD) initiative, and provides information on programs, resources, and accomplishments.

Through HBD-led projects, U.S. and Japanese regulators (including the FDA), academia, and industry collaborate regularly to promote regulatory convergence and address barriers that may delay patients in both countries from getting timely access to safe and effective medical devices.

Content current as of:
07/13/2023

https://www.fda.gov/medical-devices/cdrh-international-affairs/us-japan-regulatory-collaboration

Thank you!

ご清聴ありがとうございます！