FDA PERSPECTIVE ON SOFTWARE AS A MEDICAL DEVICE

Vinay M. Pai, PhD, MBA

Digital Health Specialist, CDRH Digital Health Center of Excellence

Office of Science and Technology (OST), Center for Devices & Radiological Health (CDRH), US FDA

Patients are at the Heart of What We Do

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

CDRH's Digital Health Center of Excellence

is advancing health care by fostering responsible and high-quality digital health innovation.

Digital Health Technologies are TRANSFORMING health care.

AI-enabled device for skin cancer evaluation

Digital therapy device to reduce sleep disturbance for psychiatric conditions

Virtual reality behavioral therapy device for pain relief

Digital therapy device for Attention Deficit Hyperactivity Disorder

Electrocardiograph software for over-the-counter use

In 2023, the DHCoE focused on …

Fostering Responsible Innovation

CDRH has authorized more than **700 AI/ML-enabled medical devices**, and more are under development.

Published "**Frequently Asked Questions**" resource for developers / innovators.

Ensuring Safe & Effective Digital Health Technology

Issued draft guidance on **Predetermined Change Control Plans** for Artificial Intelligence–enabled devices.

Issued final guidance to support stakeholders with **premarket submissions for device software functions.**

Collaborating Across the Ecosystem

Created a **Digital Health Advisory Committee** to solicit views from subject matter experts to improve FDA's understanding of DHTs.

Became a Federal Observer to the **Coalition for Health AI** (CHAI); and **international collaboration** with IMDRF, DH think tank, Health Canada, MHRA, among others**.**

Increasing Digital Health Literacy and Advancing Equity

Released infographics to support patients & health care professionals considering **Augmented Reality or Virtual Reality** in health care.

Issued final guidance to support the use of **DHTs for remote data collection** in clinical investigations.

… And more is on the horizon.

Publish final guidance on **Predetermined Change Control Plans** for **AI-enabled devices** and draft guidance on **AI/ML Content and Lifecycle Management**.

Continue developing educational digital health resources for innovators / developers / patients.

Hold our first **Digital Health Advisory Committee meeting.** Continue engaging **nationally and internationally** to explore regulatory approaches to digital health technologies.

Continue to **develop software and digital health technical expertise**.

Continued focus on health equity in how **DHTs can support decentralized trials and remote patient monitoring**, which will help underserved populations access health care.

We foster digital-health focused collaborations and interactions that advance public health

CERSIs

FDA's Centers of Excellence in Regulatory Science and Innovation

Collaborations between FDA and academic institutions through innovative research, training, and scientific exchanges.

Collaborative Communities

Continuing forums in which private- and public-sector members work together on medical device challenges. These groups can invite CDRH to participate.

Public-Private Partnerships

Initiatives that promote the development of new tools, methods and approaches to foster innovation and efficiency into FDA regulated product development.

NoDEx

FDA Network of Digital Health Experts

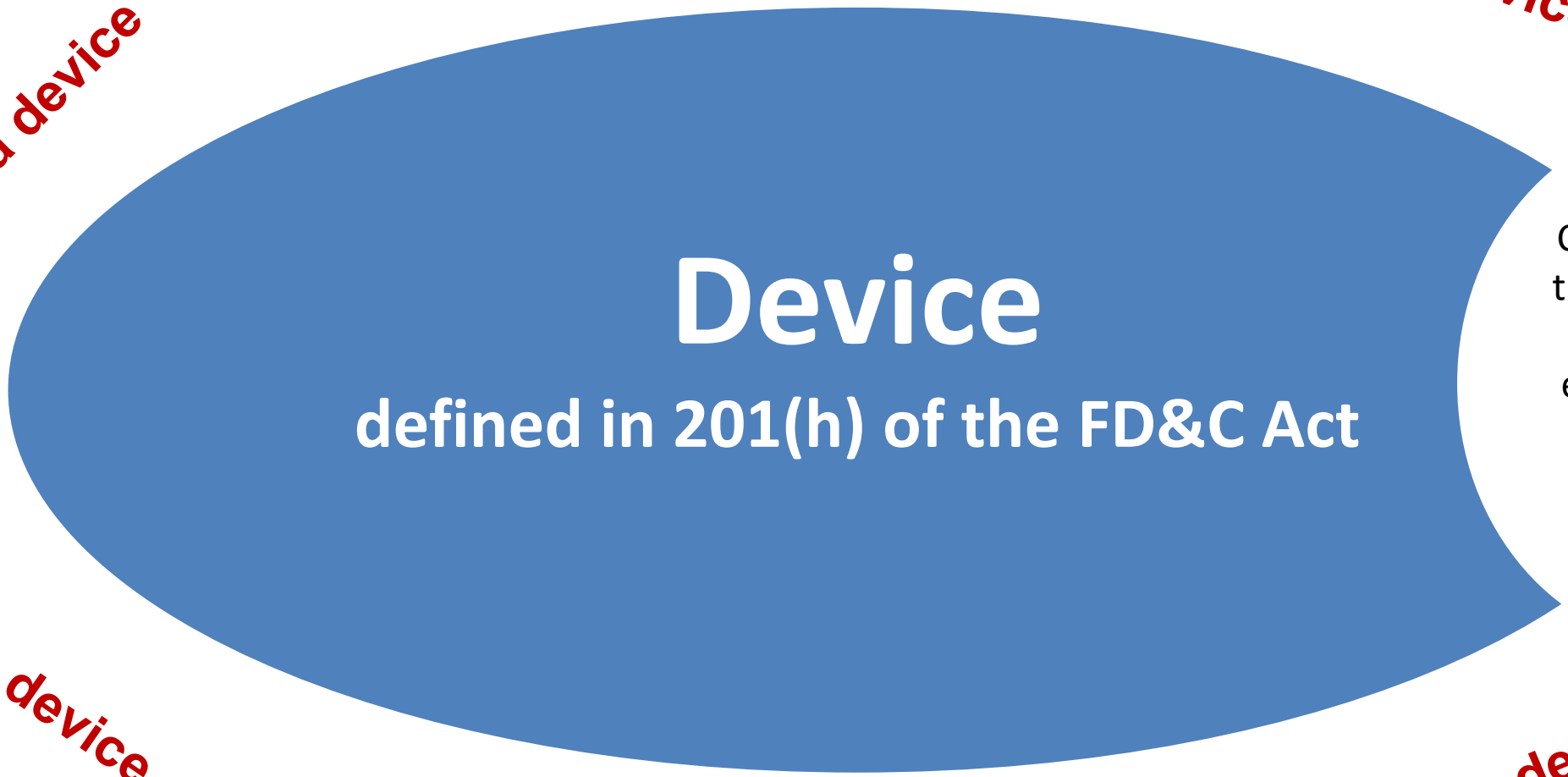
A pool of vetted experts who share knowledge and experience regarding digital health issues with FDA staff on an as-needed basis.

FDA Digital Health Inbox

Help navigating the FDA's current policies on digital health products and providing informal feedback.

www.fda.gov/digitalhealth

What is a device?



21st Century Cures amended the definition of "device" to exclude certain **software functions** pursuant to section 520(o)

Changes resulting from 21st Century Cures Act

December 13, 2016, the Cures Act amended the definition of "device" in the Federal Food, Drug, and Cosmetic Act to **exclude certain software functions**, pursuant to section 520(o), intended for...

- **Certain software functions intended for administrative support of a health care facility;**
- **Certain software functions intended for maintaining or encouraging a healthy lifestyle with no reference to any disease or condition;**
- **Certain software functions intended to serve as electronic patient records;**
- **Certain software functions intended for transferring, storing, converting formats, or displaying data and results;**
- **Certain software functions that are intended for clinical decision support.**

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act

Definitions

Function	A distinct purpose of a product
Device Function	A function that meets the definition of a device under section 201(h)(1) of the FD&C Act
Device Software Function	Software function that meets the device definition in section 201(h) of the FD&C Act.
Other Function	A function that: – does not meet the definition of a device; – meets the definition of device, but is not subject to premarket review (e.g., 510(k)-exempt); or – meets the definition of device, but for which FDA has expressed its intention not to enforce compliance with applicable regulatory controls.
Device Function-Under-Review	A function for which FDA is conducting a premarket review
Multiple Function Device Product	A product that contains at least one device function and at least one other function.

Function could be the intended use or a subset of the intended use of the product.

Examples

A product with an intended use to analyze data has one function: analysis.

A product with an intended use to store, transfer, and analyze data has three functions: (1) storage, (2) transfer, and (3) analysis.

Intended Use (21 CFR 801)

- Final rule amended 21 CFR 801.4 (effective September 1, 2021)

- **Provides more clarity and direction regarding the types of evidence relevant to determining a product's intended use**, such as:
  - Express Claims and Representations
  - Implied Claims
  - Circumstances of the Sale or Distribution
  - Design or Composition
  - **Any relevant source of evidence may be considered**

- Better reflects the Agency's current practices in evaluating whether a product is intended for use as a device

What is the Regulatory Pathway?

Intend to Exercise Enforcement Discretion

Not a Device

Focus of FDA's Oversight

Examples of Software Function Regulatory Approach

Not a Device

Software functions that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness, with no reference to a disease or condition

Intention to Exercise Enforcement Discretion

Software functions that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women

Focus of FDA's Oversight

Software functions that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG)

Increasing Risk

We provide digital health stakeholders ongoing clarity through guidance

15 Digital Health Guidance Documents Published Since FY2018

GUIDANCE DOCUMENT **Content of Premarket Submissions for Device Software Functions**	DRAFT GUIDANCE DOCUMENT **Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions**	GUIDANCE DOCUMENT **Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act**
GUIDANCE DOCUMENT **Clinical Decision Support Software**	GUIDANCE DOCUMENT **Policy for Device Software Functions and Mobile Medical Applications**	GUIDANCE DOCUMENT **Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices**
GUIDANCE DOCUMENT **Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions**	GUIDANCE DOCUMENT **Digital Health Technologies for Remote Data Acquisition in Clinical Investigations**	GUIDANCE DOCUMENT **Multiple Function Device Products: Policy and Considerations**
GUIDANCE DOCUMENT **Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act**	GUIDANCE DOCUMENT **General Wellness: Policy for Low Risk Devices**	GUIDANCE DOCUMENT **Off-The-Shelf Software Use in Medical Devices**
GUIDANCE DOCUMENT **Medical Device Accessories - Describing Accessories and Classification Pathways**	GUIDANCE DOCUMENT **Software as a Medical Device (SAMD): Clinical Evaluation**	GUIDANCE DOCUMENT **Deciding When to Submit a 510(k) for a Software Change to an Existing Device**

www.fda.gov/digitalhealth

Notable Digital Health Device Policy Guidance Documents*

- Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act
- Policy for Device Software Functions and Mobile Medical Applications (**DSF-MMA**)
- General Wellness: Policy for Low Risk Devices
- Medical Device Data Systems (**MDDS**), Medical Image Storage Devices, and Medical Image Communications Devices
- Clinical Decision Support (**CDS**) Software
- Multiple Function Device Products: Policy and Considerations

*We encourage you to visit the Guidances with Digital Health Content webpage (https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content) for a full list of guidances involving digital health policy.

Guidance Document: Policy for Device Software Functions and Mobile Medical Applications

GUIDANCE HIGHLIGHTS

Policies described in this guidance are independent of the platform on which they might run, are function-specific, and apply across platforms

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Regulatory oversight focused on those software functions that are medical devices and whose functionality could pose a risk to a patient's safety if the device were to not function as intended

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The guidance includes examples of software functions:

(1) that are NOT medical devices

(2) for which the FDA intends to exercise enforcement discretion

(3) that are the focus of FDA's regulatory oversight

EXAMPLES

Example - Not a medical device

Software functions that provide patients with simple tools to organize and track their health information

Example - FDA intends to exercise enforcement discretion

Software functions that guide a user through a questionnaire of signs and symptoms to provide a recommendation for the type of health care facility most appropriate to their needs

Example - Focus of FDA's regulatory oversight

Software functions that connect to an existing device type for purposes of controlling its operation, function, or energy source

Guidance Document: General Wellness Policy

CDRH does not intend to examine low risk general wellness products to determine whether they are devices within the meaning of the FD&C Act or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FD&C Act.

CDRH defines general wellness products as products that meet the following two factors:

(1) are intended for only general wellness use, as defined in this guidance;
(2) and present a low risk to the safety of users and other persons

There are <u>two categories</u> that describe the low-risk general wellness uses:

Category One

Products that have claims about sustaining or offering general improvement to functions associated with a general state of health that **<u>do not</u>** make any reference to diseases or conditions

Category Two

Relates to sustaining or offering general improvement to functions associated with a general state of health while **<u>making reference to diseases or conditions</u>**.

What is Clinical Decision Support (CDS)?

Clinical Decision Support (CDS) is a tool that provides health care professionals and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[1]

CDS includes:[2]

- computerized alerts and reminders for providers and patients;
- clinical guidelines;
- condition-specific order sets;
- focused patient data reports and summaries;
- documentation templates;
- diagnostic support;
- contextually relevant reference information.

[1]*See Office of the National Coordinator for Health Information Technology, "What is Clinical Decision Support (CDS)?" at* www.healthit.gov/topic/safety/clinical-decision-support

[2]FDASIA Health IT Report, April 2014, available at www.fda.gov/about-fda/cdrh-reports/fdasia-health-it-report

Your Clinical Decision Support Software: Is It a Device?

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions. *

Your software function must meet all four criteria to be Non-Device CDS.

Summary interpretation of CDS criteria

1. Your software function does **NOT** acquire, process, or analyze medical images, signals, or patterns.
2. Your software function displays, analyzes, or prints medical information normally communicated between health care professionals (HCPs).
3. Your software function provides recommendations (information/options) to a HCP rather than provide a specific output or directive.
4. Your software function provides the basis of the recommendations so that the HCP does not rely primarily on any recommendations to make a decision.

Your software function may be non-device CDS.

Non-Device Examples

Non-Device examples display, analyze, or print the following examples of medical information, which must also not be images, signals, or patterns:

- Information whose relevance to a clinical decision is well understood
- A single discrete test result that is clinically meaningful
- Report from imaging study

AND

Non-Device examples provide:

- Lists of preventive, diagnostic, or treatment options
- Clinical guidelines matched to patient-specific medical info
- Relevant reference information about a disease or condition

AND

Non-Device examples provide:

- Plain language descriptions of the software purpose, medical input, underlying algorithm
- Relevant patient-specific information and other knowns/unknowns for consideration

Device Examples

Device examples acquire, process, or analyze:

- Signal acquisition systems
- In vitro diagnostics
- Magnetic resonance imaging (MRI)
- Next Generation Sequencing (NGS)
- Continuous Glucose Monitoring (CGM)
- Computer aided detection/diagnosis (CADe/CADx)

OR

Device examples display, analyze or print:

- Continuous signals/patterns
- Medical images
- Waveforms (ECG)
- More continuous sampling (aka – a signal or pattern)

OR

Device examples provide:

- Risk scores for disease or condition
- Probability of disease or condition
- Time-critical outputs

OR

Device examples:

- Basis of recommendations is not provided

Your software function is a device.

***Disclaimer:** This graphic gives a general overview of Section IV of the guidance ("Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act"). Consult the guidance for the complete discussion. The device examples identified in this graphic are illustrative only and are not an exhaustive list. Other software functions that are not listed may also be device software functions.

Interpretation of Criteria in Section 520(o)(1)(E) of the FD&C Act

A software function must meet all of the four statutory criteria in section 520(o)(1)(E) of the FD&C Act to be excluded from the device definition.

- The functions excluded from the device definition are independent of the platform on which they might run.
- The term Non-Device CDS is used to refer to decision support software functions that do not meet the definition of device in section 201(h) of the FD&C Act.

Policy: Premarket Review of Multiple Function Device Products

- "Other functions" are not the subject of the FDA's review simply because they are part of a multiple function device product.
- However, the FDA may assess the impact of "other functions" when assessing the safety and effectiveness of the device functions-under-review of a multiple function device product.[1]

Other Function

- does not meet the definition of a device;
- meets the definition of device, but is not subject to premarket review (for example, 510(k)-exempt); or
- meets the definition of device, but for which the FDA has expressed its intention not to enforce compliance with applicable regulatory controls.

Software Example:
A general-purpose computing platform is not regulated by the FDA.

The FDA may assess its impact on the safety and effectiveness of a device function-under-review, such as a mobile medical application.

Hardware Example:
Product includes an intragastric balloon subject to premarket approval and an endoscope accessory that is 510(k)-exempt (for example, an endoscope guidewire).

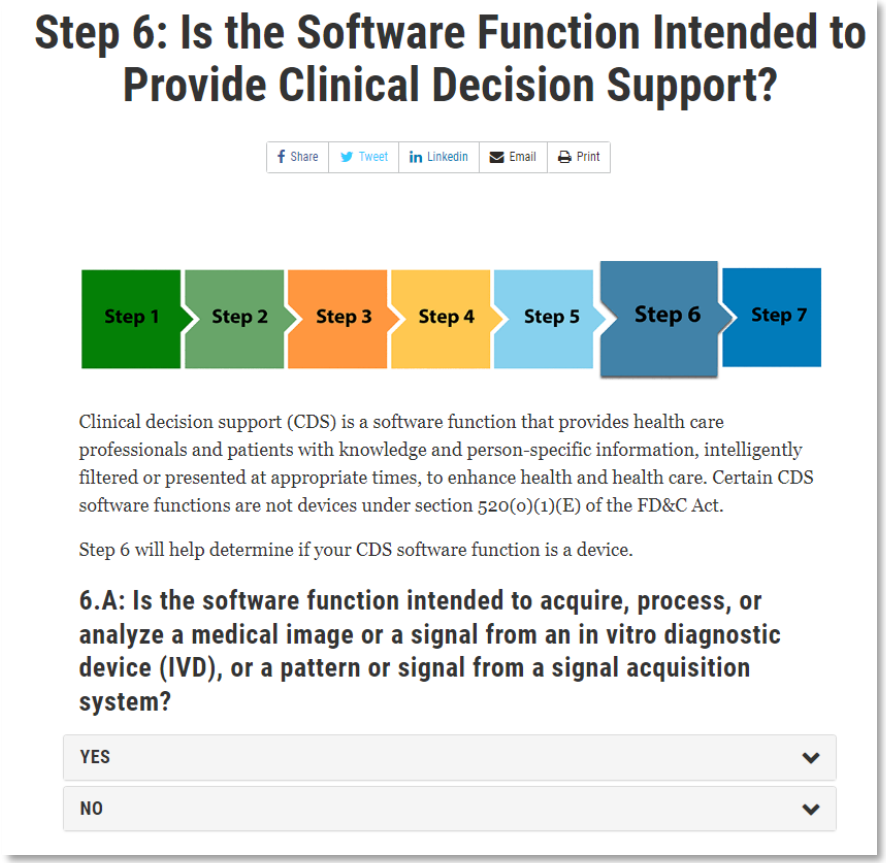
The FDA may assess the impact of the endoscope accessory on the safety and effectiveness of the intragastric balloon.

[1] Section 520(o)(2) of the FD&C Act

Digital Health Policy Navigator

https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator

- A public facing tool to help in determining whether a product's software functions are potentially the focus of the FDA's oversight
- The Digital Health Policy Navigator provides considerations for whether a software function is potentially subject to or the focus of FDA's regulatory oversight as a device. The Digital Health Policy Navigator does not address:
  - Considerations on how to design, develop, and test software functions; or
  - Considerations relating to the regulation of software used with other medical products (e.g., drugs, biologics), or software intended for other purposes (e.g., electronic consent forms).
- The Navigator includes seven steps, each with a set of questions intended help guide you through the most relevant FDA medical device regulatory considerations and guidance documents.



We are Participating in International Harmonization Efforts

2013


IMDRF International Medical Device Regulators Forum

Final Document

Title: Software as a Medical Device (SaMD): Key Definitions

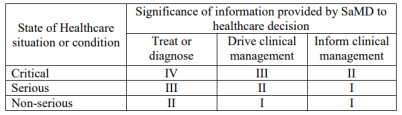
Authoring Group: IMDRF SaMD Working Group

Date: 9 December 2013

Software as a Medical Device (SaMD): Key Definitions

International Medical Device Regulators Forum (IMDRF) SaMD Working Group

2014



State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

SaMD: Risk Framework

IMDRF SaMD Working Group

2015

SaMD: Quality Management System

IMDRF SaMD Working Group

2017

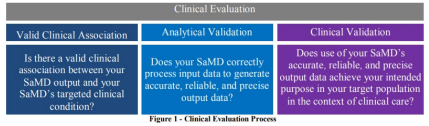


Figure 1 - Clinical Evaluation Process

SaMD: Clinical Evaluation

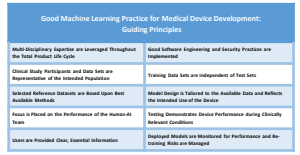
IMDRF SaMD Working Group

2020

Medical Device Cybersecurity: Principles and Practice

IMDRF Medical Device Cybersecurity Working Group

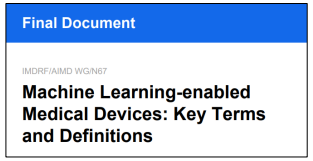
2021



Good Machine Learning Practice for Medical Device Development: Guiding Principles

Collaboration between FDA, Health Canada, and UK Medical and Healthcare products Agency

2022



Machine Learning-Enabled Medical Devices: Key Terms and Definitions

IMDRF Artificial Intelligence Medical Devices Working Group

Ongoing Efforts

- Revise IMDRF's SaMD: Possible Framework for Risk Categorization and Corresponding Considerations, and SaMD: Key Definitions
- Revise IMDRF's Principles and Practices for Cybersecurity of Legacy Medical Devices and Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity
- Joined the Global Harmonization Working Party (GHWP), specifically WG3: Pre-market: Software as a Medical Device Working Group

AI/ML-Enabled Medical Devices

Artificial Intelligence (AI):
A branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions.

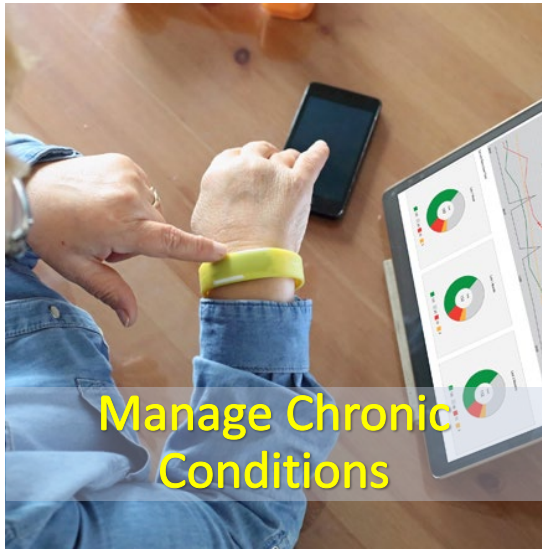
Machine Learning (ML):
A subset of AI that allows computer algorithms to learn through data, without being explicitly programmed, to perform a task.

AI/ML-Enabled Medical Device:
A medical device that uses machine learning to achieve its intended medical purpose.

Descriptions adapted from IMDRF Artificial Intelligence Medical Devices Key Terms & Definitions
Proposed document posted for public consultation Sept 2021 through Nov 29, 2021
http://www.imdrf.org/consultations/cons-aimd-mlmd-ktd.asp

Advances in AI/ML

Transforming Health Systems and Daily Lives



Some of the greatest benefits are AI/ML's ability to learn from real-world use and experience, and its capability to improve its performance.

AI/ML-Enabled Medical Devices: Opportunities & Challenges

OPPORTUNITIES

- **Significant positive impact on health care**
  - Earlier disease detection
  - More accurate diagnosis
  - New insights into human physiology
  - Personalized diagnostics and therapeutics
- **Applications across all medical fields**
- **Ability to learn, adapt, and improve performance**

CHALLENGES

- **Fit-for-purpose data sets for development and testing, including diversity**
- **Identification and minimization of bias**
- **Opacity of some algorithms**
- **Providing oversight for an adaptive system**
- **Ensuring transparency to users**

Unique Considerations

We recognize the need for careful oversight to ensure the benefits of these advanced technologies outweigh the risks to patients.

- Usability
- Trust
- Equity
- Accountability

Predetermined Change Control Plans for AI/ML-enabled Devices

This draft guidance describes a least burdensome approach to support the iterative improvement of machine learning-enabled device software functions.

Contains Nonbinding Recommendations

Draft – Not for Implementation

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

DRAFT GUIDANCE

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

Document issued on April 3, 2023.

You should submit comments and suggestions regarding this draft document 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, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact druginfo@fda.hhs.gov. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

The FDA's proposed approach would:

- Put safe and effective advancements in the hands of health care providers and users faster.
- Ensure that important performance considerations with respect to race, ethnicity, disease severity, gender, age, and geographical consideration are addressed in AI/ML-enabled devices to better meet the needs of diverse populations.

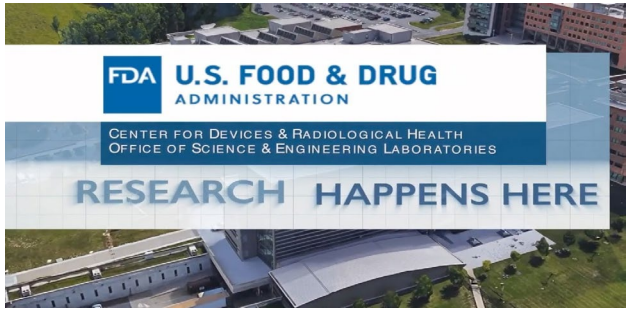
Webinar: *https://youtu.be/J26TfajAeSo*
Guidance: *https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content*

www.fda.gov/digitalhealth

Supporting Regulatory Science Tools to Assess AI/ML

Regulatory science research efforts are underway to develop methods to evaluate and address algorithmic bias and robustness in AI/ML-enabled devices.

- Investigating the impact of the difference between data used premarket setting and the postmarket deployment in different settings
- Addressing sex bias in AI for severity assessment of COVID-19 disease
- Tool to identify sub-populations over which an AI/ML-enabled medical device may perform poorly
- Tool to effectively monitor ML-based risk prediction algorithms
- Using patient and provider-informed labeling of AI/ML-enabled software to enable transparency and trust
- Using real-world data from the American Academy of Ophthalmology IRIS registry to evaluate the use and impact of approved medical devices and software algorithms for diabetic retinopathy in different patient populations



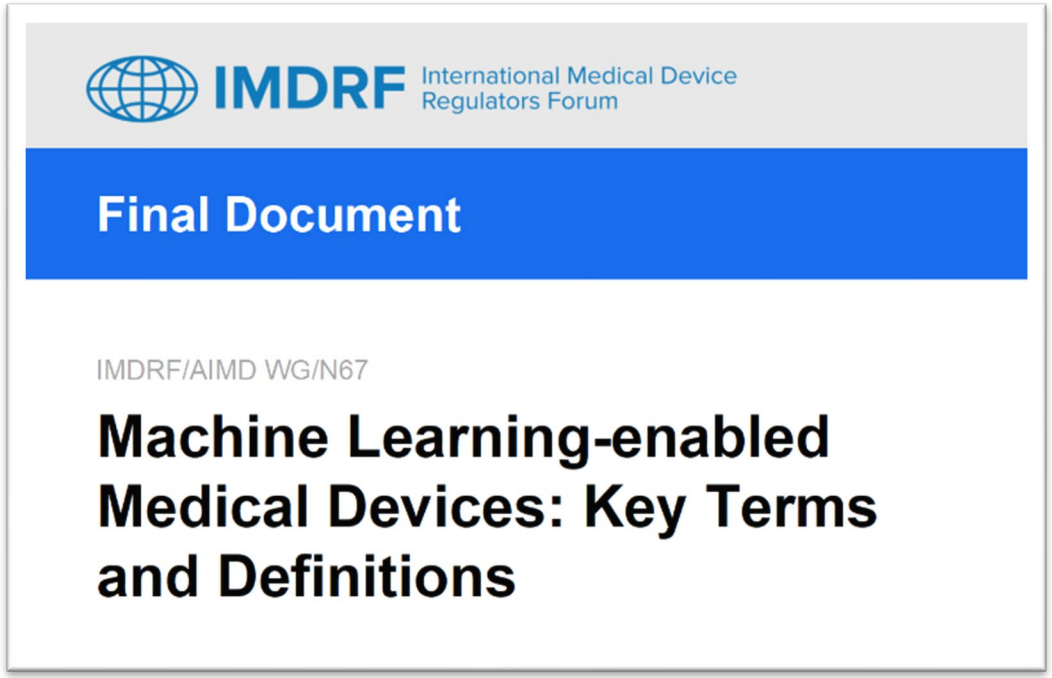
CERSI Johns Hopkins University

CERSI UCSF-Stanford

CHAI™ Coalition for Health AI

www.fda.gov/digitalhealth

IMDRF Artificial Intelligence Working Group



https://www.imdrf.org/sites/default/files/2022-05/IMDRF AIMD WG Final Document N67.pdf

- Aimed at achieving aligned approach to artificial intelligence (AI) enabled-medical devices
- Final document posted on May 9, 2022: Machine Learning-enabled Medical Devices: Key Terms and Definitions
  - Defines key terms
  - Discusses key concepts
    - Changes
    - Supervised/Unsupervised/Semi-supervised Learning
    - Validation

Good Machine Learning Practice Principles

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

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; and
- Create new practices specific for medical technology and the health care sector.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise are 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 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**

https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

Continuing our Collaborative Approach to AI

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 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)

- 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
- Draft IMDRF SaMD Risk Characterization Framework

Coming Soon

List Update

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

Future Plans (2024+)

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

Further Questions or Feedback

www.fda.gov/digitalhealth

DigitalHealth@fda.hhs.gov

Vinay M. Pai

Digital Health Specialist, Digital Health Center of Excellence (DHCoE)

Center for Devices and Radiological Health, U.S. Food and Drug Administration

Email: vinay.pai@fda.hhs.gov