FDA APPROACH TO CLINICAL DECISION SUPPORT (CDS) SOFTWARE

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Today's discussion

Overview of CDRH Digital Health Center of Excellence

Use of Digital Health Technologies in Clinical Investigations

What Clinical Decision Support Software is a Medical Device

CDRH's Digital Health Center of Excellence (DHCoE)

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

Digital Health Technologies perform an increasingly important role in health care, including:

Measuring and guiding people's behaviors

Analyzing medical images to aid in diagnosis

Helping to manage diseases like diabetes

Monitoring conditions like arrhythmias

Enabling patients to more easily report their experience

Digital health technologies are essential for bringing quality healthcare to underserved populations and communities by helping to **move healthcare to the home setting**.

FDA has authorized more than 500 Artificial Intelligence/Machine Learning-enabled devices.

FDA is continuously looking at new ways to evolve regulatory approaches to enable fast moving innovation.

www.fda.gov/digitalhealth

Promoting a Patient-Centered Approach With a Focus on Health Equity

We foster digital health collaborations 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

Performing and Supporting Leading Regulatory Science Research

Issued in October 2022

The Spotlight highlights important scientific research areas in digital health aimed at:

- Advancing patient engagement
- Leveraging connectivity
- Improving health care through software

Research Areas *Advanced Manufacturing Technologies, Artificial Intelligence/Machine Learning, Cybersecurity, Digital Imaging, Interoperability, Medical Extended Reality, Patient Generated Health Data, and Wireless Connectivity*

https://www.fda.gov/media/162644/download

Providing Regulatory Clarity and Predictability

We issue guidance on the broad set of Digital Health applications.

GUIDANCE DOCUMENT

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

GUIDANCE DOCUMENT

Content of Premarket Submissions for Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

GUIDANCE DOCUMENT

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations

Draft Guidance for Industry, Investigators, and Other Stakeholders

GUIDANCE DOCUMENT

Multiple Function Device Products: Policy and Considerations

GUIDANCE DOCUMENT

Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

GUIDANCE DOCUMENT

Software as a Medical Device (SAMD): Clinical Evaluation

GUIDANCE DOCUMENT

Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

GUIDANCE DOCUMENT

Off-The-Shelf Software Use in Medical Devices

GUIDANCE DOCUMENT

Medical Device Accessories - Describing Accessories and Classification Pathways

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

Deciding When to Submit a 510(k) for a Software Change to an Existing Device

GUIDANCE DOCUMENT

General Wellness: Policy for Low Risk Devices

www.fda.gov/digitalhealth

Today's discussion

Overview of CDRH Digital Health Center of Excellence

Use of Digital Health Technologies in Clinical Investigations

What Clinical Decision Support Software is a Medical Device

Digital health technologies can transform how we study medical products

Enable Remote Data Collection in Decentralized Clinical Investigation

- More frequent or continuous monitoring compared to traditional methods
- Longitudinal view of participant's health status
- Improved recruitment and retention of participants leading to less missing data

Improve Access to Clinical Investigations

- Meet a participant where they are at for a clinical investigation
- Fewer visits to a study site places less burden on participants
- Reach a more diverse population, advancing health equity

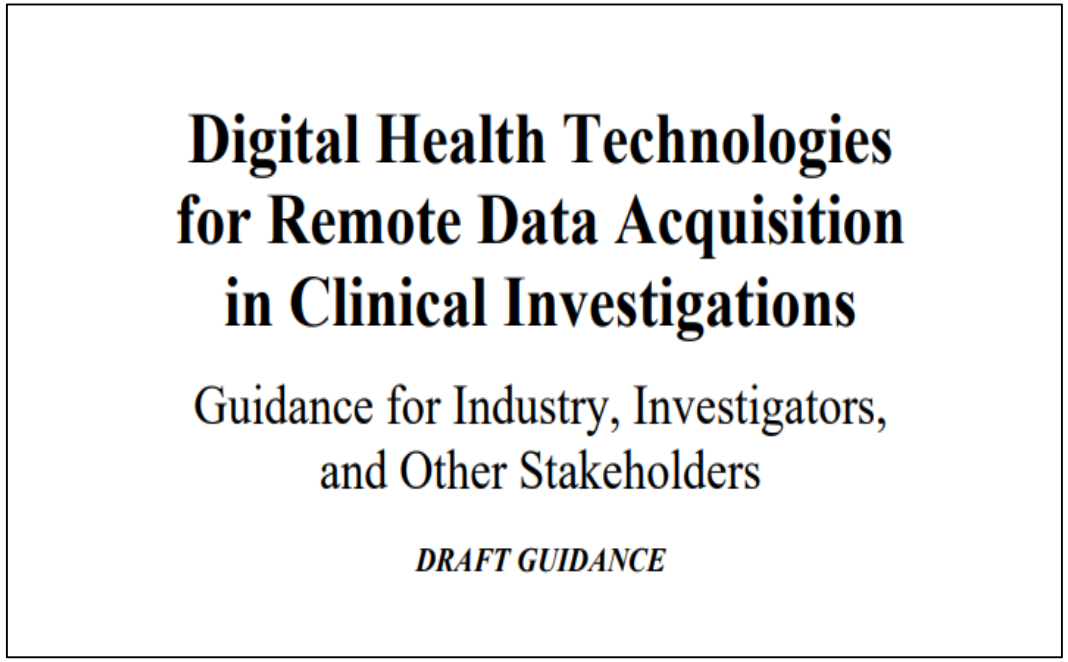
Facilitate Innovative Clinical Investigation Endpoints

- New types of data to inform novel endpoints
- Complementary to other forms of data used to support a regulatory submission

Capture Real-World Data (RWD) and Patient-Generated Health Data (PGHD)

- Data reflects a participant's daily life
- Remote and longitudinal follow-up with participants beyond the clinical investigation
- More detailed picture of the impact of a medical product on a participant

Providing Regulatory Clarity and Predictability



- The draft guidance (Dec 2021) provides recommendations to facilitate the use of DHTs in clinical investigations
- Designed to help bring new innovations and advances to patients while accelerating and modernizing medical product development
- Builds on the launch of the Digital Health Center of Excellence to empower digital health stakeholders and provide regulatory clarity and collaboration across FDA

Supporting a Least Burdensome Approach

We encourage the use of device and non-device DHTs in clinical investigations.

Some DHTs meet the definition of a medical device* while others do not.

*A device is defined by the Federal Food, Drug, & Cosmetic Act Section 201(h):

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals…

Ensuring Technologies are Fit-For-Purpose for Clinical Applications

We focus on whether a DHT in a clinical trial is Fit-For-Purpose.

***Fit-For-Purpose**: a conclusion that the level of validation associated with a DHT is sufficient to support its proposed use in the clinical investigation*

Some Questions to Consider:

- What is the clinical event or characteristic of interest, and is it meaningful?
- Can the DHT reliably measure that clinical event or characteristic?
- What is the population of interest -- including age, socio-economic background, technical aptitude, etc?
- What are other design and operation-related considerations for the DHT (for example: wearability, power charging needs, alerts, if applicable)?

Applies regardless of whether the participant is bringing their own technology

Supporting a Least Burdensome Approach

Question: Is premarket clearance or approval required to use a device in a clinical investigation?

Answer: Devices intended only for use in clinical investigations are typically exempt from many requirements applicable to devices – including premarket clearance or approval – as long as the investigation complies with applicable requirements under 21 CFR part 812 (IDE Regulations)

Other Good Clinical Practice (GCP) Regulations also apply, including those related to Institutional Review Boards and Protection of Human Subjects.

Supporting a Least Burdensome Approach

Question: When is an Investigational Device Exemption (IDE) application to FDA required?

Answer: For DHTs that are Devices,

- ***For a Non-Significant Risk Device,*** an IDE application to FDA is generally not required.
- ***For a Significant Risk Device,*** when all information required in an IDE application under 21 CFR 812.20 is also contained in an IND, FDA generally does not expect sponsors to submit a separate IDE for these clinical investigations.
- ***For a Device used in accordance with its authorized intended use,*** an IDE application to FDA is generally not required.

Other Good Clinical Practice (GCP) Regulations also apply, including those related to Institutional Review Boards and Protection of Human Subjects.

Today's discussion

Overview of CDRH Digital Health Center of Excellence

Use of Digital Health Technologies in Clinical Investigations

What Clinical Decision Support Software is a Medical Device

"CDS" is a broad term, and FDA's oversight is focused only on medical devices

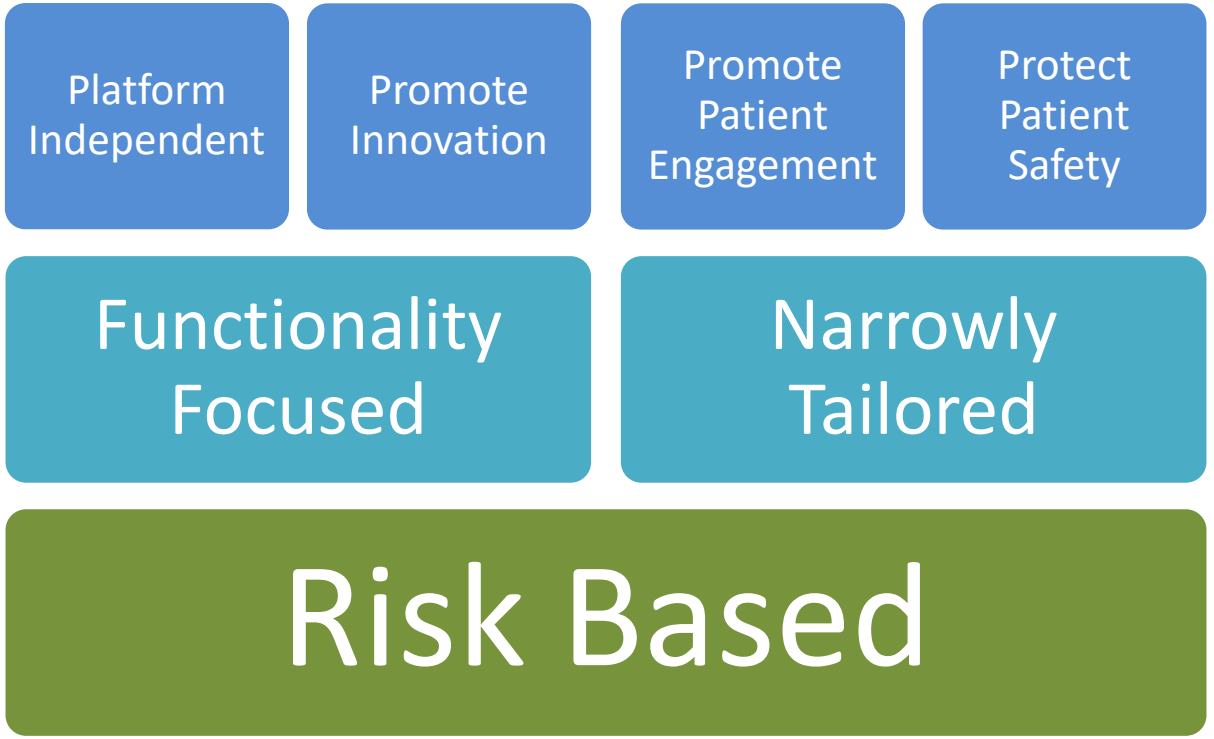
Clinical Decision Support (CDS) is a tool that provides health care professionals and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[1]

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

FDA software regulation is function-specific and risk-based



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

21st Century Cures Act built on FDA's policies

On December 13, 2016, the 21st Century Cures Act amended the definition of "device" in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to **exclude certain software functions** defined in section 520(o) of the FD&C Act. Specifically, 520(o) of the FD&C Act excludes software functions intended for:

Administrative support of a health care facility;	**Maintaining or encouraging a healthy lifestyle with no reference to any disease or condition;**	**Electronic patient records;**	**Transferring, storing, converting formats, or displaying data and results;**	**Clinical decision support.**
520(o)(1)(A)	520(o)(1)(B)	520(o)(1)(C)	520(o)(1)(D)	520(o)(1)(E)

Guidance: Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act

21st Century Cures Act Criteria for Non-Device Clinical Decision Support (CDS)

The Cures Act excludes certain software functions from device definition if all four of these Criteria are met:

1) NOT intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;

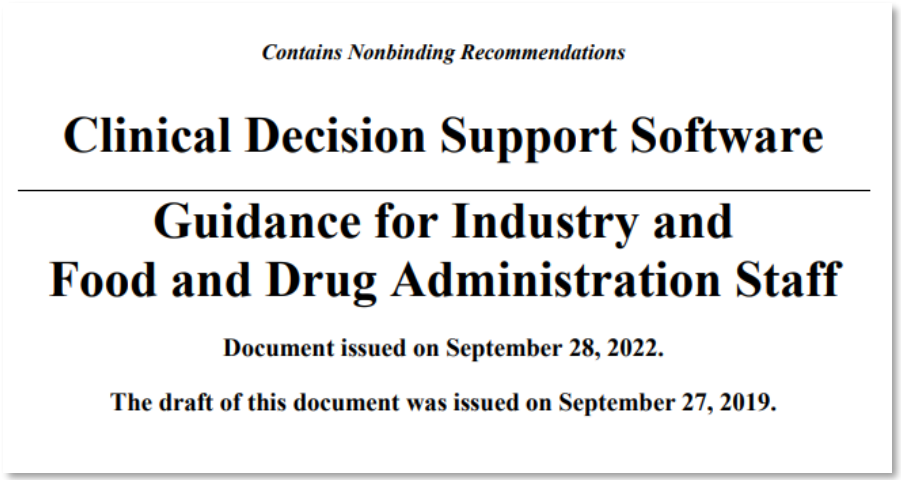
2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

4) intended for the purpose of enabling a health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

The final CDS guidance explains what's "out" of FDA's purview (and how to be "out")

This guidance presents the agency's current thinking on which CDS software functions are excluded from the definition of device by the criteria in section 520(o)(1)(E) of the FD&C Act.



Contains Nonbinding Recommendations

Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

The draft of this document was issued on September 27, 2019.

- Guidance describes CDS that does not meet the definition of a device (Non-Device CDS) including certain CDS software functions intended for HCPs.
- Guidance does not address:
  - which FDA statutory or regulatory requirements apply to device software functions;
  - which regulatory requirements may apply to a device software function that is part of a combination product;
  - labeling requirements for decision support software disseminated by or on behalf of a drug or biological product sponsor.

Criterion (1): Acquire, Process, Analyze

520(o)(1)(E)	*CDS Guidance*
Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system	If the type of data described in Criterion 1 (i.e., **medical image** or a **signal** from an IVD or a **pattern/signal** from a signal acquisition system) is **acquired, processed, or analyzed** (used as an input), then the software function **remains a device** within the meaning of section 201(h). Such products **have been regulated** as devices for many years.

Criterion (2): Medical Information

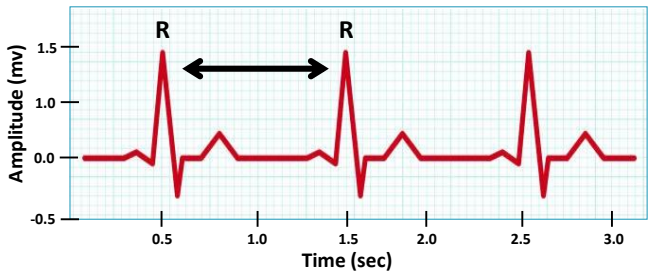
520(o)(1)(E)(i)

Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines)

CDS Guidance

- Non-device CDS are intended to display, analyze, or print **medical information about a patient or other medical information**.
- What is medical information?
  - demographic information, symptoms,
  - test results, certain medical device outputs (such as a heart rate or blood pressure reading),
  - patient discharge summaries,
  - other medical information, such as clinical practice guidelines, peer-reviewed clinical studies, textbooks, approved drug or medical device labeling, and government agency recommendations

Criterion (2): What is Medical Information?



CDS Guidance

- The kind of information used by the intended user to make decisions about prevention, diagnosis, or treatment of a disease or condition for an individual patient.
  - Normally is, and generally can be, communicated between HCPs or HCPs/patients
- FDA interprets medical information about a patient to be information whose relevance to a clinical decision is well understood and accepted in the practice of medicine.
- Sampling frequency is also an important consideration:
  - A single, discrete test or measurement result that is clinically meaningful (e.g., a blood glucose lab test result) = *medical information*
  - More continuous sampling of the same information (e.g., continuous glucose monitor readings) = a pattern/signal.

Criterion (3): Supporting/Providing Recommendations to Healthcare Professionals

CDS Guidance

FDA interprets Criterion 3 to refer to software that:

- ❑ provides condition-, disease-, and/or patient-specific information and options to an HCP to enhance, inform and/or influence a health care decision;
- ❑ does not provide a specific preventive, diagnostic or treatment output or directive;
- ❑ is not intended to support time-critical decision-making; and
- ❑ is not intended to replace the HCP's judgment.

Criterion (4): Enabling Independent Review

CDS Guidance

Non-Device CDS are intended to enable HCPs to **independently review the basis for the recommendations** presented by the software so that they do not rely primarily on such recommendations, but rather on their own judgment, to make clinical decisions for individual patients.

In order to satisfy Criterion 4, FDA recommends that:

a) The software or labeling include the purpose or intended use of the product, including the intended HCP user [can't be time-critical]

b) The software or labeling identify the required input medical information

c) The software or labeling provide a plain language description of the underlying algorithm development and validation that forms the basis for the CDS implementation
   i. Summary of the logic or methods (e.g., AI/ML techniques)
   ii. Description of the data relied upon
   iii. Description of results from clinical validation studies

d) The software output provide relevant patient-specific information and other knowns/unknowns for consideration

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.

Many products are “out” for reasons other than the final CDS guidance

The Digital Health Policy Navigator helps product developers consider whether a software function is potentially subject to or the focus of FDA's regulatory oversight as a device.

Interactive questions guide product developers to one of four different outcomes, reflecting policies described in relevant digital health guidances.

Interactive Questions

Step 1:	Intended for a medical purpose?
Step 2:	Intended for administrative support of a health care facility?
Step 3:	Intended for maintaining or encouraging a healthy lifestyle?
Step 4:	Intended to serve as electronic patient records?
Step 5:	Intended for transferring, storing, converting formats, or displaying data and results?
Step 6:	Intended to provide clinical decision support?
Step 7:	Does the Device Software Function and Mobile Medical Application Guidance apply?

Navigator Outcomes

Icon	Outcome
	LIKELY NOT A MEDICAL DEVICE
	LIKELY FDA INTENDS TO EXERCISE ENFORCEMENT DISCRETION
FDA	**LIKELY THE FOCUS OF FDA’S REGULATORY OVERSIGHT**
	Your product may be a device. Go to Step #.

What are the FDA considerations to investigate or use CDS software in a clinical study?

It depends….

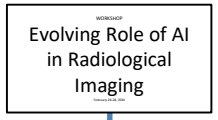
- Device CDS software *is subject to IDE requirements and applicable GCPs*
  - If the device CDS software is cleared/approved, and is **NOT** being used consistently with its authorized intended use, *the CDS software is subject to IDE requirements and applicable GCPs*
  - If the device CDS software does not pose a significant risk to human subjects, no IDE application is required. (The study only requires IRB approval prior to initiation.)
- Sponsors should evaluate and address the impact of the CDS software on the interpretation of the study results and intended use of the medical product

FDA's Collaborative Patient-Centered Approach to AI/ML-Enabled Devices

Published AI/ML-SaMD Discussion Paper

2019

First joined Collaborative Community related to AI/ML



Public Workshop on AI/ML in Radiological Imaging

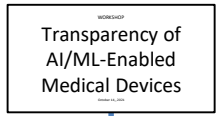
2020

PEAC Mtg on Patient Trust in AI/ML Devices

Published AI/ML Medical Device Software Action Plan

Posted List of Currently Marketed AI/ML Devices

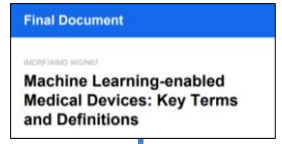
2021



Public Workshop on Transparency of AI/ML Devices

Published GMLP Guiding Principles

2022



Contributed to IMDRF's Key Terms and Definitions

FINAL GUIDANCE
Clinical Decision Support (CDS) Software

Published Final Guidance: Clinical Decision Support

AI/ML Guidance

2023

We're working collaboratively with stakeholders to build a proactive, patient-centered approach to AI/ML-enabled devices that promotes health equity.

Internationally Harmonized GMLP Guiding Principles

- **Good Machine Learning Practice (GMLP)** are accepted practices in AI/ML algorithm design, development, training, and testing
- GMLP facilitate the development and assessment of high quality AI/ML-enabled technologies
- US FDA, MHRA (UK) and Health Canada issued 10 Guiding Principles to help inform the development of GMLP
- These 10 principles are intended to promote global harmonization and encourage broad stakeholder engagement

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

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

Promoting Development of Safe and Effective AI/ML-Enabled Devices

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 draft guidance:

- Proposes a science-based approach to put safe and effective advancements in hands of health care providers and users faster. The Predetermined Change Control Plan (PCCP):
  - Helps to enable more personalized medicine and increase pace of medical device innovation
  - Is informed by FDA's experience in regulating AI/ML-enabled devices

Additional Resources

- *Digital Health Center of Excellence website: www.fda.gov/digitalhealth*
- *Clinical Decision Support Guidance Webinar:*

  https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-clinical-decision-support-software-final-guidance-10182022
- *DHTs for Remote Data Acquisition in Clinical Investigations Guidance Webinar:*

  https://www.fda.gov/drugs/news-events-human-drugs/digital-health-technologies-dhts-remote-data-acquisition-draft-guidance-02102022
- *AI/ML Change Control Plan Draft Guidance Webinar – **draft open for comment***

  https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-marketing-submission-recommendations-predetermined-change-control-plan-artificial
- *Draft Guidance: Decentralized Clinical Trials for Drugs, Biological Products, and Devices – **draft open for comment***

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices

Providing Regulatory Clarity and Predictability

We encourage you to engage with the Agency early and often.

- Medical Product Development Tool Programs (e.g., MDDT, DDT, ISTAND)
- Public-Private Partnerships
- Digital Health Center of Excellence

Engage early with the Center responsible for the medical product being studied, to discuss use of DHTs in a specific clinical investigation.

Further Questions or Feedback

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