Digital Health and Regulations for Artificial Intelligence

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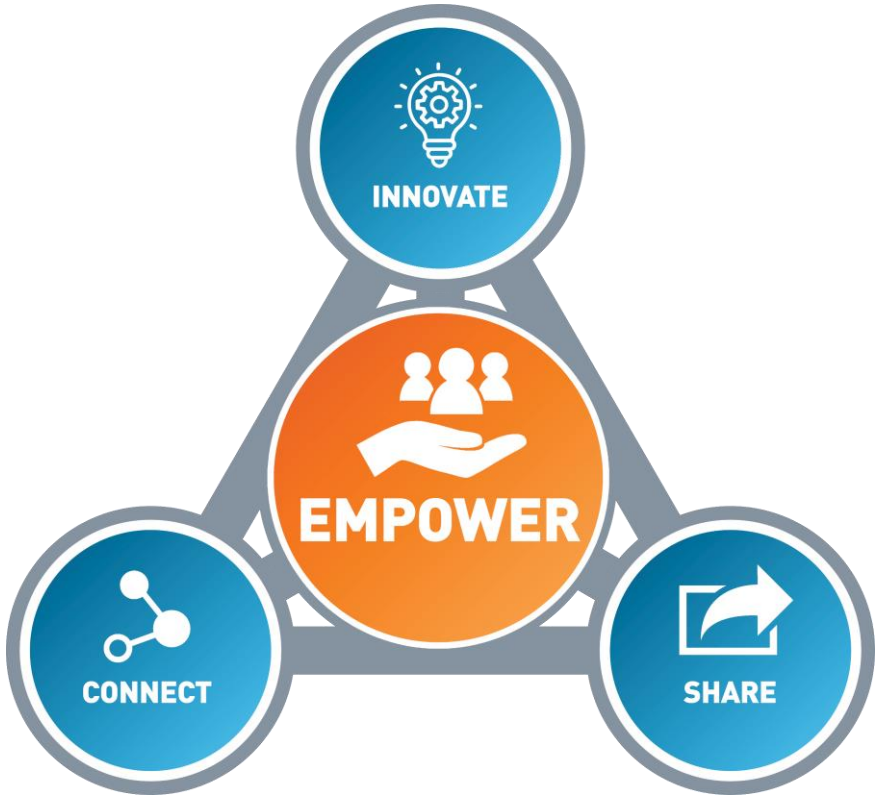
Overview
US FDA's Digital Health Efforts

New opportunities: CDRH's Digital Health Center of Excellence (DHCoE) was established in 2020 to help FDA address growing public health opportunities in the digital health space.

A strong start: FDA's efforts to date have identified new paths forward for novel technologies, such as AI/ML, have improved regulatory clarity and international harmonization, and have provided patients with access to novel, safe and effective digital health devices for diabetes, cancer, substance use disorder, chronic pain, and more.

Continuing the momentum: As we move into the next phase, we're redoubling our efforts not just for medical devices, but also to support FDA's public health mission across the medical products we regulate and beyond the Agency.

We are setting the stage for the advancement of digital health to help protect and promote public health



Select Accomplishments

29	14	80+	3400+	5000+
Public Documents	Guidance Documents since FY18	Experts in the Network of DH Experts	Inquiries addressed since FY18	Medical device submissions with DH considerations since FY18

Notable Authorizations

- Substance use disorder
- Opioid use disorder
- Colon Cancer
- Chronic Pain Reduction
- Capture Cardiac Ultrasounds
- Diabetes Management

New Regulatory Frameworks

- Released AI/ML Action Plan
- Piloted a software pre-certification program
- Published list of currently marketed AI/ML-enabled medical devices
- Jointly published list of 10 Good Machine Learning Practice (GMLP) Principles with the UK and Canada
- Workshop on Transparency of AI/ML-enabled medical devices

CDRH's Digital Health Center of Excellence (DHCoE) launched in September 2020.

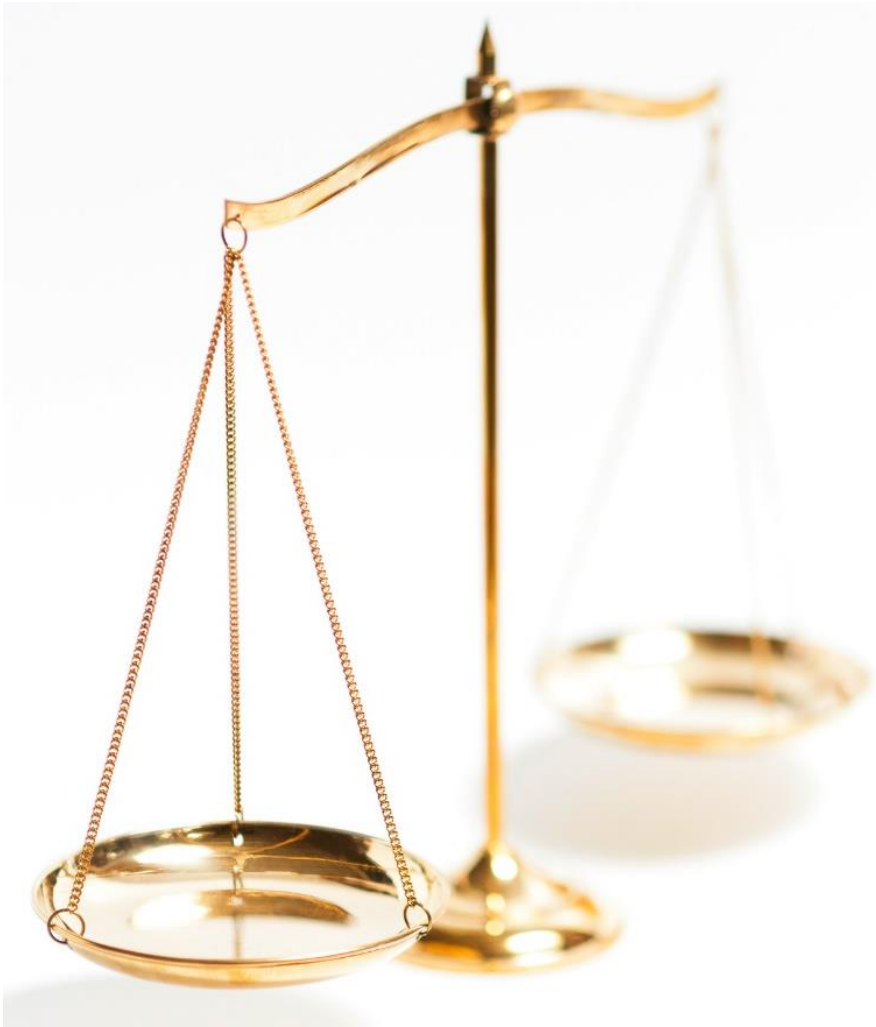
Goals for a Tailored Regulatory Framework

Fostering Responsible Digital Health Innovation

- Enhance patients access to high quality digital medical products
- Enable manufacturers to rapidly improve software products with minor changes
- Maintain a reasonable assurance of safety and effectiveness
- Minimally burdensome

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

Proposing a Regulatory Framework for AI/ML-Enabled Device Software

Published in 2019

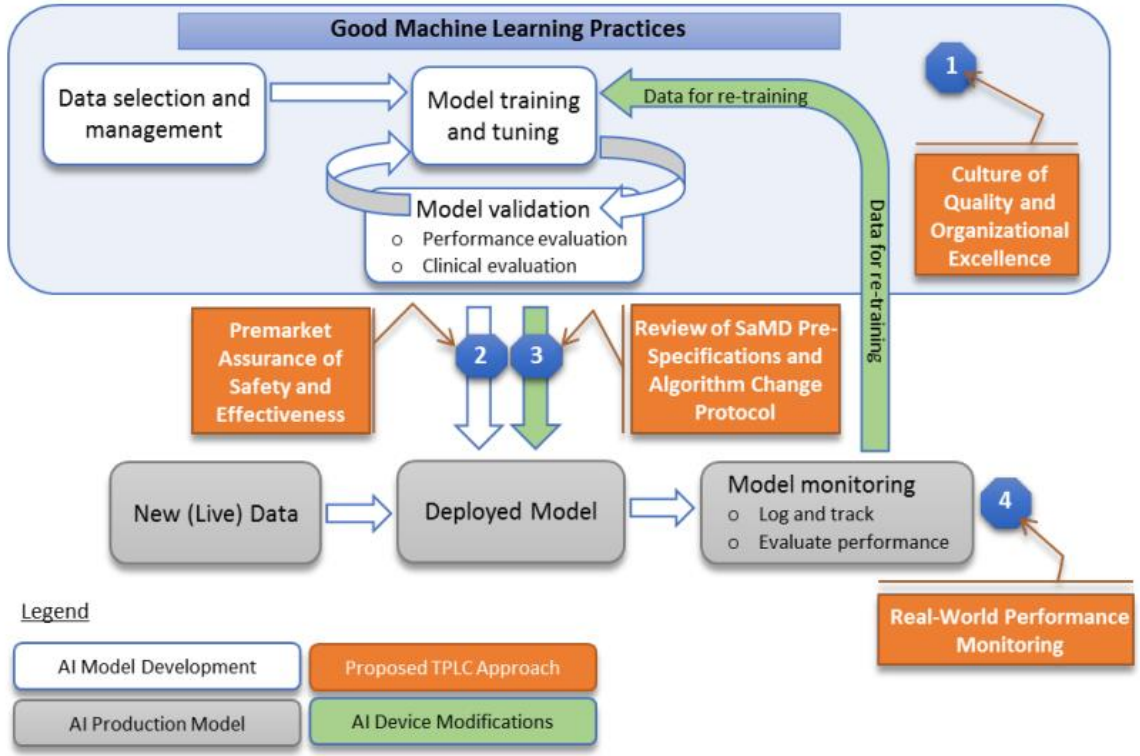
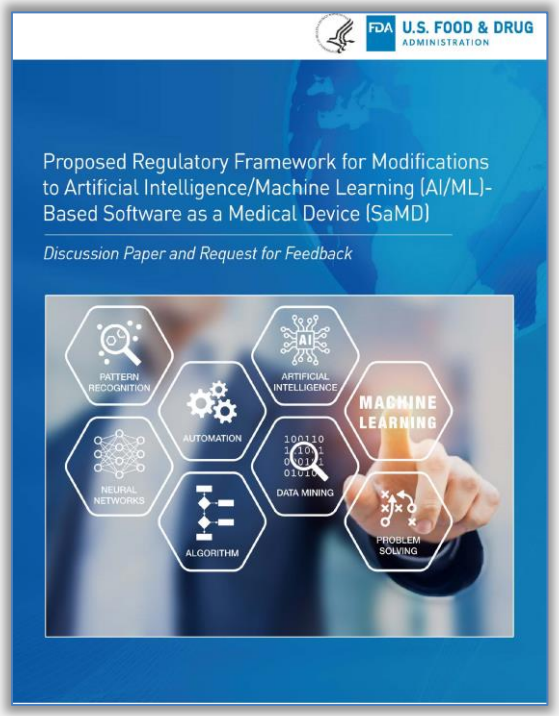


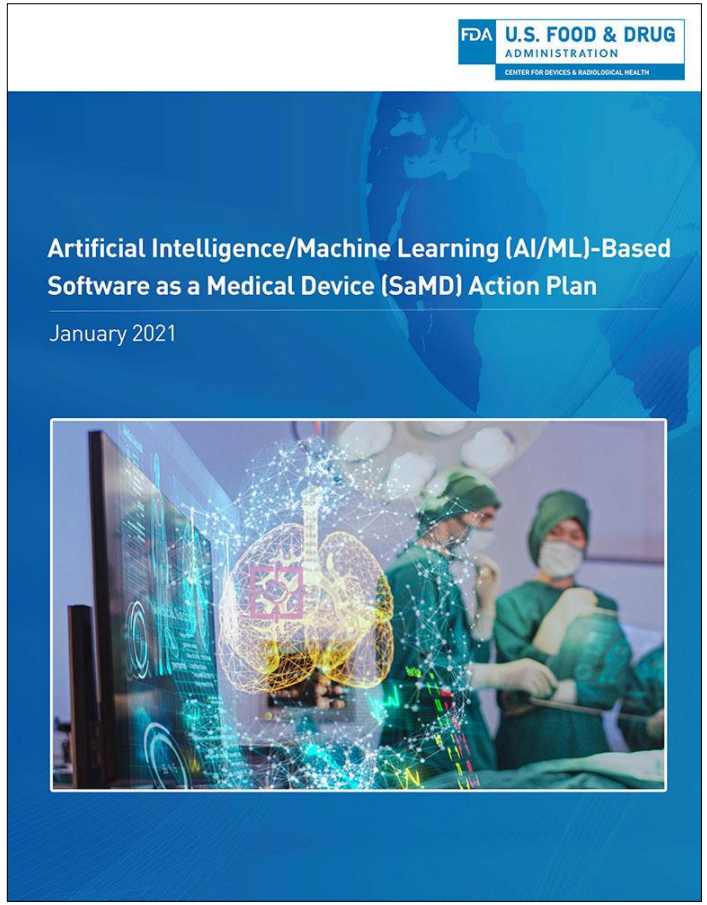
Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow



Received stakeholder feedback through:

- > 1,000 comments on public docket
- > 30 publications in peer-reviewed journals
- Pre-submission meetings on AI/ML devices
- Patient Engagement Advisory Committee Meeting

US FDA
Tailoring a Regulatory Framework



Action Plan for AI/ML-Based SaMD

Published in 2021

Outlines five next steps to advancing access:

1. Update the proposed AI/ML regulatory framework
2. **Strengthen FDA's role in harmonizing GMLP**
3. Foster a patient-centered approach
4. Support development of regulatory science methods
5. Advance real-world performance pilots

Continuing our Collaborative Approach

Published AI/ML-SaMD Discussion Paper

Evolving Role of AI in Radiological Imaging

Public Workshop on AI/ML in Radiological Imaging

Published AI/ML Medical Device Software Action Plan

Transparency of AI/ML-Enabled Medical Devices

Public Workshop on Transparency of AI/ML Devices

Contributed to IMDRF's Key Terms & Definitions

DRAFT GUIDANCE

Predetermined Change Control Plan for AI/ML-Enabled Devices

Draft Guidance on PCCP for AI/ML-Enabled Devices

2019

First joined Collaborative Community related to AI/ML

2020

PEAC Mtg on Patient Trust in AI/ML Devices

2021

Posted List of Currently Marketed AI/ML Devices

2022

Published GMLP Guiding Principles

Issued Final Guidance on Clinical Device Support Software

FINAL GUIDANCE

Clinical Decision Support (CDS) Software

September 27, 2022

Coming Soon

We recognize that by working collaboratively with stakeholders we can lay out a clear path toward building a proactive patient-centered approach to the development and use of AI/ML-enabled devices.

We are Participating in International Harmonization Efforts

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

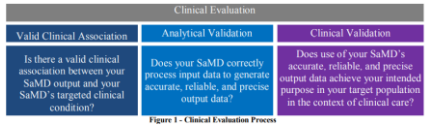
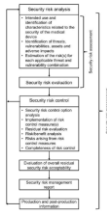


Figure 1 - Clinical Evaluation Process

SaMD: Clinical Evaluation

IMDRF SaMD Working Group

2020



Medical Device Cybersecurity: Principles and Practice

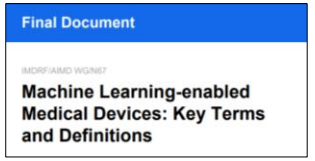
IMDRF Medical Device Cybersecurity Working Group

2021

Good Machine Learning Practice for Medical Device Development: Guiding Principles

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

2022



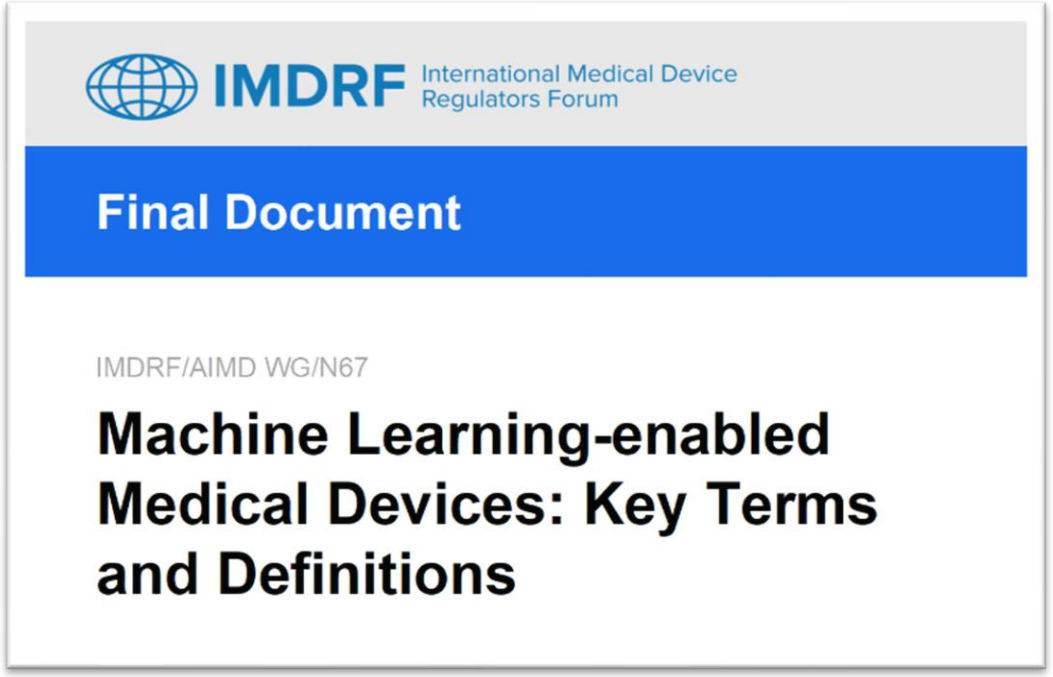
Machine Learning-Enabled Medical Devices: Key Terms and Definitions

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

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 (GMLP) 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

Good Machine Learning Practice (GMLP)

Examples of Collaborative Efforts

- Standards Development:
  - IEEE AI Medical Device Working Group
  - ISO/IEC SubCommittee on AI 42 (ISO/ IEC JTC 1/SC 42)
  - AAMI/BSI Initiative on AI in Medical Technology
  - CTA R13 Artificial Intelligence in Healthcare
- Collaborative Communities:
  - Collaborative Community on Ophthalmic Imaging
  - Pathology Innovation Collaborative Community
  - Digital Health Measurement Collaborative Community
  - AFDO/RAPS Healthcare Products Collaborative*
- Other Collaborations:
  - IMDRF AI Medical Devices WG – NWIP

CCOI

Collaborative Community on Ophthalmic Imaging

Pathology Innovation Collaborative Community

Pathology Innovation Collaborative Community

DATAcc

Digital Health Measurement Collaborative Community

Digital Health Measurement Collaborative Community

AFDO RAPS

HEALTHCARE PRODUCTS COLLABORATIVE

Healthcare Products Collaborative Community

*Recently transitioned from Xavier AI World Consortium Collaborative Community to the Association of Food and Drug Officials/Regulatory Affairs Professionals Society (AFDO/RAPS)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ADMINISTRATION