

Digital Health Center of Excellence

Empowering digital health stakeholders to advance health care

FDA



Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices: Tailoring a Regulatory Framework to Encourage Responsible Innovation in AI/ML

Shawn Forrest, MS

Digital Health Specialist, Center for Devices & Radiological Health (CDRH)

CDRH Digital Health Center of Excellence, US FDA



Disclaimer

These PowerPoint slides are the intellectual property of the U.S. Food and Drug Administration and the individual presenter and are protected under copyright Laws of the United States of America and other countries. All rights reserved.

Outline



- Digital Health and the CDRH DH Center of Excellence
- Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices
- FDA AI/ML Action Plan



Outline



- **Digital Health and the CDRH DH Center of Excellence**
- Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices
- FDA AI/ML Action Plan



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

Empowering All to Advance Healthcare

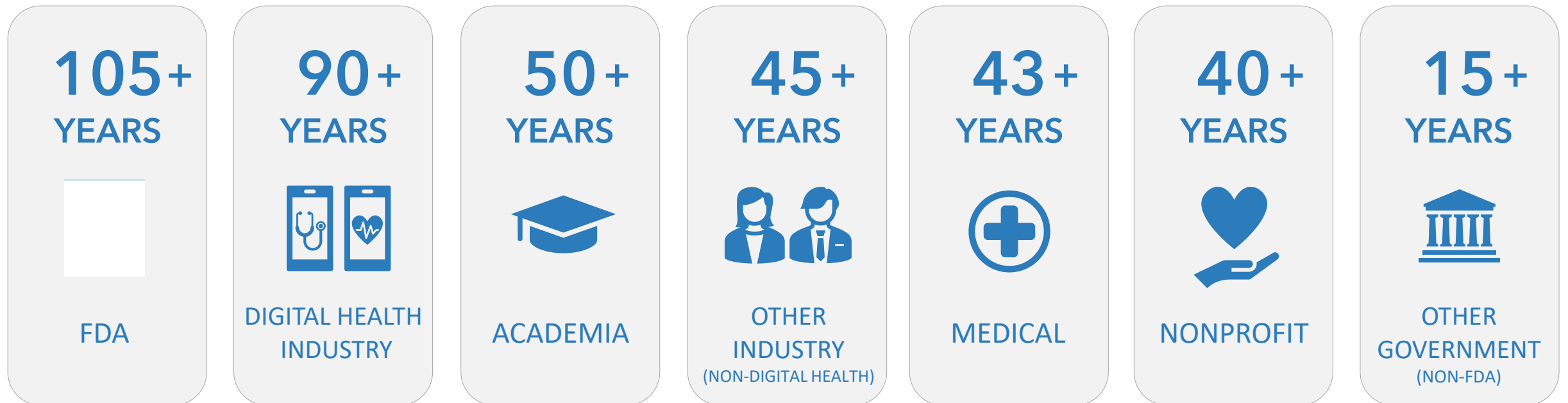
Our goal: Empower stakeholders to advance public health by fostering responsible and high-quality digital health innovation.

- **Connect and build** partnerships to accelerate digital health advancements.
- **Share knowledge** to increase awareness and understanding, drive synergy, and advance best practices.
- **Innovate regulatory approaches** to provide efficient and least burdensome oversight while meeting the FDA standards for safe and effective products.



CDRH's Digital Health Center of Excellence provides world-class digital health expertise and policy direction

Our staff brings extensive experience:



Current as of June 2022

Healthy Living Prevention Diagnosis Treatment Recovery Home Care Management



Moving healthcare from the clinic to the patient

Understanding physiology and behavior in the real world

Leveraging computing power, sensors, connectivity, and software

The Need for a Tailored Approach

“Traditional” Device World

Product Development Timeline

- Months to years +
- Less frequent modifications



Evolving Digital Health Device World

Weeks to months + (incremental, iterative) and potentially frequent modifications

Postmarket Data

- Limited availability and access to real world data (522, PAS, MDRs, MedSun)



*Potential for **high availability** and access to rich real world data (benefits and risks)*

FDA Premarket Program Volume:

- Stable (~3,500 510(k) submissions / 2200 pre-submissions)

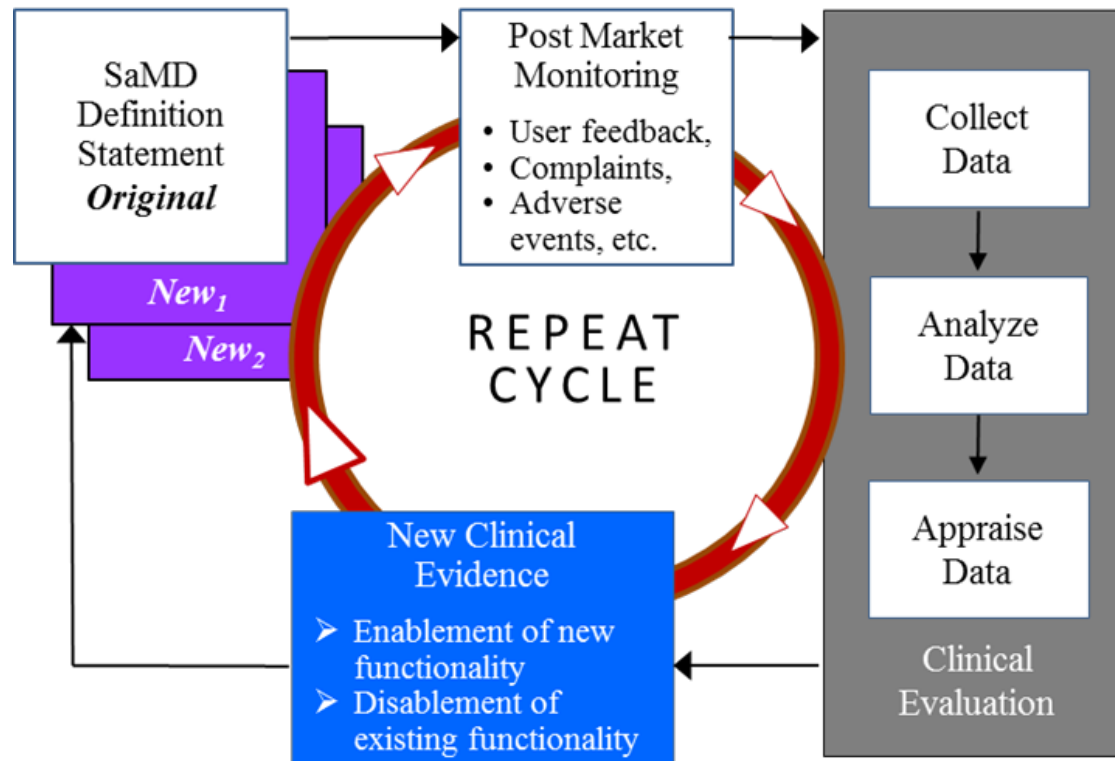


*Potential for **exponential** increase in volume of submissions*

Continuous Learning for Software as a Medical Device



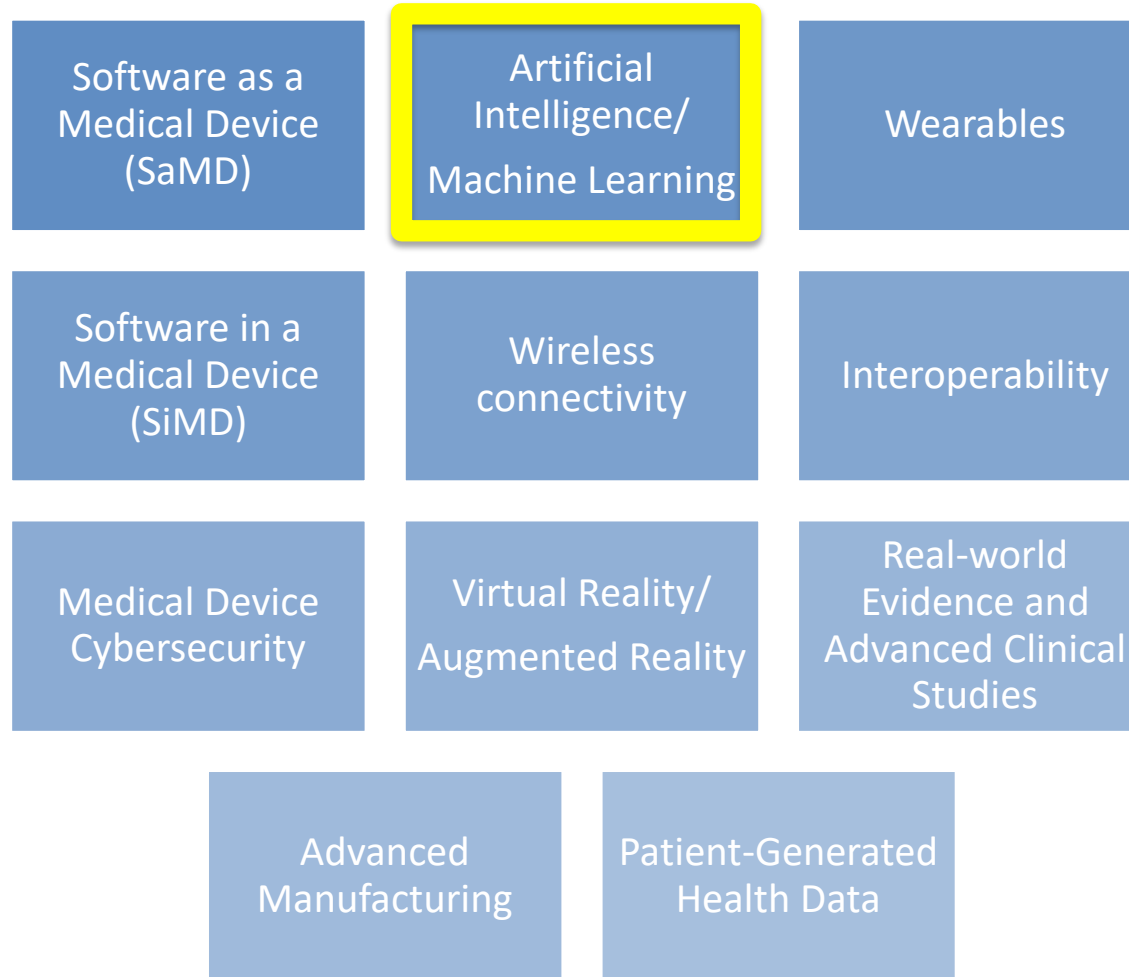
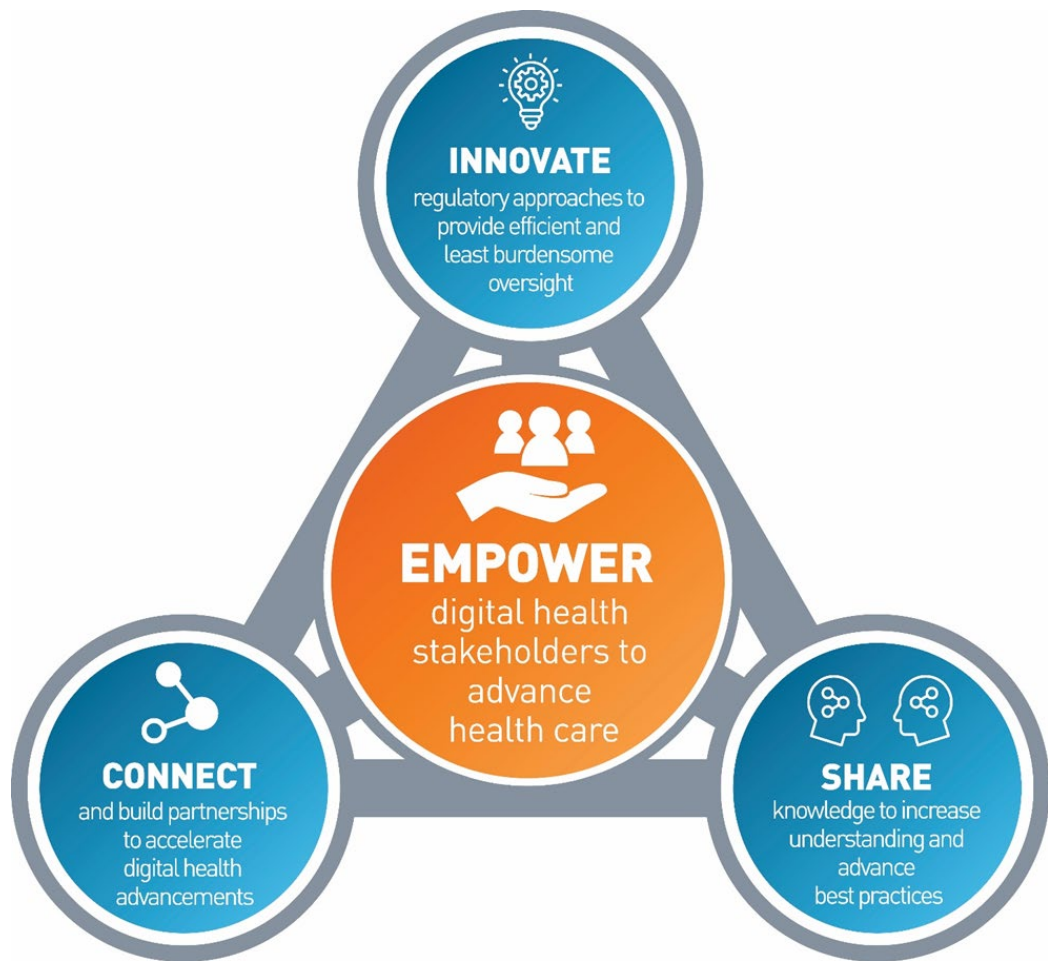
Medical software manufacturers are encouraged to leverage the software technology's capability to capture real world performance data to understand user interactions with the SaMD, and to conduct ongoing monitoring of analytical and technical performance to support future intended uses.



CDRH Digital Health Center of Excellence



Empowering All to Advance Healthcare



Outline

- Digital Health and the CDRH DH Center of Excellence
- **Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices**
- FDA AI/ML Action Plan



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 ML models to be developed by ML training algorithms through analysis of data, without models being explicitly programmed.

ML-Enabled Medical Device (MLMD):

A medical device that uses machine learning, in part or in whole, to achieve its intended medical purpose.

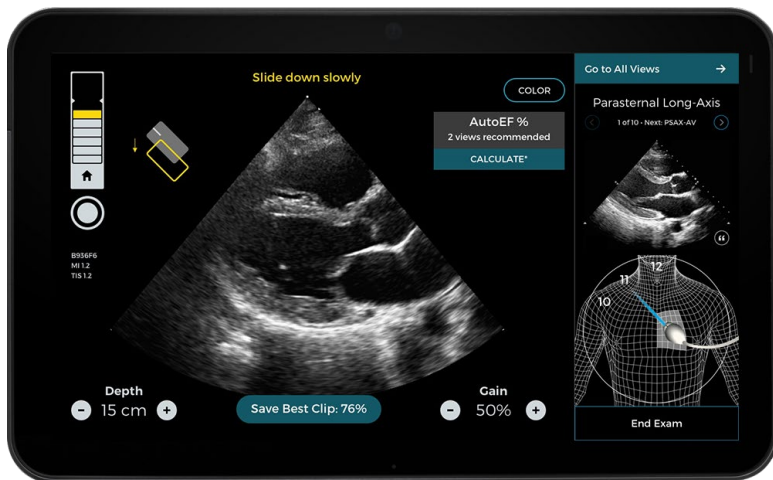
Adapted from IMDRF Artificial Intelligence Medical Devices Key Terms & Definitions

Final document posted May 9, 2022 at:

<https://www.imdrf.org/documents/machine-learning-enabled-medical-devices-key-terms-and-definitions>

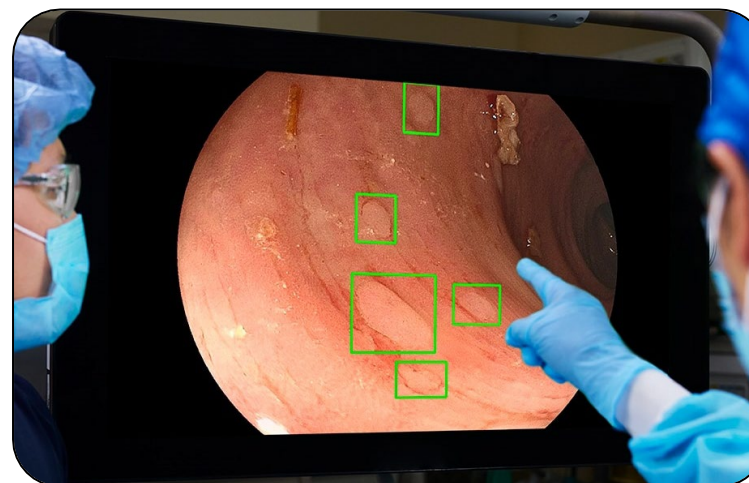


We are ensuring patient access to safe and effective AI/ML-Enabled Medical Devices



2/7/20

[FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User, Caption Guidance™](#)



4/9/21

[FDA Authorizes Marketing of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer, GI Genius™](#)



9/21/21

[FDA Authorizes Software that Can Help Identify Prostate Cancer, Paige Prostate](#)



U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Medical Devices / Digital Health Center of Excellence / Software as a Medical Device (SaMD) / Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices

Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices

Date of Final Decision	Submission Number	Device	Company	Panel (Lead)	Primary Product Code
06/17/2021	K203514	Precise Position	Philips Healthcare (Suzhou) Co., Ltd.	Radiology	JAK
06/16/2021	K202718	Qmenta Care Platform Family	Mint Labs, Inc., D/B/A. QMENTA	Radiology	LLZ
06/11/2021	K210484	LINQ II Insertable Cardiac Monitor, ZELDA AI ECG Classification System	Medtronic, Inc.	Cardiovascular	MXD
06/10/2021	K203629	IDx-DR	Digital Diagnostics Inc.	Ophthalmic	PIB
06/02/2021	DEN200069	Cognoa Asd Diagnosis Aid	Cognoa, Inc.	Neurology	QPF
05/19/2021	K210237	CINA CHEST	Avicenna.AI	Radiology	QAS
04/30/2021	K210001	HYPHER AiR	Shanghai United Imaging Healthcare Co.,Ltd.	Radiology	KPS
04/23/2021	K203314	Cartesion Prime (PCD-1000A/3) V10.8	Canon Medical Systems Corporation	Radiology	KPS
04/23/2021	K203502	MEDO-Thyroid	MEDO DX Pte. Ltd.	Radiology	QIH
04/21/2021	K210556	Preview Shoulder	Genesis Software Innovations	Radiology	QIH
04/20/2021	K203610	Automatic Anatomy Recognition (AAR)	Quantitative Radiology Solutions, LLC	Radiology	QKB
04/19/2021	K203469	AI Segmentation	Varian Medical Systems	Radiology	MUJ
04/16/2021	K203517	Saige-Q	DeepHealth, Inc.	Radiology	QFM
04/14/2021	K202992	BriefCase, RIB Fractures Triage (RibFx)	Aidoc Medical, Ltd.	Radiology	QFM
04/09/2021	DEN200055	GI Genius	Cosmo Artificial Intelligence - AI, Ltd.	Gastroenterology-Urology	QNP

Top

<https://www.fda.gov/medical-devices/digital-health-center-excellence>

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

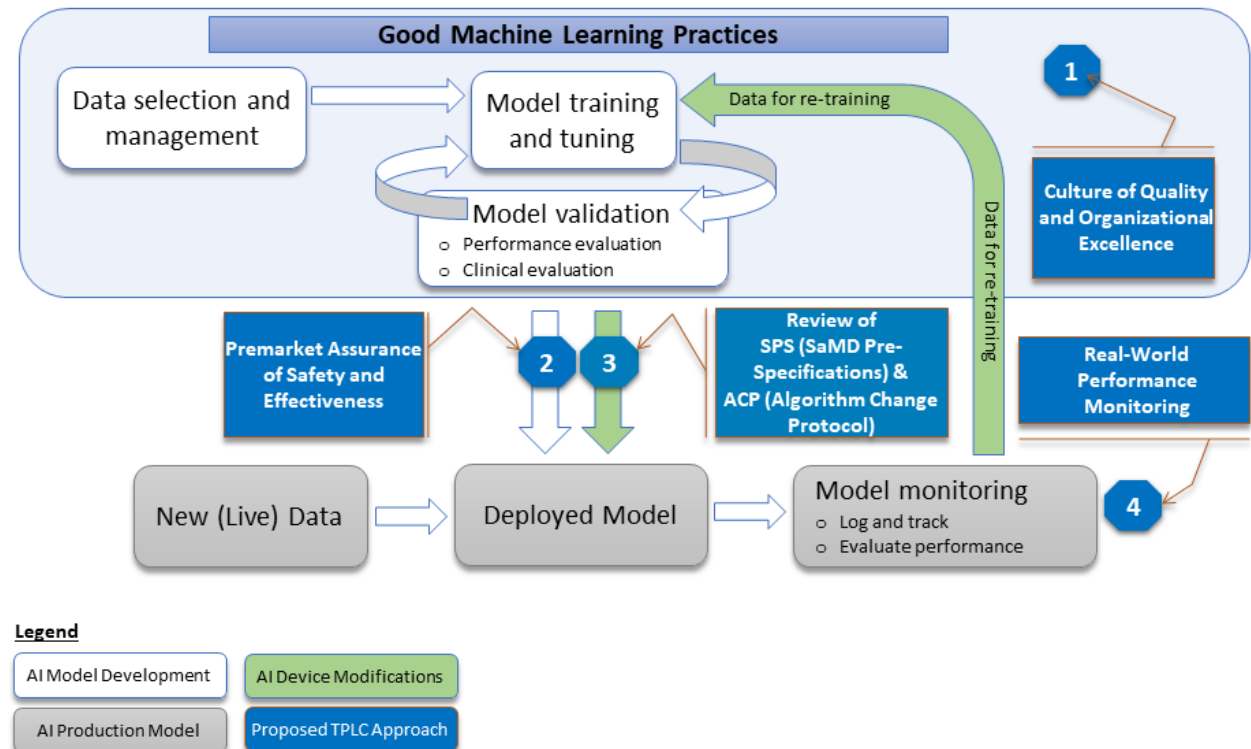
- **Fit-for-purpose data sets for development and testing, including diversity**
- **Identification and minimization of bias**
- **Opacity of some algorithms**
- **Providing oversight for an adaptive system**
- **Ensuring transparency to users**

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback



Overlay of FDA's TPLC Approach on AI/ML Workflow



Proposed Regulatory Framework for AI/ML-Enabled Device Software

Gathering Stakeholder Feedback



Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback

The central graphic consists of eight hexagonal icons arranged in a cluster, each representing a key AI/ML concept: Pattern Recognition (magnifying glass), Artificial Intelligence (circuit board), Machine Learning (hand pointing at a screen), Automation (gears), Neural Networks (neural network diagram), Data Mining (hand pointing at binary code), Algorithm (flowchart), and Problem Solving (crosses and arrows).

Since publishing in April 2019 FDA's **Proposed Regulatory Framework for Modifications to AI/ML-Based SaMD**, we've received stakeholder feedback through:

- > 1,000 comments on public docket from a diverse community of stakeholders
- > 30 publications in peer-reviewed journals
- Public Workshops on the Evolving Role of AI in Radiological Imaging (Feb 2020) and Transparency of AI/ML-Enabled Devices (Oct 2021)
- Patient Engagement Advisory Committee (PEAC) Meeting (October 2020)
- Pre-submission meetings on AI/ML devices

Outline



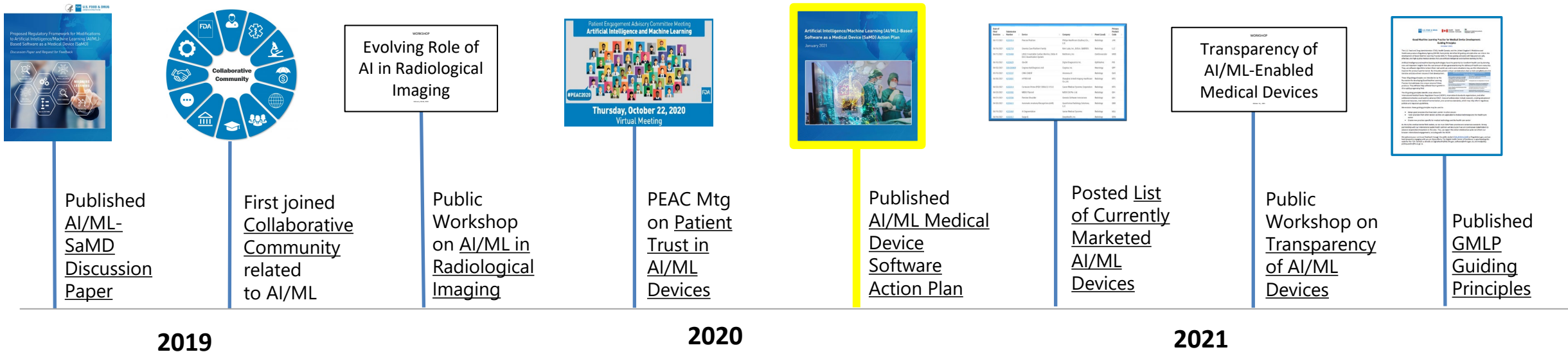
- Digital Health and the CDRH DH Center of Excellence
- Artificial Intelligence/ Machine Learning (AI/ML)-Enabled Medical Devices
- **FDA AI/ML Action Plan**



A Collaborative Approach to AI/ML-Enabled Devices



Recent Milestones



Current/Future Work (2022+) AI/ML Medical Device Software Action Plan

- Update the proposed AI/ML framework
- Strengthen FDA’s role in harmonizing GMLP
- Foster a patient-centered approach
- Support development of regulatory science methods
- Advance real-world performance pilots

Stakeholder Feedback on AI/ML Approach

What we heard, and what we're doing

What we heard from stakeholders:

1. **Regulatory Framework:** Requested further development of proposed regulatory framework for AI/ML-based SaMD
2. **Good Machine Learning Practices (GMLP):** Supported the idea of GMLP and the need for harmonization of its efforts
3. **Transparency:** Asked for further discussion with FDA on how these technologies interact with people, including transparency to users
4. **Regulatory Science:** Described need for improved methods related to algorithmic bias and robustness.
5. **Real-World Performance (RWP):** Sought clarity on RWP monitoring for AI/ML software.

What we're doing -- The AI/ML Action Plan:

1. **Update the proposed AI/ML framework,** including through Guidance
2. **Strengthen FDA's role in harmonizing GMLP** through standards development & other initiatives
3. **Foster a patient-centered approach,** starting with a workshop on transparency to users
4. **Support development of regulatory science methods** related to algorithm bias and robustness
5. **Advance real-world performance pilots** in coordination with stakeholders and other programs

**Part 1: Regulatory
Framework**

**Part 2: GMLP and
Harmonization**

**Part 3: Pt-Centered
Transparency**

**Part 4: Regulatory
Science Methods**

**Part 5: RWP
Considerations**

**Part 1: Regulatory
Framework**

Part 2: GMLP and
Harmonization

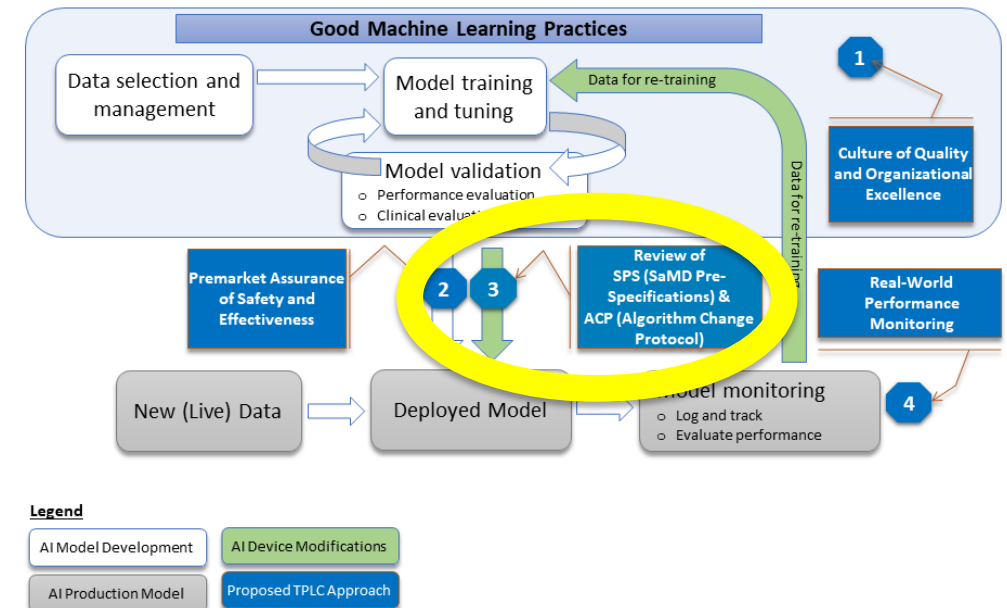
Part 3: Pt-Centered
Transparency

Part 4: Regulatory
Science Methods

Part 5: RWP
Considerations

Tailoring a Regulatory Framework for AI/ML-Enabled SaMD

- A strength of AI/ML systems is their ability to learn from real world data and improve performance over time
- Change Control Plan includes:
 - **Software Pre-Specifications (SPS):** describes "what" aspects the manufacturer intends to change through learning,
 - **Algorithm Change Protocol (ACP):** explains "how" the algorithm will learn and change while remaining safe and effective
- Developing Draft Guidance on Change Control Plan



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

Adapted from Proposed Regulatory Framework for Artificial Intelligence/Machine Learning (AI/ML)-Based SaMD

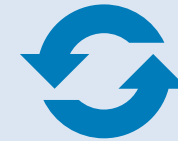
Tailoring a Regulatory Framework for AI/ML-Enabled Devices



Enhance patient access to high quality digital medical products



Maintain a reasonable assurance of safety and effectiveness



Enable manufacturers to rapidly improve software products with minor changes



Least burdensome

Part 1: Regulatory
Framework

**Part 2: GMLP and
Harmonization**

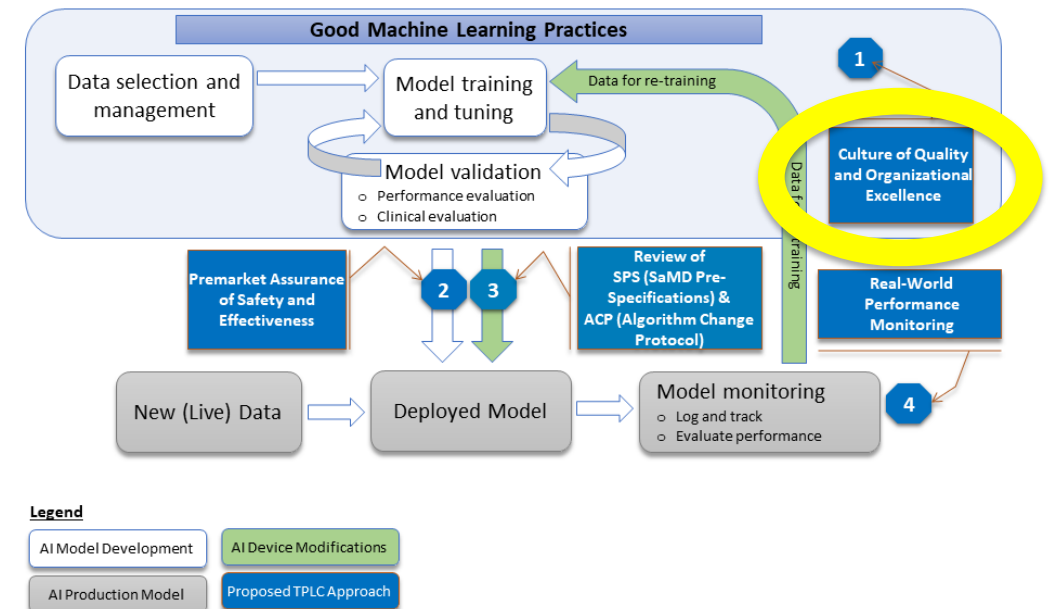
Part 3: Pt-Centered
Transparency

Part 4: Regulatory
Science Methods

Part 5: RWP
Considerations

Good Machine Learning Practice (GMLP)

- Accepted practices in ML/AI algorithm design, development, training, and testing that facilitate the quality development and assessment of ML/AI-enabled devices
- Based on concepts from quality systems, software reliability, machine learning, and data analysis



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

Adapted from Proposed Regulatory Framework for Artificial Intelligence/Machine Learning (AI/ML)-Based SaMD

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 Community on Ophthalmic Imaging



Pathology Innovation Collaborative Community

- Collaborative Communities:

- Collaborative Community on Ophthalmic Imaging
- Pathology Innovation Collaborative Community
- Digital Health Measurement Collaborative Community
- AFDO/RAPS Healthcare Products Collaborative*



Digital Health Measurement Collaborative Community




HEALTHCARE PRODUCTS COLLABORATIVE

Healthcare Products Collaborative Community

- Other Collaborations:

- IMDRF AI Medical Devices WG

IMDRF Artificial Intelligence Working Group



Final Document

IMDRF/AIMD WG/N67

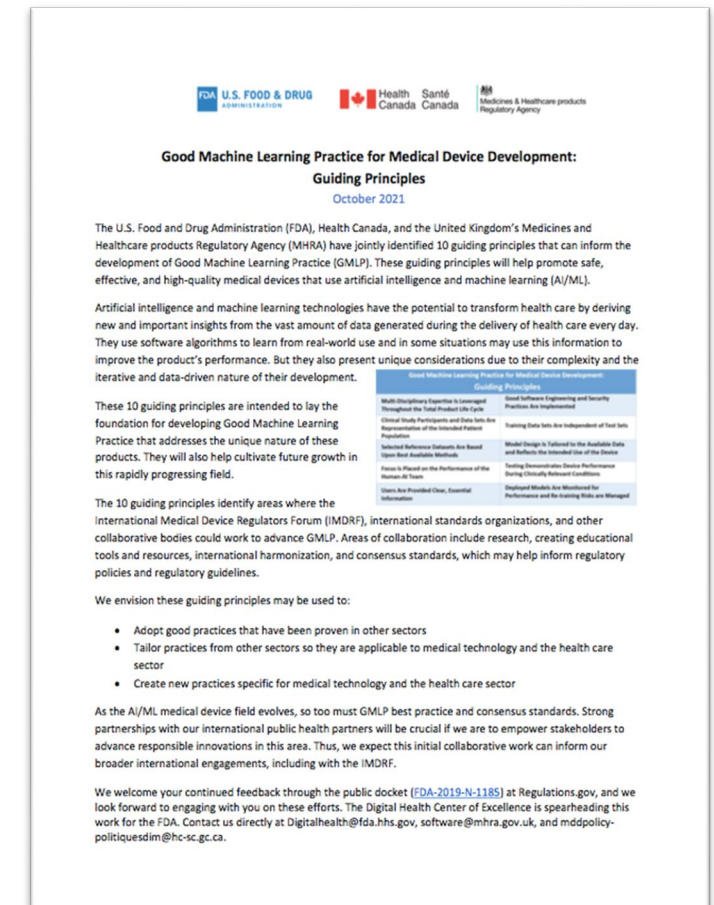
Machine Learning-enabled Medical Devices: Key Terms and Definitions

- Aimed at achieving aligned approach to artificial intelligence (AI) enabled-medical devices
- Final document posted May 6, 2022: [Machine Learning-enabled Medical Devices: Key Terms and Definitions](#)
 - Defines key terms
 - Discusses key concepts
 - Changes
 - Supervised/Unsupervised/Semi-supervised Learning
 - Validation

<https://www.imdrf.org/sites/default/files/2022-05/IMDRF%20AIMD%20WG%20Final%20Document%20N67.pdf>

Good Machine Learning Practice (GMLP) Guiding Principles

- Ten guiding principles issued by US FDA, MHRA (UK) and Health Canada
- Intended to help inform the development of GMLP and encourage broad stakeholder engagement
- Promote global harmonization in efforts for the identification of best practices and the creation of standards





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

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

Principle 1

Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle:

- In-depth understanding of a model's intended integration into clinical workflow, and the desired benefits and associated patient risks, can help ensure that ML-enabled medical devices are safe and effective and address clinically meaningful needs over the lifecycle of the device.



Principle 2

Good Software Engineering and Security Practices Are Implemented:

- Model design is implemented with attention to the “fundamentals”: good software engineering practices, data quality assurance, data management, and robust cybersecurity practices.
- These practices include methodical risk management and design process that can appropriately capture and communicate design, implementation, and risk management decisions and rationale, as well as ensure data authenticity and integrity.



Principle 3

Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population:

- Data collection protocols should ensure that for clinical study, training and test datasets, the following are sufficiently represented in a sample of adequate size:
 - the relevant characteristics of the intended patient population (e.g., age, gender, sex, race, and ethnicity),
 - use, and
 - measurement inputs

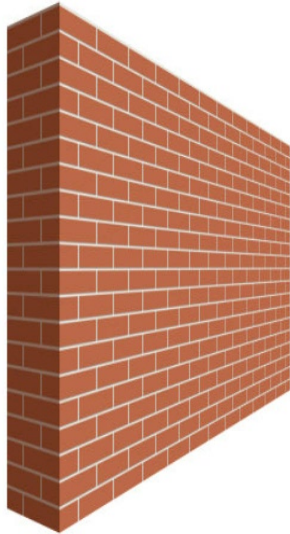
so that results can be reasonably generalized to the population of interest.

- This is important to manage any bias, promote appropriate and generalizable performance across the intended patient population, assess usability, and identify circumstances where the model may underperform.



Principle 4

**Training
Data
Set**



**Test
Data
Set**

Training Data Sets Are Independent of Test Sets:

- Training and test datasets are selected and maintained to be appropriately independent of one another.
- All potential sources of dependence, including patient, data acquisition, and site factors, are considered and addressed to assure independence.

Principle 5

Selected Reference Datasets Are Based Upon Best Available Methods:

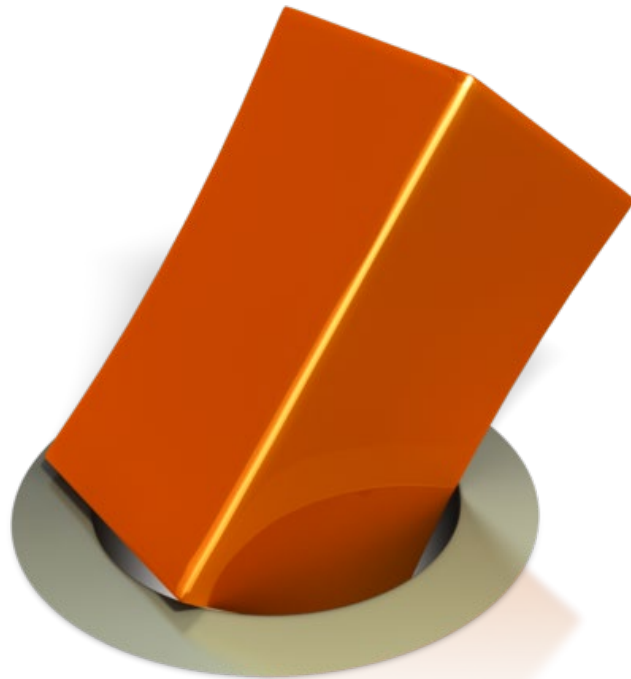
- Accepted, best available methods for developing a reference dataset (that is, a reference standard) ensure that clinically relevant and well characterized data are collected and the limitations of the reference are understood.
- If available, accepted reference datasets in model development and testing that promote and demonstrate model robustness and generalizability across the intended patient population are used.



Principle 6

Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device:

- Model design is suited to the available data and supports the active mitigation of known risks, like overfitting, performance degradation, and security risks.
- The clinical benefits and risks related to the product are well understood, used to derive clinically meaningful performance goals for testing, and support that the product can safely and effectively achieve its intended use.
- Considerations include the impact of both global and local performance and uncertainty/variability in the device inputs, outputs, intended patient populations, and clinical use conditions.



Principle 7

Focus Is Placed on the Performance of the Human-AI Team

- Where the model has a “human in the loop,” human factors considerations and the human interpretability of the model outputs are addressed with emphasis on the performance of the Human-AI team, rather than just the performance of the model in isolation.



Principle 8

Testing Demonstrates Device Performance During Clinically Relevant Conditions:

- Statistically sound test plans are developed and executed to generate clinically relevant device performance information independently of the training data set.
- Considerations include:
 - the intended patient population,
 - important subgroups
 - clinical environment and use by the Human-AI team,
 - measurement inputs, and
 - potential confounding factors.



Principle 9

Users Are Provided Clear, Essential Information:

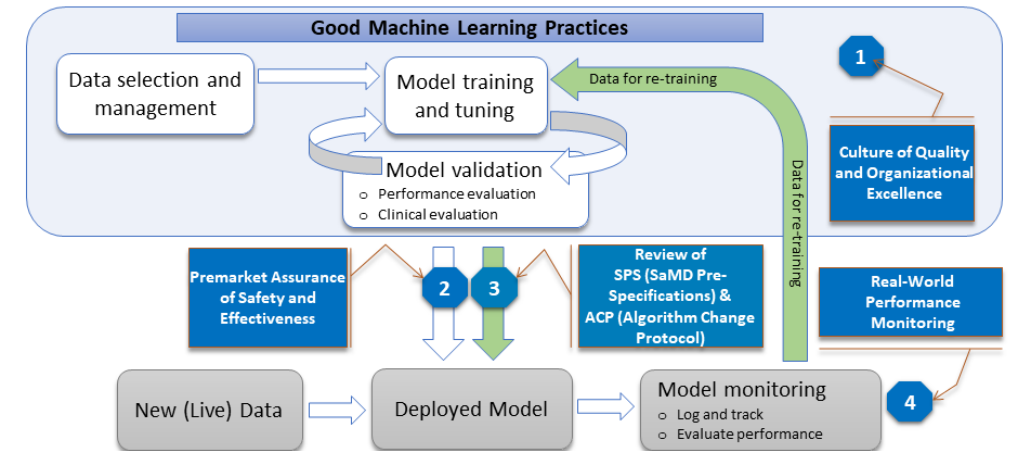
- Users are provided ready access to clear, contextually relevant information that is appropriate for the intended audience (such as health care providers or patients) including:
 - the product’s intended use and indications for use,
 - performance of the model for appropriate subgroups,
 - characteristics of the data used to train and test the model,
 - acceptable inputs,
 - known limitations,
 - user interface interpretation,
 - and clinical workflow integration of the model.
- Users are also made aware of device modifications and updates from real-world performance monitoring, the basis for decision-making when available, and a means to communicate product concerns to the developer.



Principle 10

Deployed Models Are Monitored for Performance and Re-training Risks Are Managed:

- Deployed models have the capability to be monitored in “real world” use with a focus on maintained or improved safety and performance.
- Additionally, when models are periodically or continually trained after deployment, there are appropriate controls in place to manage risks of overfitting, unintended bias, or degradation of the model (for example, dataset drift) that may impact the safety and performance of the model as it is used by the Human-AI team.





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

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

Part 1: Regulatory
Framework

Part 2: GMLP and
Harmonization

Part 3: Pt-Centered
Transparency

Part 4: Regulatory
Science Methods

Part 5: RWP
Considerations

Patient-Centered Approach Incorporating Transparency to Users

AI/ML-enabled devices have unique considerations that necessitate a proactive patient-centered approach:

- that takes into account issues including usability, equity, trust, and accountability
- that promotes transparency to all users and to patients more broadly

Patient Engagement Advisory Committee (PEAC) Meeting held Oct 2020

Workshop on Transparency of AIML-enabled devices held Oct 2021



Working Definition of Transparency



TRANSPARENCY:

Degree to which appropriate information about a device
– *including its intended use, development,*
performance, and, when available, logic –
is clearly communicated to stakeholders

**Working definition of Transparency, above, for purposes of this workshop adapted from ISO/IEC JTC1 SC42 WG1 25059 (draft)*

Transparency is fundamental to a patient-centered approach and supports the safe and effective use of AI/ML-enabled devices.

1. Allows patients, providers, and caregivers to make informed decisions
2. Supports proper use of a device
3. Promotes health equity
4. Facilitates evaluation and monitoring of device performance
5. Fosters trust and promotes adoption



Continuing to Improve Transparency



- What are the needs of specific stakeholders?
- What is the appropriate information to communicate?
- What is the best way to communicate that information?
 - How can device labeling be improved?
 - How can other public-facing information be improved?
 - What else can be done to promote transparency?

Workshop Participation

- **3800 workshop participants**
 - Patients, healthcare professionals, academia, advocacy groups, and industry
- **Discussion Themes (Workshop and Docket)**
 - Health equity and bias
 - Labeling
 - Public education efforts
 - Decision summaries
 - Databases
 - Post market pathways
 - Real world performance monitoring
 - Industry guidance
 - Data set requirements
 - Validation of transparency measures
 - Promoting GMLP

Topics of AI/ML Transparency Workshop Discussion

What does AI/ML Transparency mean?

- Safe and effective
 - Clear intended use
 - Works as described
- Health equity
 - Fair to all people
 - Bias management
- Real world performance
 - Assurance of improved health outcomes

How to promote AI/ML Transparency?

- User facing information/ labeling
 - Accessible language/terminology
 - Clear functionality and limitations
- Public education on AI/ML
- Dataset requirements
- Pre-market guidance
- Post-market monitoring

Part 1: Regulatory
Framework

Part 2: GMLP and
Harmonization

Part 3: Pt-Centered
Transparency

**Part 4: Regulatory
Science Methods**

Part 5: RWP
Considerations

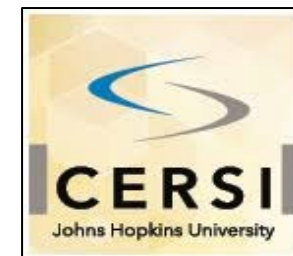
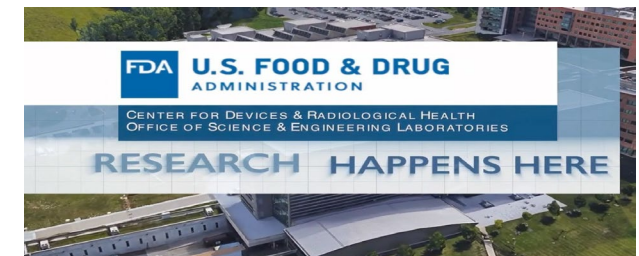
Regulatory Science Methods Related to Algorithm Bias & Robustness

- Need for improved methodologies for the evaluation and development of machine learning algorithms
- Includes methods for the identification and minimization of bias, and on the robustness and resilience of these algorithms to withstand changing clinical inputs and conditions



Regulatory Science Methods Related to Algorithm Bias & Robustness

- Regulatory science research efforts to develop these methods to evaluate AI/ML-enabled medical software.
- Ongoing research being conducting in collaboration with Centers for Excellence in Regulatory Science and Innovation (CERSIs) at:
 - University of California San Francisco (UCSF)/ Stanford University;
 - Johns Hopkins University.
- These collaborations complement the ongoing research efforts and the AI/ML program charter at the Office of Science & Engineering Laboratories (OSEL).

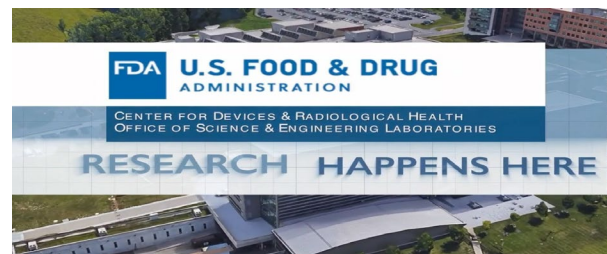


Major Regulatory Science Gaps and Challenges Driving the OSEL AI/ML Program

- Need for methods to enhance AI/ML algorithm training for clinical datasets that are typically much smaller than non-clinical datasets
- Need for clear definition or understanding of artifacts, limitations, and failure modes for fast-growing applications of Deep-Learning (DL) algorithms in the denoising and reconstruction of medical images
- Need for assessment techniques to evaluate the trustworthiness of adaptive and autonomous AI/ML devices (for example, continuously learning algorithms)
- Need for systematic approaches to address the robustness of various AI/ML input factors, such as data acquisition factors, patient demographics, and disease factors, to patient outcomes in a regulatory submission
- Need for a clear reference standard for assessing accuracy of AI/ML-based Quantitative Imaging (QI) and radiomics tools

OSEL Research Related to Algorithm Bias & Robustness

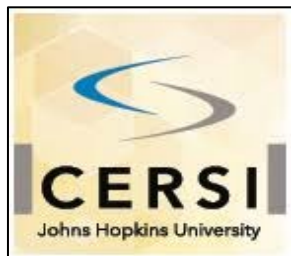
- Data
 - Data augmentation
 - Weakly-labeled data
 - Synthetic data
 - Bias
 - Distribution shift
 - Sex-bias
- Evaluation
 - Metrics
 - Multi-class decision support systems
 - Performance metric selection tool
 - Continual learning systems
 - New evaluation framework



CERSI Research Related to Algorithm Bias & Robustness



- Safe Algorithmic Change Protocols for Modifications to AI/ML-Based Software as a Medical Device



- Assessing the Robustness of Clinical Machine Learning Models to Changes in Context of Use

Part 1: Regulatory
Framework

Part 2: GMLP and
Harmonization

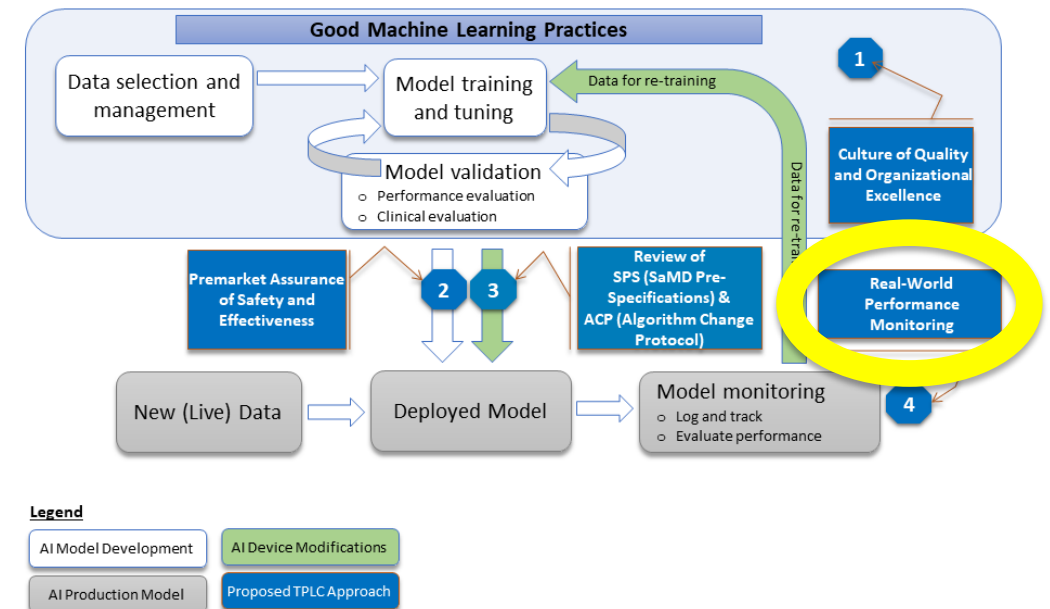
Part 3: Pt-Centered
Transparency

Part 4: Regulatory
Science Methods

Part 5: RWP
Considerations

Real World Performance

- Collection and monitoring of real-world data will support a total product lifecycle (TPLC) approach to the oversight of AI/ML-enabled software
- By gathering data on real-world use and performance of software, manufacturers can:
 - Improve their understanding of how their products are being used
 - Identify opportunities for improvements, and
 - Respond proactively to safety or usability concerns

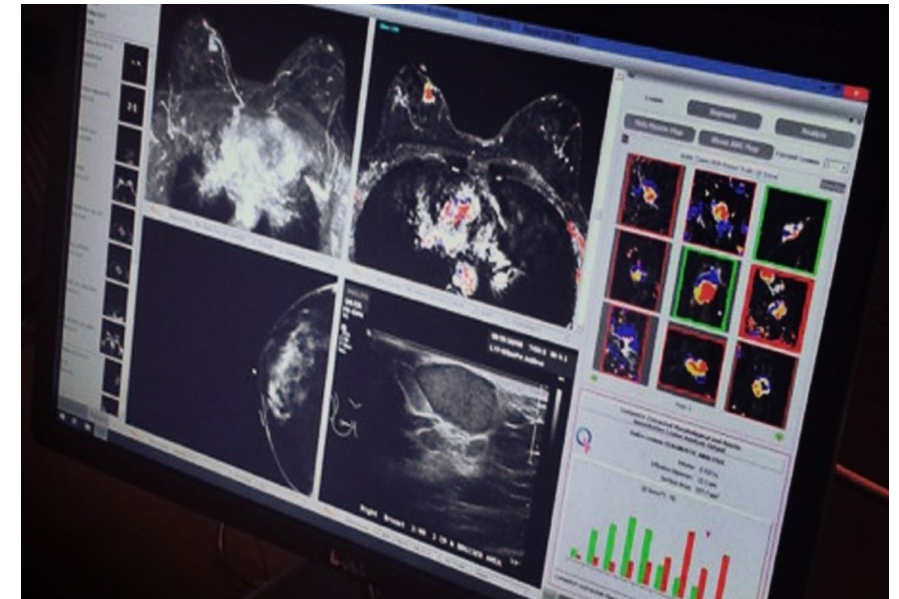


Overlay of FDA's TPLC approach on AI/ML workflow

Adapted from Proposed Regulatory Framework for Artificial Intelligence/Machine Learning (AI/ML)-Based SaMD

Real World Performance

- What type of reference data are appropriate to utilize in measuring the performance of AI/ML software devices in the field?
- How much of the oversight should be performed by each stakeholder?
- How much data should be provided to the Agency, and how often?
- How can the algorithms, models, and claims be validated and tested?
- How can feedback from end-users be incorporated into the training and evaluation of AI/ML-enabled software?

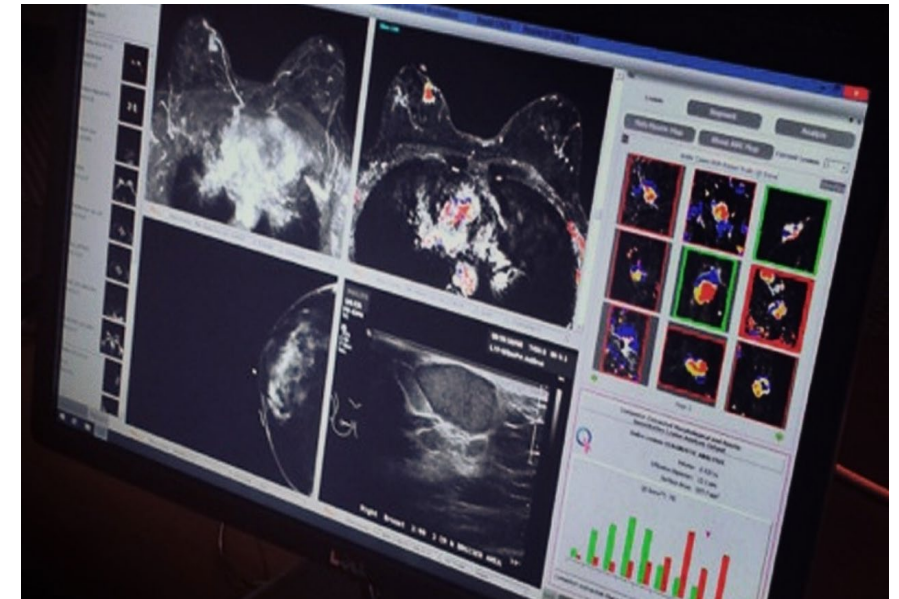


<https://angel.co/quantitative-insights>

Real World Performance

Actions:

- Support the piloting of real-world performance monitoring by working with stakeholders on a voluntary basis
- Coordination with other ongoing FDA programs focused on the use of real-world data
- Develop a framework for seamless gathering, validation, and evaluation of relevant real-world performance metrics
- Continued stakeholder and public engagement



<https://angel.co/quantitative-insights>

**Part 1: Regulatory
Framework**

**Part 2: GMLP and
Harmonization**

**Part 3: Pt-Centered
Transparency**

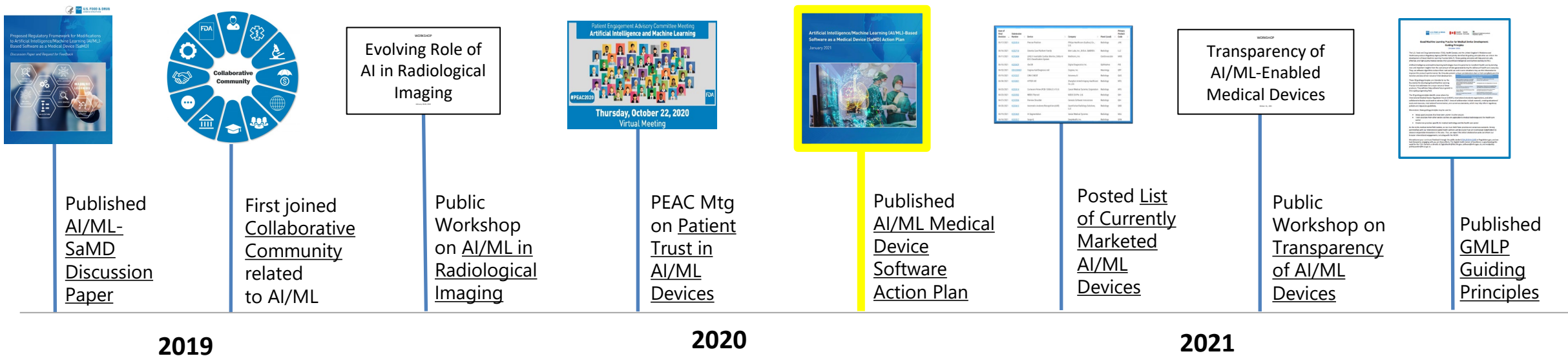
**Part 4: Regulatory
Science Methods**

**Part 5: RWP
Considerations**

A Collaborative Approach to AI/ML-Enabled Devices



Recent Milestones



Current/Future Work (2022+) AI/ML Medical Device Software Action Plan

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

Digital Health Collaborations

Collaboration efforts focus on digital health technology, artificial intelligence / machine learning, health equity, measurement, and real-world evidence

FDA's Centers of Excellence in Regulatory Science and Innovation



CERSI's are collaborations between FDA and academic institutions to advance regulatory science through innovative research, training, and scientific exchanges.



Collaborative Communities are continuing forums in which private- and public-sector members, which can include the FDA, work together on medical device challenges to achieve common objectives and outcomes

Further Questions or Feedback:

FDA



www.fda.gov/digitalhealth



DigitalHealth@fda.hhs.gov

Shawn Forrest, MS

Digital Health Specialist

CDRH Digital Health Center of Excellence

Office of Strategic Partnerships & Technology Innovation (OST)

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

shawn.forrest@fda.hhs.gov

(301) 796-5386

