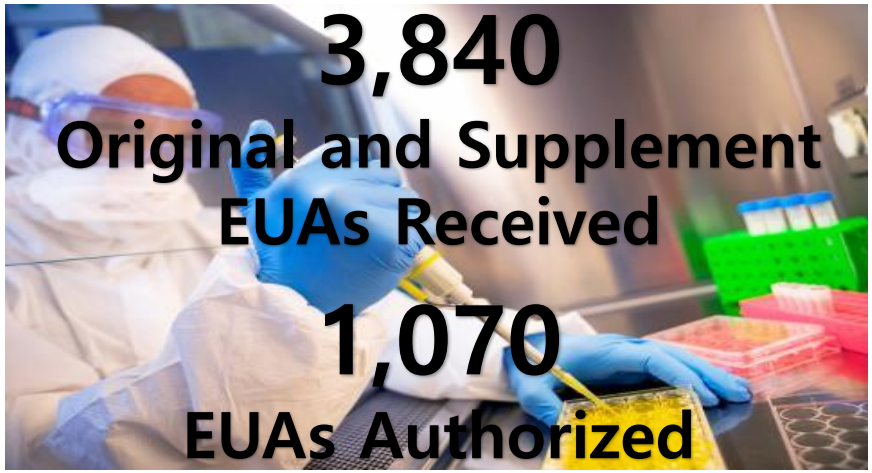
IMDRF International Medical Device Regulators Forum

US FDA Update

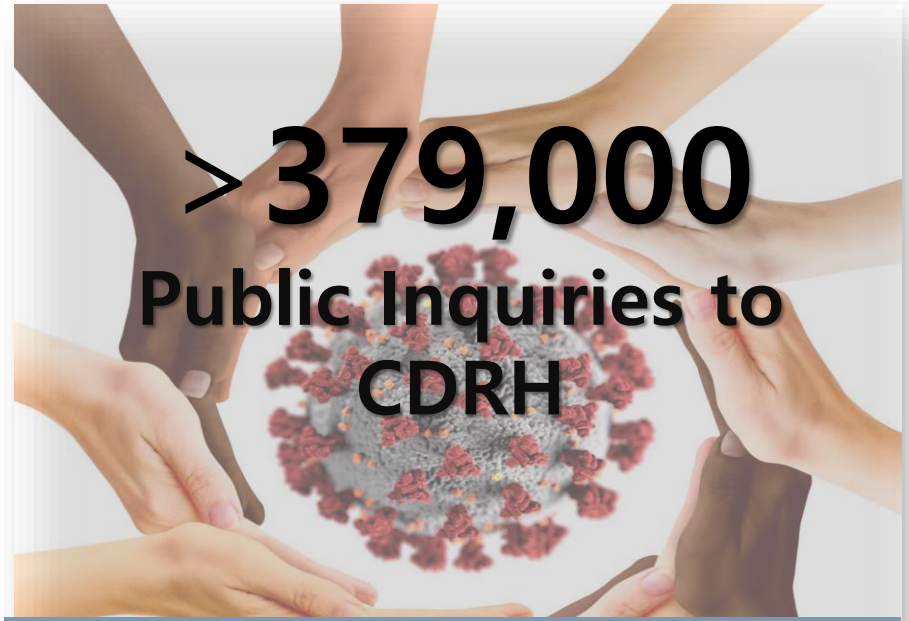
IMDRF Open Stakeholder Session

March 2021

COVID-19 Overview



27
GUIDANCE DOCUMENTS



>47,000
WEBINAR PARTICIPANTS

*Data as of February 12, 2021

Medical Device User Fee Amendments (MDUFA)

- Program where industry pays user fees which the agency uses to increase review capacity to meet performance goals on review timelines and implement targeted process improvements.
- Helps assure patients have access to safe, effective, high-quality devices in a timely fashion and there is a clear, predictable path to market for new innovations.
- The user fees authorized by MDUFA are crucial to enabling CDRH to continue to modernize our regulatory programs.
- The program is reauthorized every five years based on new negotiated agreements and new legislation:
  - MDUFA I: FY 2003-2007
  - MDUFA II: FY 2008-2012
  - MDUFA III: FY 2013-2017
  - MDUFA IV: FY 2018-2022

MDUFA V Reauthorization

- The authorization for the current program (MDUFA IV) expires in September 2022 and will need to be reauthorized (MDUFA V).
  - MDUFA V: FY 2023-2027
- Initial public meeting was held on October 27, 2020 involving various stakeholders to present their views on reauthorization.
- Periodic stakeholder consultation meetings will be held during which public stakeholders — including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts — can discuss their views on the MDUFA V reauthorization and provide suggestions for improving the program.
  - First scheduled for March 10, 2021
- Meetings will also be held with industry representatives to develop recommendations for MDUFA V.

Device Safety Guidances: Breast Implant Guidance Documents

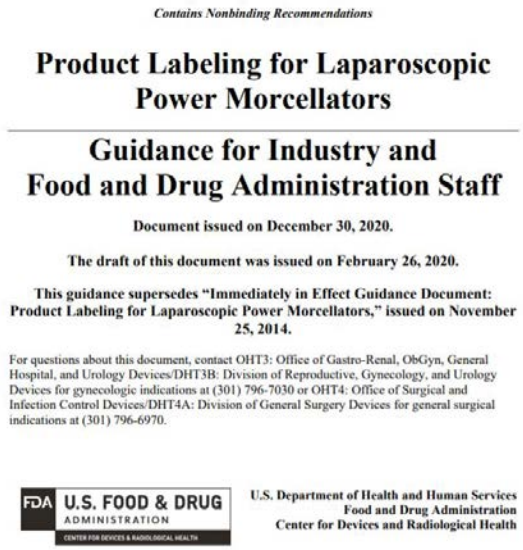
- *Breast Implants – Certain Labeling Recommendations to Improve Patient Communication*
  - Contains recommendations concerning the content and format for certain labeling information for saline and silicone gel-filled breast implants to help ensure that a patient receives and understands the benefits and risks of these devices.
  - https://www.fda.gov/media/131885/download

- *Saline, Silicone Gel, and Alternative Breast Implants*
  - Identifies the device description, non-clinical, clinical, and labeling information that should be included in a premarket approval application (PMA) for a saline, silicone gel, or alternative filler breast implant.
  - https://www.fda.gov/media/71081/download

Device Safety Guidances: Laparoscopic Power Morcellators

Product Labeling for Laparoscopic Power Morcellators (LPMs)

- Contains recommendations concerning the content and format for certain labeling information for laparoscopic power morcellators in order to enhance the physician-patient discussion of the benefits and risks of use of LPMs that uniquely pertain to individual patients. Specifically:
  - Labeling should provide greater specificity regarding the risk of use as it relates to age, information regarding the risk of spreading malignant and benign uterine tissue, and information regarding the use of LPM containment systems.



Contains Nonbinding Recommendations

Product Labeling for Laparoscopic Power Morcellators

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 30, 2020.

The draft of this document was issued on February 26, 2020.

This guidance supersedes "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators," issued on November 25, 2014.

For questions about this document, contact OHT3: Office of Gastro-Renal, ObGyn, General Hospital, and Urology Devices/DHT3B: Division of Reproductive, Gynecology, and Urology Devices for gynecologic indications at (301) 796-7030 or OHT4: Office of Surgical and Infection Control Devices/DHT4A: Division of General Surgery Devices for general surgical indications at (301) 796-6970.

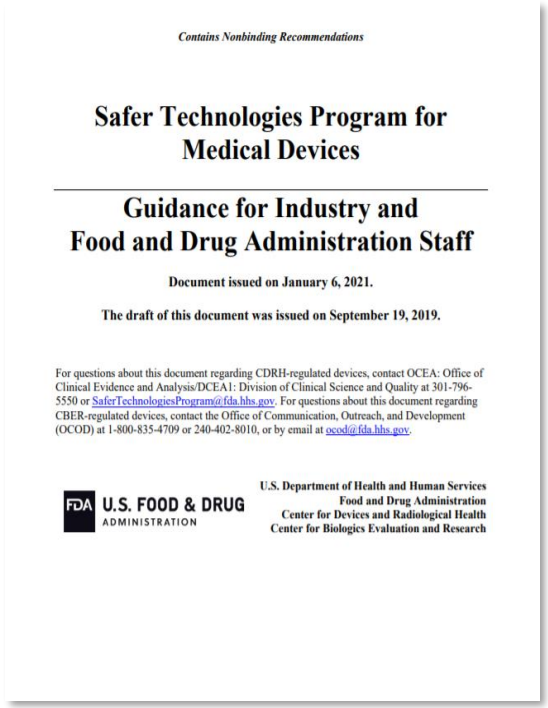
FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators

Safer Technologies Program (STeP) for Medical Devices

- ✓ Final guidance published on January 6, 2021.
- ✓ Voluntary program for certain types of medical devices that are reasonably expected to significantly improve the safety of currently available medical treatments and diagnostics through innovative technological features.
- ✓ Focuses on increasing timeliness of patient access to these medical devices.
- ✓ Key features:
  - ✓ Expedites device development and review
  - ✓ Provides opportunities for interaction to efficiently support device development
  - ✓ Provides increased opportunity for senior management involvement



Contains Nonbinding Recommendations

Safer Technologies Program for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on January 6, 2021.

The draft of this document was issued on September 19, 2019.

For questions about this document regarding CDRH-regulated devices, contact OCEA: Office of Clinical Evidence and Analysis/DCEA1: Division of Clinical Science and Quality at 301-796-5550 or SaferTechnologiesProgram@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

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

https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices

Safety and Performance Based Pathway

- Program where devices must meet FDA-identified performance criteria to demonstrate it is as safe and effective as predicate device.
- Device specific guidances issued:
  - Spinal Plating Systems
  - Orthopedic Non-Spinal Metallic Bone Screws and Washers
  - Magnetic Resonance Receive-Only Coils
  - Cutaneous Electrodes for Recording Purposes
  - Conventional Foley Catheters
- Benefits:
  - Promotes the use of modern predicate devices, and adoption of up-to-date benchmarks and standards for performance.
  - Promotes the use and development of international consensus standards rather than reliance on comparison to predicate devices.
  - Facilitates greater harmonization of pre-market requirements with other regulatory jurisdictions.

https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway

AI/ML Medical Device Software 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

AI/ML Medical Device Software Action Plan: Tailored Regulatory Framework for AI/ML Based SaMD

- A strength of AI/ML systems is their ability to learn from real world data and improve performance over time
- Predetermined Change Control Plan includes:
  - **SaMD 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
- Goal is to issue a Draft Guidance on the Predetermined Change Control Plan in 2021

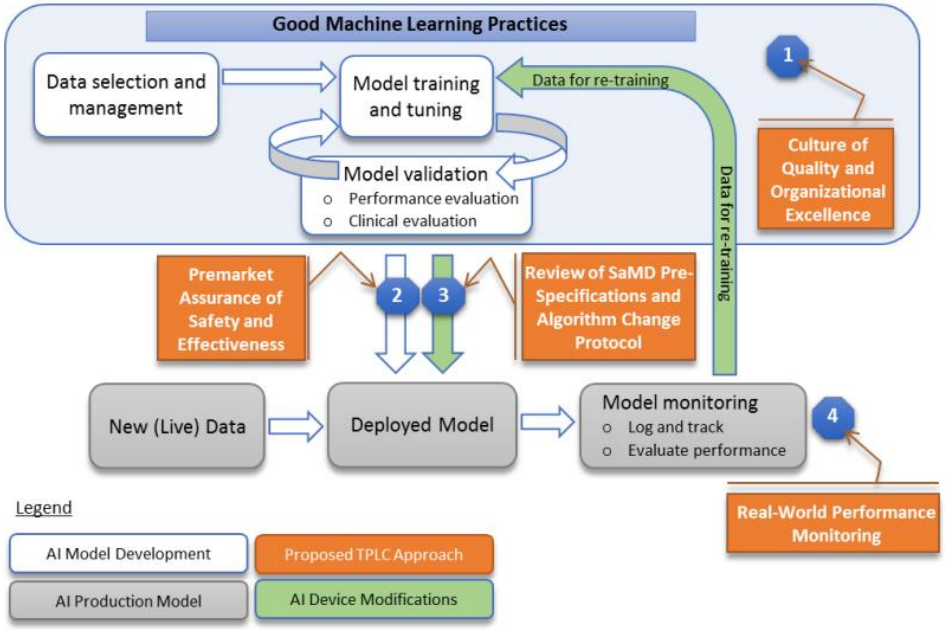
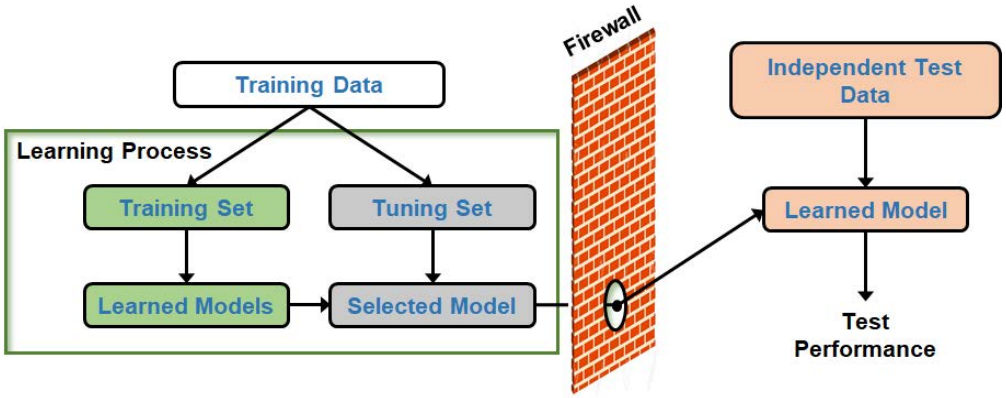


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

AI/ML Medical Device Software Action Plan: 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-based algorithms
- Based on concepts from quality systems, software reliability, machine learning, and data analysis
- Ongoing work through standards development, collaborative communities, and other collaborations



AI/ML Medical Device Software Action Plan: Patient-Centered Approach Incorporating Transparency to Users

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

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

Patient Engagement Advisory Committee (PEAC) Meeting held Oct 2020

Next Step: Workshop on Transparency planned for 2021

AI/ML Medical Device Software Action Plan: Regulatory Science Methods Related to Algorithm Bias & Robustness

- Need for improved methodologies for the evaluation and improvement of machine learning algorithms
- Includes methods for the identification and elimination of bias, and on the robustness and resilience of these algorithms to withstand changing clinical inputs and conditions
- Regulatory science research efforts to develop these methods to evaluate AI/ML-based medical software
- Ongoing research being conducting in collaboration with Centers for Excellence in Regulatory Science and Innovation (CERSIs)

Opinion

A.I. Could Worsen Health Disparities

In a health system riddled with inequity, we risk making dangerous biases automated and invisible.

By Dhruv Khullar

Dr. Khullar is an assistant professor of health care policy and research.

Jan. 31, 2019

HEALTH TECH STAT+

AI could help rid health care of biases. It also might make them worse

By STAT STAFF / SEPTEMBER 15, 2020 Reprints

Racial Bias Found in a Major Health Care Risk Algorithm

Black patients lose out on critical care when systems equate health needs with costs

AI/ML Medical Device Software Action Plan: Real-World Performance (RWP)

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

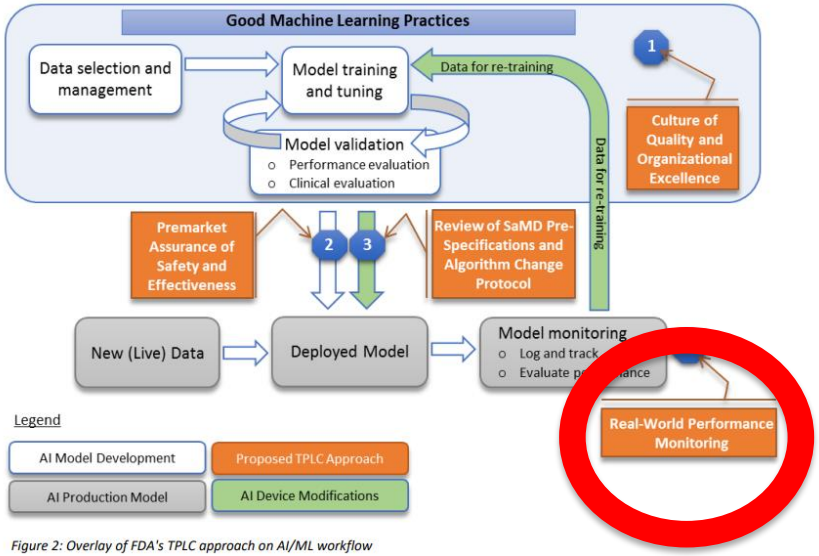


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

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

Thank you