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Update on FDA's Digital Health Policies

Yarmela Pavlovic, Partner

San Francisco, CA

Agenda

1 Recent Policy Developments

2 Overview of Pre-Cert Pilot

3 Future Horizons

1. Recent Policy Developments

FDA and IMDRF

- International Medical Device Regulators Forum (IMDRF)
  - Includes representatives from Australia, Brazil, Canada, China, Europe, Japan, Russia and the U.S. and builds on earlier work by the Global Harmonization Task Force on Medical Devices (GHTF) to develop harmonized medical device regulatory approaches
- *Software as a Medical Device (SaMD): Clinical Evaluation*
  - Describes clinical evaluation principles based on nature of SaMD product
  - Relies on four categories of intended purpose – treat, diagnose, drive clinical management, inform clinical management and risk associated with the medical condition (non-serious, serious, critical)

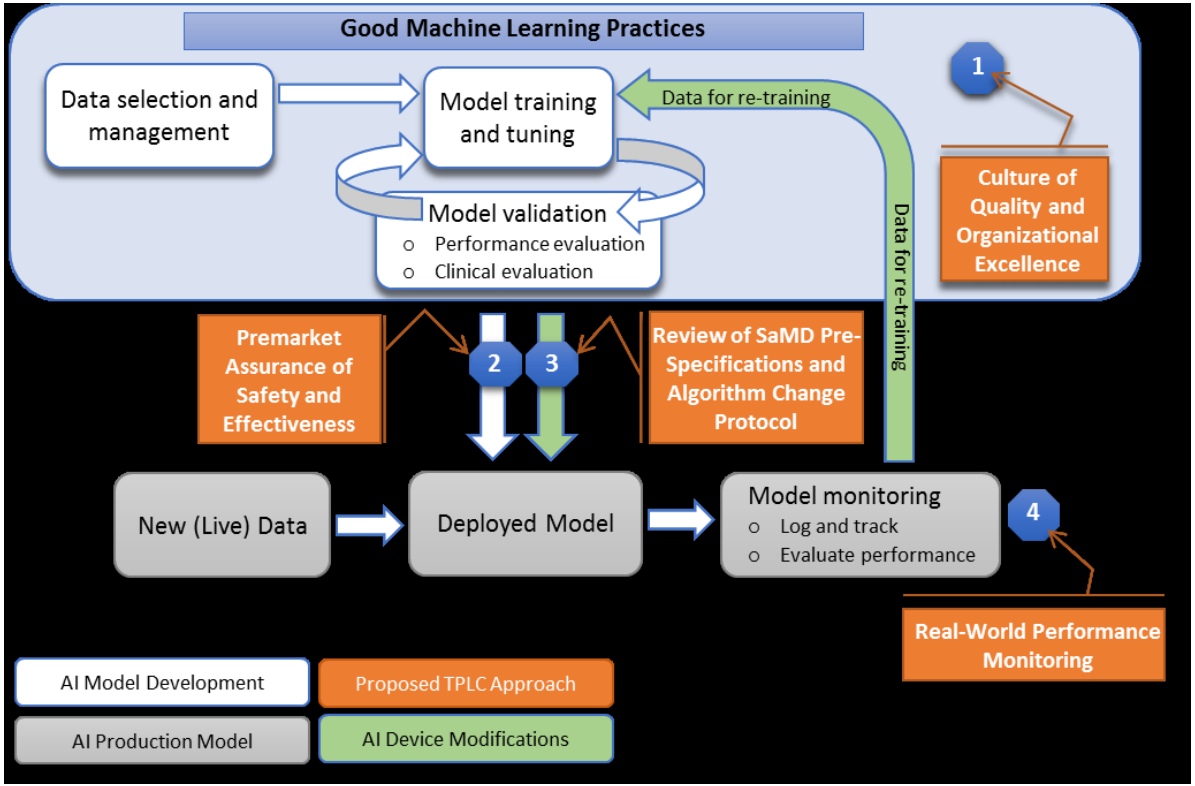
State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Policy Framework for AI/ML Products

- Historically, all algorithm/model-based products have been frozen and validated, reviewed by FDA and future changes may require additional FDA review
- Machine learning potentially allows for more continual optimization of algorithms
- Discussion paper released by FDA on April 3, 2019
  - *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)*
  - Proposes framework for allowing for postmarket changes without necessarily triggering FDA review
  - Relies on IMDRF risk categorizations for determining level of FDA involvement in postmarket changes
  - Focuses on defining guardrails for future changes

Policy Framework for AI/ML Products

- Proposes concept of Good Machine Learning Practices



21st Century Cures Modifies Device Description

- Modified statutory definition to exclude:

Administrative Software	Health and Wellness	Electronic Health Records	MDDS + Functionality	Clinical Decision Support
Examples •Billing •Scheduling	Must be unrelated to medical purposes	If created by a healthcare provider, and fits within the Health IT certification under section 3001(c)(5) of the Public 20 Health Service Act No analysis functions	Includes lab data and "findings" by a healthcare professional and associated "background information"	Must be transparent and not intended to be the sole basis for a determination. Not analyzing laboratory, imaging or sensor data.

Clinical Decision Support Tools

- FDA draft guidance, *Clinical and Patient Decision Support Software* (CDS Guidance), issued by FDA in December 2017
  - Interprets Cures Act changes and explains proposed FDA policy for CDS
  - Tools meeting all of the following four criteria are no longer considered devices subject to FDA regulation:
    - *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;
    - intended to display, analyze, or print medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
    - 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
    - intended to enable such 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.
  - Also describes proposed policy for Patient Decision Support (PDS) tools

Draft CDS Guidance

- CDS function is *only* excluded from the definition of a device when it also meets criterion #4
  - i.e., enables independent review of the software's basis for clinical recommendations
  - Health care professional must be able to rely on his/her own judgment, rather than primarily on the software's recommendations, to make clinical decisions for individual patients
  - Requires that the tool clearly explain:
    - its purpose or intended use,
    - the intended user,
    - the inputs used to generate the recommendation (*e.g.*, patient age), and
    - the rationale or support for the recommendation
  - Intended user should be able to reach the same recommendation on his/her own
  - Sources supporting the recommendation or underlying the rationale should be identified, easily accessible, and understandable to the intended user

Patient Decision Support

- Software intended for use by patients and caregivers who are not healthcare professionals
- Not carved out by the Cures Act, but FDA intends to use enrocement discretion if PDS tools meet the first two Cures Act criteria and:
  - Support or provide recommendations to patients or non-health care professional caregivers, in terms understandable to the intended recipient, about prevention, diagnosis, or treatment of a disease/condition; and
  - Enable the patient or non-health care professional caregiver to independently review the basis for the recommendation so that it is not the intent that such person rely primarily on the recommendation to make a decision regarding a patient.

FDA General Wellness Guidance

- Enforcement discretion for two categories of products intended only for general wellness:
  - Maintaining or encouraging a general state of health or a healthy activity (now excluded by statute)
  - Associates healthy lifestyle with helping to reduce the risk or impact of a disease/condition
- Only low-risk products - cannot be invasive, pose a risk to user safety, raise novel questions of usability, or raise questions of biocompatibility
- Examples:
  - Product X plays music to relax an individual and "manage stress," without reference to anxiety disorders or any other disease/condition;
  - Software Product Y tracks caloric intake and helps users manage an eating plan to maintain a healthy weight and balanced diet, which may help in living well with high blood pressure and type 2 diabetes;

FDA Mobile Medical Applications Guidance

- Some "mobile apps" not medical devices. All "mobile medical apps" are medical devices, some are subject to enforcement discretion
- Examples:

Not a Medical Device

- Generic tools like magnifying glass or notes application
- Reference texts
- Educational Materials

Medical Device, but "Subject to Enforcement Discretion"

- Tracking and trending health data for patient's use
- Automate simple tasks for health care providers
- Video games for physical therapy

Actively Regulated Medical Device

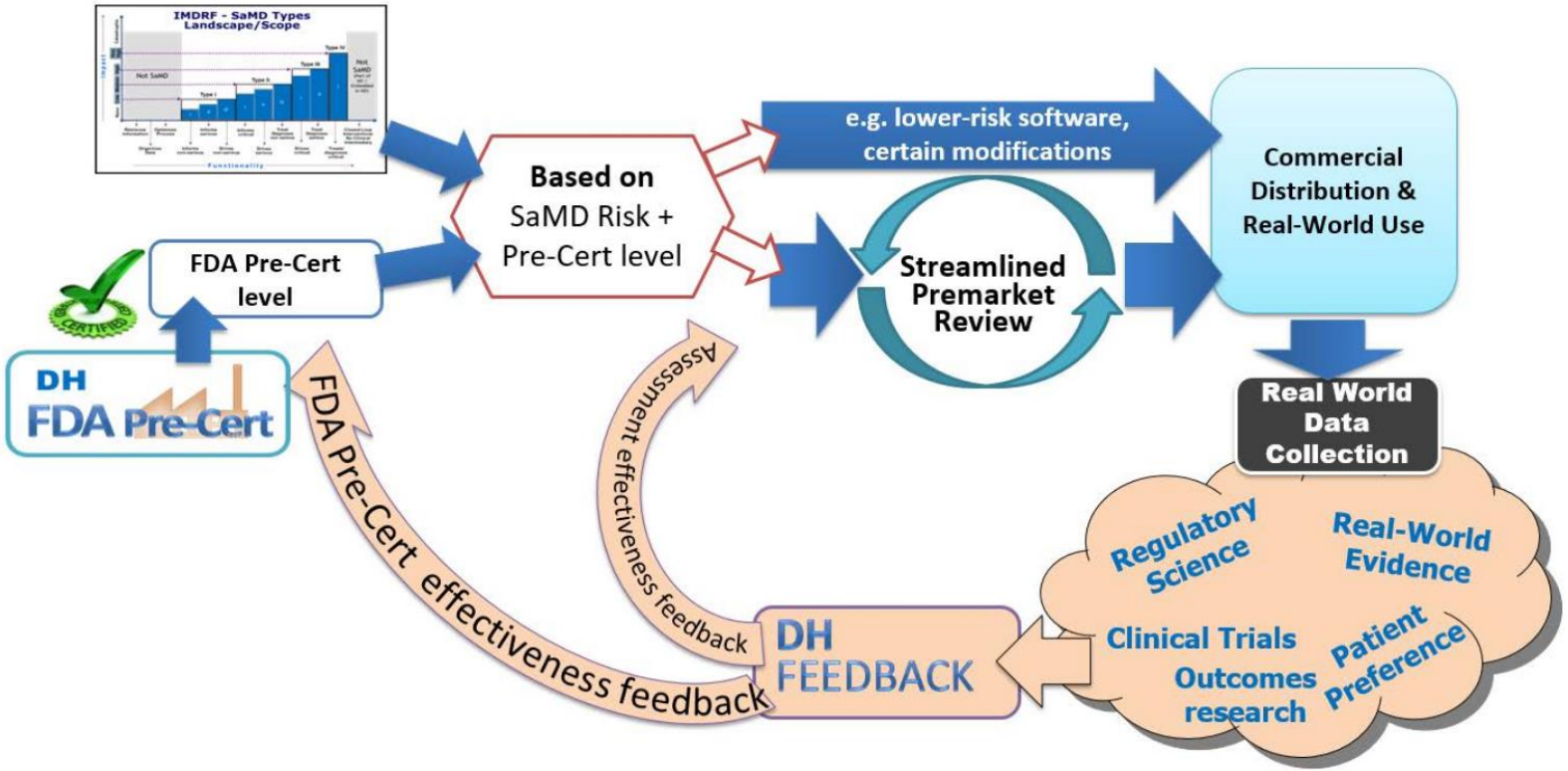
- Motion sensor for sleep apnea
- Radiation therapy dose calculation
- Remote display of ICU bedside monitoring data

2. Overview of Pre-Cert Pilot

Background

- Unveiled July 27, 2017 as part of FDA's Digital Health Innovation Action Plan
- Now conducting first "pilot" with 9 companies
- Shifting focus to certifying SaMD developers instead of traditional focus on product clearance or approval
- Purpose to reduce time and cost of market entry for digital health software companies with track record of developing and testing quality products

Pre-Cert Lifecycle



Working Model

- SaMD developers will be assessed by FDA or accredited third party
- Four key components:
  - Excellence appraisal and precertification
  - Premarket review pathway determination
  - Streamlined premarket review
  - Real world performance, i.e., postmarket surveillance and feedback
- Two-tier precertification, tier determines premarket review pathway
  - Level 1: companies that demonstrate excellence principles but have limited or no experience in delivering products
  - Level 2: companies that demonstrate excellence principles and have demonstrated track record in delivering products

Table 4. Proposed Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD in Future Pre-Cert Program				
IMDRF Risk Categorization		**Level of Review for Level 1 and Level 2 Precertified Organizations' SaMD**		
Type	**Description**	**Initial product**	**Major changes**	**Minor changes**
Type IV	Critical x diagnose/treat	SR	SR	No Review
Type III	Critical x drive		L1 – SR L2 – No Review	
Type III	Serious x diagnose/treat			
Type II	Serious x drive	L1 – SR L2 – No Review	No Review	
Type II	Non-serious x diagnose/treat			
Type II	Critical x inform			
Type I	Non-serious x drive	No Review		
Type I	Serious x inform			
Type I	Non-serious x inform			

3. Future Horizons

Future Horizons

- Finalization of CDS policy
- Finalization of AI framework
- Finalization and expansion of pre-cert program
- Continued focus on cybersecurity
- Potential for increased compliance

Questions?

Yarmela Pavlovic
Partner
+1 415 374 2336
yarmela.pavlovic@hoganlovells.com

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