Machine Learning, AI, and Digital Health

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EXPLORING A TAILORED REGULATORY FRAMEWORK FOR AI/ML

PRESENTED BY BAKUL PATEL

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Goals for a Tailored Regulatory Framework

Fostering Responsible Digital Health Innovation

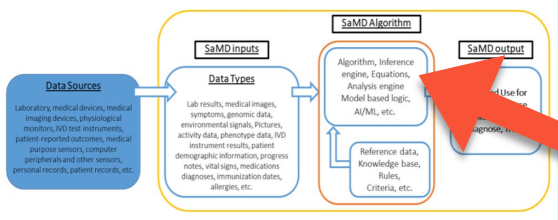
- Enhance patients access to high quality digital medical products
- Enable manufacturers to rapidly improve software products with minor changes
- Maintain a reasonable assurance of safety and effectiveness
- Minimally burdensome

The Need for a Tailored Approach

While maintaining reasonable assurance of safety and effectiveness

Today's Device World (Hardware-based)	Digital Health Device World (Software-Based)
Product Development Timeline • Months to years + • Less frequent modifications	**Product Development Timeline** • Weeks to months (**incremental, iterative**) + • Frequent modifications
Postmarket Data • Limited availability and access to real world data (522, PAS, MDRs, MedSun)	**Postmarket Data** • 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)	**FDA Premarket Program Volume:** • Potential for **exponential** increase in volume of submissions

Artificial Intelligence & Machine Learning



Artificial Intelligence (AI)

Programming computers to perform tasks to mimic human capabilities- such as understanding language, recognizing objects and sounds, learning, and problem solving – by using logic, decision trees, machine learning, or deep learning

Machine Learning (ML)

Subset of AI that gives "*Computers the ability to learn without being explicitly programmed*" -Arthur Samuel, 1959

Supervised Learning
(labeled data)

Unsupervised Learning

Deep Learning
Subset of ML: enable computer to teach itself by exposing it to vast amount of data

Reinforcement Learning

Open Questions

Evaluation of safety and effectiveness:

Open Questions:

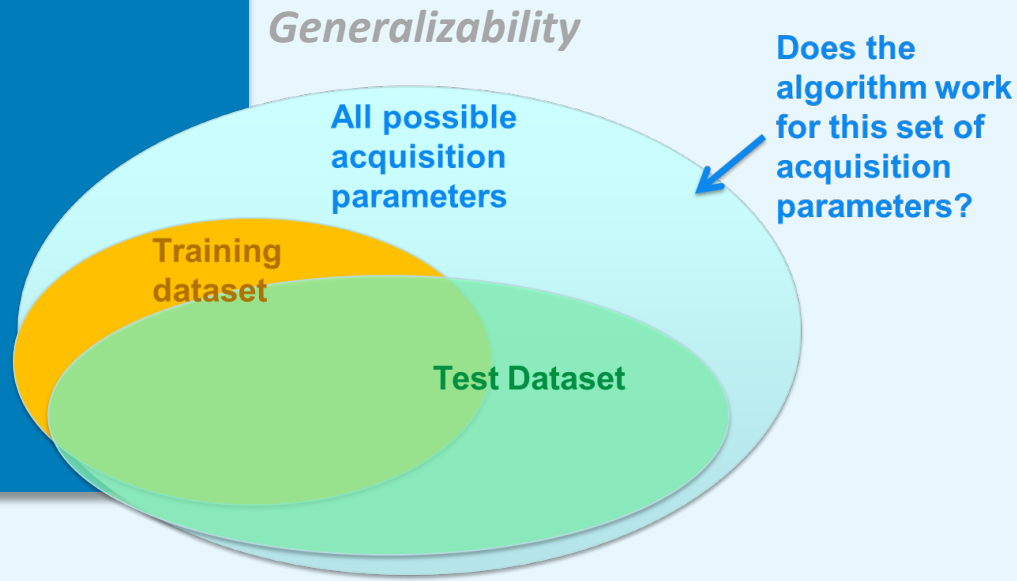
- Continuous learning while assuring safety and effectiveness?
- Availability for large and robust datasets with representable clinical variability
- Continuous algorithm updates
- Interpretability and explain-ability of the “basis of the recommendation”

Assurance for Safety and Effectiveness

IDx

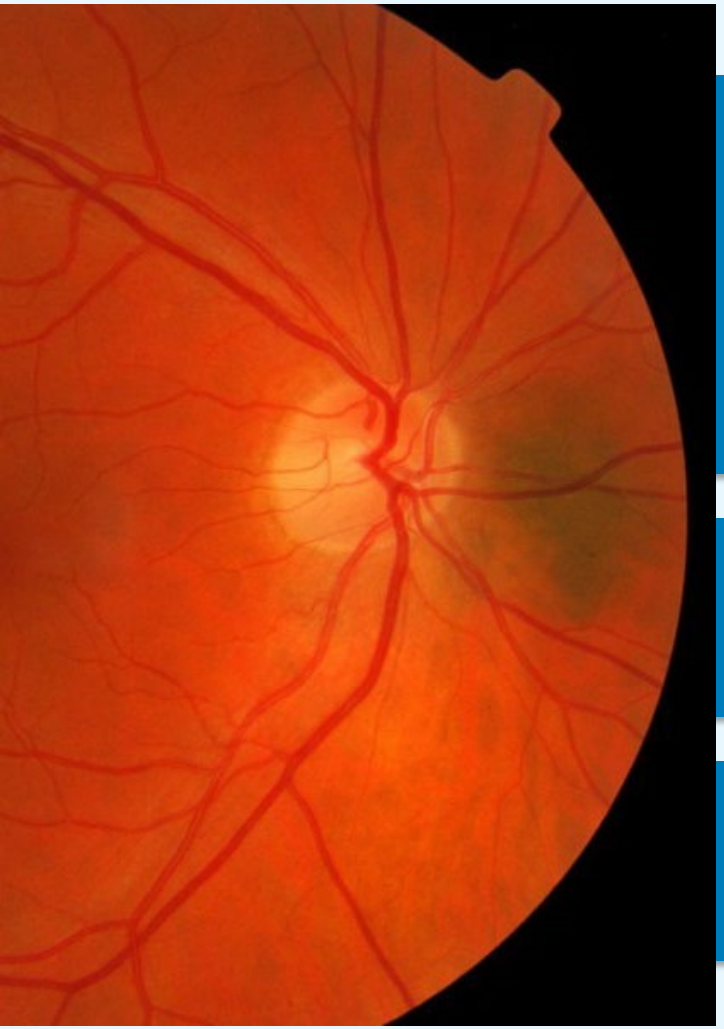
IDx-DR is intended for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy

- High data quality for training
- Algorithm “correctness” (verification)
- Performance testing (validation)
- Generalizability (addressing bias)
- Interpretability



AI/ML-Based Medical Devices

IDx-DR



Potential to fundamentally transform the delivery of health care:

E.g., Earlier disease detection, more accurate diagnosis, new insights into human physiology, personalized diagnostics and therapeutics

Ability for AI/ML to learn from the wealth of real-world data and improve its performance

Already seen AI/ML lead to the development of novel medical devices

Examples of AI/ML-Based SaMD

FDA News Release

FDA permits marketing of clinical decision support software for alerting providers of a potential stroke in patients

February 13, 2018

Viz.Ai

FDA News Release

FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems

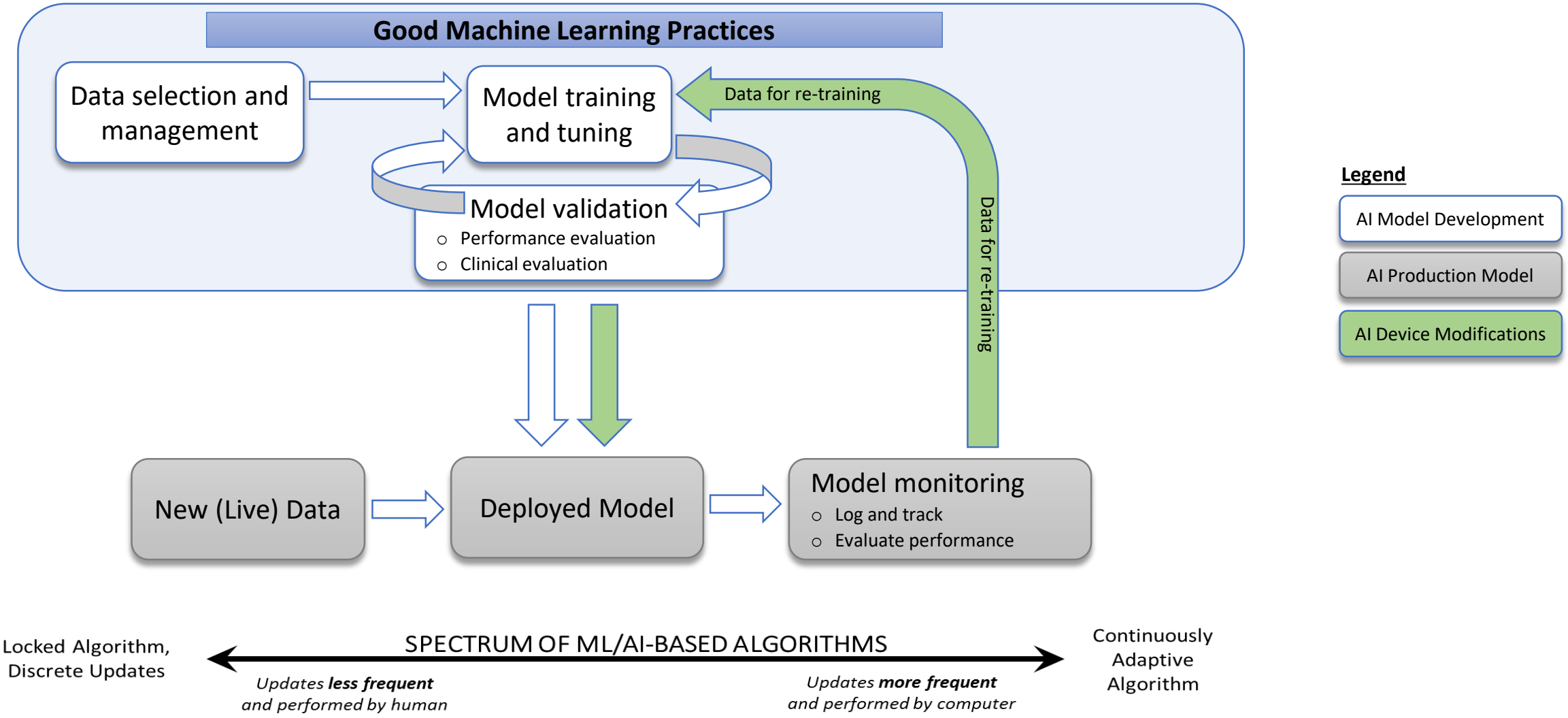
April 11, 2018

IDx-DR

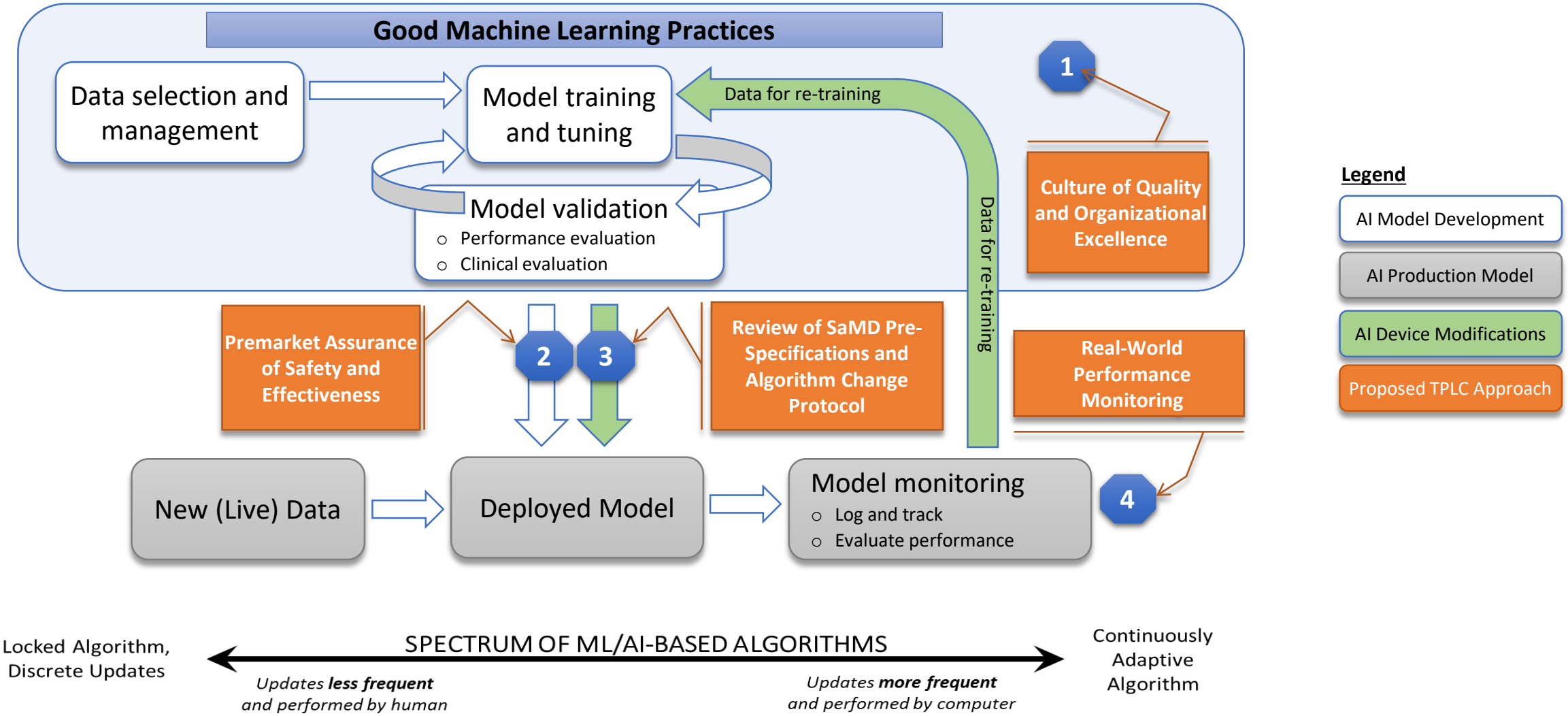
Discussion Paper

A **TPLC** approach
for modifications to Ai/ML
Software as a Medical Device (SaMD)

Typical AI/ML Model Lifecycle



FDA's Proposed TPLC Approach Overlaid on AI/ML Workflow



SPS & ACP: A Pre-Determined Change Control Plan

SaMD Pre-Specifications (SPS):

- Delineates the proposed types of modifications to the SaMD (i.e., what types of changes the sponsor plans to achieve)
- Draws a virtual "region of potential changes" around the initial specifications and labeling of the original device

Algorithm Change Protocol (ACP):

- Describes the methods for performing and validating the changes pre-specified in SPS (i.e. how the sponsor intends to achieve the changes)
- Typically specific to the device and type of change
- Expected to contain a step-by-step delineation of the procedures to be followed

Good ML Practices (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, etc

Q&A

Further Questions or Feedback

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FDA is seeking input on the concepts explored in the AI/ML Discussion Paper.

Please submit comments by June 3, 2019.

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