Regulation and Machine Learning at the "Frontiers of Science"

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Case Studies

Patent Office

FDA

Themes

- public and private capacity
- secrecy and accountability

What's New with ML?

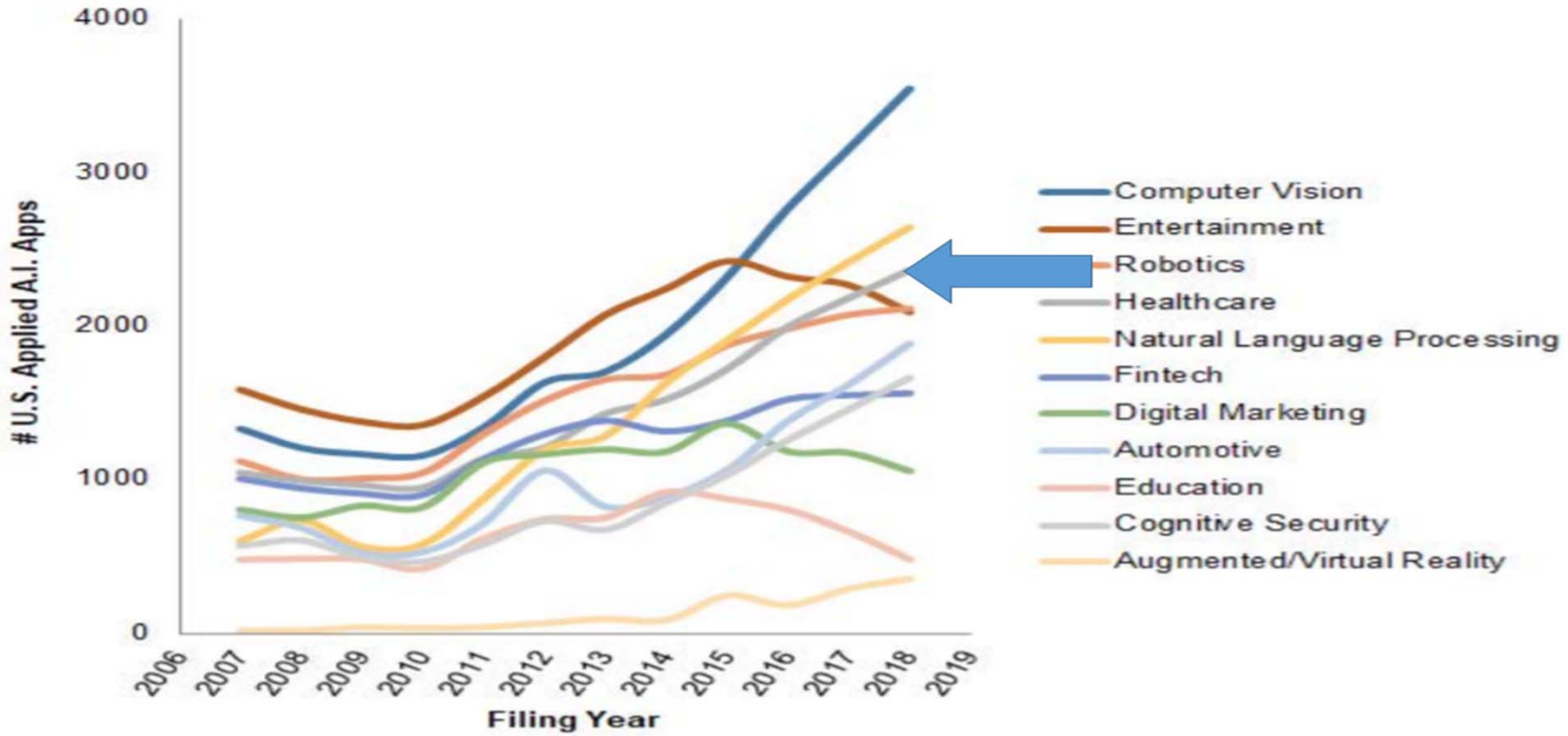
- complexity
- synergy of complexity and secrecy

Capacity and Secrecy at Patent Office

Application #	Description	Score (%)	Characteristics
US11235512	System and Method for Observing Patients in Geographically Dispersed Health Care Locations	100.00	
US11061715	System and Method for Standardizing Care in a Hospital Environment	99.14	
US11096189	System and Method for Displaying a Health Status of Hospitalized Patients	95.22	
US11096189	System and Method for Displaying a Health Status of Hospitalized Patients	95.22	
US11072359	Remote Command Center for Patient Monitoring	94.65	
US9443072	System and method for providing continuous, expert network critical care services from a remote location(s)	94.30	
US11061715	System and Method for Displaying a Health Status of Hospitalized Patients	92.07	
US11118950	System and Method for Accounting and Billing Patients in a Hospital Environment	91.71	
US11200554	System and Method for Providing Continuous, Expert Network Care Services From a Remote Location(s) to Geographically Dispersed Healthcare Locations	91.52	

AI Patents

Capacity at the Patent Office (2)

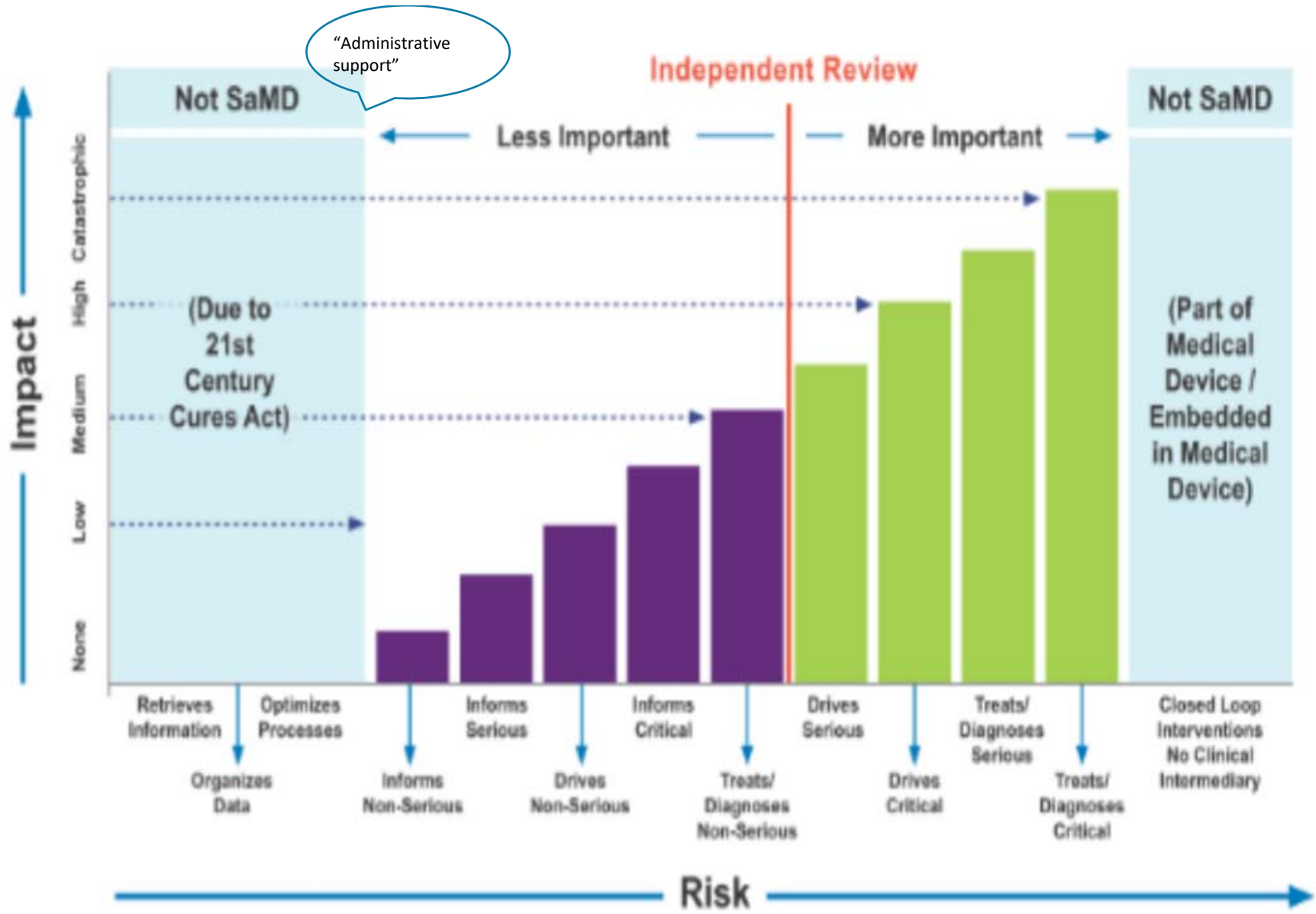


FDA and 21st Century Cures Act

Exempts algorithms that acquire and analyze medical information to make recommendations *so long as* the algorithm

"enabl[es] such health care professional to *independently review* the basis for such recommendations that such software presents . . ."

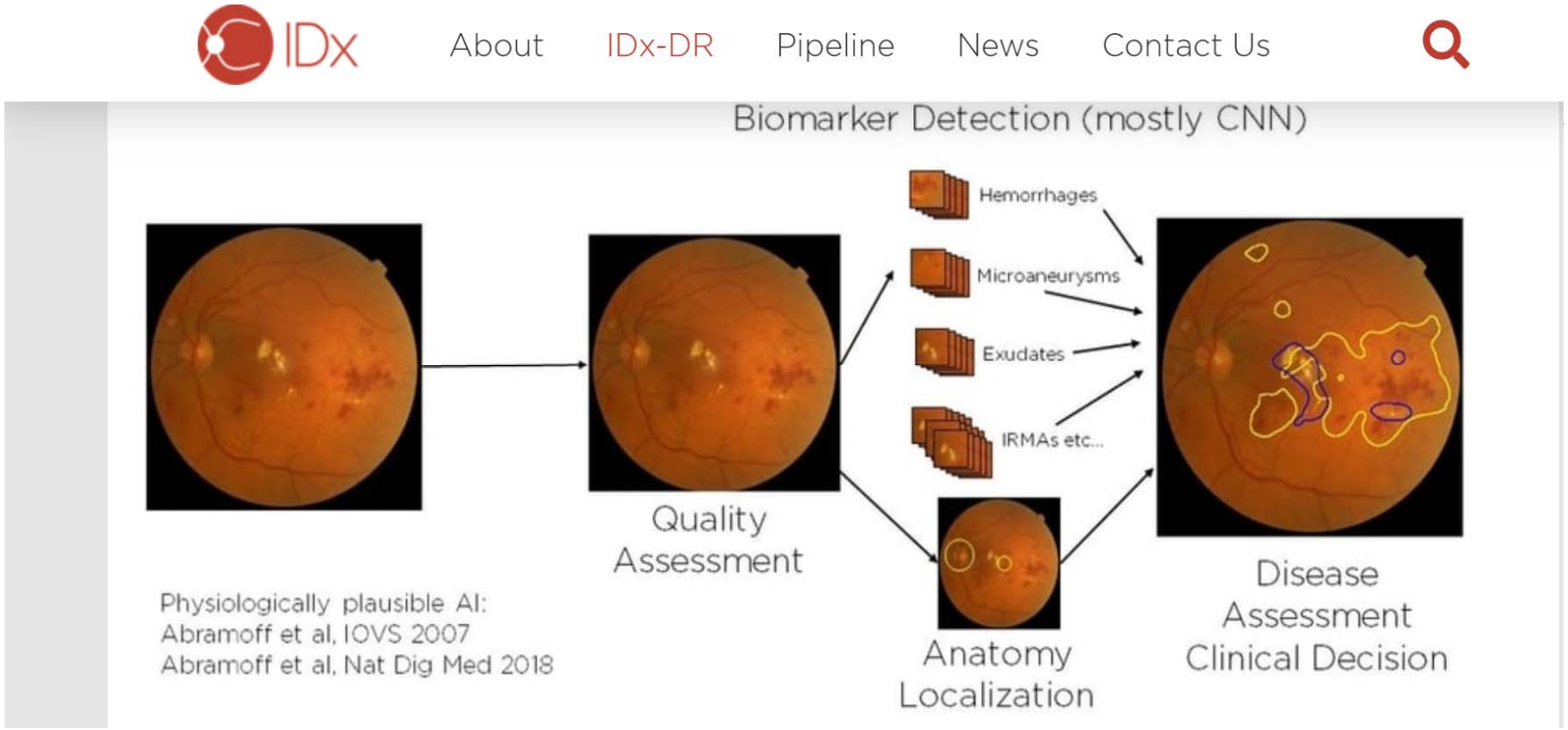
FDA: regulate if software is *proprietary* or *highly complex*


"Administrative support"
Independent Review
Not SaMD
Less Important
More Important
Not SaMD
Impact
None
Low
Medium
High
Catastrophic
(Due to 21st Century Cures Act)
(Part of Medical Device / Embedded in Medical Device)
Retrieves Information
Optimizes Processes
Organizes Data
Informs Non-Serious
Informs Serious
Drives Non-Serious
Informs Critical
Treats/ Diagnoses Non-Serious
Drives Serious
Drives Critical
Treats/ Diagnoses Serious
Treats/ Diagnoses Critical
Closed Loop Interventions No Clinical Intermediary
Risk

Stroke Triage

Viz.AI ContaCT: triage based on signs of large vessel occlusion (LVO) in CT scan

Diabetic Retinopathy Detection



3. Software Algorithm Summary (Special Control 1.i.)

The ContaCT algorithm identifies applicable CTA series and verifies that contrast is visible in the soft matter of the brain and that no metallic artifacts such as aneurism clips are present in the soft matter of the brain. Skull stripping and registration steps are performed. The large vessels are identified and segmented, and the amount of extension of the contrast filled segments is compared to a pre-defined threshold. If the threshold exceeds the magnitude of the contrast filled segment, a notification is generated.

Training CTA studies were used from multiple facilities to develop and train the algorithm. Three algorithm training phases included: initial development and training; pre- and post- processing fine-tuning; and threshold optimization. The training cases are

independent from the cases used to validate device performance.

(b) (4)

The following figure presents the ROC and performance curves of the algorithm in the standalone performance dataset. The estimated area under the curve (AUC) is .91; the fixed optimum threshold, 60mm, is marked with the vertical dashed line:

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

Pre-cert program

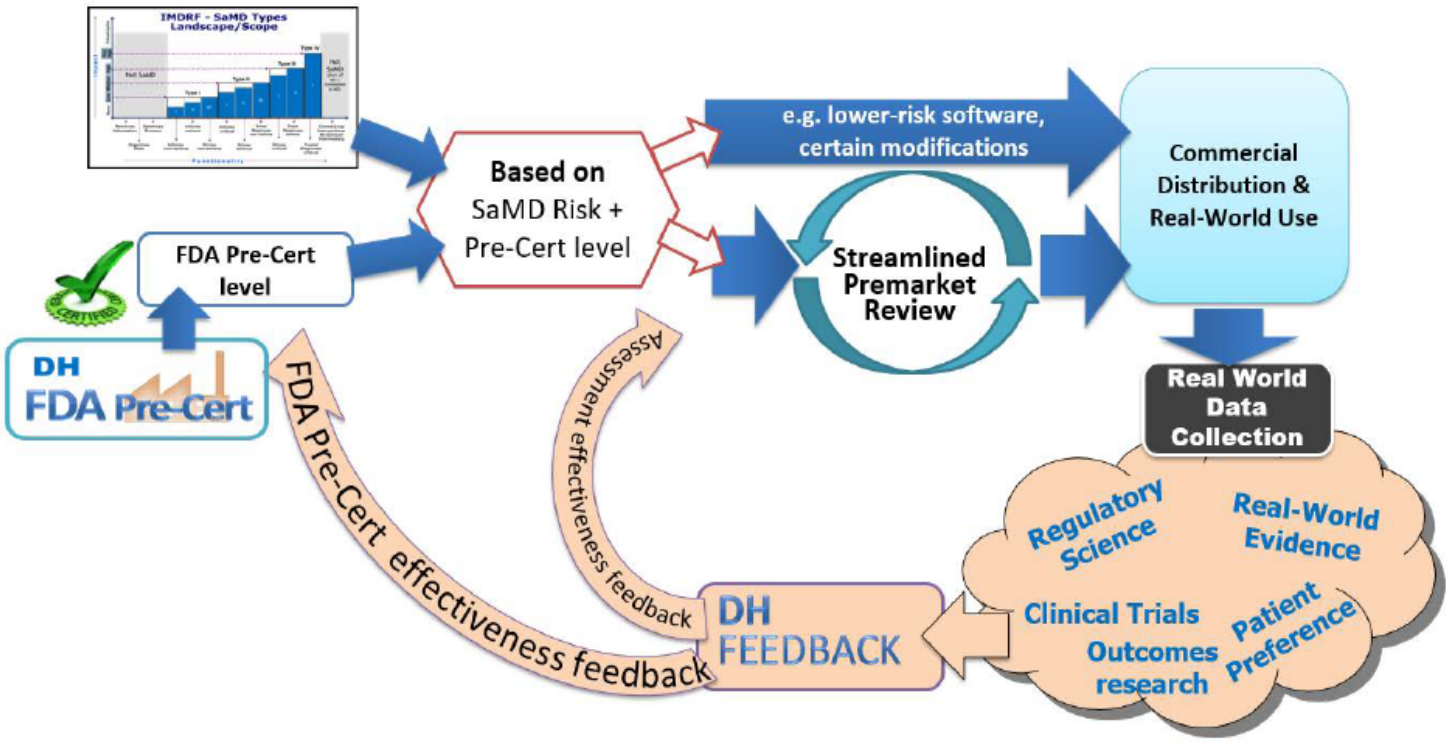


Figure 1. A reimagined approach for the regulation of software

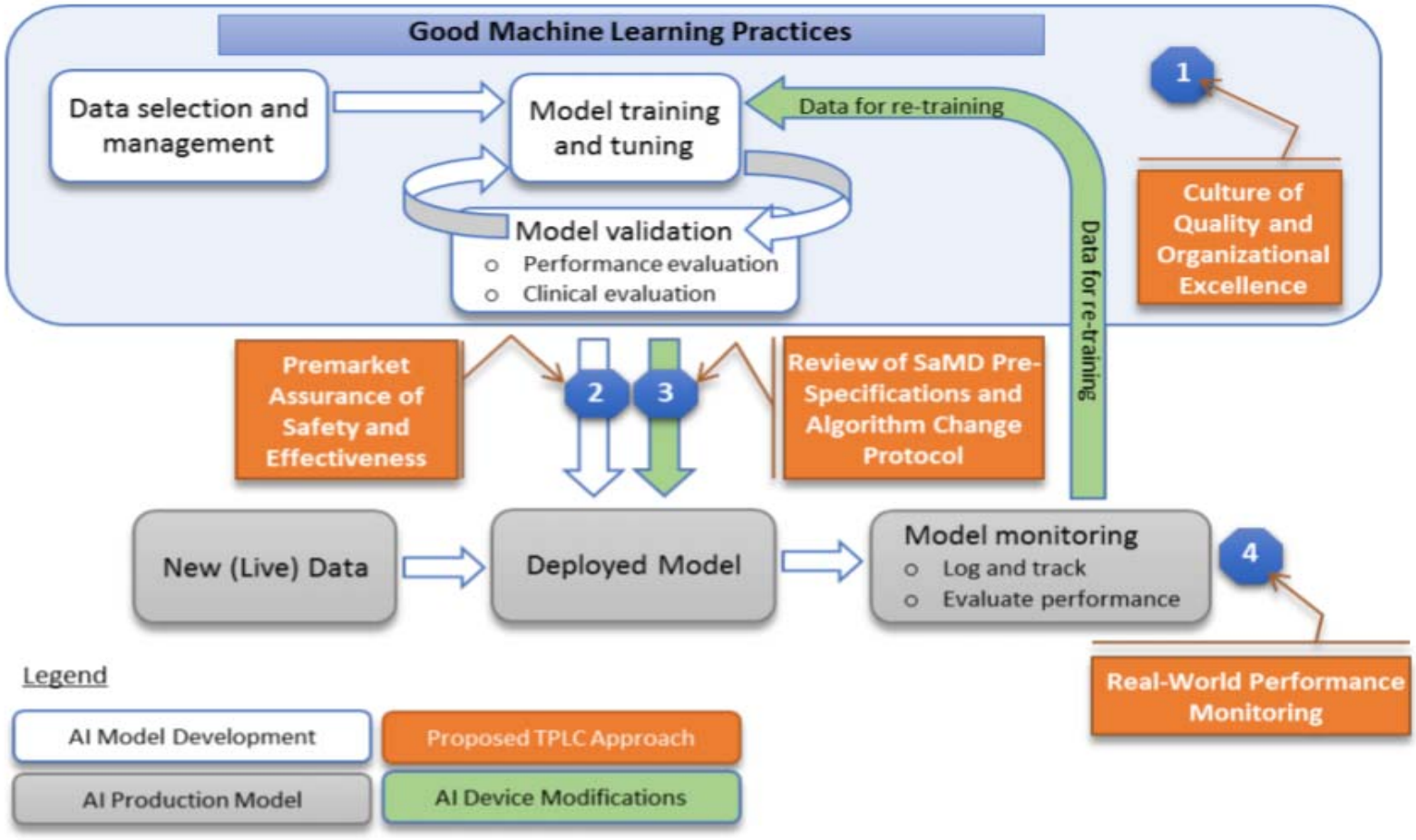


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow