# FDA Proposes New Regulatory Framework of AI-Based Software as a Medical Device

The FDA recently issued the discussion paper "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)" and a request for comments.

Commissioner Scott Gottlieb issued a statement at the time of the paper's release lauding artificial intelligence and machine learning as having "the potential to fundamentally transform the delivery of health care." He stated that the "ability of artificial intelligence and machine learning software to learn from real-world feedback and improve its performance is spurring innovation and leading to the development of novel medical devices." However, he recognized the inadequacy of traditional regulatory pathways to foster the growth of this technology, saying the FDA was "announcing steps to consider a new regulatory framework specifically tailored to promote the development of safe and effective medical devices that use advanced artificial intelligence algorithms."

FDA employs a risk-based approach to determine whether a new premarket submission is required each time a manufacturer makes substantial, iterative changes through a software update or makes other changes that would significantly affect the device's performance. But, this approach is not a match for review of AI and machine learning-based algorithms, medical devices that may continuously update themselves in response to real-world feedback.

Gottlieb noted as an example, "an algorithm that detects breast cancer lesions on mammograms could learn to improve the confidence with which it identifies lesions as cancerous or may learn to identify specific sub-types of breast cancer by continually learning from real-world use and feedback." The agency concluded that it had to change its approach to foster software that evolves over time to improve care, while still guaranteeing safety and effectiveness. As a first step, the FDA released the paper exploring a new proposed framework that it believes will encourage development and may allow some modifications without review—"[I]t would be a more tailored fit than our existing regulatory paradigm for software as a medical device."

Under the proposed framework, AI/ML-based SaMD would require a premarket submission when a software change or modification "significantly affects device performance or safety and effectiveness; the modification is to the device's intended use; or the modification introduces a major change to the SaMD algorithm." This approach was developed based on harmonized SaMD risk categorization principles that were established via the International Medical Devices Regulators Forum, FDA's benefit-risk framework, risk management principles in FDA's 2017 guidance on submitting new 510(k)s for software changes to existing devices, Software Pre-certification Pilot Program's organizational-based total product life cycle approach, as well as the 510(k), De Novo classification request, and premarket application pathways.

So, where it is anticipated that the software will evolve over time and not remain static, the "evolution" will be described at the time of submission along with specific plans for post-market surveillance and modification of intended use where appropriate.

FDA will accept comments through June 3, 2019, via its website. This will be an important part of evolving the proposal into something that better fits the needs of this growing technology