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Artificial Intelligence and Machine Learning Action Plan by FDA – A Response to SaMD Manufacturers

Written By Dr. Yew Sheng Qian (Senior Lecturer, Department of Public Health Medicine, Faculty of Medicine, Universiti Kebangssan Malaysia)

Software as a Medical Device (SaMD) manufacturers harness the power of artificial intelligence (AI) and machine learning (ML) technologies to revolutionize their products, enhancing their ability to support healthcare providers and elevate patient care. Among the myriad advantages of incorporating AI and ML into SaMD, one stands out—their unparalleled capacity to learn from real-world usage and experiences, enabling a continuous enhancement of medical device performance. Unsurprisingly, the U.S. Food and Drug Administration (FDA) receives an overwhelming influx of marketing submissions and pre-submissions for cutting-edge products that leverage on these transformative AI and ML technologies.

In response to the rapid advancements in AI and ML-based SaMD, and the various challenges reported from SaMD manufacturers, the FDA unveiled its groundbreaking "Artificial Intelligence and Machine Learning-Based Software as a Medical Device (SaMD) Action Plan" on 12 January 2021. This comprehensive plan sets forth five strategic approaches to effectively oversee these technologies, prioritizing both the safe delivery and optimal functionality of SaMD. By implementing these approaches, the FDA aims to enhance patient care and elevate the overall quality of healthcare services provided.

Challenges		Action Plans
The current regulatory framework for AI and ML-based SaMD is still evolving and requires further development.	**Action Plan 1** Regulatory Framework for AI and ML-based SaMD	FDA has taken proactive steps to update the regulatory framework by introducing the "Draft Guidance on the Predetermined Change Control Plan" [1]. This guidance aims to strengthen the safety and effectiveness of AI and ML-based SaMD algorithms.
The absence of established standards and best practices in the development of AI and ML-based SaMD is a recognized challenge.	**Action Plan 2** Good Machine Learning Practice (GMLP)	FDA has taken proactive measures to create the Good Machine Learning Practice (GMLP) guidelines [2], which serves as a comprehensive set of best practices to guide the development of AI and ML-based SaMD.
Manufacturers have difficulties in describing the data that were used to train the algorithm, the relevance of its inputs, the logic it employs, and the evidence of the device's performance.	**Action Plan 3** Incorporating Transparency to Users	To enhance transparency, FDA is actively working on identifying the specific types of information that manufacturers should include in the labeling of AI and ML-based SaMD.
Efforts are underway to develop methods for evaluating and mitigating algorithmic bias and promoting algorithmic robustness, addressing a crucial need in the field.	**Action Plan 4** Methods Related to Algorithm Bias and Robustness	FDA is actively engaged in developing robust methodologies to evaluate and enhance AI and ML algorithms, with a particular focus on identifying and eliminating biases and promoting algorithmic robustness.
Manufacturers require guidance on how to validate and test algorithms, ensuring their accuracy, reliability, and safety in real world.	**Action Plan 5** Real-World Performance	FDA is adopting a total product lifecycle (TPLC) approach to the oversight of AI and ML-based SaMD. Modifications to these SaMD applications may be supported by collecting and monitoring real-world data.

Further Readings:
1. https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-issues-draft-guidance-predetermined-change-control-plans-artificial-intelligencemachine
2. https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles