MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING FOR IN VITRO DIAGNOSTICS

As technology advances, software incorporating artificial intelligence (AI) and machine learning (ML) has become a critical component of medical devices including in vitro diagnostics (IVDs). Currently, there is no suitable regulatory framework for addressing post-launch improvements of artificial intelligence-machine learning-enabled medical devices while ensuring their safety and effectiveness for their intended use.

The project was established in pursuit of a consensus for how to perform and evaluate iterative improvements. The FDA document "Proposed Regulatory Framework for Modification to Artificial Intelligence/Machine Learning-Based Software as a Medical Device– Discussion Paper and Request for Feedback" from 2019 discussed the concept of a plan for change control in devices of this nature. In addition to evaluating the use of real-world data, the output will evaluate appropriate metrics used to address the changing applications including software in a medical device (SiMD) and software as a medical device (SaMD).

Initiative Goals

1. Develop a predetermined change control plan for AI/ML-enabled IVDs including both Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD) that leverages the use of Real-World Data.
2. Address iterative improvements that can occur post-launch for AI/ML-enabled medical devices, including in vitro diagnostics, while ensuring their safety and effectiveness for their intended use.
3. Produce tools and resources to establish common terminology across the sector and to include a software pre-specifications (SPS) template and an algorithm change protocol (ACP) template.

ABOUT MDIC

The Medical Device Innovation Consortium (MDIC) is a public-private partnership that brings together representatives of the FDA, NIH, CMS, NIST, and other agencies, industry, non-profits, and patient advocacy organizations to improve the processes for development, assessment, and review of new medical technologies.

MDIC coordinates the development of methods, tools, and resources used in managing the total product life cycle of a medical device to improve patient access to cutting-edge medical technology.

We are driving faster, safer, and more cost-effective innovation for patient benefit.

LEARN MORE

- **MDIC Website – AI/ML for In Vitro Diagnostics**
  www.mdic.org/program/aiml/
- **FDA Documents:**
- **Artificial Intelligence and Machine Learning (AI/ML) Enabled Medical Devices**
  www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices
- **Proposed Regulatory Framework for Modification to Artificial Intelligence/ Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) – Discussion Paper and Request for Feedback**
  www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

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