

Artificial Intelligence/Machine Learning-Enabled Devices

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About US

The AI/ML Working Group (WG) seeks to prioritize consensus in the AI/ML sector, where rapid technological advancements and an influx of manufacturers from sectors beyond medical devices is seen and was formed in 2023. Regulatory consensus for AI/ML has a close interplay with Software as a Medical Device (SaMD) for many jurisdictions, it's therefore also a priority to maintain alignment with broader software guidance.

The group meets monthly, with subgroups meeting more frequently as required, and is currently working to produce an AI Lifecycle document that outlines the considerations for manufacturers, and the broader community, on AI/ML-enabled medical devices over the lifetime of the devices.



Publications

Good Machine Learning Practice for medical device development: Guiding Principles. *IMDRF/AIML WG/N88 Final:2025*

This document outlines 10 guiding principles bringing together medical device regulations with data science and software development to encourage the multidisciplinary and unified approach to creating safe and effective AI/ML-enabled medical devices.

Machine Learning-enabled Medical Devices: Key Terms and Definitions. *IMDRF/AIML WG/N67 (Edition 1) 2022*

This document describes and defines some useful terms in this emerging field to improve consensus due to stakeholders coming from multiple backgrounds that may use terminology differently.



Ongoing work

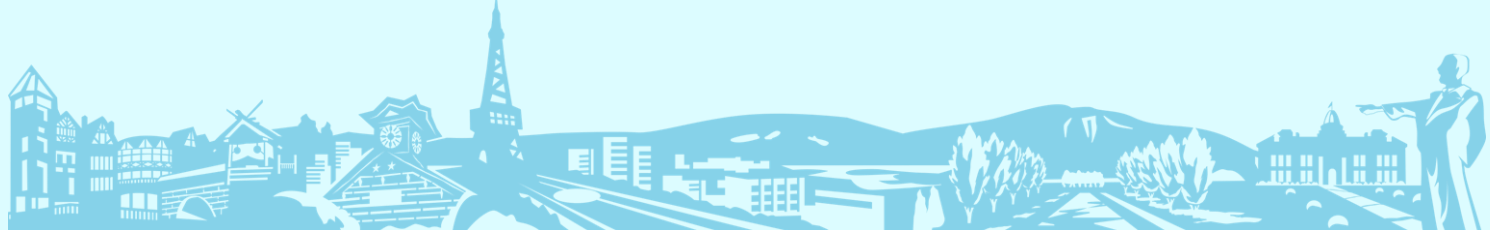
For 2025, the working group is focused on the development of an AI Lifecycle document that outlines the considerations that manufacturers (and users) of AI/ML-Enabled medical devices should be aware of over the lifetime of use. This document is being designed for use in addition to existing IMDRF SaMD (Software as a Medical Device) and AI/ML publications due to AI being a sub-set of SaMD in some jurisdictions and many of the fundamental principles being the same.

Throughout this calendar year, the working group has been drafting and reviewing individual sections of the AI lifecycle draft document. The last few sections have a target completion date of early September 2025. After this the full draft document will be reviewed by the working group and comments addressed to progress towards a version for public consultation after MC submission (targeted for the first MC meeting in 2026).



Opportunities and Challenges

- Opportunity to impact development of emerging technologies
- Opportunity to provide clarity to developers looking to market globally
- Challenges related rapidly advancing field
- Need to maintain alignment with other related work, especially Software as a Medical Device (SaMD)



Thank you/ Questions