



Artificial Intelligence/Machine Learning Working Group

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IMDRF

International Medical Device
Regulators Forum

• **Agenda Item 5g: Good Machine Learning Practice (GMLP) NWIP:**

- GMLP provides fundamental principles to promote the development of safe, effective, and high-quality AI-enabled medical devices
- AIWG is drafting Guiding Principles for GMLP based on earlier trilateral GMLP document, including updates reflecting recent advancements in AI
- Two focus areas being addressed by subgroups are:
 - (1) Addressing needs of Generative AI/ Large Language Models (LLMs); and
 - (2) Ensuring alignment with and referencing of other IMDRF documents
- Target for public consultation of the GMLP document is Summer-Fall 2024

• **Future work:**

- Deeper dive into GMLP for Pre-determined Change Control Plans
- AI Lifecycle Management proposed as NWIP to MC



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