Artificial Intelligence/Machine Learning Working Group

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• 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