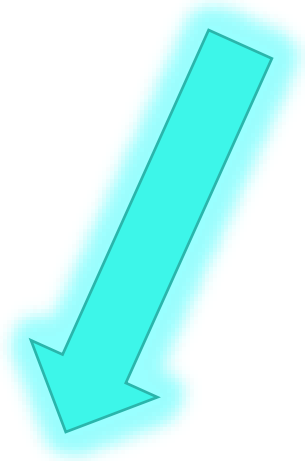
IMDRF International Medical Device Regulators Forum

Artificial Intelligence/Machine Learning-Enabled (AI/ML) Working Group

Matthew Diamond (FDA) and Russell Pearson (MHRA)



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IMDRF 24th Session – Berlin, Germany

About US

Established in summer 2023. 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. 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 working group convenes monthly starting from September 13th 2023

Working group Membership

We have participants from;

African **M**edical **D**evices **F**orum (AMDF), Argentina, Australia, Brazil, Canada, European Union, Israel, Japan, **P**an **A**merican **H**armonization **O**rganisation (PAHO),Singapore, South Africa, South Korea, Switzerland, United Kingdom, United Stated of America, Global **D**iagnostic **I**maging, Healthcare IT and Radiation **T**herapy **T**rade **A**ssociation (DITTA), **G**lobal **H**ealth **W**orking **P**arty (GHWP) and **G**lobal **M**edial **T**echnology **A**lliance (GMTA).

Alignment with the IMDRF Strategic Plan

Our working groups initial task is develop a new document on Good Machine Learning Practice (GMLP) principles that looks to generate safer AI/ML-enabled medical devices and global alignment across the total product lifecycle. This aligns primarily with the IMDRF's pre-market strategic objective.

Publications

There have been no publications from this new WG to date.

Our current work item is focused on producing Good Machine Learning Practice (GMLP) Principles.

GMLP brings together high-level, fundamental principles important for the development of ML-enabled medical devices (MLMD). These MLMDs have unique considerations that can be addressed, at least in part, with GMLP implemented across the product life cycle. The rapid technological advancements in the AI/ML sector, combined with an influx of manufacturers from sectors beyond medical devices (e.g., pharmaceuticals, software engineering and data science) makes rapid consensus building on the topic of GMLP an important priority to lower product and development risks and to protect against regulatory divergence.

Upcoming work

The working will meet for the first time on 13th September and is currently undergoing a review of 10 GMLP principles previously published by the UK MHRA, US FDA and Health Canada as a starting point for generating the IMDRF GMLP principles.

Opportunities and Challenges

A challenge for the AI working group is to generate consensus rapidly in order to generate relevant guidance documents.

More specific challenges and opportunities will be uncovered as the work progresses.

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Thank you/Questions

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