IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

14:45 – 15:00

Good Machine Learning Practice (USA / UK)

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IMDRF International Medical Device Regulators Forum

Artificial Intelligence (AI)/Machine Learning (ML) Enabled Medical Devices Working Group Update

Co-Chairs:
Matthew Diamond – US FDA
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Background

Good Machine Learning Practice (GMLP) brings together high-level, fundamental principles important for the development, use and monitoring of Machine Learning (ML)-enabled medical devices.

ML-enabled products have unique considerations that can be addressed, at least in part, with GMLP implemented across the product life cycle.

Rapid technological advancements in AI/ML, combined with manufacturers from sectors beyond medical devices, makes development of GMLP an important priority to lower product and development risks and to protect against regulatory divergence.

Rationale

- There is a close interplay between ML-enabled medical devices and other software based medical devices.
  - GMLP must be developed to be compatible with best practice SaMD guidance and built upon existing core aspects of medical device regulations.
    - Core aspects include quality management systems, risk management and clinical evaluation to ensure the GMLP complements the state of the art and regulatory compliance.
- Work is aligned with the IMDRF Strategic Plan to develop a harmonized approach to the management of AI medical devices.
- Generating consensus across the product lifecycle via creation of a GMLP document will also assist with the IMDRF objectives to strengthen post-market activities and a total product lifecycle regulatory approach to medical devices.

Goal

- To develop a new document on the topic of Good Machine Learning Practice (GMLP) that will provide internationally harmonized principles to help promote the development of safe and effective ML-enabled medical devices.
  - Generate consensus on the key considerations for how AI/ML products can meet regulatory, risk management, quality management and clinical evaluation in order to promote consistency across jurisdictions.
  - Build upon the US FDA/Health Canada/UK MHRA joint document on GMLP Guiding Principles.

Good Machine Learning Practice Principles

U.S. FOOD & DRUG ADMINISTRATION

Health Canada Santé Canada

Medicines & Healthcare products Regulatory Agency

These guiding principles may be used to:

- Adopt good practices that have been proven in other sectors;
- Tailor practices from other sectors so they are applicable to medical technology and the health care sector; and
- Create new practices specific for medical technology and the health care sector.

Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise are Leveraged Throughout the Total Product Life Cycle	**Good Software Engineering and Security Practices are Implemented**
Clinical Study Participants and Data Sets are Representative of the Intended Population	**Training Data Sets are Independent of Test Sets**
Selected Reference Datasets are Based Upon Best Available Methods	**Model Design is Tailored to the Available Data and Reflects the Intended Use of the Device**
Focus is Placed on the Performance of the Human-AI Team	**Testing Demonstrates Device Performance during Clinically Relevant Conditions**
Users are Provided Clear, Essential Information	**Deployed Models are Monitored for Performance and Re-training Risks are Managed**

Current Status

- New Work Item Proposal approved in January 2022
- Working group is currently being established
  - Call for participants/representatives from IMDRF regulatory authorities, RHIs, and industry
  - IMDRF website updates
  - Expect work to begin in the next couple of weeks

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Thank you!
Questions?

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