

AI Working Group

Co-Chairs:

UK MHRA & US FDA

WG Activities Update



AI Working Group: About Us

- Chairs: UK MHRA & US FDA
- Broad international representation
- Purpose to provide internationally harmonized principles to help promote the development of safe and effective artificial intelligence (AI)-enabled medical devices.
- Current Work Item: “Technical Framework for AI Lifecycle Management”



Publications

IMDRF AIWG documents:

- IMDRF/AIMD N88 Good Machine Learning Practice for Medical Device Development - Guiding Principles
- IMDRF/AIMD WG (PD1)/N67:2021 Machine Learning-enabled Medical Devices – a subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions

Other relevant documents include:

- IMDRF SaMD Documents
- IEC 62304: Medical Device Software – Software Life Cycle Processes
- IEC 62366: Medical Devices - Application of Usability Engineering to Medical Devices



Ongoing Work: “Technical Framework for AI Lifecycle Management”

Aim

- Provide an internationally harmonized technical framework to generate consensus across AI product lifecycle

Progress

- Document outline created
- Two subgroups are drafting subsections of the document
- Planned initial draft of document by Summer 25

Timeline

- Management committee first draft submission by Winter 25 / Spring 26



Opportunities and Challenges

Opportunities

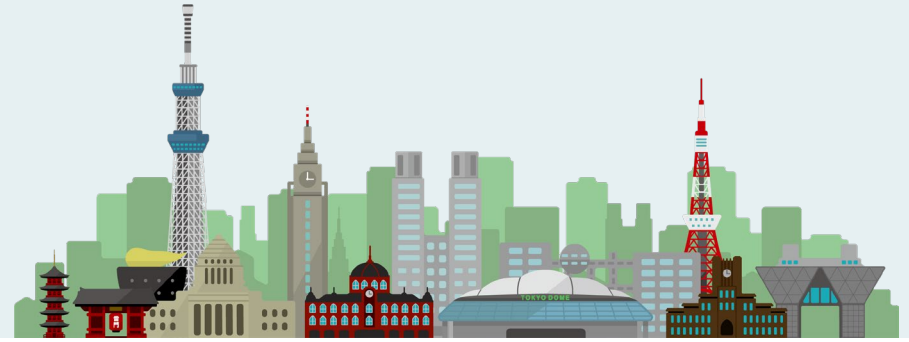
- Promote responsible innovation in AI-enabled devices through harmonization of approach to key technical considerations and best practices for these devices
- Provide initial and foundational guidance on lifecycle management for AI-enabled devices, building on existing work on Software as a Medical Device
- Explore full breadth of product lifecycle, including late-stage management steps
- Plan for future work including updates to this harmonized framework in emerging areas of lifecycle management for AI-enabled devices

Challenges

- Maintain a focused scope amidst a broad and quickly emerging area



IMDRF International Medical Device
Regulators Forum



Thank you/ Questions
