IMDRF International Medical Device Regulators Forum

Artificial Intelligence Medical Device (AIMD) Working Group Update

Medical Device Evaluation Department,
Ministry of Food & Drug Safety, South Korea

Purpose of AIMD WG

- Achieve a harmonized approach to the management of Artificial Intelligence (AI) medical devices
- Establish a guidance to share the views of member jurisdictions on terminology

IMDRF International Medical Device Regulators Forum

AIMD WG Members

WG members from RA		
Country	Name	Affiliation
Australia (3)	Dr David Hau	Therapeutic Goods Administration (TGA)
	Mr David Wotton (ISO/IEC SC42)	
	Mrs Olivia Reeves	
Brazil (3)	Mr Helio Bomfim de Macedo Filho	Agência Nacional de Vigilância Sanitária (ANVISA)
	Mr Francisco Iran Cartaxo Barbosa	
	Mr Jangley Bahia Costa	
Canada (2)	Daniel Yoon	Health Canada
	Janet Hendry	
China (5)	Mr. Zhang Song	Center for Medical Device Evaluation (CMDE), NMPA
	Mr. Liu Xiaoyin	
	Mr. Wang Zehua	
	Mr. Wang Hao	National Institute for Food and Drug Control (NIFDC), NMPA
	Mr. Wang Chenxi	
European Union (4)	Steffen Buchholz	Federal Ministry of Health (BMG)
	Mariana Madureira	INFARMED
	Rolf Oberlin	Danish Medicines Agency
	Nada Alkhayat	European Commission
Japan (6)	Mr Yuhei Fukuta	Ministry of Health, Labour and Welfare (MHLW)
	Ms Yoko Tateno	
	Ms Kanako Sasaki	
	Mr Watanabe Yoshitomo	Pharmaceuticals and Medical Devices Agency (PMDA)
	Mr Sato Yuchi	
	Mr Kuniki Imagawa	

WG members from RA		
	Name	Affiliation
Russia (1)	Vladimir Kutichev	Roszdravnadzor
Singapore (2)	Dr Yow Soh Zeom	Health Sciences Authority (HSA)
	Mr Lin Anle	
South Korea (7)	Dr Young-Kyu Kang	Ministry of Food & Drug Safety (MFDS)
	Mr Seung-Ho Son	
	Dr Se-Il Park	
	Mr Hyun-Soo Kim	
	Mr Byeong-Nam Kim	
	Mr Dong-Jun Kim	
	Ms Ki-Na Kim	
United States of America (2)	Bakul Patel	U.S. Food and Drug Administration (FDA)
	Matthew Diamond	

WG members from organizations		
World Health Organization (2)	Dr Philippe Boeuf	
	Anita Sands	
GMTA (4)	Pat Baird (ISO/IEC SC42)	Philips Healthcare
	Mr. Toshiaki Nakazato	Canon Medical Systems cooperation
	Patricia A. Krantz-Zuppan	Medtronic
	Mr. Hyun-Bae Park	VUNO
DITTA (4)	Koen Cobbaert	Philips Healthcare
	Naoki Morooka	Shimadzu Corporation
	Camille Vidal	GE Healthcare
	Annika Eberstein	COCIR
Total 45		

Main Contents of the Guidance

1. Title
2. Introduction (Background and purpose of the document)
3. Scope of ML enabled Medical devices, and Definitions of the Relevant Terms
4. Standardized Terminology

Main Contents of the Guidance

1. Title

- Machine Learning enabled Medical devices

  - a subset of Artificial Intelligence:

    Key Terms and Definitions

Main Contents of the Guidance

2. Introduction (Background and purpose of the document)

'1.0 Introduction'

- **Background**

  - Increase significance of AI based medical devices

  - Limitations with existing regulations on AI based medical devices

- **Purpose**

  - Establish relevant terms and definitions across the total product life cycle (TPLC) to promote consistency, support global harmonization efforts

Main Contents of the Guidance

3. Scope of ML enabled Medical devices, and Definitions of the Relevant Terms

'2.0 Scope'

- **All medical devices that enabled by ML techniques (MLMD) to achieve its intended medical purpose(s), including Software as a Medical Device (SaMD), Software in a Medical Device (SiMD), and In-Vitro Diagnostics (IVD).**
- **Focus on terms and definitions relevant to MLMD.**
  (not define established definitions in the field of computer science; however, it highlights and clarifies conflicting terms and definitions as necessary.)

Main Contents of the Guidance

4. Standardized Terminology

- Discussions about selection of relevant terms and definitions on machine learning enabled medical devices, in progress

✓ Review the 25 relevant terms

ex: *Machine Learning(ML):* Process using computational techniques to enable systems to learn from data or experience. (ISO.IEC CD 22989)

- Consider adding Concept and Description Sections

Progress Status

- Host a monthly meeting
- Researched and analyzed regulations and guidance of member jurisdictions, Combined relevant terms and definitions on ML enabled medical devices from members (~ Sep ’20)
- Established the scope of the guidance (~Oct ’20)
- Discussed the terms regarding process (~Nov ‘20)
- Discussed the concepts of pre and post market (Dec ‘20)
- Discussed the title of the document (Jan ‘21)
- Established the title and introduction of the guidance and review the relevant 25 terms (Feb ’21)

Work Plan

● Work Plan and Time

1) Draft Review (May, 2021)

2) Asking Public Comment (July, 2021 ~ October, 2021)

✓ Draft Submission to IMDRF MC to ask public comment in May

3) Final document development (January, 2022)

4) Endorsement (March, 2022)

● Time schedule

	1Q '21	2Q '21	3Q '21	4Q '21	1Q '22
Draft Development	→	May '21			
Draft Submission to MC		May '21			
Asking Public Comment		←	Jul '21 ~ Oct '21	→	
Meeting for Comment Review				← Nov '21~Jan '22 →	
Submit Final Document					Jan '22
Endorsement					Mar '22


Thank you