IMDRF International Medical Device Regulators Forum

Artificial Intelligence Medical Devices(AIMDs) Working Group Update

Working Group Chair : Dr. Young-kyu Kang,
Ministry of Food & Drug Safety, South Korea

Purpose of NWIP

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

Rationale

- Machine learning and rapid data processing allow AI medical devices to have a development cycle significantly different from existing medical devices

➡ Traditional regulatory approaches are inappropriate to efficiently manage AIMDs

Rationale

- It is necessary to establish a guidance in its infancy to share the views of member jurisdictions on terminology.

Benefits

- Facilitating innovation in technology and regulations in the field of medical devices
- Stimulating innovation of the industry by implementing effective and harmonized pre-market management

Main contents of the guidance

- Definitions and Scope of AI medical devices
- Standardization of terminology

Relevant documents

FDA	Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device
HC	An Overview of Clinical Applications of Artificial Intelligence
HSA	Safe use of Artificial Intelligence Medical Devices in Healthcare
MFDS	Guidance on Review and Approval of AI and Big Data based Medical Devices
	Guidance on Clinical Validation of AI Based Medical Devices
NMPA	Reviewing Criteria for Medical Decision Support Software with Deep Learning
PMDA	Guidance for Evaluation of Artificial Intelligence-Assisted Medical Imaging Systems for Clinical Diagnosis

IMDRF International Medical Device Regulators Forum

AIMDs Members

AIMDs members from RA		
Country	**Name**	**Affiliation**
Australia (3)	Dr David Hau	Therapeutic Goods Administration (TGA)
	Mr David Wotton	
	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	<To be advised>	
European Union (4)	Steffen Buchholz	Federal Ministry of Health (BMG)
	Mariana Madureira	INFARMED
	Alexander Norup Nielsen	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	

AIMDs members from RA		
	Name	**Affiliation**
Russia (1)	Vladimir Kutichev	
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	
World Health Organization (1)	Dr Philippe Boeuf	
Industry		
GMTA (2)	Pat Baird	Philips Healthcare
	<to be advised>	
DITTA (4)	Koen Cobbaert	Philips Healthcare
	Naoki Morooka	Shimadzu Corporation
	Camille Vidal	Shimadzu Corporation
	Annika Eberstein	COCIR

Work Plan

● Work Plan and Time

1) Draft development (February, 2021)
2) Asking Public Comment (July, 2021 ~ October, 2021)
   - ✓ Draft Submission to IMDRF MC to ask public comment in March
3) Final document development (December, 2021)
4) Endorsement (March, 2022)

● Time schedule

	3Q '20	4Q '20	1Q '21	2Q '21	3Q '21	4Q '21	1Q '22
Research		Dec '20					
Draft development			Feb '21				
First FTF meeting			Feb '21				
Draft submission to MC			Mar '21				
Asking Public Comment				←	Jun '21 ~ Oct '21		→
Second FTF meeting						Nov '22	
Submit final document						Dec '21	
Endorsement							Mar '22


Thank you