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International Medical  
Device Regulators Forum

# **Artificial Intelligence Medical Devices(AIMDs) Working Group Update**

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## 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.



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## 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



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# Main contents of the guidance

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



## Relevant documents

<b>Canada</b>	An Overview of Clinical Applications of Artificial Intelligence
<b>China</b>	Reviewing Criteria for Medical Decision Support Software with Deep Learning
<b>Japan</b>	Guidance for Evaluation of Artificial Intelligence-Assisted Medical Imaging Systems for Clinical Diagnosis
<b>Singapore</b>	Safe use of Artificial Intelligence Medical Devices in Healthcare
<b>South Korea</b>	Guidance on Review and Approval of AI and Big Data based Medical Devices
	Guidance on Clinical Validation of AI Based Medical Devices
<b>USA</b>	Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device



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## AIMDs Work Group Members

### AIMDs members from RA

Country	Name	Affiliation
<b>Australia (3)</b>	Dr David Hau	Therapeutic Goods Administration (TGA)
	Mr David Wotton	
	Mrs Olivia Reeves	
<b>Brazil (3)</b>	Mr Helio Bomfim de Macedo Filho	Agência Nacional de Vigilância Sanitária (ANVISA)
	Mr Francisco Iran Cartaxo Barbosa	
	Mr Janglely Bahia Costa	
<b>Canada (2)</b>	Daniel Yoon	Health Canada
	Janet Hendry	
<b>European Union (4)</b>	Steffen Buchholz	Federal Ministry of Health (BMG)
	Mariana Madureira	INFARMED
	Alexander Norup Nielsen	Danish Medicines Agency
	Nada Alkhatay	European Commission
<b>Japan (6)</b>	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		
<b>Russia (1)</b>	Vladimir Kutichev	FGBU "VNIIMT"

### AIMDs members from RA

	Name	Affiliation
<b>Singapore (2)</b>	Dr Yow Soh Zeom	Health Sciences Authority (HSA)
	Mr Lin Anle	
<b>South Korea (7)</b>	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	
<b>United States of America (2)</b>	Mr Dong-Jun Kim	U.S. Food and Drug Administration (FDA)
	Ms Ki-Na Kim	
	Bakul Patel	
	Matthew Diamond	
<b>Liaison</b>		
<b>World Health Organization (1)</b>	Dr Philippe Boeuf	
<b>GMTA (3)</b>	Pat Baird	Philips Healthcare
	Toshiaki Nakazato	Canon Medical System
	Patricia A. Krantz-Zuppan	Medtronic
<b>DITTA (4)</b>	Koen Cobbaert	Philips Healthcare
	Naoki Morooka	Shimadzu Corporation
	Camille Vidal	Shimadzu Corporation
	Annika Eberstein	COCIR
<b>Total 38</b>		







Thank you

