



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 Machine Learning-enabled Medical Devices (MLMD)
- Establish a guidance to share the views of member jurisdictions on terminology



Member Recruitment

- Purpose: In order to collect opinions from more diverse organizations
- Ongoing: Adjusting the number of members to be 3 or less per member country (organization)
 - * (Present) 42 → (Future) 36 or less members in total
 - * Avg. AIMD Meeting Attendees : 30.8 / meeting
- Future Plan: Allowing RHIs (such as PAHO) to join



Main Contents of the Guidance

- 1) Title
- 2) Introduction (Background and purpose of the document)
- 3) Scope of Definitions of the Terms related to ML-enabled Medical Devices
- 4) Definitions and Concepts of Terms related to ML-enabled Medical devices



Main Contents of the Guidance

1) Title

IMDRF/AIMD WG/N#



IMDRF International Medical Device Regulators Forum

Working Draft

Title: Machine Learning-enabled Medical Devices—A subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions

Authoring Group: IMDRF AIMD Working Group

Date: 16 September 2021

Title : Machine Learning-enabled Medical Device—A subset of Artificial Intelligence-enabled Medical Device: Key Terms and Definitions

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Main Contents of the Guidance

2) Introduction (Background and purpose of the document)

‘1.0 Introduction’

- Background
 - Increase significance of ML enabled medical devices
 - Limitations with existing regulations on ML enabled 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 Definitions of the Terms related to ML-enabled Medical Devices

‘2.0 Scope’

- This document applies to key terms and definitions relating to Machine Learning-enabled Medical Devices (MLMD).

Note 1 : MLMD are medical devices. A product must first meet the definition of a medical device before it can be an MLMD.

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Note 3 : This document does not attempt to define established definitions in the field of computer science; however, it does strive to highlight and clarify conflicting terms and definitions as necessary. This document does not provide guidelines for the development, risk management or evaluation of MLMD.



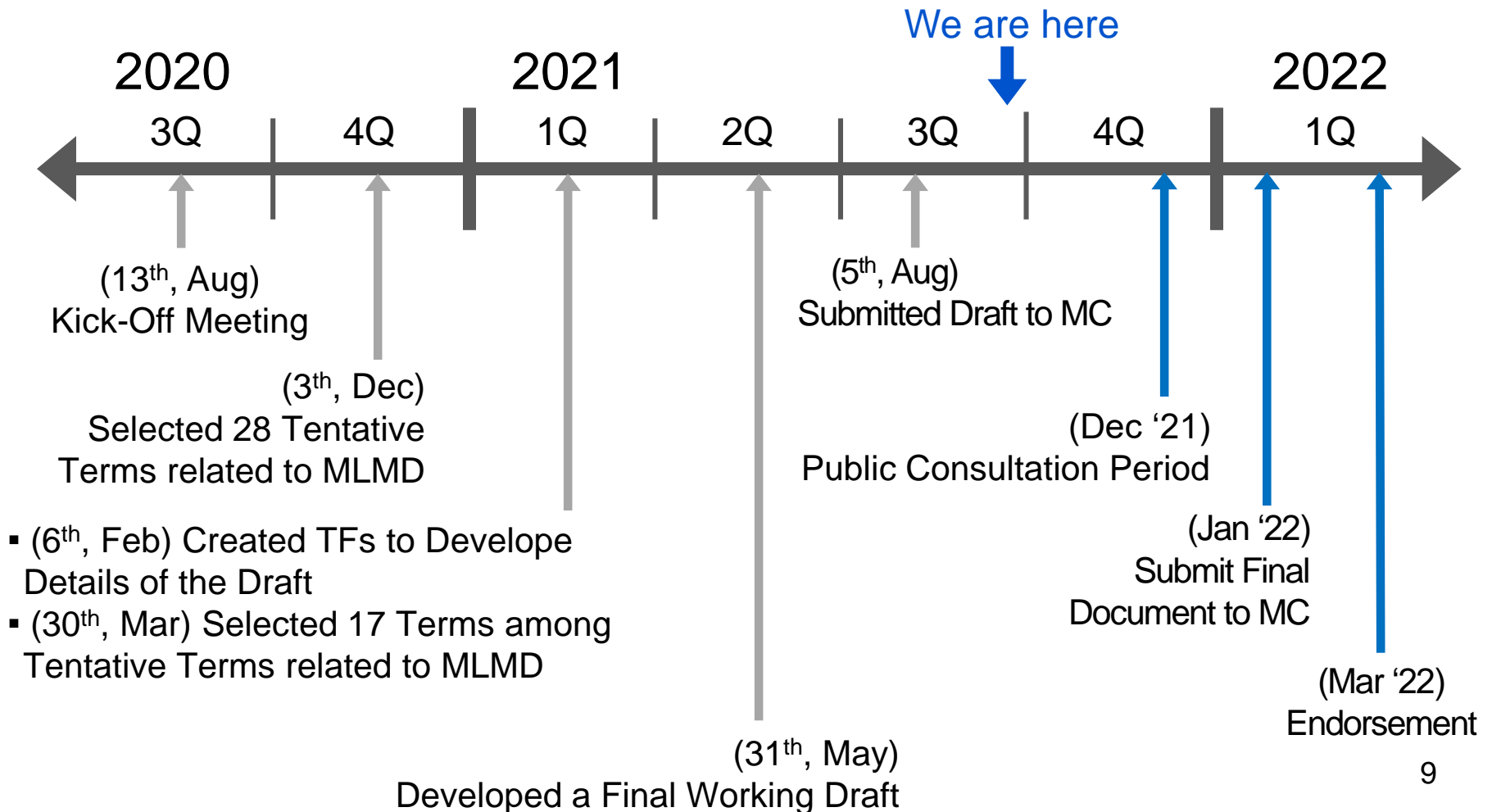
Main Contents of the Guidance

4) Definitions and Concepts of 18 Terms related to ML-enabled Medical devices

- Definition (12 Terms) : Definitions of the terms in terms of both MLMD and technologies
- Discussion (6 Terms) : Descriptions of the terms with different meanings or the terms needed additional explanations



Progress Status & Work Plan





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Thank you