# 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



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

# **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.
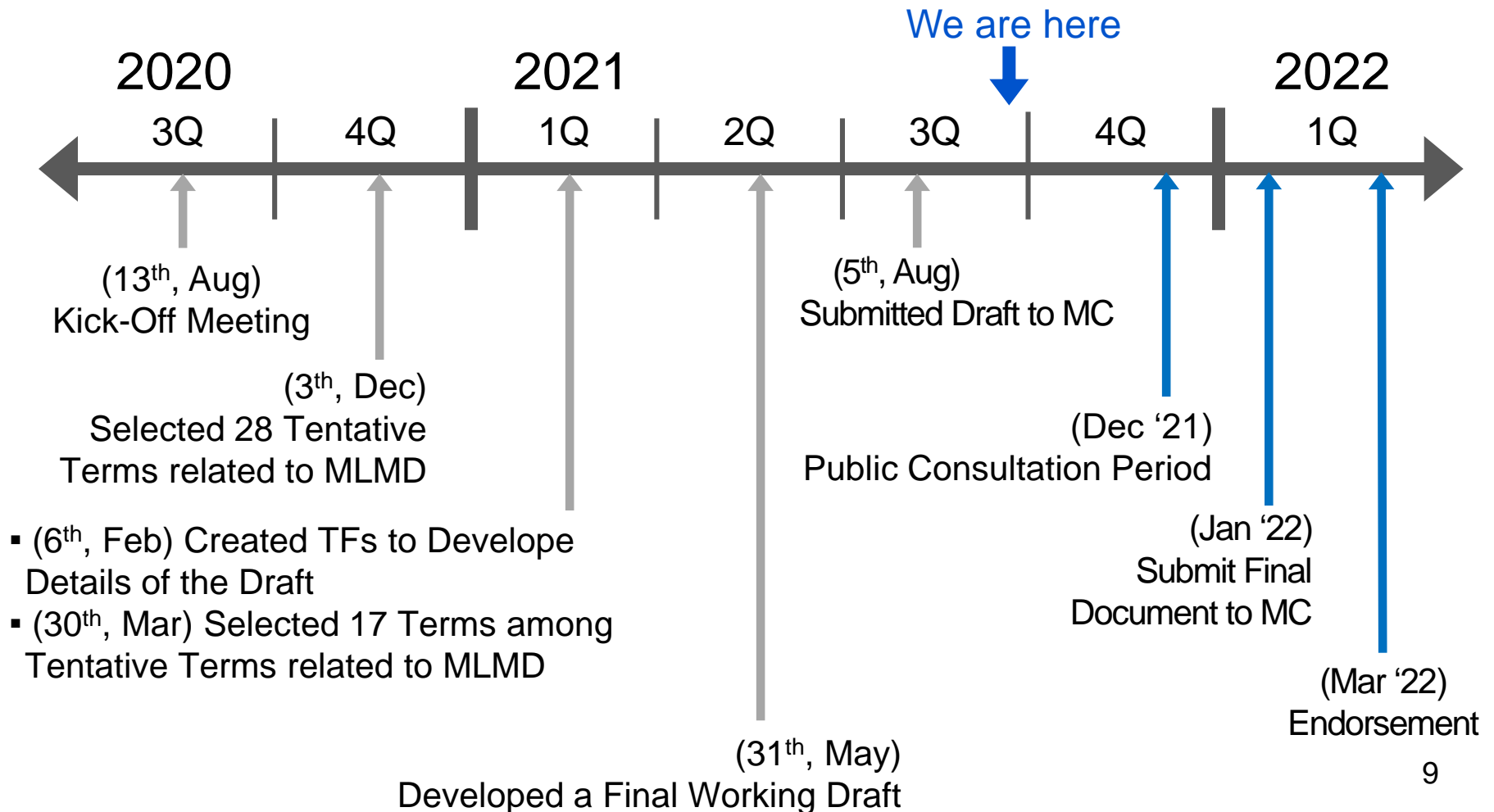
# Main Contents of the Guidance

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

We are here

| 2020 | | 2021 | | | | 2022 |
| 3Q | 4Q | 1Q | 2Q | 3Q | 4Q | 1Q |

(13th, Aug)
Kick-Off Meeting

(3th, Dec)
Selected 28 Tentative
Terms related to MLMD

- (6th, Feb) Created TFs to Develope
  Details of the Draft
- (30th, Mar) Selected 17 Terms among
  Tentative Terms related to MLMD

(31th, May)
Developed a Final Working Draft

(5th, Aug)
Submitted Draft to MC

(Dec '21)
Public Consultation Period

(Jan '22)
Submit Final
Document to MC

(Mar '22)
Endorsement

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Thank you