



**IMDRF**

International Medical  
Device Regulators Forum

# **Status of IMDRF AIMD (Artificial Intelligence Medical Device) WG Guidance**

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



## **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 International Medical  
Device Regulators Forum

#### Proposed Document

**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**

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.



## 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.

⋮

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.



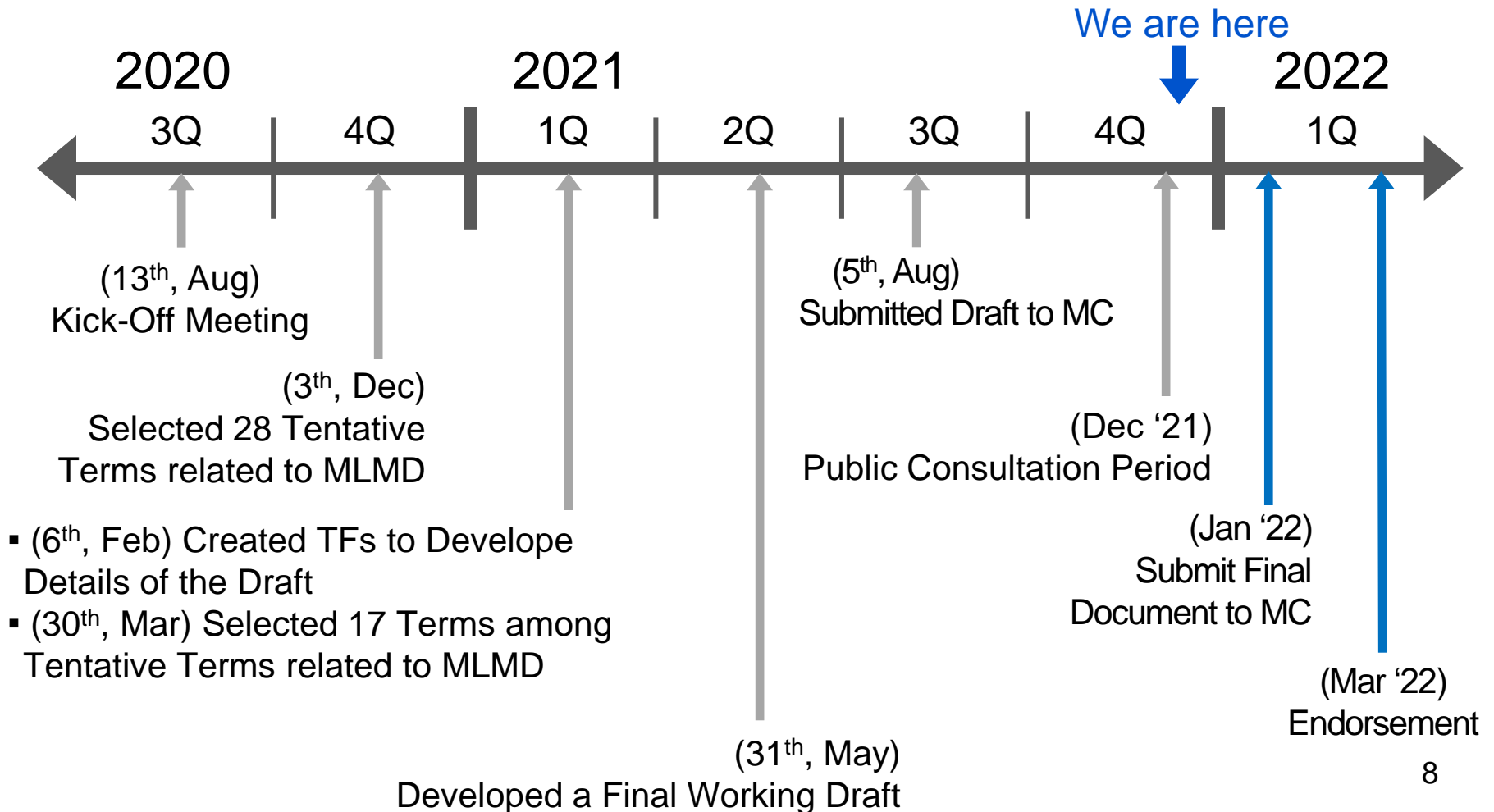
## Main Contents of the Guidance

### 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







# IMDRF International Medical Device Regulators Forum

