IMDRF International Medical Device Regulators Forum

Artificial Intelligence Medical Devices(AIMD) Working Group Update

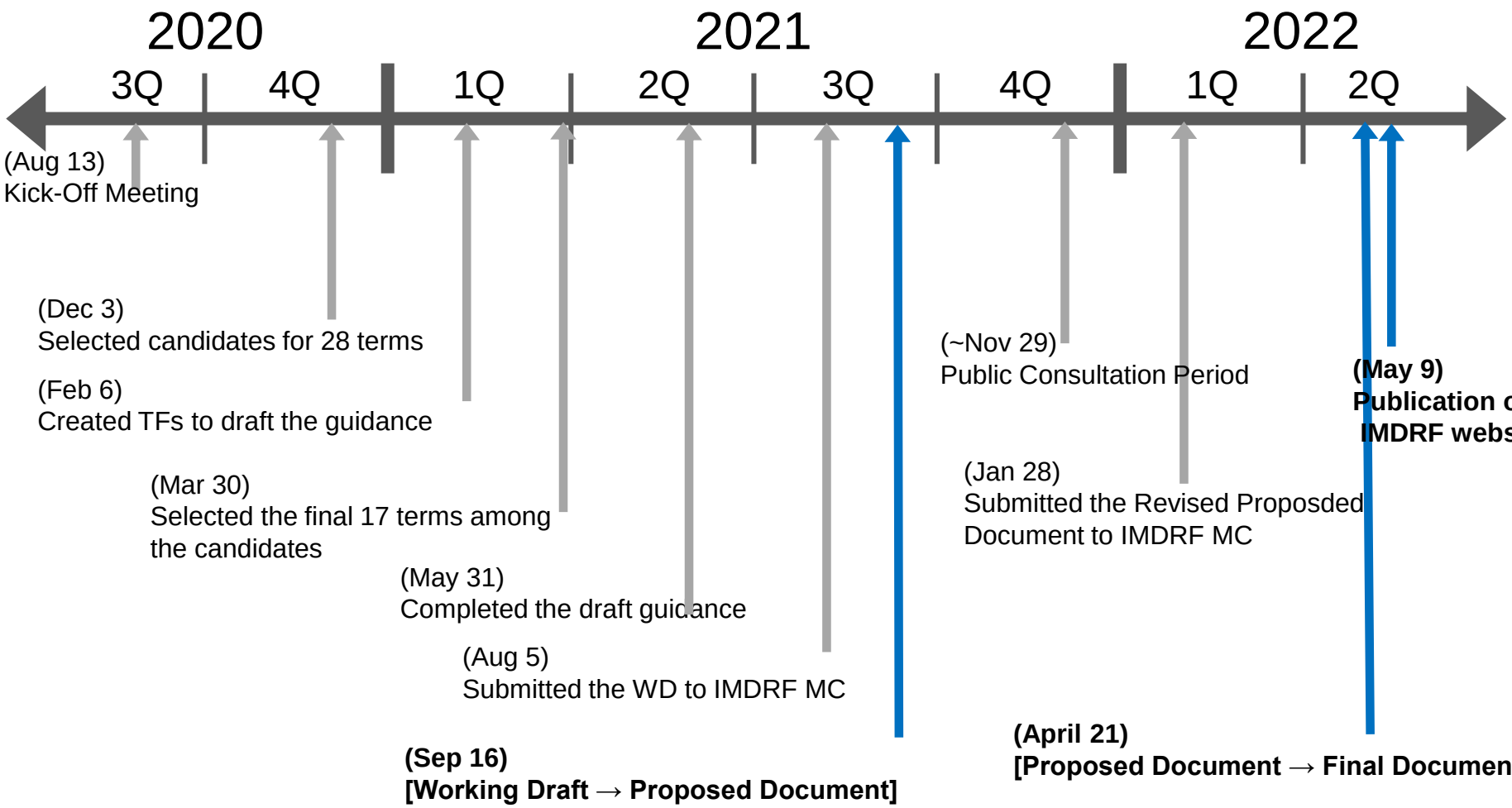
13. Sep. 2022

Medical Device Evaluation Department,
Ministry of Food & Drug Safety, South Korea

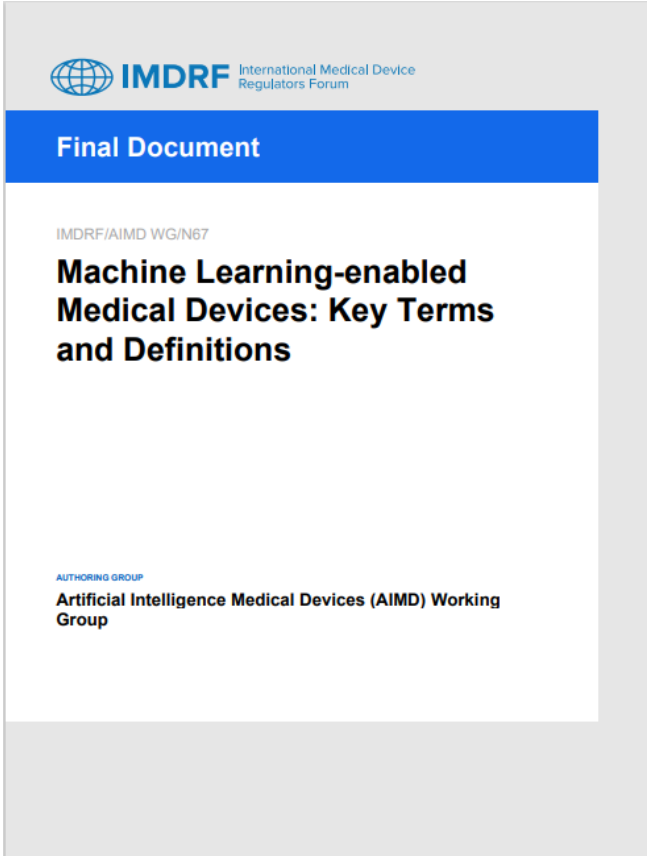
Purpose of AIMD WG

- Established the WG to create a common approach within IMDRF member countries on safety management of the artificial intelligience medical devices (AIMD)
  - Scope of AIMD subject to safety management
  - Harmonization of regulatory terminology applying to AIMD

Progress


2020
2021
2022
3Q
4Q
1Q
2Q
3Q
4Q
1Q
2Q
(Aug 13)
Kick-Off Meeting
(Dec 3)
Selected candidates for 28 terms
(Feb 6)
Created TFs to draft the guidance
(Mar 30)
Selected the final 17 terms among the candidates
(May 31)
Completed the draft guidance
(Aug 5)
Submitted the WD to IMDRF MC
(Sep 16)
[Working Draft → Proposed Document]
(~Nov 29)
Public Consultation Period
(Jan 28)
Submitted the Revised Proposded Document to IMDRF MC
(April 21)
[Proposed Document → Final Document)]
(May 9)
Publication on IMDRF website

Deliverable - Guidance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Final Document

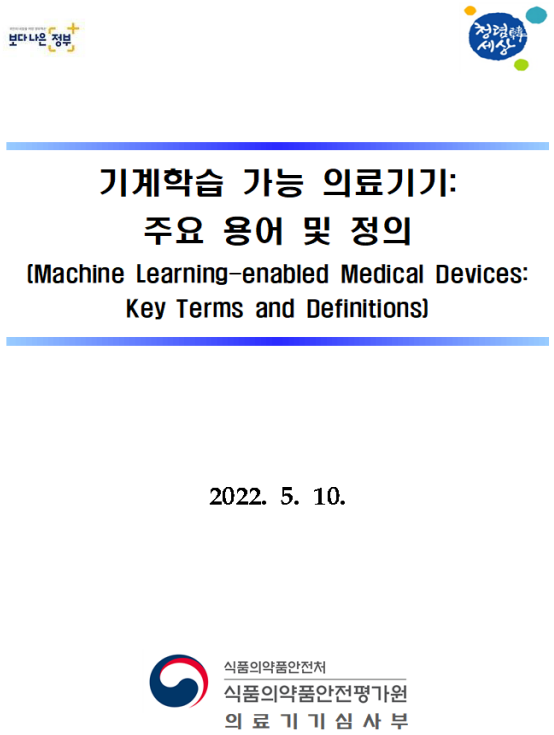
IMDRF/AIMD WG/N67

Machine Learning-enabled Medical Devices: Key Terms and Definitions

AUTHORING GROUP

Artificial Intelligence Medical Devices (AIMD) Working Group

< source : www.imdrf.org (ENG)


보다나은 정부

정책혁신

기계학습 가능 의료기기:
주요 용어 및 정의
(Machine Learning-enabled Medical Devices:
Key Terms and Definitions)

2022. 5. 10.

식품의약품안전처
식품의약품안전평가원
의 료 기 기 심 사 부

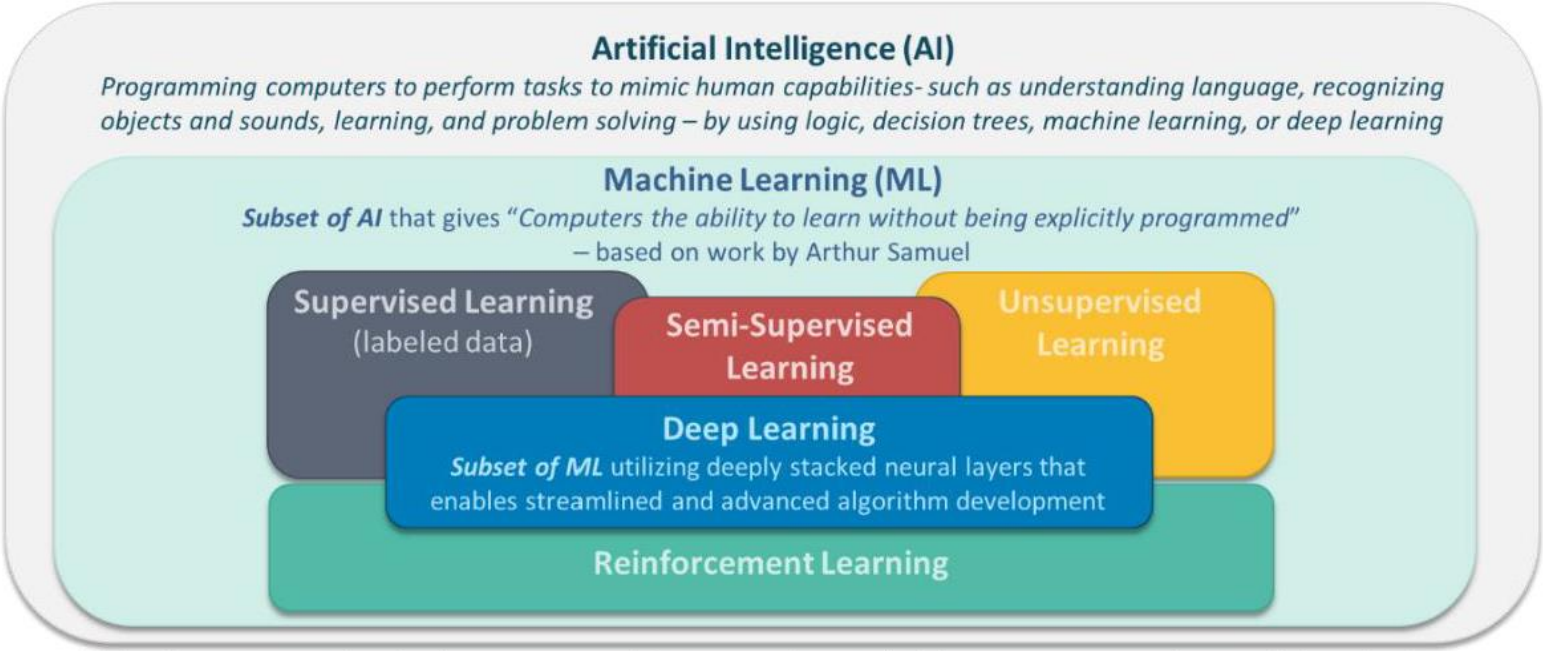
< source : www.mfds.go.kr (KOR)

Main Contents (The Guidance)

The Scope

Focusing on 'Machine Learning enabled Medical Device, MLMD' only, which is a part of artificial intelligence (AI)

- The group reached a consensus to cover MLMD only since there is a wide range of definitions on the term "AI"



※ The descriptions within the diagram are not definitions, and are included to convey a general sense of the technology.

Main Contents (The Guidance)

Definition / Discussion

- Defined 11 regulatory terms including MLMD
- Added descriptions on 5 terms difficult to define

#	Cate.	Terminology
1	Def.	Machine Learning-enabled Medical Device
2		Bias
3		Continuous Learning
4		Reference Standard
5		Reliability
6		Semi-Supervised Machine Learning
7		Supervised Machine Learning
8		Test Dataset
9	Def.	Training
10		Training Dataset
11	Diss.	Unsupervised Machine Learning
12		Aspects of MLMD Changes
13		Supervised Learning
14		Unsupervised Learning
15		Semi-Supervised Learning
16		Validation

Significance

- **A vehicle for communication b/t industries and regulators**
  - ✓ The meaning of the term ‘Validation’ in medical devices (e.g. Checking if the results have been achieved compared to the plan) and the meaning in AI field (ex. data curation/model tuning) are different
- **The cornerstone of IMDRF AI guidance to be developed in the future**
  - ✓ If individual jurisdictions define the scope and principles, these may inharmoniously develop. Consequently, it’s necessary to establish a guideline in its infancy to share the views of member jurisdictions on terminology

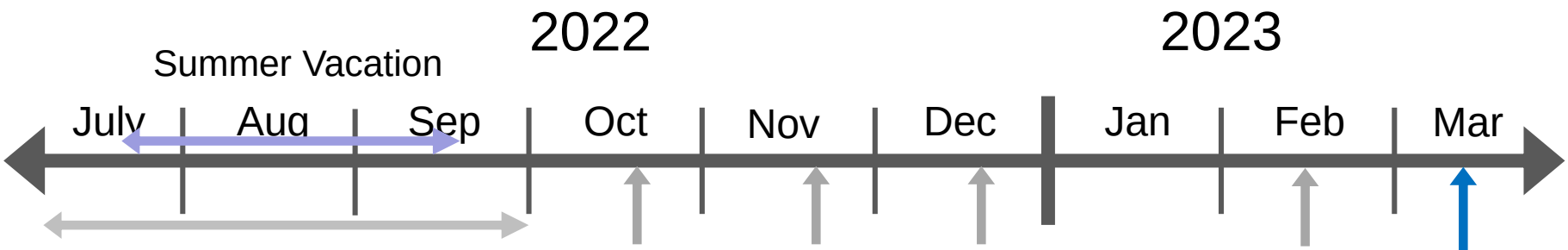
Future Plan

Background

- The necessity of Future Work Plan suggested during the commenting period on WD within the group
- The group agreed to prepare the plan after issusing the guidance (8 July 2021)

#	Line Number	Country / Organization	Section	Consolidated Draft (2021-06-02)	Proposed change	Type of commer*	Rationale / Comment
1	All	Australia/TGA	entire document	N/A	N/A	Ge	Would it be possible to explain how the definitions and discussion terms will be used in the future? What are the next steps? What documents are the working group planning to develop in future? How will this document be used and/or inform things? To understand the context of the definitions without knowing what the future documents might be. The need to be able to go back and adjust them if the need arising from a future document.

Timeline



(July - Sep)
Collecting Wgmembers' opinions by email(3 or 4 times)
•Bring some issues on Future Work Plan(FWP) into agenda (including alternatives)

(3rd Thursday of Oct)
F2F Teleconference(The 29th ~ 31th)
•Discuss resolutions on agenda
•Discuss how to submit the NWIE and share timeline according to the IMDR SOP
•Share the IMDRF SOP relating to nominating the next WG chair

(3rd Thursdays of every month from Nov to Dec)
Online Meetings(The 32th ~ 35th)
•Discuss issues related to FWP, develop alternatives and final FWP

(15 Feb)
Submit NWIE

(expected to be 16 March)
Be endorsed NWIE by MC

※ Timescale for developing NWIE may be delayed depending on the schedule of FWP to be discussed.


Thank you