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 intelligence medical devices (AIMD)
  – Scope of AIMD subject to safety management
  – Harmonization of regulatory terminology applying to AIMD
Progress

2020
- 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- May 31: Completed the draft guidance
- Sep 16: [Working Draft → Proposed Document]
- Oct 5: Submitted the WD to IMDRF MC

2021
- (Nov 29): Public Consultation Period
- Jan 28: Submitted the Revised Proposed Document to IMDRF MC

2022
- May 9: Publication on IMDRF website
- Apr 21: [Proposed Document → Final Document]
Deliverable - Guidance

< source: www.imdrf.org (ENG)

< source: www.mfds.go.kr (KOR)
Main Contents (The Guidance)

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"
### Main Contents (The Guidance)

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

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<tr>
<th>#</th>
<th>Category</th>
<th>Terminology</th>
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<td>1</td>
<td>Def.</td>
<td>Machine Learning-enabled Medical Device</td>
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<td>2</td>
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<td>Bias</td>
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<td>Continuous Learning</td>
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<td>Reference Standard</td>
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<td>5</td>
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<td>Reliability</td>
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<td>6</td>
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<td>Semi-Supervised Machine Learning</td>
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<td>Supervised Machine Learning</td>
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<td>8</td>
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<td>Test Dataset</td>
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<td>Unsupervised Machine Learning</td>
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<td>Aspects of MLMD Changes</td>
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<td>16</td>
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<td>Validation</td>
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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

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

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<tr>
<th>#</th>
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<th>Country / Organization</th>
<th>Section</th>
<th>Consolidated Draft (2021-06-02)</th>
<th>Proposed change</th>
<th>Type of commer*</th>
<th>Rationale / Comment</th>
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<td>All</td>
<td>Australia/TGA</td>
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<td>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.</td>
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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

Summer Vacation

Jul, Aug, Sep

Oct, Nov, Dec

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

2023

Jan, Feb, Mar

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.