2022 IMDRF/GMTA Workshop– Opportunities for Global Convergence and Prioritization of AI

Maximizing potential benefits of AI/ML-based Devices

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Agenda

- Potential Benefits of Artificial Intelligence/Machine Learning (AI/ML)-based Software as a Medical Device (SaMD)
- Realizing the Potential of AI/ML-based SaMD
- Current Global Regulatory Landscape for AI/ML-based SaMD
- Opportunities for Global Collaboration for Overcoming Obstacles for innovative AI/ML-based SaMD

Potential Benefits of AI/ML -based SaMD

The data-driven nature of AI/ML-based SaMD can lead to highly accurate and effective products for healthcare.

- Effectively incorporating both anatomical variability and pathological characteristics/variability
- Reducing human reader variability as an aid to the physician
- Enabling the physician to judiciously choose patient images to review for medical decision making
- AI/ML-based CAD products in either US or EU market
  - ✓ Computer assisted detection, diagnosis, detection/diagnosis, triage/notification, e.g., lung nodule detection, lung cancer diagnosis, breast cancer detection/diagnosis, bone fracture detection/diagnosis, triage/notification of PE, pneumothorax, or stroke(s).

Potential Benefits of AI/ML -based SaMD

Successful AI/ML-based SaMD fulfill unmet clinical needs.

- Clinically meaningful and rigorous AI/ML-based CAD products help improve radiologists' performance with its accuracy and efficiency.
- Innovative AI/ML-based SaMD can fill existing gaps in the clinical space.
  - ✓ 1st FDA-cleared autonomous AI, IDx-DR, for screening patients for diabetic retinopathy
- Innovative AI/ML-based SaMD can reduce radiologists' burden of reading enormous amount of image data which often results in burnout.
  - ✓ Filtering out normal mammograms from the radiologist's workload.

Realizing the Benefits of AI/ML SaMD

Due to the data-driven nature of AI/ML-based SaMD, more frequent product updates are desired. To realize the full potential of AI/ML-based SaMD, manufacturers should be able to do the following:

- Develop AI/ML-based SaMD that meets unmet clinical needs and fill gaps.
- Effectively update already-cleared AI/ML-based SaMD in a timely manner as additional useful patient data become available.
- Effectively utilize regulatory intelligence in planning a long-term regulatory strategy for both new AI/ML product registration and updates.
  - ✓ Traditional pathways, such as 510(k), can be time consuming, resulting in delayed access to updated products for improved patient care.

Current Global Regulatory Landscape

US FDA's efforts on consistency and transparency:

- Existing Guidance for CAD and others applies to AI/ML-based CAD and SaMD plus detailed descriptions for both training and testing datasets
- PMA Summary of Safety and Effectiveness Data for Class III devices
- 510(k) Summary for Class II predicates
  - ✓ Still needing increased level of detail
- Pre-sub pathway to gain the FDA's input on the company's approach
  - ✓ Pre-determined change control plan (PCCP) via De Novo, recommended by US FDA

Current Global Regulatory Landscape

European Unions' Medical Device Regulation (EU MDR) replaced Medical Device Directives (MDD) as of May 21, 2021

- Improvement and clarity on device classification and performance requirements for both pre-market and post-market at high level
- Ambiguity on testing requirements for clearance (both standalone and clinical performance testing)
  - ✓ Summary of predicates through EUDAMED are not yet available
- Flexibility to allow for regulatory clearance of innovative AI/ML-based software medical devices beyond CAD
  - ✓ Oxipit's ChestLink for filtering out normal chest x-ray cases – clinical use is still limited to the local legal requirement on the physician's review of patient images

Opportunities for Global Collaboration

Three Areas for Collaborative Projects or Working Groups

1. Clarifying unclear regulatory requirements for performance assessment
   - ✓ Define appropriate clinical assessment approaches for specific areas of AI/ML-based products (both CAD and non-CAD) with consideration of risk-benefit profiles and post-market monitoring needs

2. Easing difficulty in developing a PCCP which requires multi-disciplinary expertise from AI algorithm development and testing, software V&V, regulatory and clinical assessment strategy
   - ✓ Develop a detailed mock PCCP for specific areas of AI/ML-based CAD and beyond.

Opportunities for Global Collaboration

Three Areas for collaborative projects or working groups

3. Need for generating clinical evidence via real-world data and evidence (RWD/RWE), using AI/ML-based CAD as a training wheel for autonomous or other innovative devices
   - ✓ Define essential data elements.
   - ✓ Examine the feasibility of data element collection, using the existing infrastructure (EMR, platform, DICOM, etc.).
   - ✓ If additional needs for data element dictionary exist, investigate what can be done realistically to fulfill the goal of generating RWD in practice.
   - ✓ Proceed to the next stage for a pilot project to collect RWD data and synthesize RWE for a specific product area.

Summary

1. AI/ML-based SaMD products have the potential to meet unmet clinical needs and fill gaps in the clinical space for improving healthcare.
2. The potential benefits of AI/ML-based SaMD can be realized by global collaboration on developing and demonstrating clinical assessment approaches for both pre- and post-market evaluation of the device, and thereby streamlining regulatory pathways with real-world evidence needed for ensuring the safety and effectiveness of the device.

Thank you!

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