Current Regulatory Approaches for AI Medical Devices in Singapore

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Artificial Intelligence in Medical Devices

• AI that is intended for **medical purposes** (i.e. diagnosis, treatment, patient monitoring) are regulated by HSA as Medical Device (AIMD)
  o AI that are used in hospitals solely for administrative functions (e.g. patient appointment scheduling) are **not** regulated by HSA as MD
  o AI that are used for manufacturing process optimisation are **not** regulated by HSA as MD

• AI-MD are risk classified based on their intended purpose assigned by their manufacturer/developer (i.e. by design and by claims)
  o Functionalities and Features (e.g. analyse, monitor, adjust or control therapy)
  o Output from the AI-MD (e.g. triage, recommend, diagnose, therapy recommendations)
  o The risk classification approach and considerations are similar to other software medical devices

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*Legislative definition of “Medical Device” can be found in the First Schedule of the Health Products Act 2007: [http://statutes.agc.gov.sg/](http://statutes.agc.gov.sg/)*
• This document provides clarity on the regulatory requirements for software medical devices in its entire life cycle.

• The following topics are covered in this document:
  – Quality Management System (QMS) for software medical devices
  – Dealer’s licensing requirements
  – Pre-market product registration requirements
  – Change notification
  – Post-market management of software medical devices
  – Cybersecurity
  – Artificial Intelligence Medical Device
    • Focuses mainly on Machine Learning enabled Medical Devices (MLMD)

Process of developing and deployment of the MLMD

Device Development

- Training Dataset
- Validation Dataset
- Labelling

Model Selection, Training, Tuning and Maintenance

Performance and Clinical Evaluation

Device Deployment and Implementation

- ML medical device deployed
- Performance Monitoring
- Re-training of model

Continuous Learning

Real world data

Development/ Retraining/Deployment under Quality Management System ISO 13485

MLMD: Regulatory Requirements

- Define the intended purpose and functionalities
  - features/attributes used to generate the corresponding output
  - Device workflow including how the output result should be used
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- Data Quality - Training & Validation Data sets
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- Data Quality - Training & Validation Data sets

- Pre-clinical/Analytical & Clinical Validation
Additional Considerations for Continuous Learning MLMD

- Process controls to effectively manage the learning process

- Process to ensure data integrity, reliability and validity of the real world data used for learning

- Validation strategy and verification activities for continuous learning to ensure the performance is within the pre-defined boundaries / envelope
• Review and address all foreseeable risks and failure modes of the software in its product life cycle

• Where there are changes made to a software, these should be systematically evaluated to determine if any additional risk could arise from these changes.

A schematic representation of the risk management process
Adapted from ISO 14971:2007 Medical devices -- Application of risk management to medical devices

Ensure that residual risk is acceptable
**Post-approval monitoring**

A post-approval requirement to submit periodic reports/updates on the real world performance of the MLMD globally (e.g. reported device failures or inaccurate results)

This is in addition to the mandatory reporting of Adverse Events, Field Safety Actions & Recalls to HSA.

**Change Management**

Significant changes made to the MLMD (e.g. change in the type of input data), will require approval from HSA prior to deployment. Requirements are aligned to our current approach for software.
Regulating MLMD – Product Lifecycle Approach

Experience gathered from Real World use is applied to improve the next version or model of the MD

MLMD Development, Pre-clinical/Analytical and Clinical validation

Regulatory approval from HSA Deployment/Implementation

Re-training/ Monitoring/ Deployment of upgraded version

Research Lab/Bench Design & Manufacture Clinical Trial Marketing Authorisation Post-market surveillance

Pilot and Pivotal clinical studies Medical Device Registration (SMDR) Monitoring real world effectiveness, Adverse Events and FSCA/Recalls
Implementation of AIMDs

- The Ministry of Health has collaborated with HSA and IHiS* to publish a guideline on good practices for AI developers and implementers (e.g. healthcare institutions – hospitals, clinics, laboratories, etc.)

- Some key recommendations on AIMD’s implementation include:
  - Exercise clinical governance and oversight over the adoption and implementation
  - Contingency plans to remove the AIMD from the operational workflow

*Integrated Health Information Systems (IHIS)

IMDRF N67 - Implementation Status

- Partially implemented in Singapore
- Work in progress to align definitions and terminologies with the IMDRF document

Reference: https://www.imdrf.org/documents/machine-learning-enabled-medical-devices-key-terms-and-definitions
THANK YOU

For Product Regulation related queries: