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)
  - AI that are used in hospitals solely for administrative functions (e.g. patient appointment scheduling) are **not** regulated by HSA as MD
  - AI that are used for manufacturing process optimisation are **not** regulated by HSA as MD

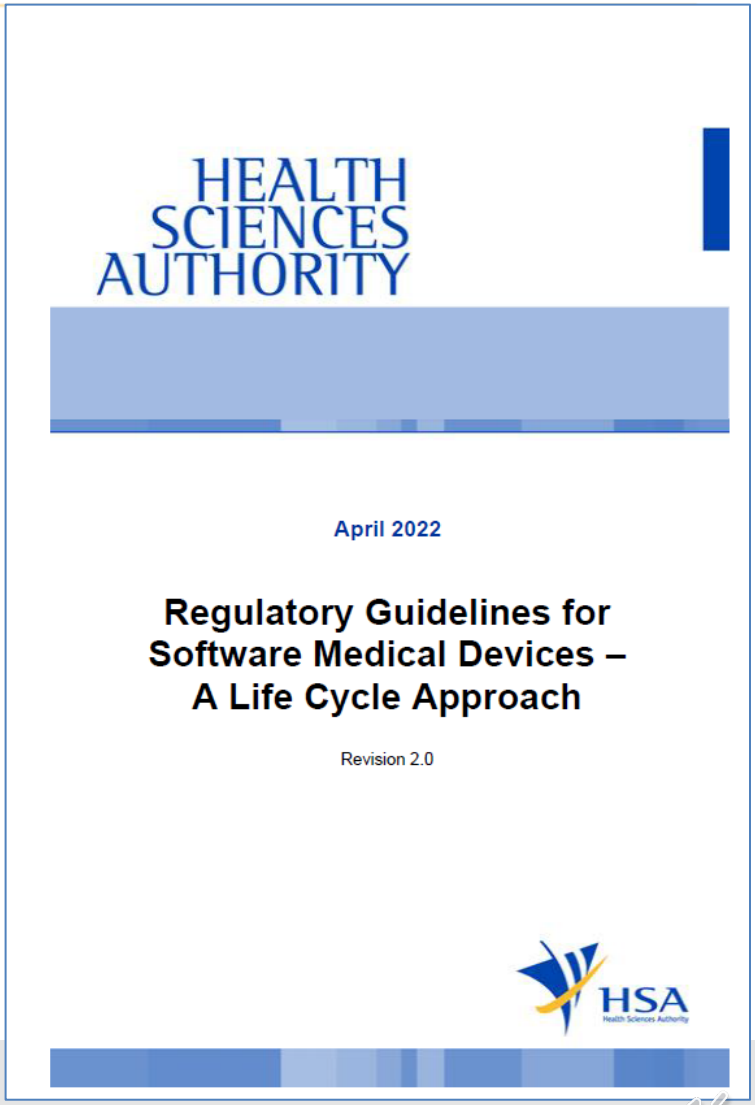
- AI-MD are risk classified based on their intended purpose assigned by their manufacturer/developer (i.e. by design and by claims)
  - Functionalities and Features (e.g. analyse, monitor, adjust or control therapy)
  - Output from the AI-MD (e.g. triage, recommend, diagnose, therapy recommendations)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

Legislative definition of "Medical Device" can be found in the First Schedule of the Health Products Act 2007: http://statutes.agc.gov.sg/

Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach

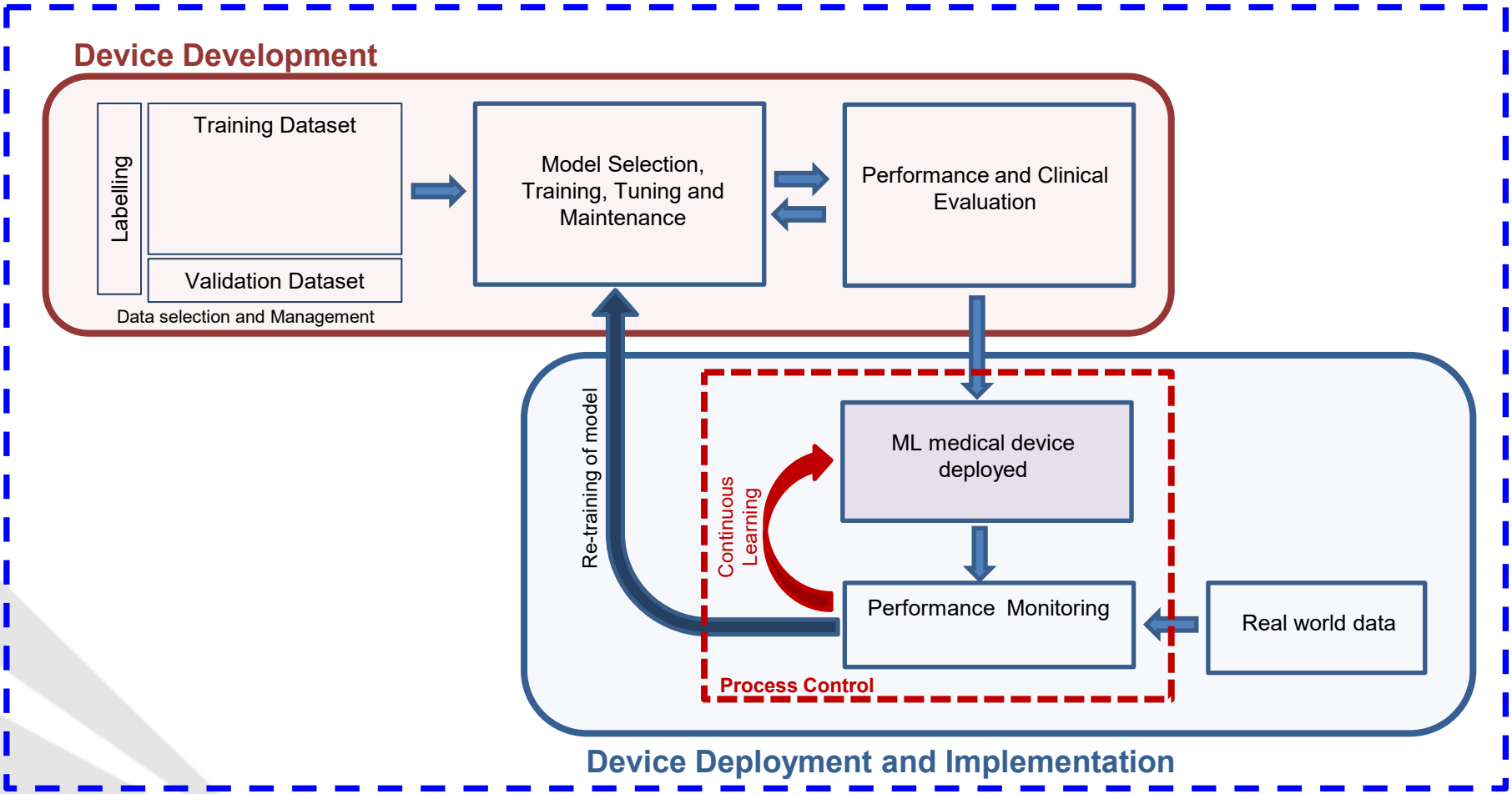
- This document provides clarity on the regulatory requirements for software medical devices in its entire life cycle.

- 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)



Reference: "Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach" available at HSA | Guidance documents for medical devices

Process of developing and deployment of the MLMD

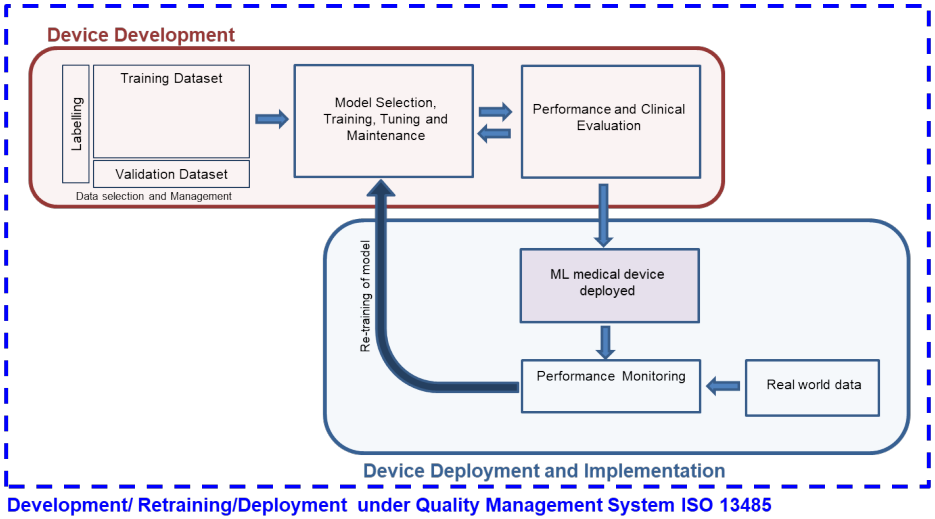


Development/ Retraining/Deployment under Quality Management System ISO 13485

Reference: "Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach" available at HSA | Guidance documents for medical devices

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



MLMD: Regulatory Requirements

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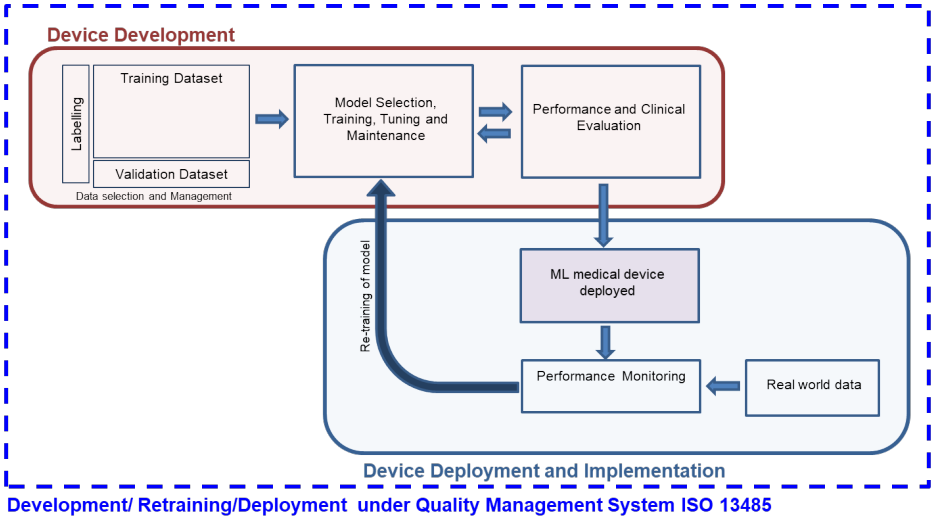
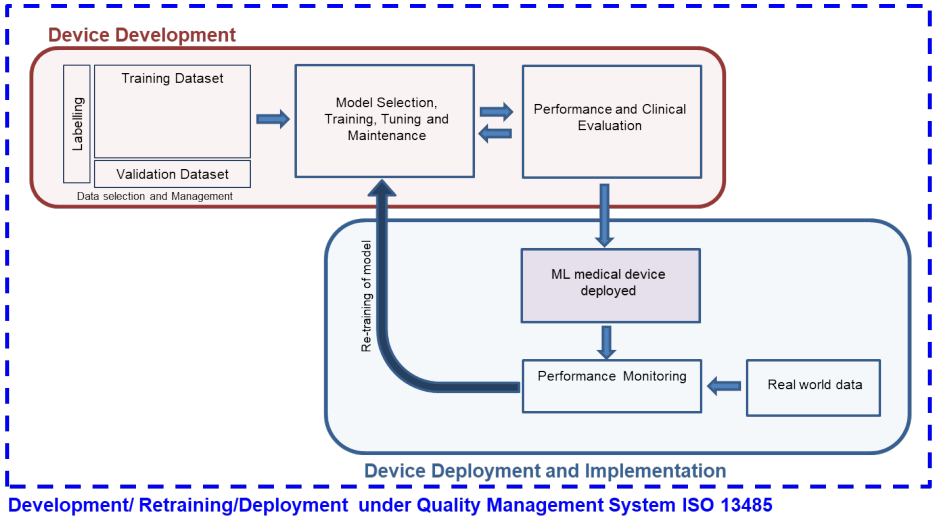
- Data Quality - Training & Validation Data sets



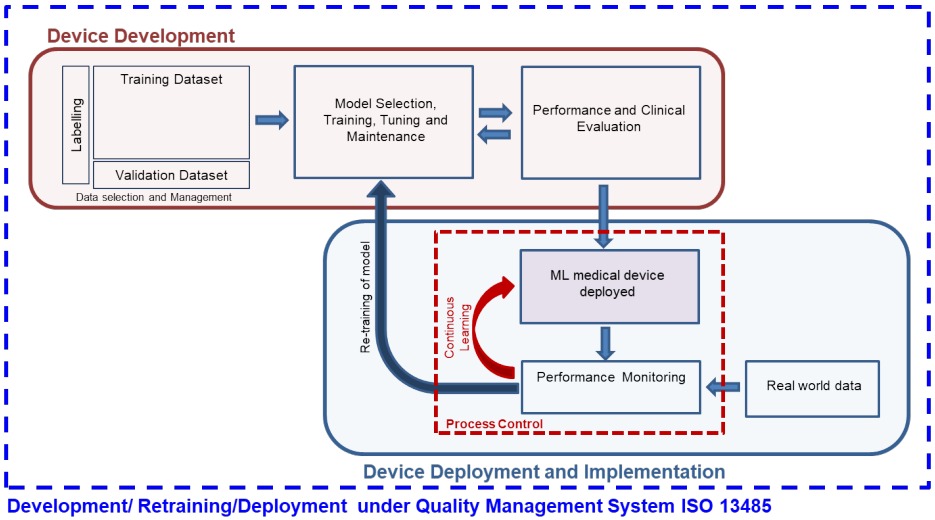
MLMD: Regulatory Requirements

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



Additional Considerations for Continuous Learning MLMD

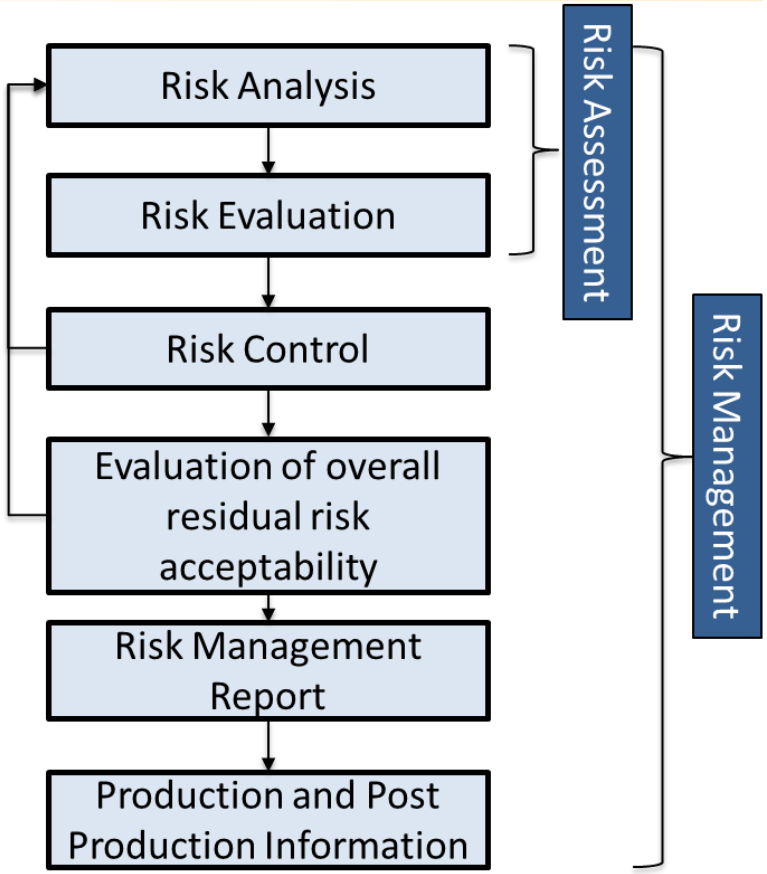
- Process controls to effectively manage the learning process
- Process to ensure data integrity, reliability and validity of the real world data used for learning
- Validation strategy and verification activities for continuous learning to ensure the performance is within the pre-defined boundaries / envelope



Benefit-Risk Considerations

- 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 and Management

Post-approval monitoring

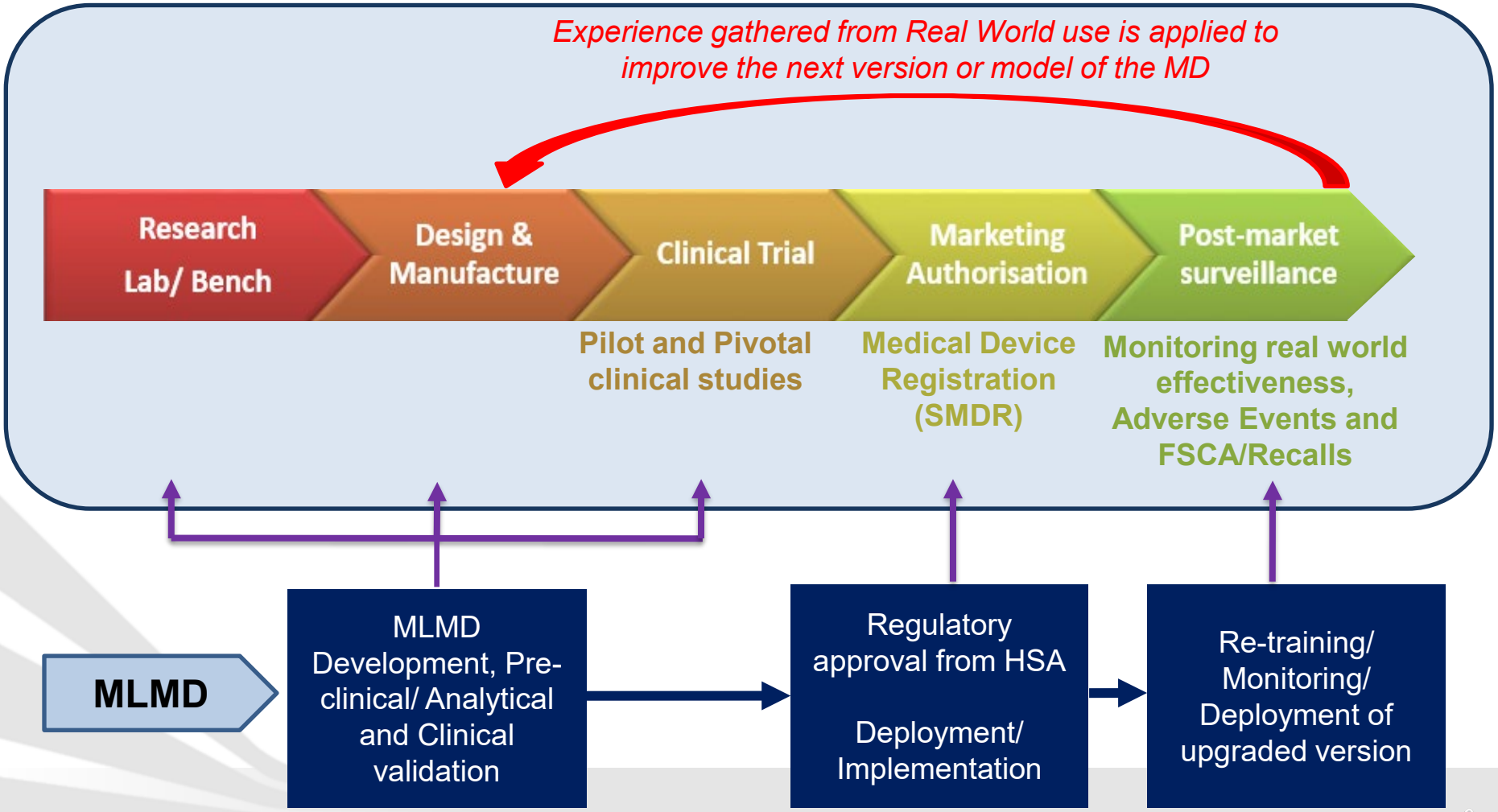
A post-approval requirement to submit periodic reports/updates on the real world performance of the MLMD globally (e.g. reported device failures or inaccurate results)

This is in additional 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

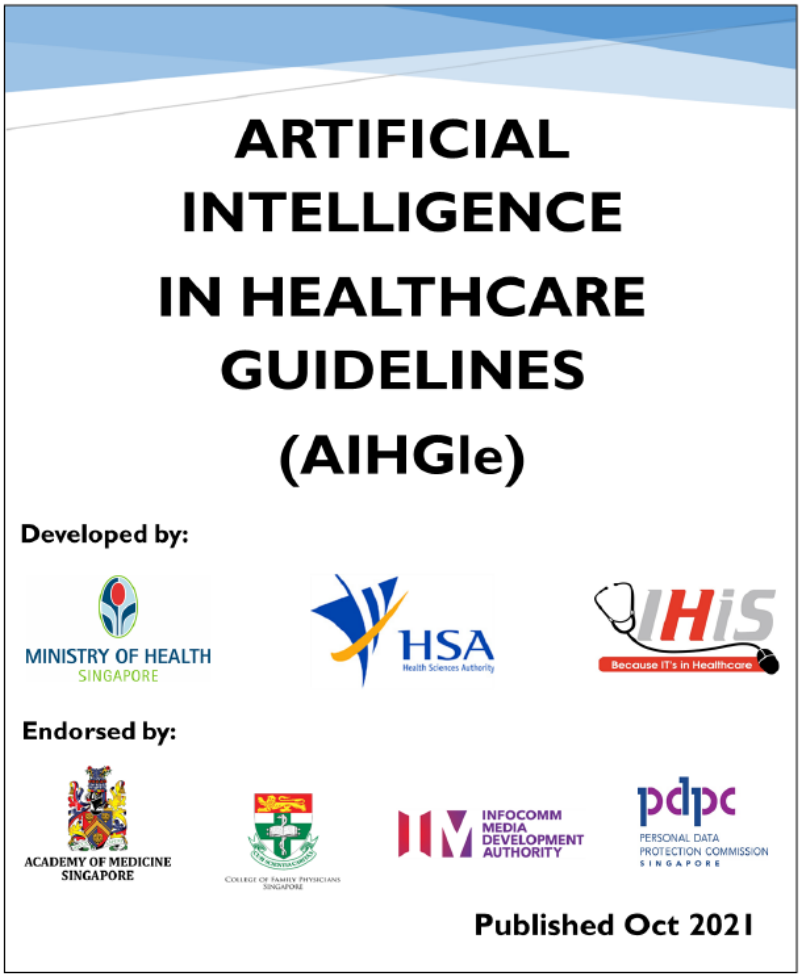
Regulating MLMD – Product Lifecycle Approach



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, clinicals, 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

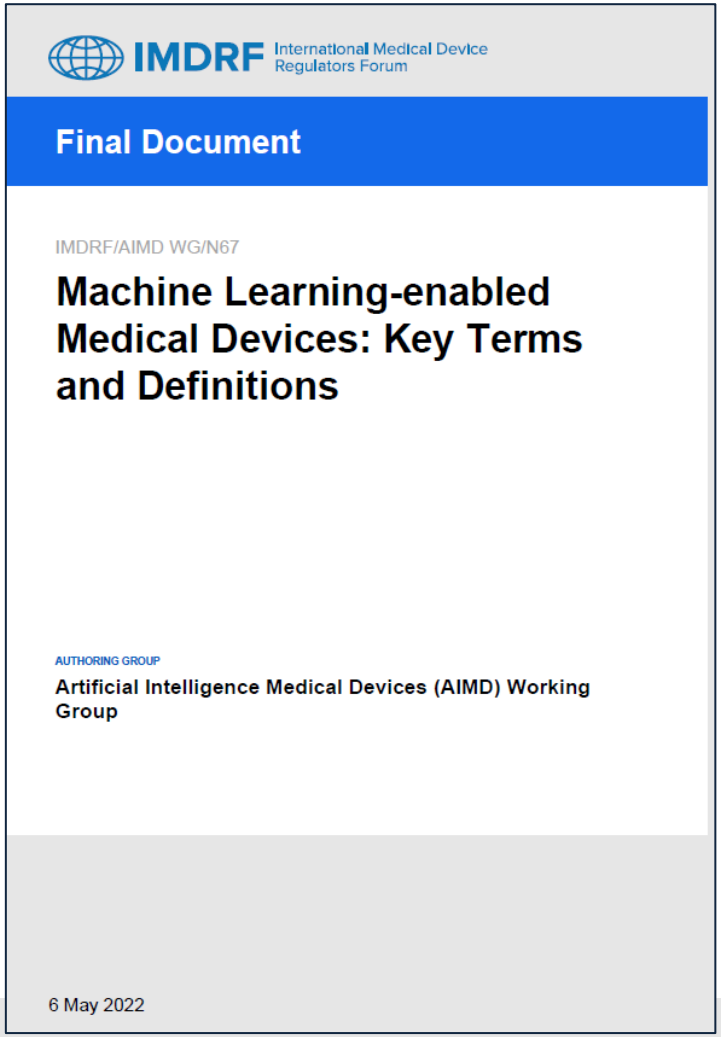


*Integrated Health Information Systems (IHiS)

Reference: https://www.moh.gov.sg/licensing-and-regulation/artificial-intelligence-in-healthcare

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: