Regulations of Software as Medical Device (SaMD)

PAMDRAP 24th General Membership Meeting 2022

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2 December 2022 Manila, Philippines

The Issue…

Traditional IVDs/MDs	vs.	Software
Longer development timelines (years)	**Timelines**	Short development lifecycles (months)
Modifications generally take time to implement	**Modifications**	Constant change and delivery (expected and accepted)
Physical products with relatively well-defined risks	**Products**	Virtual products with emerging issues (e.g. cybersecurity)
Submission volume is generally predictable	**Submissions**	Submission volume is expected to increase exponentially
Distributed through typical logistical channels	**Distribution**	Can be distributed through the cloud or app store

Global Efforts: Define a Risk-Based, Fit-For-Purpose Regulatory Framework…

…that allows timely patient access to high-quality, safe and effective medical technology while fulfilling the unique needs of stand-alone software.

Topics for Discussion

Qualification and Software with Multiple Functions

SaMD Classification

Alternative Pathways

Predetermined Change Control Plan

APAC Best Practices in Digital Health Regulation

Qualification and Software with Multiple Functions

Software Qualification

Is this software regulated?

- IMDRF recognizes that only “a subset of software used in healthcare meets the definition of a medical device…”[1]
- As with all medical products, software is qualified or regulated based on whether or not it has a **medical purpose**.
  - IMDRF defines medical purpose as “software that meets the definitions of a medical device or IVD.”

Appropriate qualification of software allows regulators to focus their resources on software that presents the highest risk to patients.

[1] Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations: IMDRF/SaMD WG/N12FINAL:2014

Qualification of Software in the EU

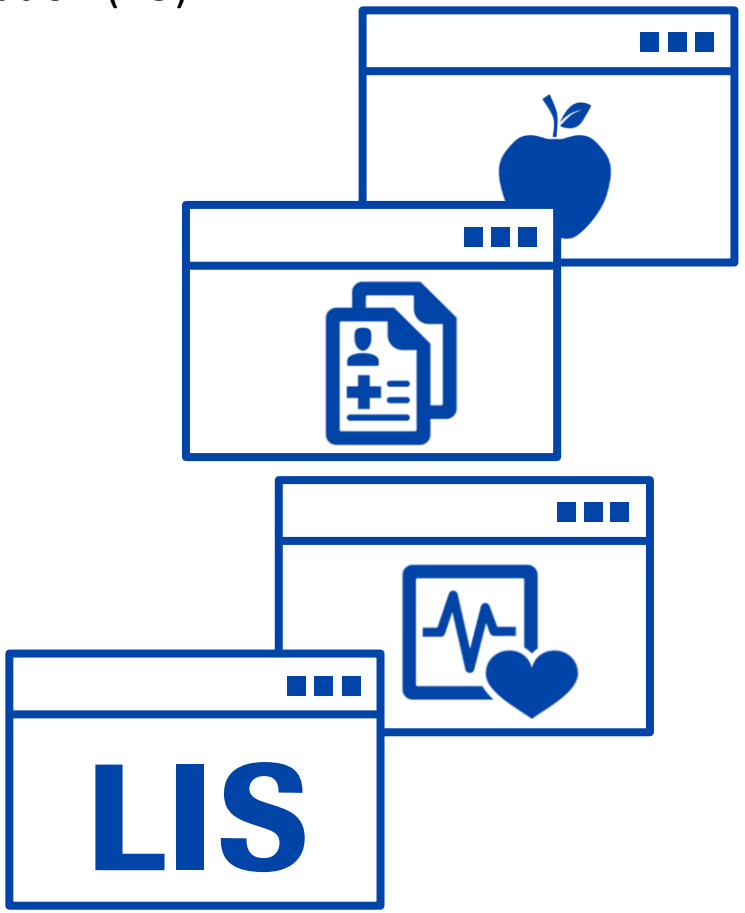
Non-Regulated Software MDCG 2019-11

MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

Examples of Non-Regulated Software

(Based on MDCG 2019-11)

- Software apps for tracking diet and exercise
- Electronic patient health records
- Software for monitoring non-medical performance (such as maintenance and repair) of IVDs
- Laboratory Information Systems (LIS)
- Software that transfers and stores information from connected IVDs
- Software that modifies the representation of IVD results through basic operations of arithmetic (such as averaging) and/or plotting



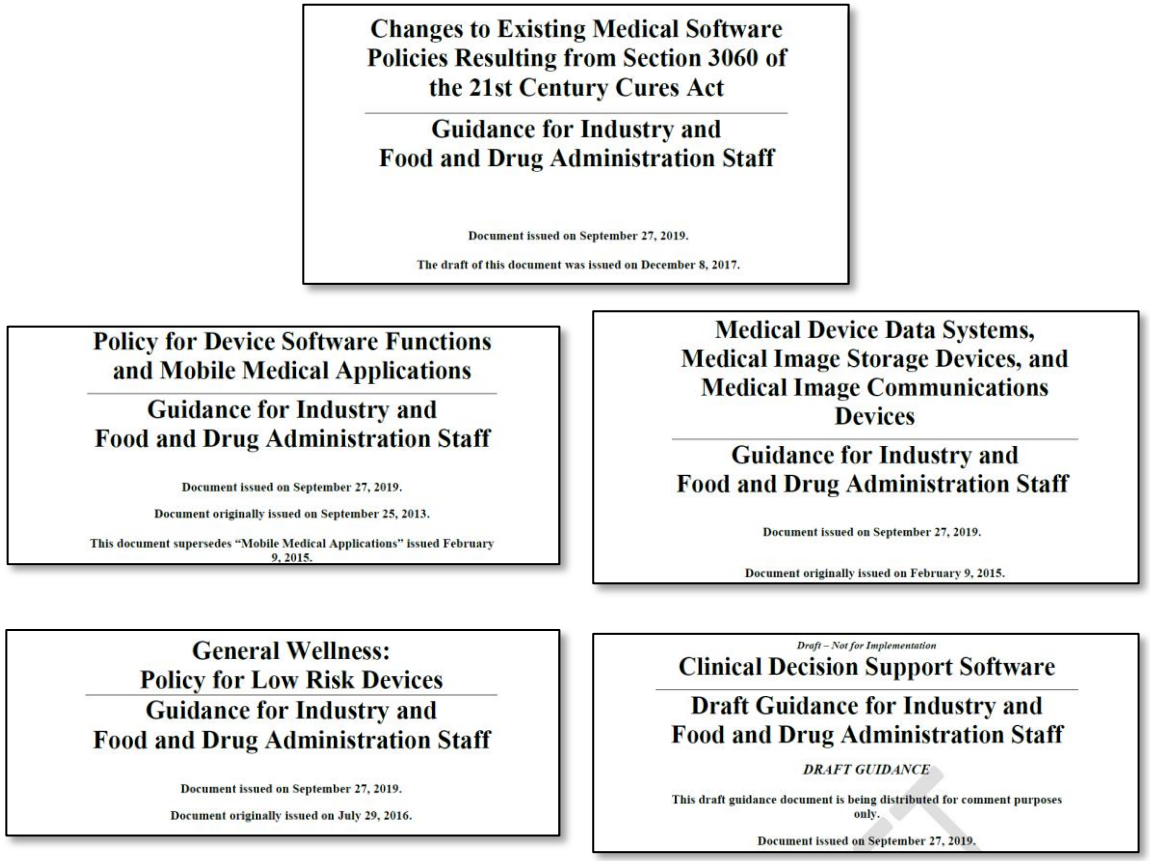
Qualification of Software in the US

21st Century Cures Act and Related Guidance

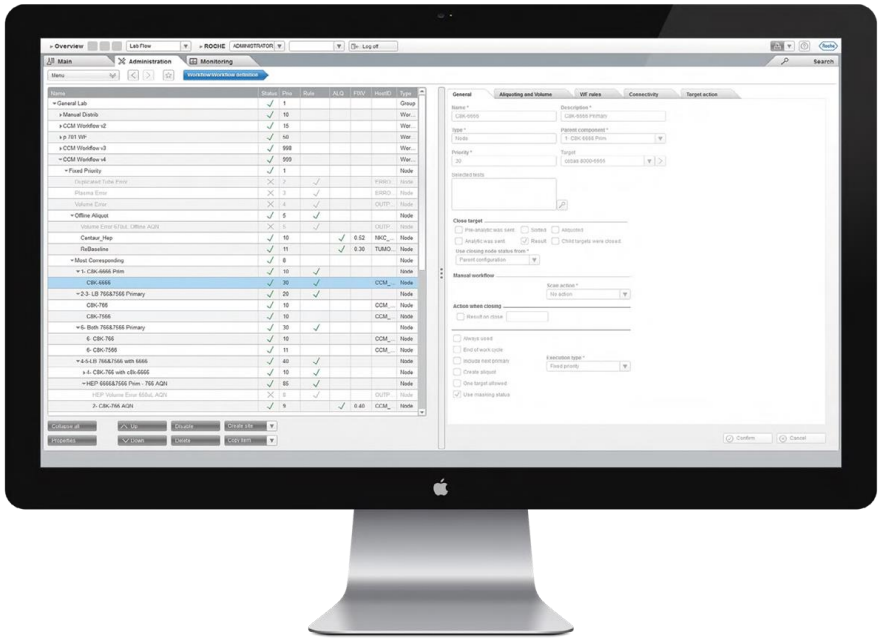
Legislation and numerous guidance documents to define when software is and is not a medical device

Examples of Non-Regulated Software

- Software used to provide administrative support
- Software apps for tracking diet and exercise
- Electronic patient health records
- Laboratory Information Systems (LIS)
- Software that transfers, stores, converts formats, or displays laboratory and device data and results (MDDS)
- Non-device clinical decision support software



Qualification Example – *cobas infinity*



Test Information | **Quality Control** | **Previous Results**

Intended Use (Abbreviated)

cobas infinity is intended to be used for:

- *Configuration and connectivity management* of instruments and software systems.
- The *management of data* regarding samples, technical validation, and quality control.
- The *management and storing of information and data,* such as sample archiving, rules engines, patient data, and order data.

Qualification Example – *cobas infinity*

US – Not regulated as a device.

Rationale: Per **US FDA Guidance "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act":**

Laboratory Information Systems (LIS) are not within the definition of the term device, according to 201(h) of the FDA&C Act, as amended by the Cures Act.

EU – Not regulated as a device.

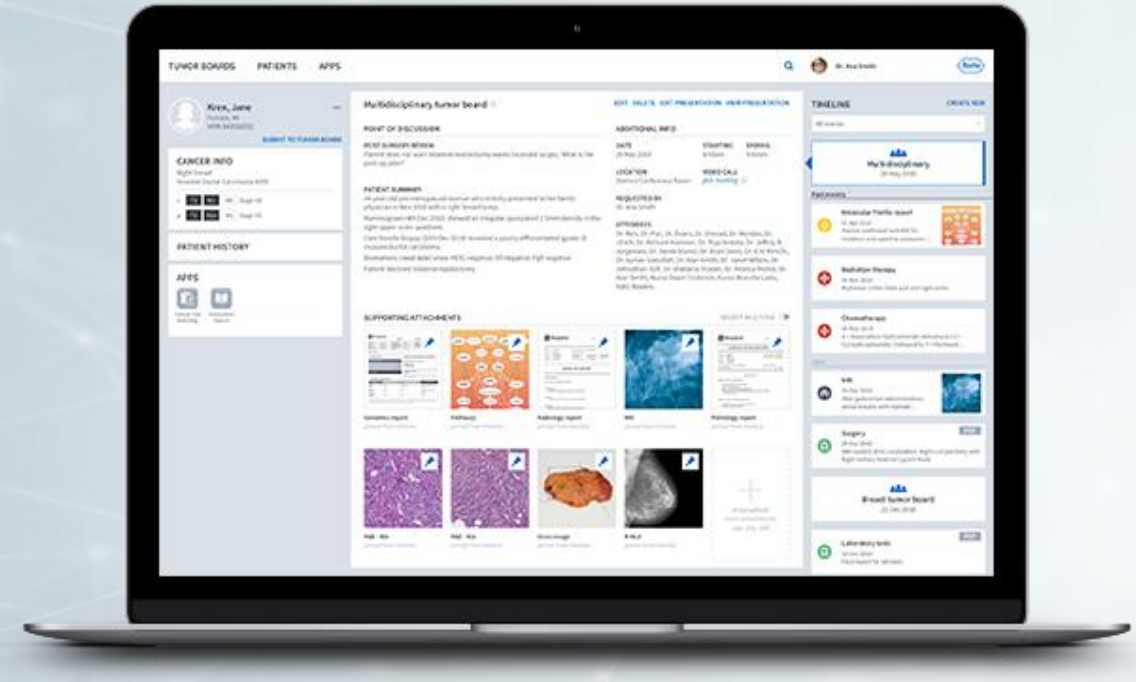
Rationale: Per **MDCG 2019-11 – Guidance on LIS and WAM:** The software [Laboratory Information Systems and Work Area Managers] normally supports the following functions:

- *Ordering* of laboratory tests, samples with labels, and sorting;
- *Technical and clinical validation,* connection to analytic instruments;
- *Laboratory results and reports*…that can be directly returned to e.g. the ordering clinic's patient record;
- Analytical instruments can be *interfaced* with Hospital Information Systems, Electronic Patient Record Systems…

Laboratory Information Systems (LIS) and Work Area Managers (WAM) are *not qualified* as medical devices in themselves.

Qualification Example – *NAVIFY Tumor Board*

NAVIFY Tumor Board



A cloud-based workflow product that securely integrates and displays relevant aggregated data into a single, holistic patient dashboard for oncology care teams to review, align and decide on patient care.

Intended Use

NAVIFY Tumor Board is a software product that is intended to *optimize the workflow* of a multidisciplinary care team meeting (tumor board). It is a *patient data aggregation and visualization tool* for care management.

The NAVIFY Tumor Board application is *not intended for use as an active patient monitoring device* (i.e., a device which notifies caregivers of a clinical context or condition which requires a timely response).

This product is *not intended to interpret or analyze* clinical laboratory test or other device data, results, or findings.

Qualification Example – *NAVIFY Tumor Board*

US – Not regulated as a device

Rationale: Per **21st Century Cures Act (USA),** the term device, as defined in section 201(h), shall *not include* a software function that is intended –**…**

(D) For *transferring, storing, converting formats, or displaying clinical laboratory test* or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

EU – Not regulated as a device

Rationale: Per **MDCG 2019-11**…

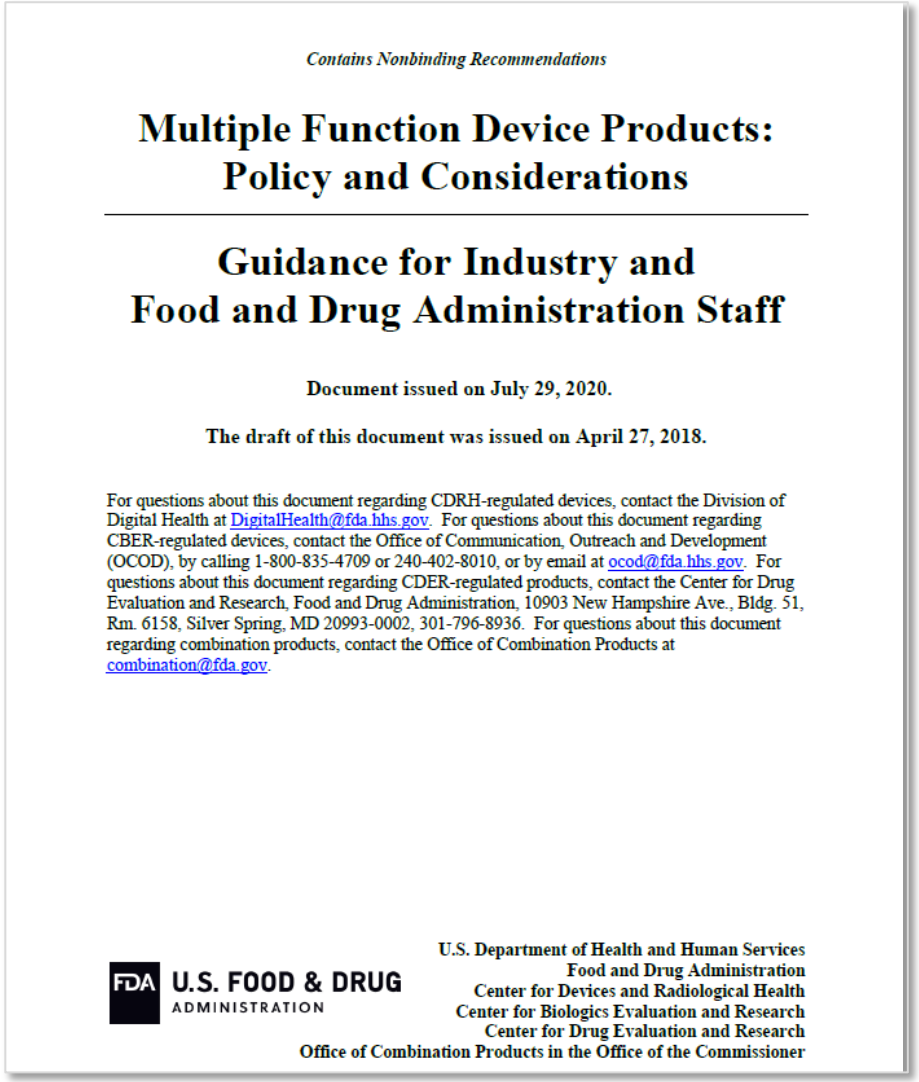
Information systems that are intended only to store, archive and transfer data are not qualified as medical devices themselves.

US FDA – Software with Multiple Functions

- For a software product with **multiple functions, only** those **functions** which have an **intended use** that fulfills the definition of a **medical device** are subject to **FDA oversight.**

- FDA may assess the **impact** of **"other functions"** when assessing the **safety and effectiveness** of a **device function** under review for a multiple function product.

- Considerations in SW architecture, hazard analysis, requirements, labeling, and validation.



Contains Nonbinding Recommendations

Multiple Function Device Products: Policy and Considerations

Guidance for Industry and Food and Drug Administration Staff

Document issued on July 29, 2020.

The draft of this document was issued on April 27, 2018.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach and Development (OCOD), by calling 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact the Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

Regulation of SW with Multiple Functions Example – *mySugr App*

mySugr App

mySugr Logbook

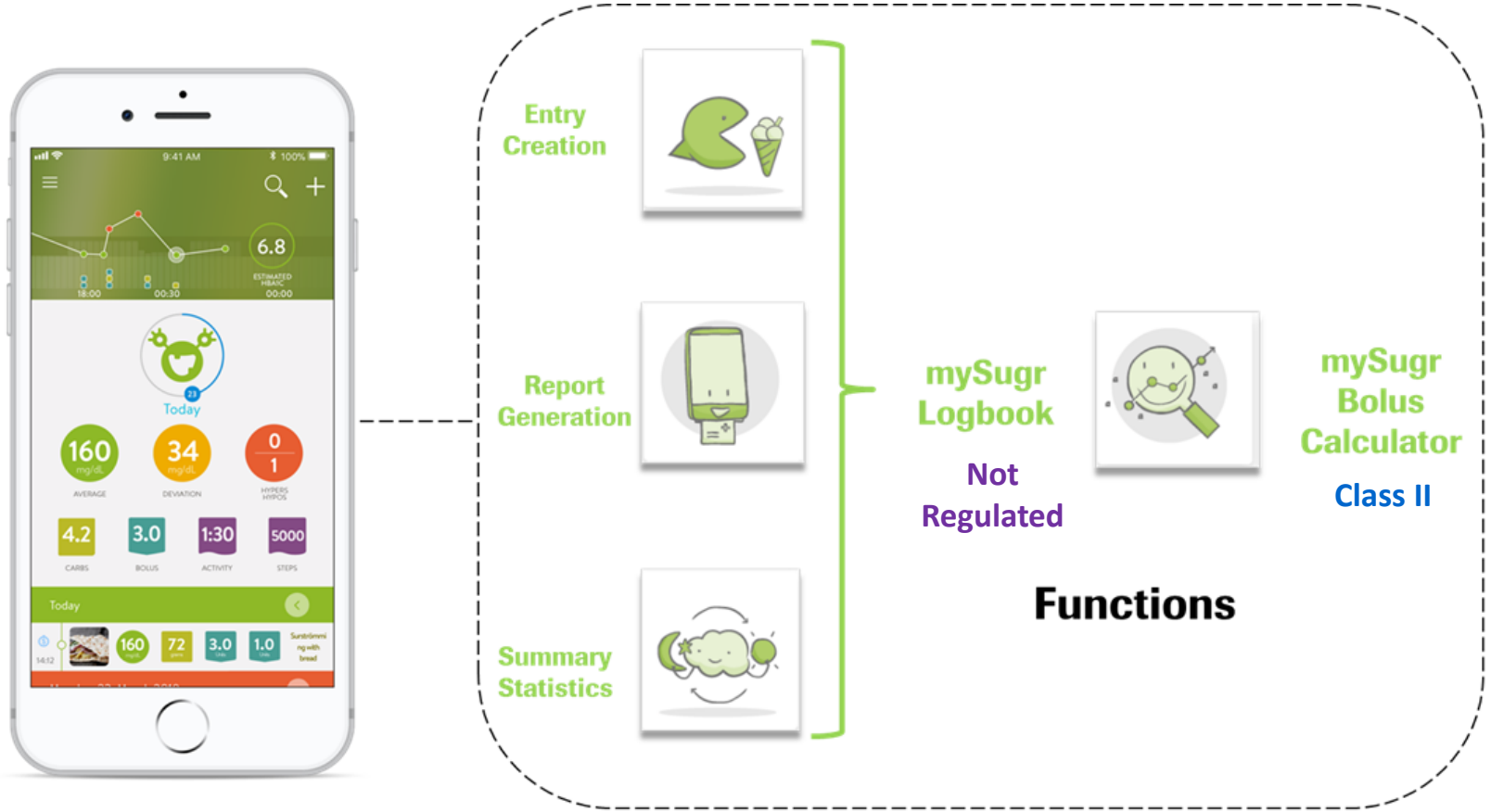
Supports patients with diabetes in tracking their disease.

Not actively regulated as a medical device by US FDA.

mySugr Bolus Calculator

Provides insulin dosing and carbohydrate intake recommendations to patients with diabetes.

Class II device regulated by the US FDA



Software Qualification

Key Takeaways

- ✓ Certain lower risk software functions should be excluded – either by regulation or law – from regulatory oversight to allow all Health Authorities to focus their authority and resources on software products that pose a higher risk to patients. These functions include software intended to:
  - provide administrative support for healthcare facilities;
  - be used for general health and wellness;
  - serve as electronic patient records;
  - transfer, store, convert formats, or display laboratory and device data and information; or
  - serve as clinical decision support software that meets certain criteria.
- ✓ For software products with multiple functions, regulatory authorities should exercise oversight only over those functions with an intended purpose that fulfills the medical device definition.

SaMD Classification

SiMD vs. SaMD

Medical Device Software May Be SiMD or SaMD

Software in a Medical Device (SiMD): Necessary for a hardware medical device to achieve its intended purpose. Clinical evaluation and review of the software occurs concurrently with the device itself. Also referred to as "dependent" or "embedded" software.

Software as a Medical Device (SaMD): Intended to be used for one or more medical purposes and performs that purpose without being part of a hardware medical device, meaning the software has its own intended use.
Also referred to as "independent" or "standalone" software.

Source: *Software as a Medical Device: (SaMD): Key Definitions,* IMDRF/SaMD WG/N10FINAL:2013

IMDRF SaMD Risk Categorization Matrix

Increasing Significance

Increasing Criticality

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Source: *Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations,* IMDRF/SaMD WG/N12FINAL:2014

Alternative Pathways

Streamlined approaches to increase patient and clinician access

Alternative Pathways

A wide range of possibilities. . .

Software Precertification-Type Programs

Predetermined Change Control Plans

Streamlined Review

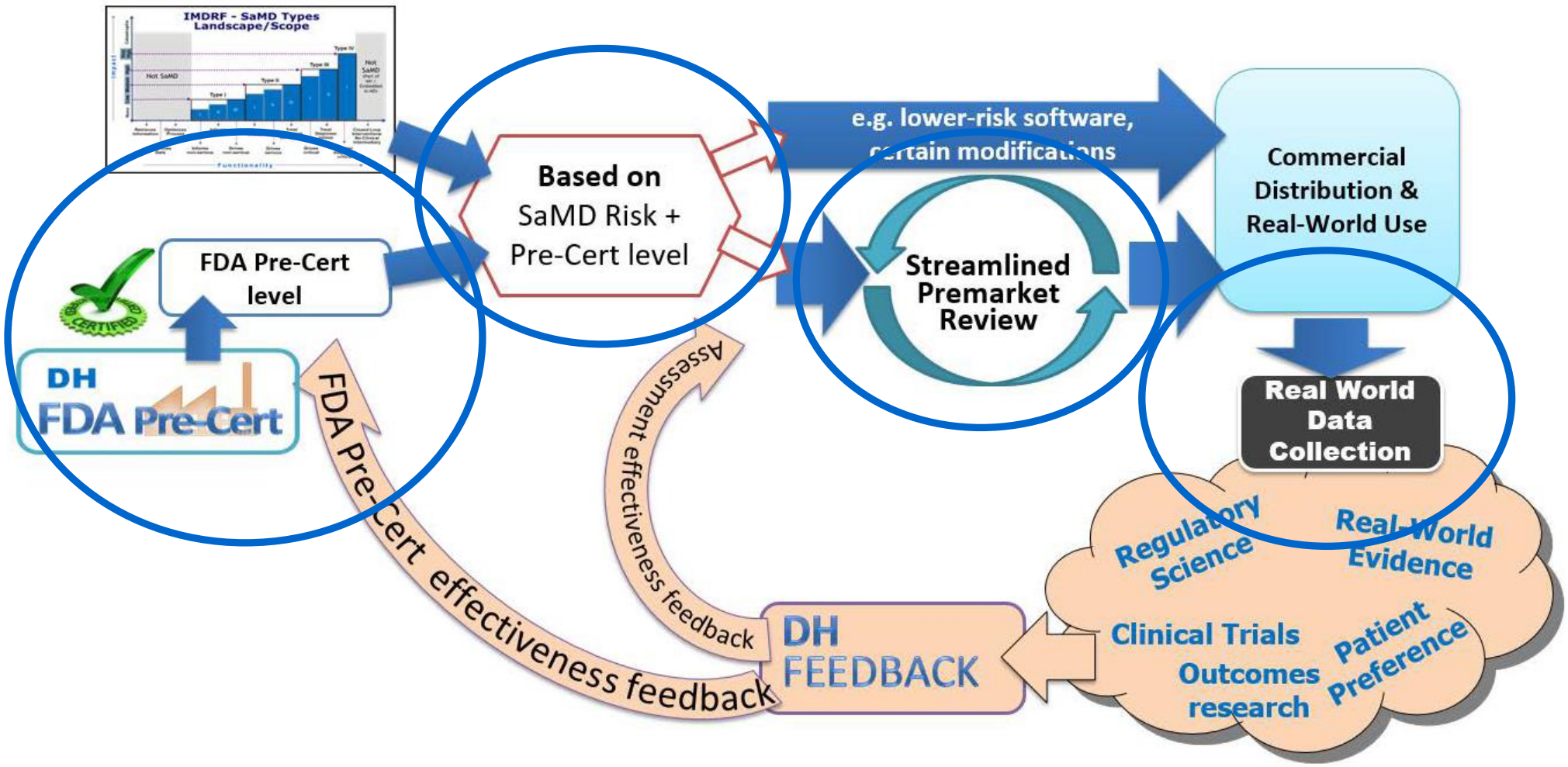
Recognition and/or Reliance on Reference Countries

What is the

US FDA Software Precertification Pilot Program

- ✓ A new voluntary pilot program that will enable the FDA to develop a **tailored** approach to regulating digital health and software technologies – an "**agile regulatory paradigm**"
- ✓ **Organization-based** rather than based on an individual product
- ✓ Applies to **Software as a Medical Device (SaMD)**
- ✓ Software developers must demonstrate a **culture of quality and organizational excellence** (CQOE) and commitment to monitoring **real-world performance** of products on the U.S. market
- ✓ Based on **existing standards of safety and effectiveness** – does not "lower the bar"

US FDA Precertification Program for Software Concept

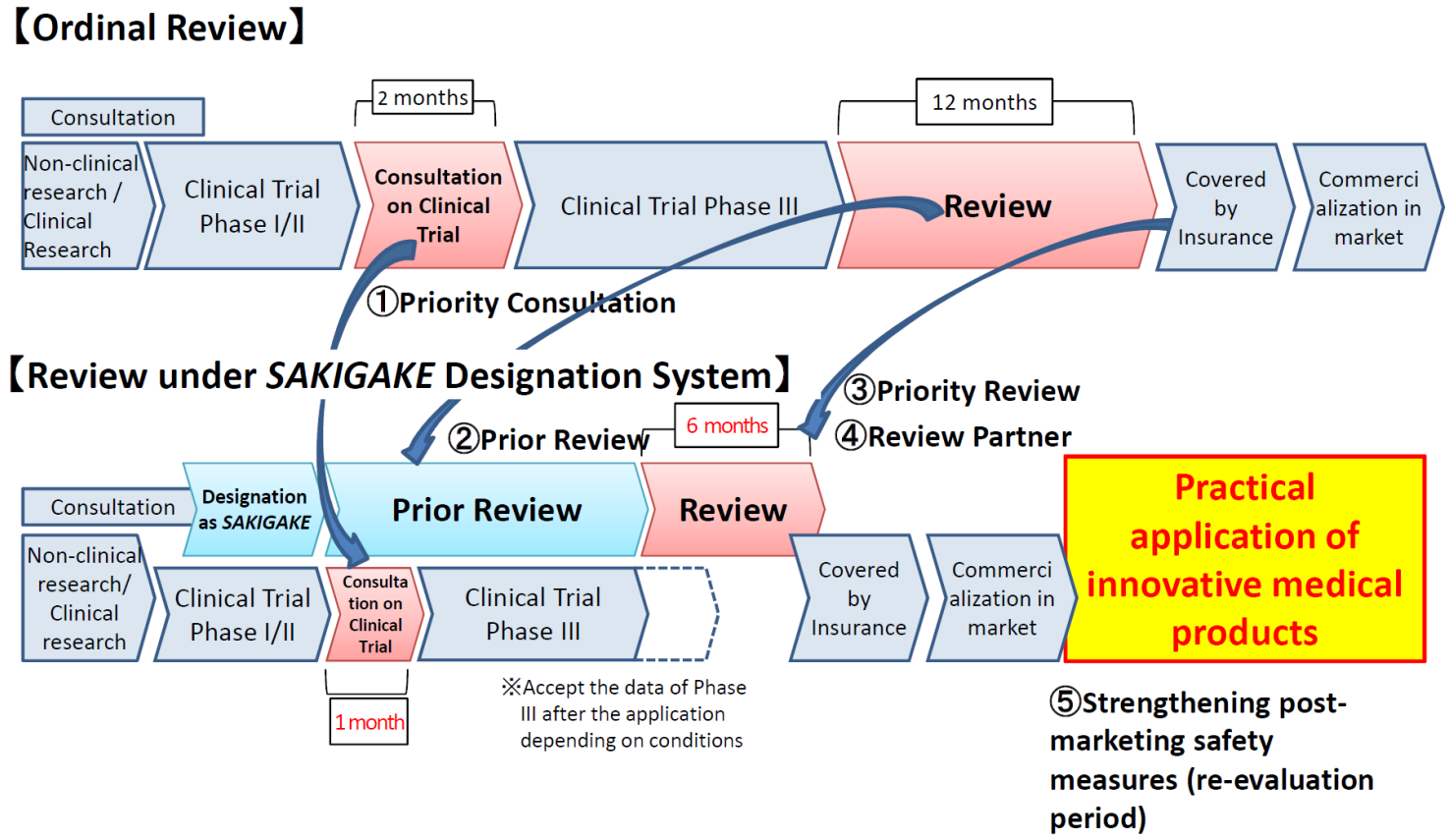


FDA Software Precertification Program: Working Model v1.0 – January 2019 https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf

Streamlined Review: Japan SAKIGAKE Track

Accelerated Regulatory Pathway

General Timeframe of *SAKIGAKE*



Recognition and Reliance Models

Example – Singapore's HSA

Reference Regulatory Agencies: TGA, Health Canada, US FDA, EU Notified Bodies, Japan's MHLW

Abridged Evaluation Route: Any new product that has been approved by at least one reference regulatory agency is eligible for an abridged evaluation route (reduced submission requirements and review time).

Immediate Class B Registration (IBR) and Immediate Class C Registration (ICR) Evaluation Routes (Solely for Standalone Medical Mobile Applications):

- Products can be eligible if approved by at least 1 of HSA's independent reference regulatory agencies.
- There can be no safety issues globally associated with the use of the product in the last 3 years or since market introduction of the product globally.
- There can be no rejection/withdrawal of the medical device from any of the independent reference regulatory agencies due to quality, performance or safety issues.

Alternative Regulatory Pathways

Key Takeaways

- ✓ Regulatory authorities are encouraged to consider alternative approaches to the SaMD regulation that are tailored to their unique and iterative aspects. Such approaches can take a variety of forms and can include:
  - Recognition and reliance models
  - Implementation of expedited review pathways
  - Development of pre-certification type programs
  - Use of Predetermined change control plans

Predetermined Change Control Plan

Current Regulatory Approaches to Change Management Are Not Ideal for the Unique Needs of SaMD

- Due to their unique and *iterative* nature, SaMD products can be *updated* on a *regular basis*.
  - Frequent changes are *expected* and *accepted* by customers.
  - SaMD products *leveraging AI* are likely to be *updated* with *significant frequency*.

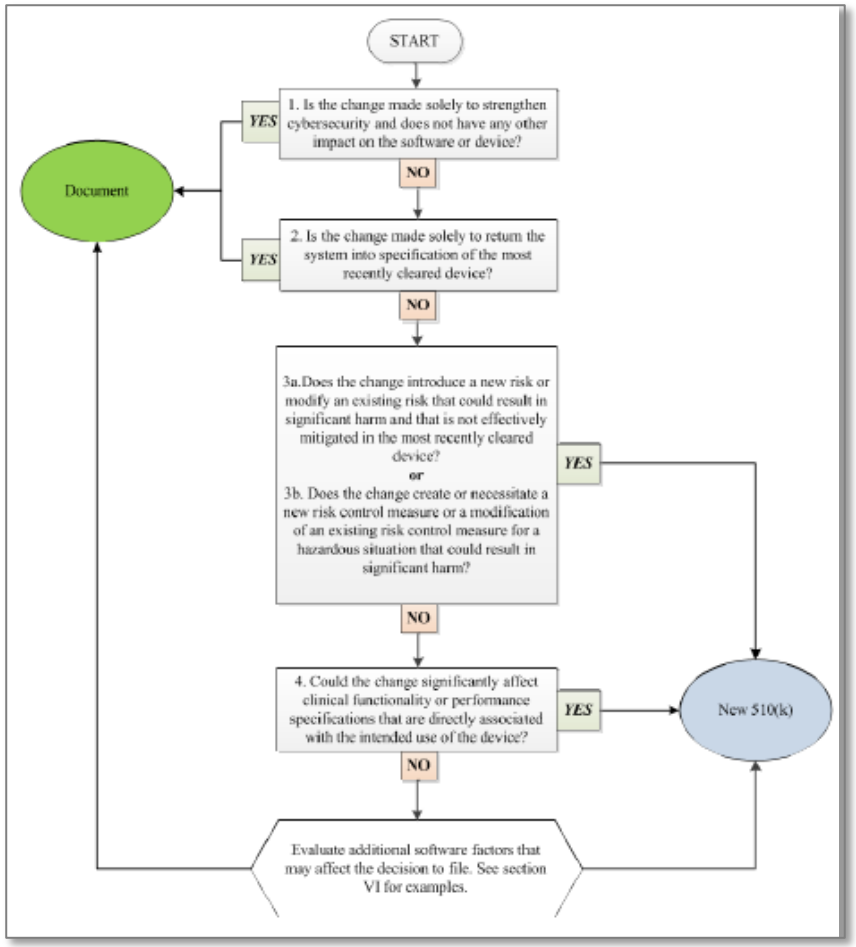
- Existing regulatory frameworks have *not* been built to accommodate the *frequent changes* that accompany SaMD products. In most cases:
  - "Minor" changes can be rolled out according to a developer's *Quality Management System*.
  - "Major" changes require *premarket review* (often taking months of time) prior to implementation.

- To facilitate and accelerate digital health innovation, are there alternative regulatory pathways that enable faster implementation of "major" changes while ensuring safety and effectiveness?

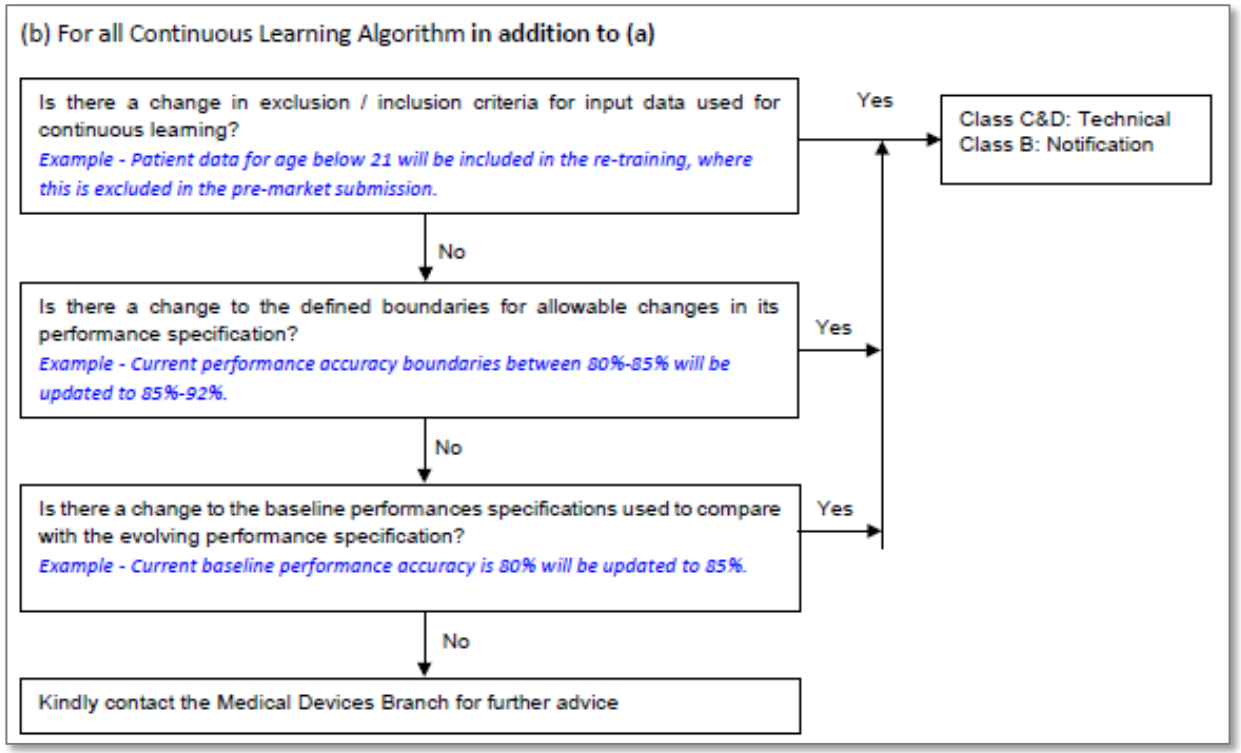
Examples of Current Approaches to SW Change Management

Risk-Based Approaches Where "Major" Changes Require Premarket Review

US FDA SW Modifications Guidance



HSA Regulatory Guidelines for Software



Are there alternative, more fit-for-purpose approaches for addressing modifications for SaMD products?

Predetermined Change Control Plans

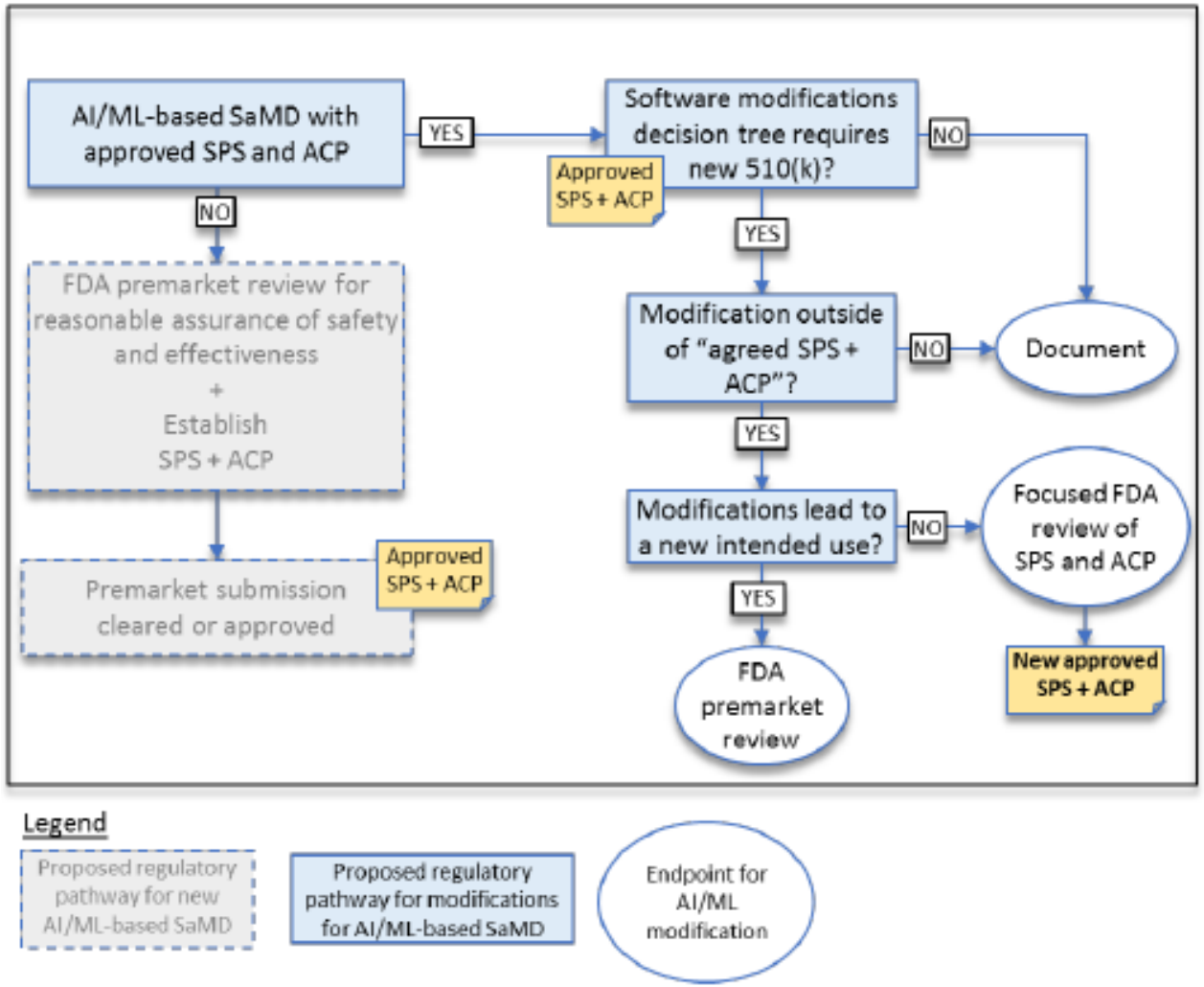
An Innovative Approach to Addressing SaMD Modifications

Concept

- During initial premarket review, a software developer *pre-specifies the changes* it plans to make to its product *post-market* and how it *plans to implement* those changes.
  - These changes can include *"major" changes.*
  - Most software developers maintain a *backlog* of features/functions that they plan to *implement in future software versions.*
- When a regulatory authority *approves the product*, it also *approves the predetermined change control plan.*
- A software developer can roll out changes according to the *scope and process* outlined in the predetermined change control plan after initial launch with *no premarket review required.*

Predetermined Change Control Plans

Approach Described in US FDA AI/ML-SaMD Discussion Paper



SaMD Pre-Specifications (SPS):

Outlines the changes the developer plans to achieve while the SaMD is in use.

Algorithm Change Protocol (ACP):

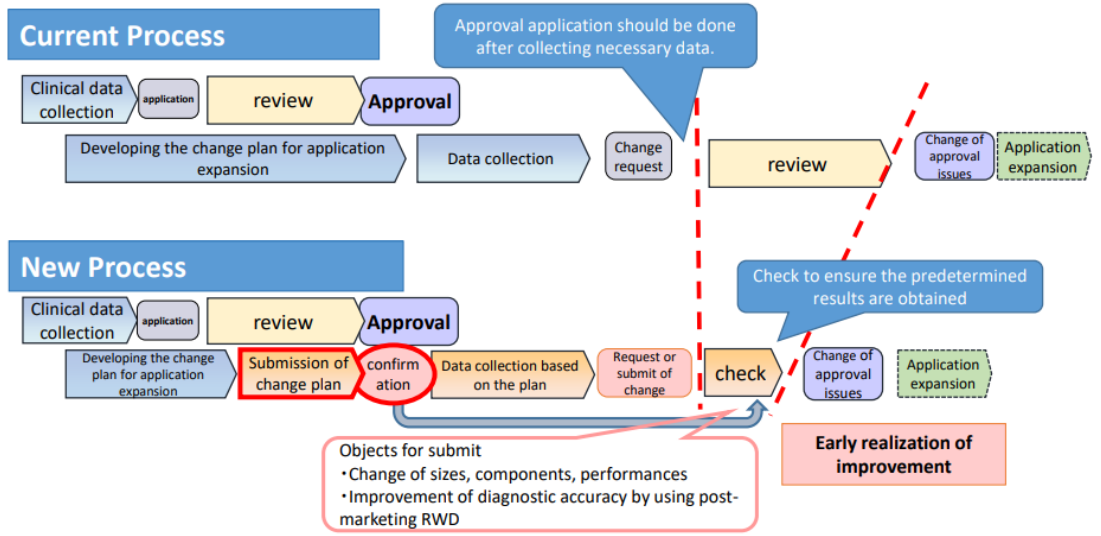
Methods the developer will utilize to achieve and appropriately control the risks of the anticipated types of modifications outlined in the SPS.

Source: *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD),* US Food and Drug Administration.

IDATEN & IDATEN-AI

Example from Japan MHLW

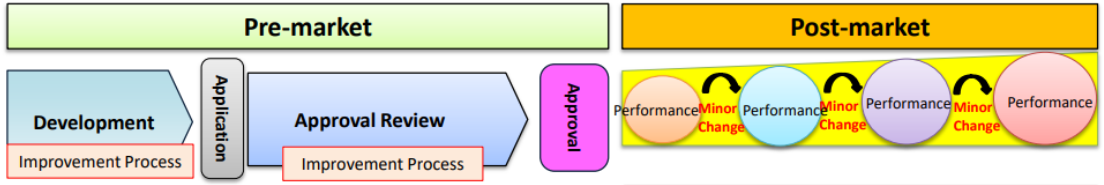
Post-Approval Change Management Protocol will be introduced for medical devices to enable continuous improvements.



"Improvement Design within Approval for Timely Evaluation and Notice（IDATEN）"

Approval review process which enables continuous improvement of performance of SaMD using AI

- Changes of performance must be in one-direction (improvement) and be managed by MAH.
- MAH may develop a process which ensures such performance changes as "Improvement Process", and submit in the approval review process.



"Improvement Process" is developed and reviewed in the approval review process.

Post-market changes in line with the Improvement Process can be made by minor change notification, which does not require approval process.

*Compliance is checked in QMS audits.

"IDATEN-AI"

Source: https://www.pmda.go.jp/files/000234056.pdf

Predetermined Change Control Plans

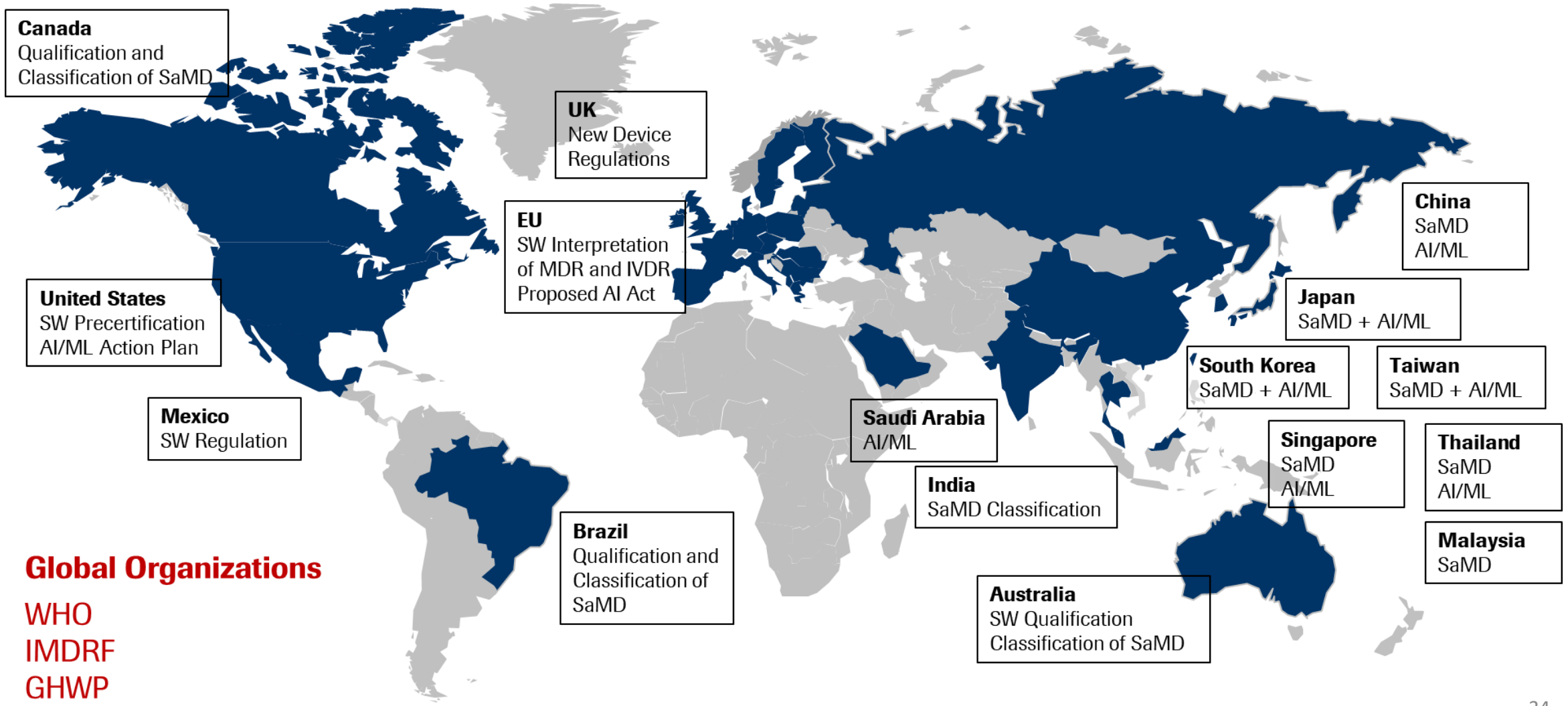
Key Takeaways

- ✓ Predetermined change control plans provide an alternative, fit-for-purpose regulatory pathway to address modifications for SaMD products.
- ✓ Predetermined change control plans support the iterative nature of SaMD products while also ensuring device safety and effectiveness.
- ✓ US FDA and other regulatory authorities are in the process of implementing predetermined change control plan-like approaches.
- ✓ Regulators should consider the implementation of predetermined change control plan approaches for SaMD and software in a medical device (SiMD).

APAC Best Practices in Digital Health Regulation

Software as a Medical Device Regulation

Significant Regulatory Interest



Global Organizations

WHO
IMDRF
GHWP

Key Considerations

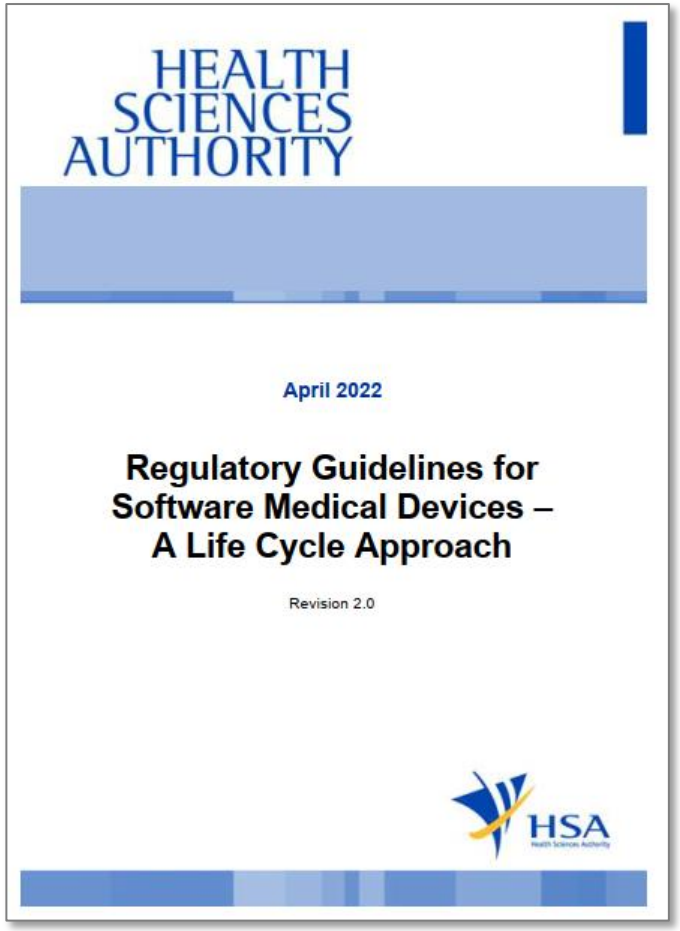
Best Practices in Digital Health Regulation

- Software Qualification and Software with Multiple Functions
- Labeling
- Change management
- SaMD Classification
- Innovative SaMD Regulatory Pathways
- Artificial Intelligence / Machine Learning

Software with Multiple Functions

Singapore's Health Sciences Authority (HSA)

- Software may contain *multiple functions,* some of which may not fall under the medical device definition.
- Applicants are *not required* to submit information/validation of non-medical device functions in premarket submissions.
- Applicants must consider the *impact* that non-medical device functions will have on device safety and performance and *analyze and mitigate the risks to an acceptable level.* This should be documented as part of a manufacturer's quality management system.



Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach. HSA. April 2022.

Labeling

Singapore's Health Sciences Authority (HSA)

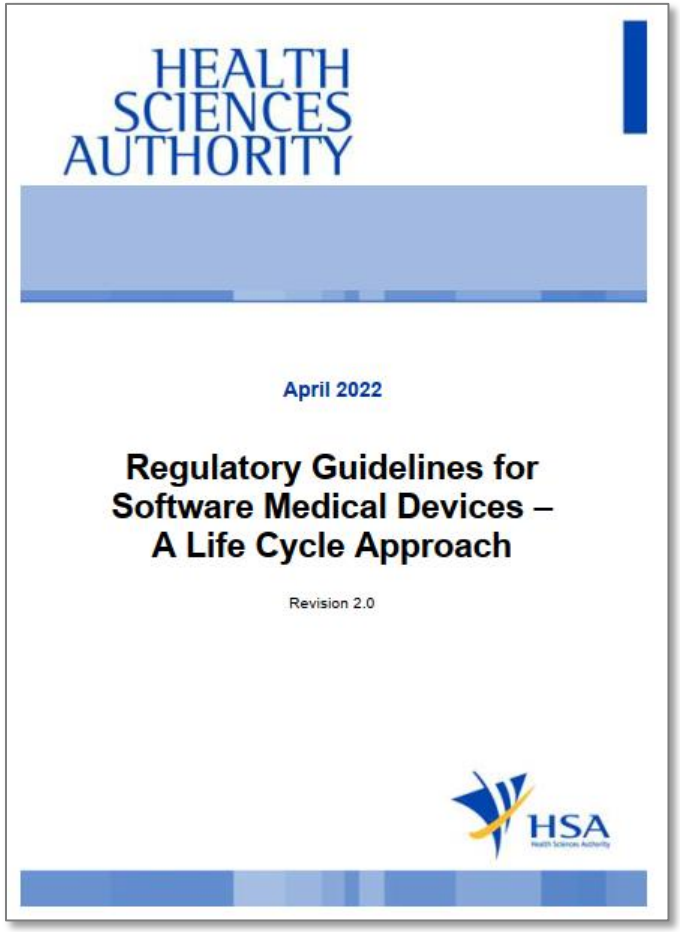
Device labelling (e.g. physical label, instructions for use, implementation manual etc.) serves to help users:

(i) identify the device;

(ii) to communicate safety and performance related information; and

(iii) ensure device traceability.

Essential information such as name of device, software version number and product owner's information have to be presented on device labels for identification of the device. For safety and performance information, the intended purpose, instructions on proper use and safety information (e.g. contraindications) have to be clearly presented for users' reference



Labeling

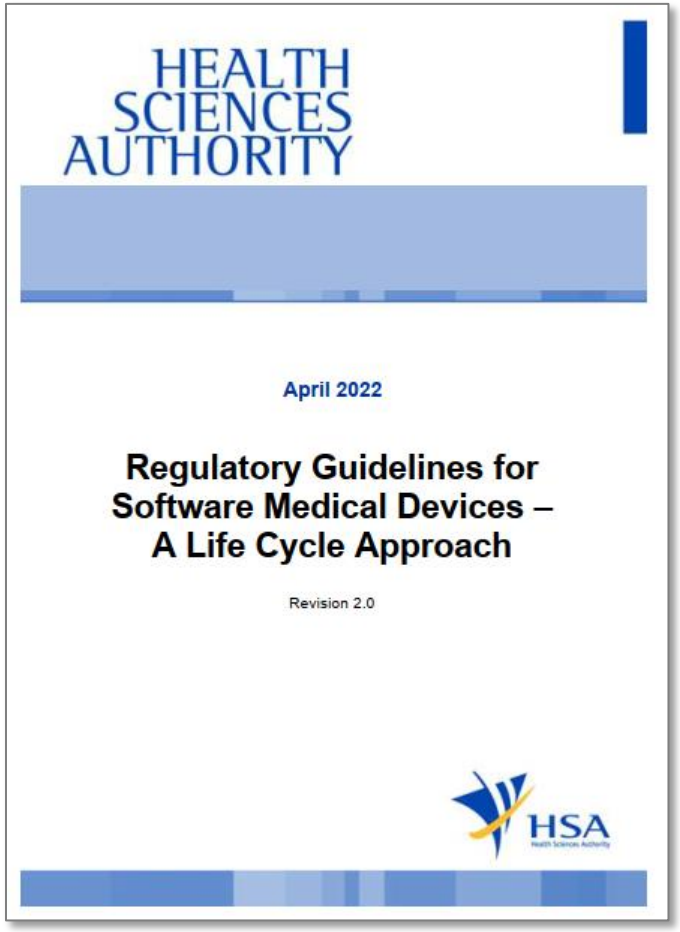
Singapore's Health Sciences Authority (HSA)

Standalone software can be supplied in different forms and there may be difficulties in presenting device information for certain forms (e.g. web-based software).

Generally, standalone software can be broadly categorised into two groups based on the mode of supply:

i) supplied in physical form or

ii) supplied without a physical form.

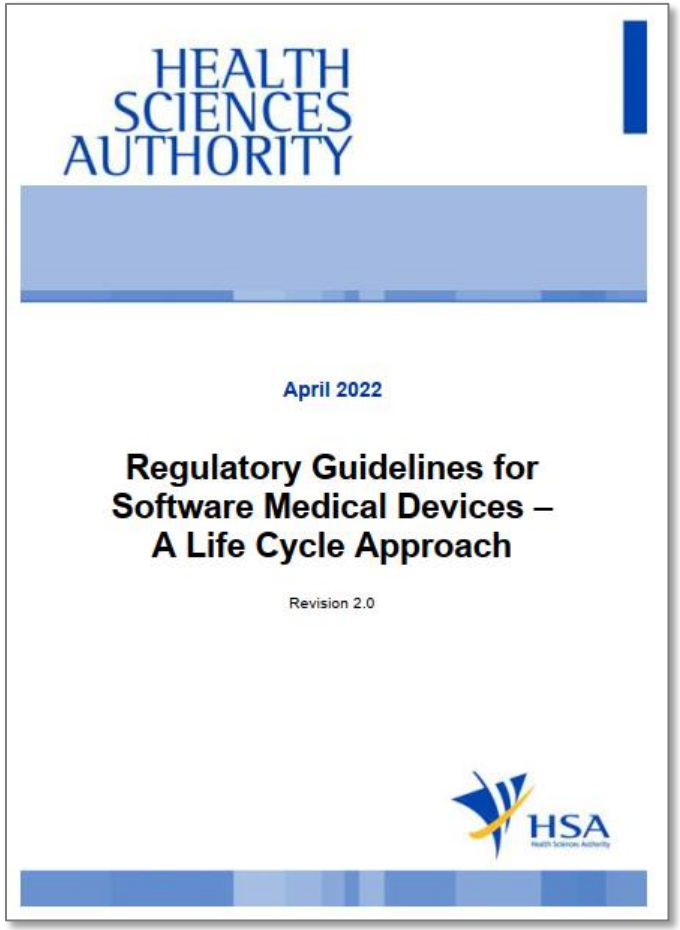


Labeling

Singapore's Health Sciences Authority (HSA)

Supplied in physical form (i.e. CD/DVD)	Supplied without any physical form (i.e. downloadable software, web-based software)
Physical label and Instructions for Use (as per GN-23)	A screenshot of the software graphical interface (e.g. splash screen) which displays the elements for identification, including software version number. In addition, for downloadable software where the downloading and installation is to be done by the end-user, the following information should be presented to the end-user: a) Internet address or web link to allow the end-user to download the software; b) The software download procedure; and c) The software installation guide or procedure. This ensures that the user has sufficient information for proper installation of such downloadable software. Although the software is supplied without physical form, the traceability of the software should not be compromised. An appropriate system for version controls and access rights controls should be in place to allow timely tracing of the software versions.

Table 3: Labelling requirements for the different forms of standalone software.



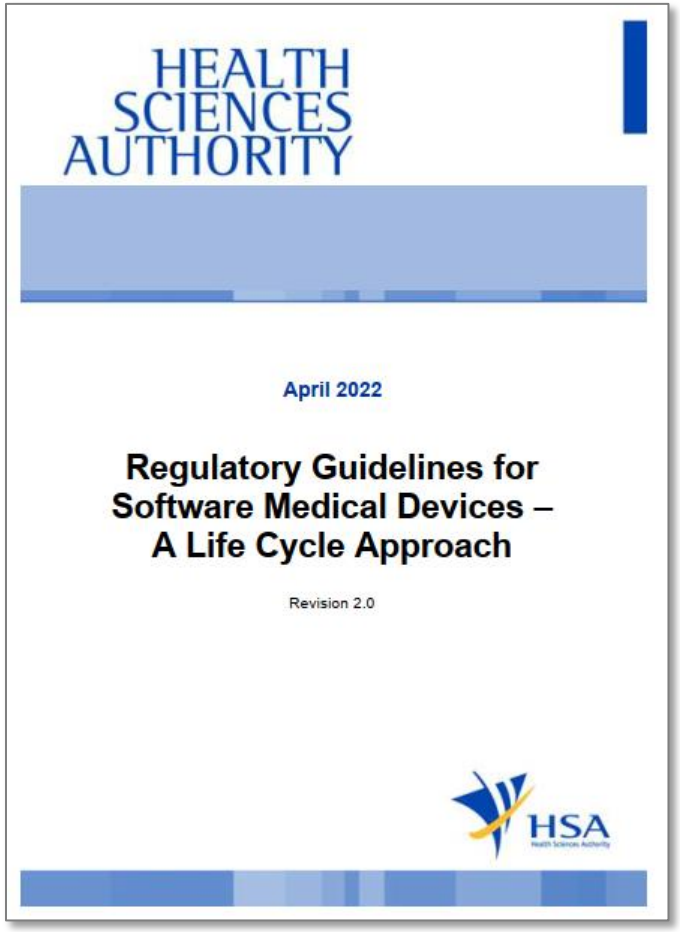
Software versioning & traceability

Singapore's Health Sciences Authority (HSA)

Software versioning is essential for identification and post-market traceability/follow-up in the event of software changes and field safety corrective actions. Description of software versioning and traceability system implemented for the software may be required during the registration process.

In addition, information on the software version being registered and to be supplied in Singapore is to be clearly presented on the device labelling (if supplied in physical form) or software graphical interface (if supplied without physical form), depending on the mode of supply of the software.

The software version information that represents all software changes/iteration (e.g. graphic interface, functionality, bug fixes) has to be submitted. This does not include Software version numbering that is solely for testing or internal use only (e.g. checking in of source code).

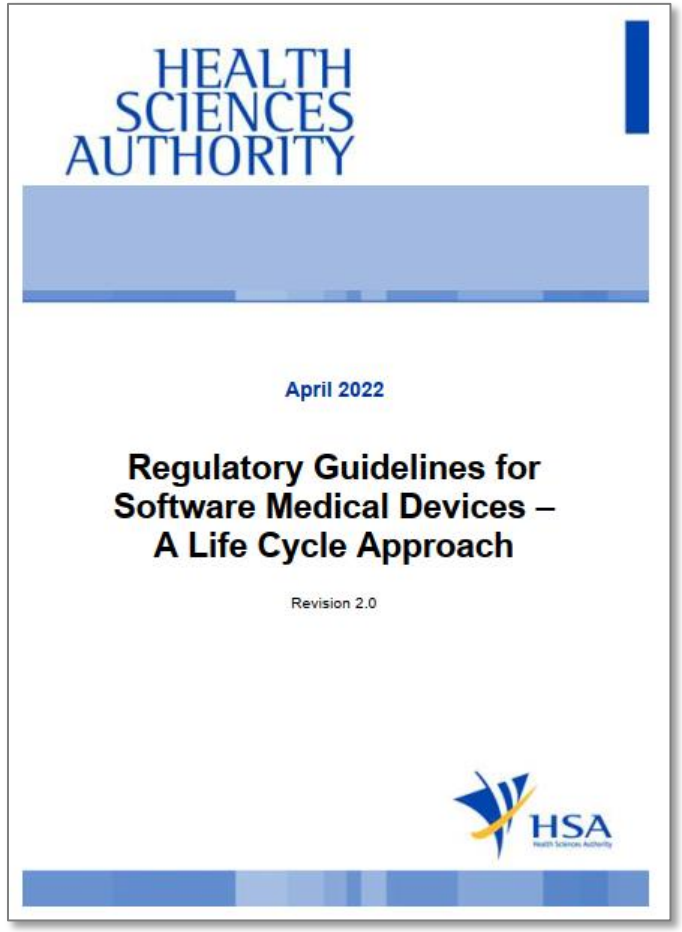


Changes to a registered software

Singapore's Health Sciences Authority (HSA)

A software medical device undergoes a number of changes throughout its product life cycle. The changes are typically meant to (i) correct faults, (ii) improve the software functionality and performance to meet customer demands and (iii) ensure safety and effectiveness of the device is not compromised (e.g. security patch).

To address the range of changes with differing risk and complexity, HSA employs a risk-based approach to managing the changes to registered software; the regulatory requirements of the change shall commensurate with the significance of the change. For instance, significant changes (i.e. Technical & Review changes) will undergo a more in-depth review (when compared to a non-significant change) to ensure that the change does not affect the safety and effectiveness of the software.



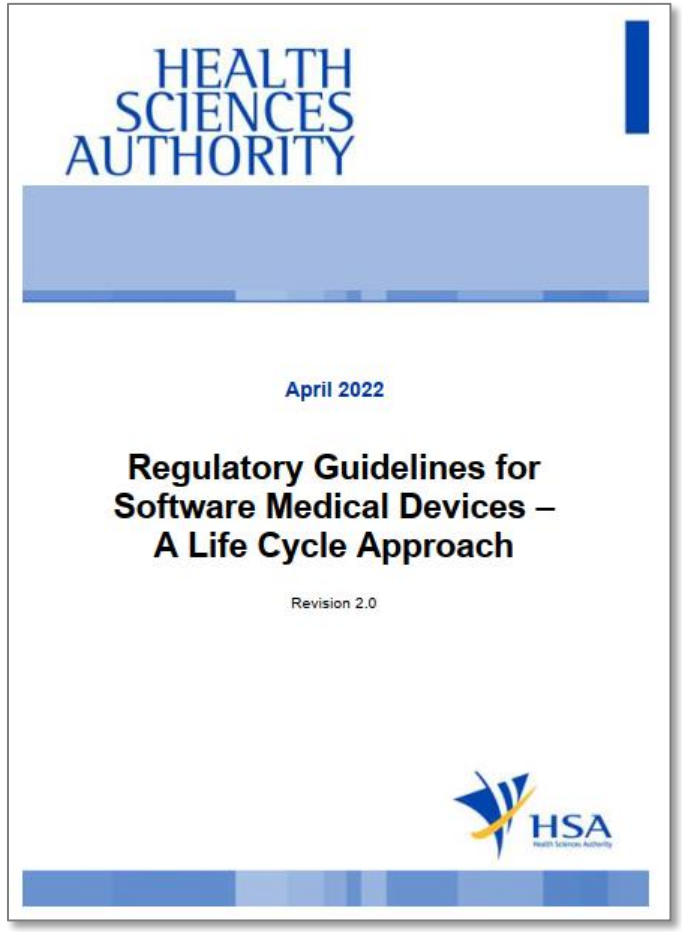
Changes to a registered software

Singapore's Health Sciences Authority (HSA)

Non-significant software changes are required to be notified to HSA and are referred to as Notification changes. Such Notification changes may be bundled and notified to HSA in one change notification application.

Alternatively, such changes could be submitted together with the next Review/Technical change of the registered software (whichever comes first).

While bundling Notification changes, any such change shall be submitted within a maximum of 6 months from the point of first implementation, globally. Prior to implementation of notification changes in Singapore, companies shall maintain relevant inventory records on file to ensure traceability of the changes as part of their QMS requirements.



Examples of Notification-only changes (SiMD/SaMD)

- Software changes solely to correct an inadvertent software error which does not add new functions, does not pose any safety risk and is intended to bring the system to specification.
- Software changes to incorporate interfacing to other nonmedical peripherals such as printers etc. and which has no diagnostic or therapeutic function.
- Software changes carried out to only modify the appearance of the user interface with no risk to diagnostic or therapeutic function of the device.
- Software changes solely to address a cybersecurity vulnerability

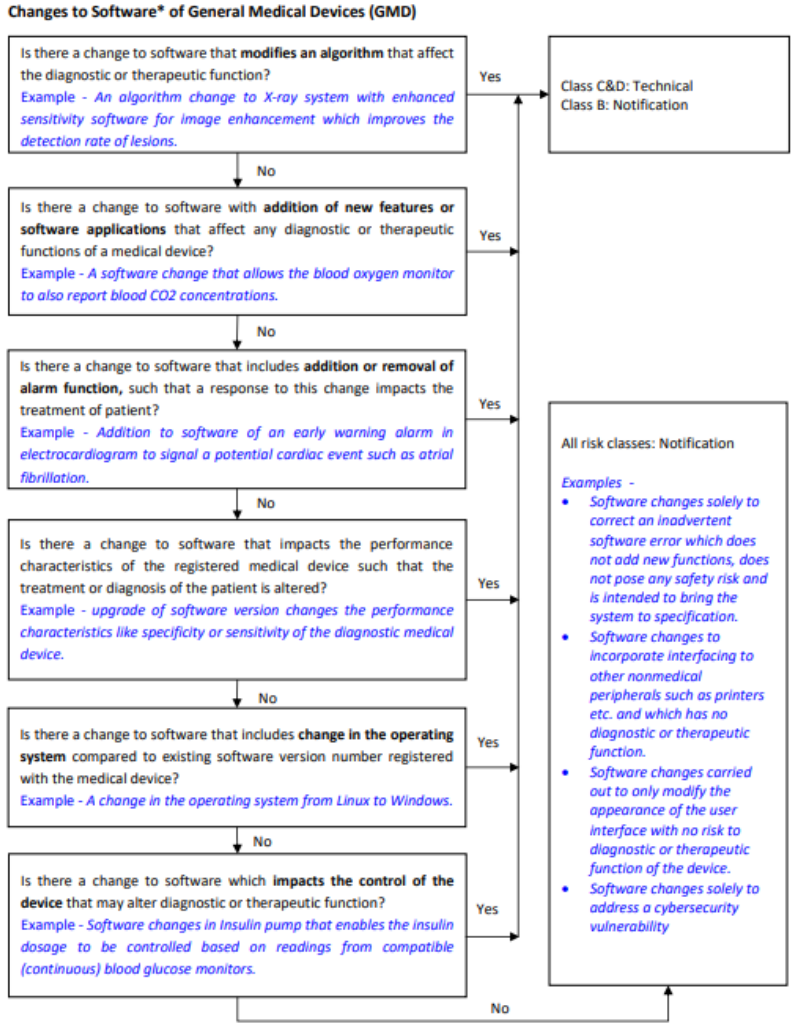


Figure 6: Flowchart for the changes to software of a GMD.
**Software refers to Standalone software/mobile applications and/or Software embedded in medical device system.*

Examples of Notification-only changes (Software of IVD devices)

Software change to

(i) correct inadvertent software error which does not add new functions, does not pose any safety risk and is intended to bring system to specification;

(ii) improve usability and data management workflow processes.

(iii) which shortens time taken to start up the IVD analyser after routine maintenance.

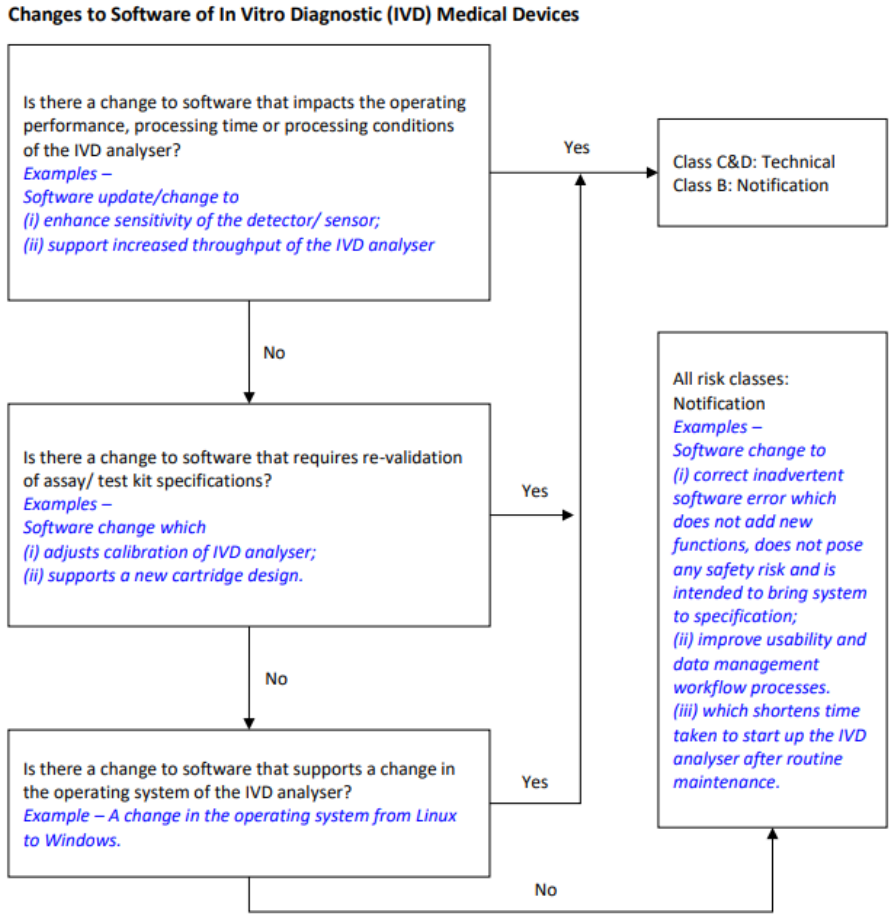


Figure 7: Flowchart for the changes to software of an IVD medical device.

SaMD Classification

Singapore's Health Sciences Authority (HSA)

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical / patient management	Inform clinical / patient management
Critical	C	C	B
Serious	C	B	A
Non-serious	B	A*	A

* Standalone Medical Mobile Applications will be classified as Class B if intended to image, measure or monitor a physiological process to drive clinical/patient management; consistent with rule 10(i) of GN-13

Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (CDSS). Medical Devices Cluster. HSA. April 2022.

Software Qualification

Australia's Therapeutic Goods Administration (TGA)

Examples include software functions used for:

- *Consumer health life-cycle prevention, management and follow up*
- *Enabling technology for telehealth, health care facility management*
- *Digitization of paper based or other published clinical rules or data*
- *Population based analytics*
- *Laboratory Information Management Systems (LIMS) and Laboratory Information Systems (LIS)*

A clinical decision support system is exempt if it meets all 3 of the following criteria:

- *does NOT directly process or analyze a medical image or a signal from another medical device (including an in vitro diagnostic device); and*
- *is solely used to provide or support a recommendation to a health professional about prevention, diagnosis, curing or alleviating a disease, ailment, defect or injury; and*
- *does NOT replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients.*

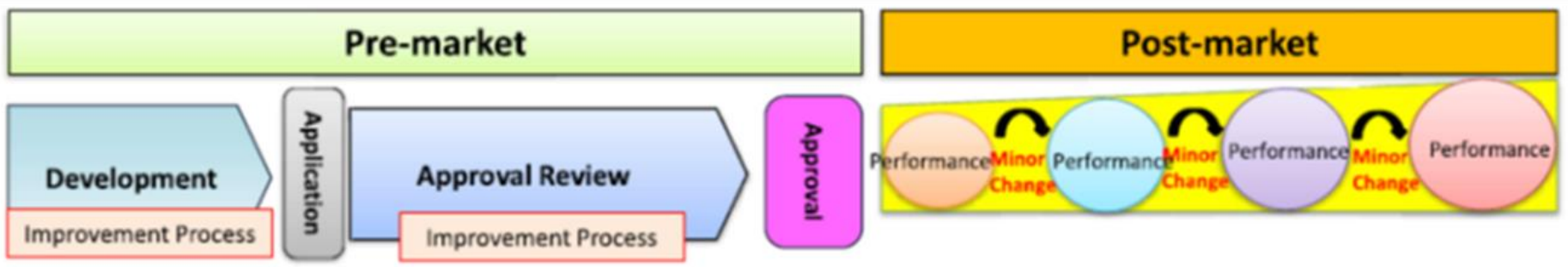
Innovative SaMD Pathways – APAC Best Practice

Singapore's HSA and Japan's MHLW

Singapore HSA's Recognition and Reliance Approach for SaMD

Reference Regulatory Agencies	Abridged Evaluation Route	Immediate Class B Registrations and Immediate Class C Registration (solely for SaMD)
TGA, Health Canada, US FDA, EU Notified Bodies, Japan MHLW	New product approved by at least one reference regulatory agency is eligible	➢ Approved by at least one reference regulatory agency ➢ No safety issues globally in the last 3 years ➢ No rejection from reference regulatory agencies due to quality issues

Japan MHLW's Improvement Design within Approval for Timely Evaluation and Notice (IDATEN)



Artificial Intelligence and Machine Learning (AI/ML)

Medical Device Regulatory Principles

Locked Models vs. Continuous Learning (Adaptive) Models

Focus on Intended Use

AI/ML-SaMD are Simply a Subset of SaMD

Innovative Approaches to Modifications are Needed to Enable AI/ML-SaMD

AI/ML – APAC Best Practice

Korea's Ministry of Food and Drug Safety (MFDS)

Guideline for Evaluation of Artificial Intelligence (AI)-based Medical Device [Guidance for Civil Petitioner]

Guideline on Review and Approval of Artificial Intelligence(AI) and Big data based Medical Device(For Industry)

Ministry of Food and Drug Safety
Medical Device Evaluation Department

- ✓ AI/ML medical devices are regulated based on their intended use and are classified in the same manner as other SaMD
- ✓ Use of retrospective data in clinical study designs to reach more timely and cost effective decisions
- ✓ Progressive regulatory approach to performance improvements derived from algorithm retraining

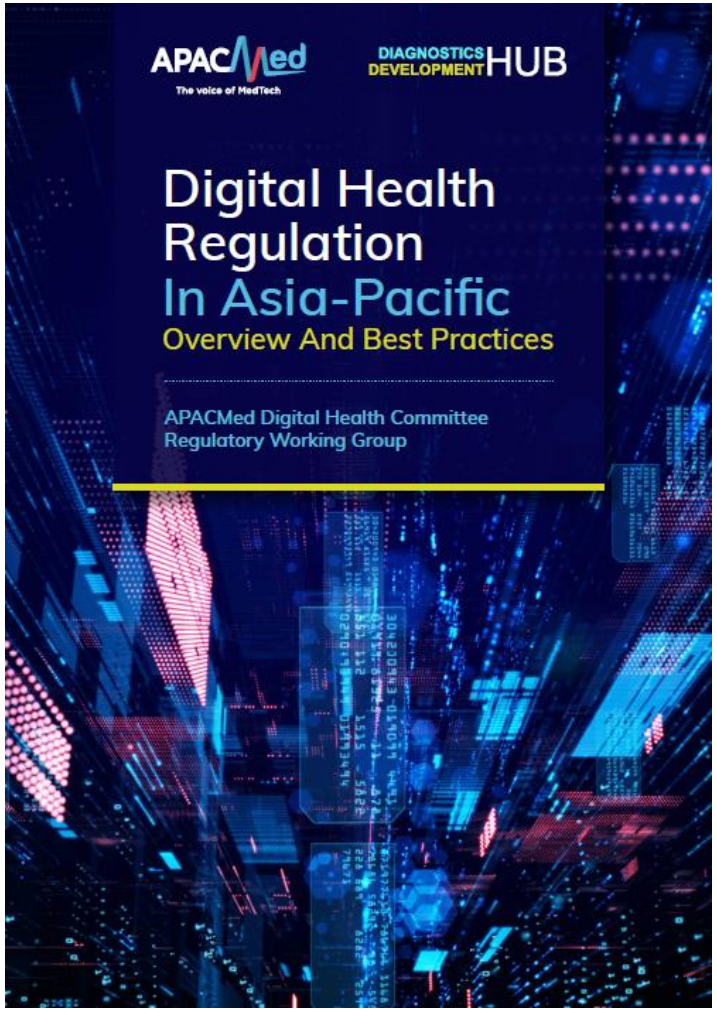
Innovative Approaches to Digital Health Regulation in APAC

Key Takeaways

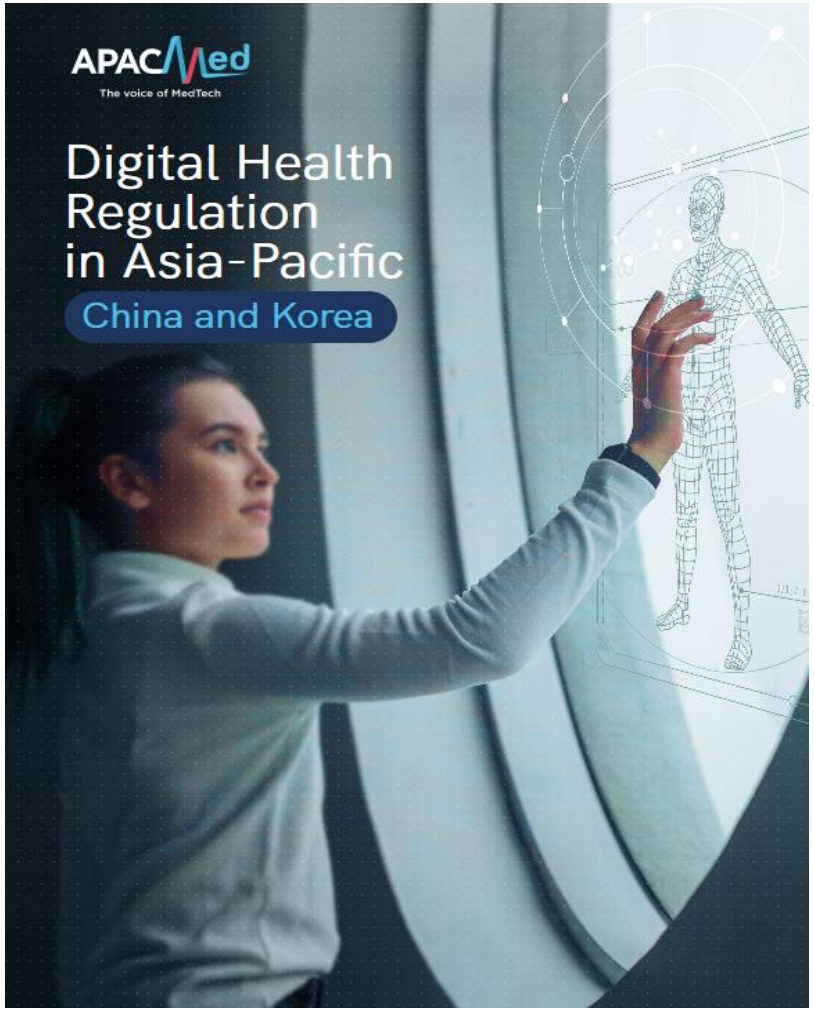
- ✓ Regulators in the APAC region are making positive steps in evolving their regulatory frameworks to be more fit-for-purpose for digital health products.
- ✓ Digital health regulatory approaches by Australia's TGA, Singapore's HSA, Japan's MHLW, and Korea's MFDS can serve as models for other regulators in the region and globally. The US also has innovative models, while the EU does not.
- ✓ Partnerships between regulators and industry can further enable the advancement of digital health regulatory frameworks in the APAC region.

APACMed Position Papers

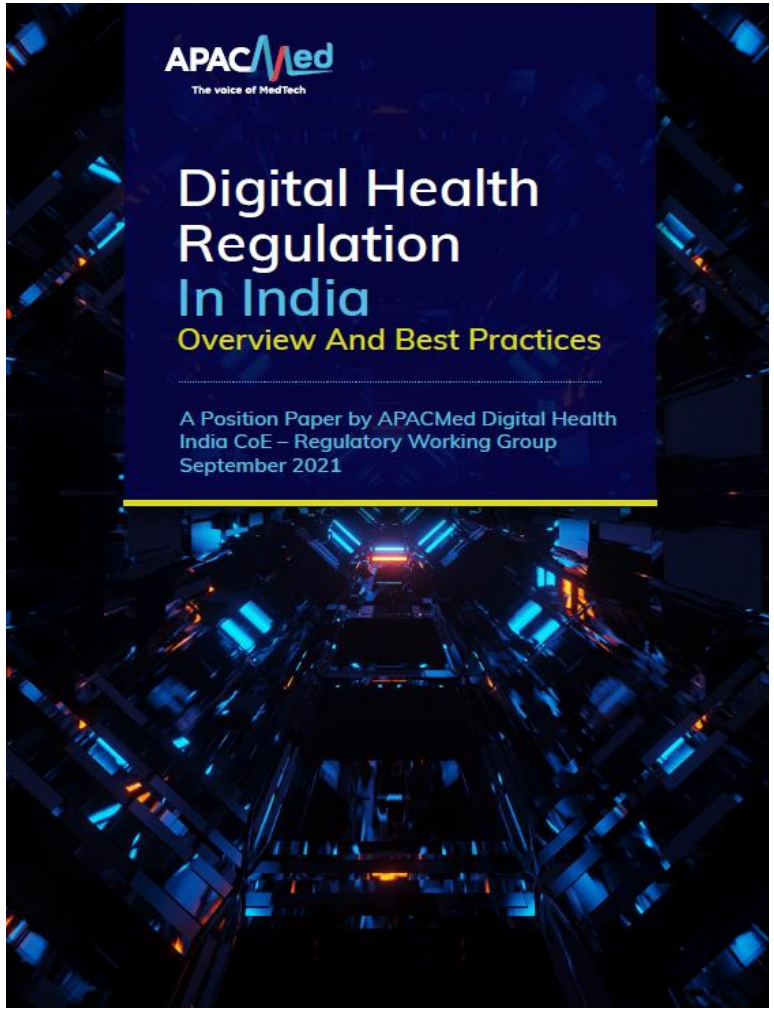
Overview and Best Practices in Digital Health Regulation



Focus Countries: Singapore, Australia and Japan



Focus Countries: China and Korea



Focus Country: India

APACMed Position Papers

Overview and Best Practices in Digital Health Regulation

- ✓ Provide an overview of Australia, Japan, Singapore, China, Korea and India regulatory approaches to digital health regulation.
- ✓ Describe best practices to digital health regulation, highlighting IMDRF principles.
- ✓ Provide an overview of US FDA advances in digital health regulation.
- ✓ Present use cases for two digital health products that have undergone premarket review.
- ✓ Describe a best practices framework that regulators can utilize when implementing a fit-for-purpose, risk-based digital health regulatory framework.

Overview of Digital Health Regulation in APAC

	Qualification	Risk Classification	Software with Multiple Functions	Alternative Pathways for DH	Pre-submission Consultation	Framework for AI/ML
Best Practices	Software must have an intended purpose that fulfils the definition of a medical device in order to qualify as a medical device.	IMDRF's N12 guidance describes that the two key factors that should be taken into account when assessing the risk categorization of a SaMD product are: 1. State of the healthcare situation or condition that the SaMD is intended for. 2. The significance of the information that is provided by the SaMD to the healthcare decision.	For software products with multiple functions, regulatory authorities exercise oversight only over those functions with an intended purpose that fulfils the medical device definition.	Approaches to regulatory review that are tailored to the unique needs of DH products.	Opportunity to engage with regulatory authorities prior to premarket submission review.	Guidance and/or framework describing the regulation of AI/ML technologies.
Australia (TGA)						
Japan (PMDA)						
Singapore (HSA)						
Korea (MFDS)						
China (NMPA)						
India (CDSCO)						

 - The best practices are not currently adopted

 - Ccurrent regulatory framework encompasses the recommended best practices

 - Some guideline is currently available, however, further improvements are recommended

Best Practices Framework

Recommendations to Health Authorities for Implementation of Fit-For-Purpose, Risk-Based Digital Health Frameworks

Fundamental Building Blocks for a Software-Focused Regulatory Framework

- ❑ Implement a clearly described approach to *software qualification* (determining when software is a SaMD) whereby the health authority only has oversight over those software functions that have a medical device intended use. This approach *should leverage international best practices* such as those used in the US, Canada, and Australia.

- ❑ Create an approach to *classification* that is *SaMD-specific*, does not leverage existing classification schemes developed specifically for traditional medical devices, and is based on *IMDRF's N12 SaMD Risk Categorization Framework.* Specifically, the "state of healthcare situation or condition" and the "significance of information provided by the SaMD to the healthcare decision" must be taken into account when making SaMD classification decisions.

- ❑ For software products with *multiple functions*, implement policies by which the health authority only exercises regulatory oversight over those functions with a medical device intended use.

Best Practices Framework

Recommendations to Health Authorities for Implementation of Fit-For-Purpose, Risk-Based Digital Health Frameworks

Pathways to Support Rapid Regulatory Review of SaMD Products and Their Modifications

- ❑ Implement *recognition and reliance models*, making use of regulatory assessments from comparable overseas regulators when conducting DH regulatory decision-making.

- ❑ *Streamline* regulatory pathways for the *introduction of SaMD products and their modifications*, such as developing expedited review pathways and endorsing the use of predetermined change control plans.

- ❑ Consider *unique regulatory approaches* tailored to the unique and iterative nature of SaMD solutions that leverage *artificial intelligence*.

Best Practices Framework

Recommendations to Health Authorities for Implementation of Fit-For-Purpose, Risk-Based Digital Health Frameworks

Collaboration and Convergence Opportunities in the APAC Region

- ❑ Support *DH regulatory global convergence* through the recognition and adoption of *internationally recognized guidance documents and standards*, such as those developed by IMDRF and ISO.

- ❑ Collaborate with software developers through *Pre-Submission Consultations.*

- ❑ Partner with industry through *industry associations*, *private-public consortiums*, and other fora *to share best practices and evolve the DH regulatory landscape* to enable the safe, effective, and timely delivery of innovative solutions benefiting healthcare professionals and patients.

Roche

Thank you

Doing now what patients need next