APACMed
The voice of MedTech

Advancing Software as a Medical Device Regulations in Asia-Pacific

REGULATORY AFFAIRS

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Introduction

The Asia-Pacific Medical Technology Association (APACMed) is a regional trade association representing the medical device and in-vitro diagnostics companies in Asia-Pacific. In close collaboration with its members, APACMed engages with governments and regulatory authorities to raise standards of care and enable timely access to innovative health technologies across the region.

This position paper is intended for regulators and policymakers, with the goal of supporting the development and refinement of fit-for-purpose, risk-based regulatory frameworks for Software as a Medical Device (SaMD). While several APAC regulatory authorities have taken important steps toward aligning with internationally harmonised approaches, progress remains uneven. We acknowledge that markets in the region are at different stages of regulatory maturity and adoption of global best practices. Greater convergence offers the opportunity to improve consistency, predictability, and efficiency across regulatory systems, ultimately benefiting patients and healthcare systems.

The rapid evolution of digital health technologies, including AI-enabled and connected software solutions, calls for regulatory frameworks that can keep pace with innovation while ensuring safety and effectiveness.

This paper aims to support that goal by identifying best practices, highlighting areas for regulatory alignment, and offering actionable recommendations that reflect the latest international guidance, particularly from reference markets such as Australia, Japan, Singapore, and the United States, which have demonstrated early and consistent alignment with the **International Medical Device Regulators Forum (IMDRF) framework.**

Tailored and modernised SaMD regulations will not only expand patient access to safe and effective innovations but also help optimise regulatory resources, foster collaboration, and enable a new generation of data-driven, personalised healthcare.

The information in this position paper reflects the regulatory landscape as of the publication date. As requirements continue to evolve, stakeholders are encouraged to consult local regulatory authorities for the latest updates.

SaMD Regulations: Overview and Best Practices

This section updates the original APACMed SaMD position paper published in 2021[1], by aligning definitions and regulatory characterisations with the latest international guidance. In particular, we reference two key documents from the International Medical Device Regulators Forum (IMDRF):

- **IMDRF/SaMD WG/N12 FINAL:2014**, which provides a framework for SaMD risk categorisation
- **IMDRF/SaMD WG/N81 FINAL:2025**, which outlines characterisation considerations and software-specific risk principles

IMDRF defines "medical device software" as encompassing a broad range of software types, including:

- **Software in a medical device (SiMD):** embedded or integral to a hardware device
- **Software as a medical device (SaMD):** independent of any physical device, often operating on widely accessible platforms (e.g., mobile phones, cloud environments)

In the Asia-Pacific region, where regulatory systems and healthcare infrastructure vary widely, the regulatory treatment of SaMD also differs significantly. SaMD products pose distinct regulatory challenges due to their global accessibility, rapid iteration cycles, and reliance on platforms outside traditional healthcare systems, but they also create unique opportunities to expand access to care.

This section provides an overview of current regulatory frameworks for SaMD, beginning with the United States as a reference model. This is followed by three APAC markets, Australia, Japan, and Singapore, that have demonstrated progressive alignment with international best practices.

To guide this analysis, we have identified six key regulatory criteria that reflect both the IMDRF framework and emerging industry considerations:

Key regulatory criteria that reflect both the IMDRF framework and emerging industry considerations

- Software Qualification
- Software with Multiple Functions
- Software as a Medical Device (SaMD) Classification
- Alternative Regulatory Pathways
- Pre-Submission Consultation
- Emerging Considerations

1.Software Qualification

International Medical Device Regulators Forum (IMDRF)

The **IMDRF** plays a central role in shaping global approaches to software regulation by providing foundational frameworks that many countries adopt or adapt within their national SaMD policies. According to IMDRF/SaMD WG/N12:2014, "Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations"[2], only a subset of software used in healthcare qualifies as a medical device.

For software to be considered a SaMD, it must have an intended medical purpose that meets the definition of a medical device. Software that is used in healthcare settings but lacks a direct medical purpose, such as data transfer or workflow management, should not be regulated as a medical device.

SOFTWARE FUNCTIONS THAT SHOULD NOT QUALIFY AS A MEDICAL DEVICE:

- Software for the administrative support of a health care facility
- Software for the management of prescription information
- Software for medication adherence (treatment regimens)
- Electronic patient records
- Software for clinical workflow and support
- Software for education, training, or guidance
- Software for transferring, storing, converting formats or displaying clinical laboratory test or other device data and results (medical device data systems (MDDS))
- Health information management/database systems
- Software for maintaining and encouraging a healthy lifestyle
- Software that extracts data from clinical trials/patient records
- Laboratory information systems
- Software that helps patients self-manage a specific disease/condition
- Software that provides “class-based or population-based analyses” rather than patient-specific diagnosis or treatment
- Low-risk clinical decision support software

Accurate qualification of software is essential. It helps regulators prioritise oversight of products that pose the highest risk to patients and public health, while reducing unnecessary regulatory burden on developers of low-risk software. Adopting the IMDRF qualification framework **promotes regulatory consistency and global convergence, benefitting regulators, developers, and, most importantly, patients.**

United States

The **U.S. Food and Drug Administration (FDA)** regulates SaMD under the same risk-based framework applied to all medical devices. However, FDA also excludes certain software functions from the definition of a medical device and applies enforcement discretion to others, resulting in a more flexible regulatory approach.

Under **Section 3060 of the 21st Century Cures Act**, several categories of software are explicitly excluded from FDA oversight. These include software intended for:

- Administrative support of healthcare facilities
- Promoting or maintaining a healthy lifestyle (unrelated to diagnosis, cure, mitigation, or treatment of disease)
- Serving as electronic patient records (if certain criteria are met)
- Transferring, storing, converting, or displaying clinical lab or device data
- Certain types of clinical decision support software (CDSS)

The FDA has also published several guidance documents to clarify its policy on software regulation, including:

- General Wellness: Policy for Low-Risk Devices (Sept 2019)
- Policy for Device Software Functions and Mobile Medical Applications (Sept 2022)
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (Sept 2022)
- Clinical Decision Support Software Guidance (Sept 2022)

Overall, the FDA’s approach reflects a commitment to an adaptive, risk-based framework that supports both regulatory clarity and innovation. This flexible model has informed regulatory strategies in other markets and provides a useful reference for authorities seeking to modernise their oversight of SaMD and other digital health technologies.

* For more information please visit this link: https://www.fda.gov/medical-devices/digital-health-center-excellence/guidances-digital-health-content

Australia

Australia's Therapeutic Goods Administration (TGA) has adopted a structured and risk-based approach to software qualification, underpinned by multiple guidance documents released since 2020.

In its March 2020 consultation paper, "Scope of regulated software-based products"[3], the TGA outlined a range of software functions that do not qualify as medical devices, such as those used solely for administrative, data handling, or wellness purposes.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

SOFTWARE FUNCTIONS THAT SHOULD NOT QUALIFY AS A MEDICAL DEVICE:

Consumer health products: General wellness or lifestyle applications.

Enabling technology: Clinical communication tools like patient registration or video calling.

Electronic patient records: Systems that store or display health information.

Population health management tools: Software used for population-level analytics.

In July 2021, the TGA published the guidance **"Is my software regulated"**[4], introducing a flowchart-based approach to assess regulatory requirements. The guidance also introduced two key pathways for regulatory relief:

- **Exclusion**: Software that falls completely outside TGA regulation
- **Exemption**: Software that avoids premarket review but remains under TGA oversight for advertising, reporting, and post-market controls

In July 2024, TGA further updated its guidance[5], offering expanded examples of regulated and unregulated software. **Software groups generally excluded from regulation include:**

- Consumer health life-cycle prevention, management and follow up
- Enabling technology for telehealth, remote diagnosis, and healthcare facility management
- Digital mental health tools
- Digitisation of paper-based other published clinical rules or data
- Population-based analytics
- Laboratory information management systems and laboratory information systems.

Additionally, certain low-risk **Clinical Decision Support Software (CDSS)** may qualify for exemption, as outlined in Part 2 of Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002[6].

These publications reflect TGA's commitment to a fit-for-purpose, risk-based regulatory approach and its alignment with international best practices, including IMDRF principles.

Japan

Japan's **Ministry of Health, Labour and Welfare (MHLW),** in collaboration with the **Pharmaceuticals and Medical Devices Agency (PMDA)**, has progressively refined its software qualification framework to better align with international best practices. Several regulatory guidelines and amendments have been issued since 2021 to clarify the classification of medical device software.

In March 2023, MHLW issued a partial amendment to the guideline for determining whether a software program qualifies as a medical device (PSEHB/MDED 0331-1; PSEHB/CND 0331-4)[7]. This amendment clarified that certain categories of software are excluded from regulation, including:

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厚生労働省
Ministry of Health, Labour and Welfare

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pmda

Non-SaMD	SaMD			
		Class II	Class III	Class IV
For health control (e.g., programs that give patients advice on meal or exercise for health maintenance and promotion)	**For treatment at home**	For use exclusively at home		
Educational program (e.g., training programs for healthcare professionals)	**For diagnostics**	For computer-assisted imaging diagnostics		
In-hospital business support program (e.g., medical appointment system, electronic medical record)		For computer-assisted diagnostics other than imaging		
			For gene mutation analysis	
Programs corresponding to Class I (e.g., eye test, programs for colour perception test)	**For treatment**	For therapy planning support		
		For surgical support		
		Application for behavioural therapy	For controlling active implantable device	

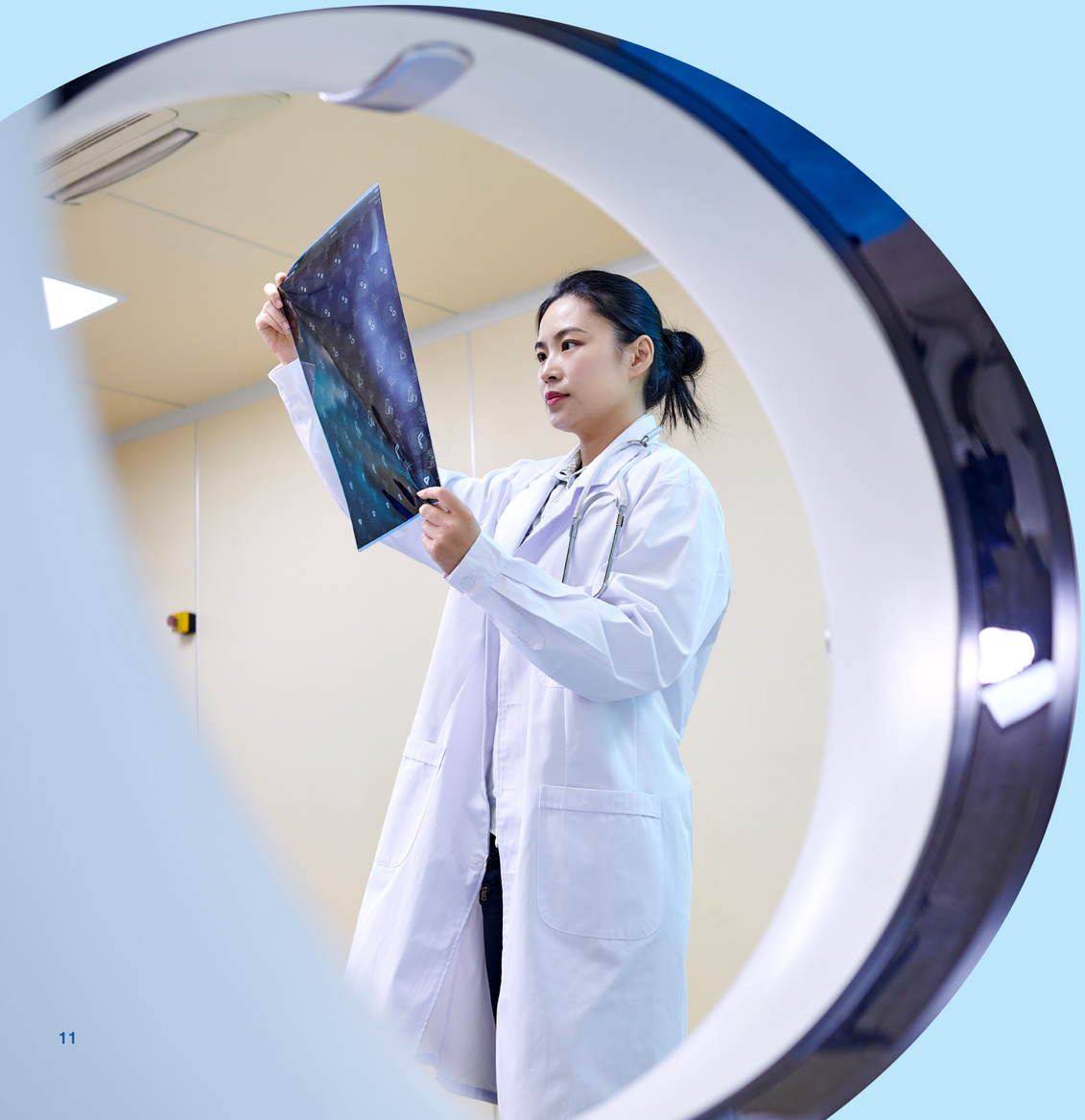
Table 1: GHWP SaMD PreMarket Submission Requirement – Comparison of requirement from Key jurisdictions[8]

Additionally, Japan's PFSB/CND Notification No. 1114-5 offers further clarification on which types of software are regulated under the Pharmaceutical and Medical Devices Act (PMD Act).

These updates reflect Japan's continued efforts to define the scope of software regulation in line with IMDRF principles, balancing innovation with risk-based oversight.

Singapore

Singapore's Health Sciences Authority (HSA) has issued detailed guidance to support software qualification and classification, particularly for standalone medical applications. Recent updates reflect its focus on emerging technologies and alignment with international frameworks.



In April 2022, HSA published the **"Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of Clinical Decision Support Software (CDSS)"**[9] alongside an update to the **"Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach"**[10].

These documents clarify that software is regulated as a medical device only if its intended use meets the definition under the Health Products Act.

The CDSS guidelines, which reference IMDRF's SaMD framework, state that Clinical Decision Support Software will not be regulated as a medical device if:

- The intended use does not meet the definition of a medical device, or
- It is used solely for displaying or printing medical information (e.g. summaries or reports).

In March 2024, HSA released Revision 3.11 of the **"Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach"**[11], which offers examples of software functions that do not qualify as medical devices in Singapore, including:

- Software used to store, format-convert, or transfer patient data
- Software for general patient education or access to reference information
- Software for automating administrative tasks such as appointment scheduling or billing

These regulatory updates underscore Singapore's risk-based approach, aiming to provide regulatory clarity while ensuring that oversight remains proportionate to the risks posed by software products. The framework reflects a commitment to enabling innovation while maintaining patient safety.

2.Software with Multiple Functions

United States

Many software products contain a combination of functions, some that qualify as medical devices and others that do not. In such cases, it is essential that regulators evaluate each function independently, based on its intended use. A single platform may include both regulated and non-regulated functions, and this modularity must be reflected in the regulatory approach.

The U.S. FDA addresses this in its guidance: **"Multiple Function Device Products: Policy and Considerations."**[11] This policy applies to both software- and hardware-based products and clarifies that FDA exercises oversight only over the functions that meet the definition of a medical device. Functions outside that definition are not regulated as devices. However, FDA reserves the right to assess how non-device functions may impact the safety and effectiveness of the device functions.

For example, consider a smartphone application that analyses photos of skin lesions to detect potential skin cancer. The diagnostic function, image analysis for cancer detection, has a medical purpose and is therefore subject to FDA regulation.

However, the supporting functions, such as the phone's operating system or camera, are not regulated as medical devices. Still, during product development and validation, the developer is responsible for assessing the risks posed by these non-device functions, ensuring they do not adversely impact the medical function's performance or safety.

→

Highlights the importance of:

- Isolating oversight to functions with a medical device intended use
- Applying risk-based regulation to each qualifying function
- Assessing the impact of non-device components during development

FDA's policy encourages clarity and innovation by ensuring that only relevant functions are subject to regulation, while still protecting patient safety.

Singapore

Singapore HSA similarly recognises that software medical devices may consist of multiple functions, not all of which meet the definition of a medical device under the Health Products Act (HPA). In "Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach" (Revision 3[12]), HSA clarifies that while non-medical device functions do not require pre-market submission, manufacturers must still evaluate their potential impact on the overall performance and safety of the regulated medical device functions.

Manufacturers are expected to:

1. Assess whether non-medical device functions could negatively affect the medical device function
2. Mitigate risks to an acceptable level
3. Conduct appropriate verification and validation activities to confirm the effectiveness of risk mitigation strategies
4. Maintain full documentation of this process as part of their quality management system (QMS)

This approach ensures that even though certain software functions fall outside regulatory scope, their interaction with regulated functions is properly assessed and managed, upholding patient safety while supporting innovation.

3. Software As A Medical Device (SaMD) Classification

Once software is determined to meet the definition of a medical device, it must be classified according to its risk. This classification determines the level of regulatory control applied across both pre-market and post-market stages.

This section outlines the global risk classification framework for SaMD, with a focus on how selected countries have adopted and implemented these approaches. We also examine how Clinical Decision Support Software (CDSS), a key subset of SaMD, is classified in certain jurisdictions, given its growing role in clinical decision-making and the differing regulatory interpretations across markets.

International Medical Device Regulators Forum (IMDRF)

IMDRF International Medical Device Regulators Forum

SaMD WG/N12 FINAL:2014

The IMDRF's SaMD WG/N12 FINAL:2014 guidance outlines a globally recognised framework for risk categorisation of SaMD, based on two core factors

- The state of the healthcare situation or condition the software is intended to address
- The significance of the information the SaMD provides in the healthcare decision-making process

These two dimensions create a risk classification matrix, resulting in four categories:

Category I (lowest risk) to Category IV (highest risk)

State Of Healthcare Situation Or Condition	Significance Of The Information Provided By SaMD To The Healthcare Decision		
	Treat Or Diagnose	Drive Clinical Management	Inform Clinical Management
Critical	IV	III	II
Serious	III	II	I
Non-Serious	II	I	I

Table 2: IMDRF SaMD risk classification matrix

This matrix enables regulators to assess how impactful and reliant the decision-making is on the software, ensuring appropriate oversight.

For example, a SaMD that diagnoses and initiates cancer treatment falls into a much higher risk category than one that simply presents educational content about cancer treatment options.

Adoption of this framework fosters international consistency and regulatory convergence. However, many authorities face challenges adapting the model within their existing medical device classification systems. APACMed recommends that regulators develop SaMD-specific classification schemes, rather than attempting to retrofit existing frameworks, using the IMDRF risk model as the foundation.

SaMD WG/N81 FINAL: 2025

The IMDRF released an additional guidance document in 2025 – N81: Medical Device Software Considerations for Device and Risk Characterisation[3], which builds upon N12 and provides further clarity on software risk and device characterisation.

Key considerations from the N81 guidance include:

1. A broadened definition of "medical device software", acknowledging varying interpretations across jurisdictions.
2. Recognition that both direct and indirect harms must be evaluated, especially for software that delivers information-based outputs.
3. The importance of considering harm not only as physical injury, but also as a reduction in device effectiveness, particularly when dealing with inaccurate or delayed information.
4. Clarification on risk management for software changes, including updates and machine learning models, with attention to the level of human oversight required.
5. Emphasis on evaluating risks in the context of the software's specific intended use and purpose.

Together, these IMDRF frameworks provide the foundation for modern, risk-based regulation of SaMD and serve as valuable tools for regulators looking to adapt their frameworks to evolving technologies.

United States

Building on the IMDRF classification framework, the U.S. has taken further steps to clarify how specific categories of software, such as Clinical Decision Support Software (CDSS), fit within or fall outside the scope of SaMD regulation. This distinction between device and non-device CDSS has become increasingly important as these tools evolve and integrate more deeply into clinical workflows.

To address this, the U.S. FDA has established criteria to determine when CDSS is not considered a medical device and is therefore not subject to FDA oversight. This classification is based on Section 3060 of the 21st Century Cures Act and further detailed in the FDA's 2022 CDSS guidance and the 2024 FAQs.

For CDSS to be excluded from FDA regulation, the software must meet all of the following four conditions:

It does not acquire, process, or analyse a medical image, an in vitro diagnostic signal, or a pattern from a signal acquisition system.

It is intended only to display or analyse medical information, such as electronic health records, clinical studies, or guidelines.

It supports clinical recommendations on prevention, diagnosis, or treatment for use by a healthcare professional.

It allows the healthcare professional to independently review the basis for the recommendation, such that the clinician does not rely primarily on the software's output.

If a CDSS fails to meet even one of these criteria, it may be considered a medical device and regulated accordingly under the existing SaMD framework. This regulatory approach attempts to balance innovation and oversight, enabling the use of lower-risk software tools without imposing unnecessary regulatory burdens, while maintaining FDA oversight over software that may directly influence clinical decisions and patient safety.

However, this boundary remains nuanced, and developers must carefully assess whether their CDSS qualifies for exclusion. The U.S. model highlights a key challenge for global regulatory harmonisation: different jurisdictions define and regulate CDSS differently, creating inconsistencies that can complicate international product development.

Australia

Australia's TGA introduced new classification rules for SaMD in December 2019, which took effect in February 2021, with a transition period ending in November 2024. These classification rules, outlined in the table below, reflect a shift toward a risk-based regulatory approach.

		INFORMATION TO AN INDIVIDUAL	INFORMATION TO A HEALTH PROFESSIONAL
RISK TO INDIVIDUAL OR PUBLIC HEALTH	**DIAGNOSING / SCREENING AND / OR SPECIFYING OR RECOMMENDING TREATMENT / INTERVENTION FOR A DISEASE OR CONDITION**		
	DEATH / SEVERE DETERIORATION / HIGH PUBLIC HEALTH RISK	III	IIb
	SERIOUS DISEASE OR CONDITION / OTHERWISE HARMFUL / MODERATE PUBLIC HEALTH RISK	IIb	IIa
	ANY OTHER CASE	IIa	I
	MONITORING THE STATE / PROGRESSION OF A DISEASE OR CONDITION		
	IMMEDIATE DANGER TO A PERSON / HIGH PUBLIC HEALTH RISK	IIb	
	OTHER DANGER TO A PERSON OR ANOTHER / MODERATE PUBLIC HEALTH RISK	IIa	
	ANY OTHER CASE	I	
	FOR PROVIDING THERAPY THROUGH PROVISION OF INFORMATION		
	MAY RESULT IN DEATH / SEVERE DETERIORATION	III	
	MAY CAUSE SERIOUS HARM	IIb	
	MAY CAUSE HARM	IIa	
	ANY OTHER CASE	I	

Table 3: TGA SaMD classification rules[13]

The TGA's framework considers:

The harm that could result from incorrect software output

The intended user, differentiating between experienced (e.g., clinicians) and inexperienced users (e.g., patients)

These factors influence how software products are classified and regulated. The classification rules are broadly aligned with the European Union's Medical Device Regulation (EU MDR, Regulation EU 2017/745)[14], but do not apply to software classified as in vitro diagnostic (IVD) devices.

While the TGA appears to reference the **IMDRF SaMD Risk Categorisation Framework**, its implementation shows partial alignment. For example:

- The "state of the healthcare situation or condition" is clearly considered.
- However, the "significance of the information provided by the SaMD to the healthcare decision", a key IMDRF factor, is less explicitly reflected.
- The TGA also incorporates user-type considerations but does not clearly distinguish whether software treats/diagnoses, drives, or informs clinical decisions, another key distinction under IMDRF.

These gaps create ambiguity regarding the extent of Australia's alignment with IMDRF, and greater clarity would help enhance international convergence.

In parallel, the TGA has issued specific guidance for CDSS[15], to clarify when it is regulated, exempted, or excluded:

- CDSS that meets the definition of a medical device must be included in the Australian Register of Therapeutic Goods (ARTG) unless exempt.
- CDSS that are either excluded or do not qualify as medical devices fall outside the scope of regulation.
- Excluded devices are entirely unregulated.
- Exempt devices require no registration but remain subject to oversight (e.g., advertising, reporting adverse events).

To be exempt, CDSS must meet all of the following criteria:

- It qualifies as a medical device (not excluded).
- It does not acquire, process, or analyse medical images or signals.
- It is solely intended to support, not replace, clinical decision-making.
- It allows the healthcare professional to independently review the basis for the recommendation.

If any of these criteria are not met, the CDSS is regulated as a medical device. This approach closely mirrors the U.S. FDA's classification logic and underscores Australia's ongoing efforts to harmonise its framework. Further refinement is expected in 2025 and beyond, following the TGA's public consultation on CDSS.

Japan

In Japan, the classification of SaMD follows the existing medical device regulatory framework under the PMD Act. The PMDA has not adopted classification rules specific to SaMD or directly based on the IMDRF SaMD Risk Categorisation Framework. Instead, SaMD is classified using the **Global Harmonisation Task Force (GHTF) medical device risk classification system:**

CLASSIFICATION	DEVICE	RISK
I	General Medical Device	Low
II	Controlled Medical Device	Relatively low
III	Specially Controlled Medical Device	High
IV	Specially Controlled Medical Device	Invasive, potentially life threatening

Table 4: PMDA classification scheme for Medical Devices

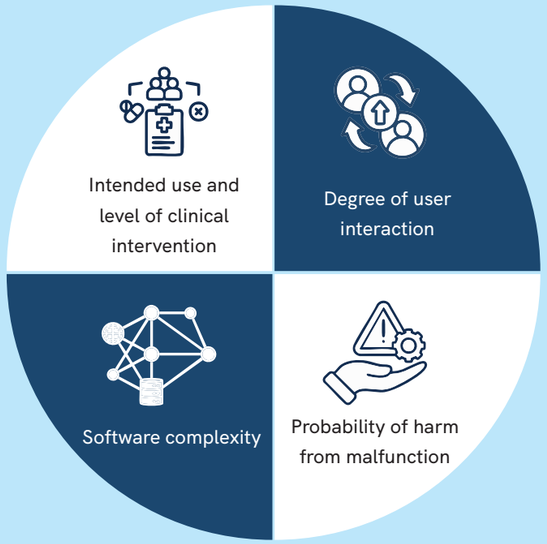
While this system accounts for the state of the healthcare situation or condition, it does not explicitly incorporate the significance of the information provided by the SaMD to the healthcare decision, a key element of the IMDRF model. When classification under GHTF categories is unclear, authorities may consider additional factors, such as:

- The SaMD's contribution to diagnosis or treatment
- The probability and severity of risk in case of malfunction

These supplemental considerations guide regulatory decisions but can introduce ambiguity. A more SaMD-specific, streamlined approach could enhance consistency and clarity for developers.

Under Japan's 2021 Partial Amendment of the Guideline for Determination of Whether Software/Programs are Classified as Medical Devices (PSEHB/MDED 0331-1; PSEHB/CND 0331-4; and PSEHB/CND 1228-2), SaMD may be classified into Class II, III, or IV, while Class I SaMD is excluded from regulation.

Japan does not have dedicated regulatory guidance for CDSS. Instead, CDSS is regulated under the broader SaMD classification system. However, the 2023 revisions to guidelines (PSEHB/MDED 0331-1 and PSEHB/CND 0331-4) offer some direction by recommending that CDSS classification be based on:



Depending on these factors, CDSS may be classified from **Class I (low risk) to Class III (high risk),** with stricter controls required for higher-risk software. However, unlike the U.S. and Australia, Japan lacks specific regulatory provisions for low-risk CDSS. This creates uncertainty for developers and may discourage innovation in low-risk decision support tools. Introducing clearer guidance and risk thresholds for exempt or excluded CDSS would improve predictability and align Japan more closely with international best practices.

Singapore

Singapore's HSA has adopted a risk-based classification system for SaMD that aligns closely with the IMDRF SaMD Risk Categorisation Framework. This alignment was further reinforced in the updated Guidelines on Risk Classification of Standalone Medical Mobile Applications and Qualification of CDSS, published in April 2022. Under this framework, risk classification is based on two key factors:

1. The state of the healthcare situation or condition the software is intended to address

2. The significance of the information provided by the SaMD to the clinical decision-making process

HSA assigns software to four risk classes, **Class A (lowest risk) to Class D (highest risk), with higher-risk classes subject to more stringent regulatory controls.** This structured approach provides greater clarity for developers and aligns with internationally harmonised principles.

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

Table 5: HSA's SaMD risk classification table

Singapore's guidance provides clear qualification criteria for determining when CDSS is regulated as a medical device. **CDSS that meets the definition of a medical device will be classified as Class A, and therefore considered low risk if it meets all of the following conditions:**

1. It is intended to analyse patient-specific medical information or general medical content.
2. It is not intended to acquire, process, or analyse medical images, IVD signals, or signal patterns from other medical devices.
3. It is solely intended to support healthcare professionals in clinical decision-making related to prevention, diagnosis, or treatment.
4. It is not intended to replace clinical judgement, and it enables the healthcare professional to independently review the basis of the recommendation.

By clearly outlining criteria for low-risk CDSS and applying a well-structured classification model, Singapore HSA has created a transparent and balanced regulatory pathway. This facilitates innovation while ensuring appropriate oversight for higher-risk SaMD.

4. Alternative Regulatory Pathways

As the digital health landscape continues to evolve, regulatory reliance and alternative approval pathways have become critical tools to improve efficiency and accelerate access to innovative SaMD. These approaches can help regulators make informed decisions while avoiding unnecessary duplication of effort. This section highlights three key mechanisms for alternative SaMD regulation:

Recognition and reliance models		Expedited review pathways	Predetermined change management pathways
Recognition: The acceptance of the regulatory decision of another regulator or trusted institution without further assessment of underlying data. In the case of SaMD with AI-enabled technologies, this includes evaluating how AI models have been deployed, implemented, and validated to ensure they meet the regulatory framework of reference regulatory authority, while addressing the evolving nature of these technologies.	**Reliance**: The act whereby the regulatory authority in one jurisdiction may consider and give significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative agency in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.	Regulatory pathways are designed to provide a faster pre-market decision than traditional regulatory pathways. For software and AI-based medical devices, these pathways provide a quicker evaluation of AI algorithms and demonstrate clear clinical benefits. FDA's breakthrough device program, among other breakthrough designated devices, allows AI developers to demonstrate software development practices, enabling faster approval for future digital health products.	These pathways enable manufacturers to obtain regulatory pre-approval for specific post-market modifications to a medical device, including software-based changes. These pathways streamline the approval process by allowing manufacturers to implement certain pre-authorised changes without undergoing a separate, additional premarket review. This is especially beneficial for software and AI-enabled devices, which are often updated iteratively. By incorporating a change management plan during the initial premarket submission, manufacturers can outline anticipated changes, such as software version updates or algorithm refinements, and propose supporting data and mitigation strategies. This proactive approach supports both regulatory compliance and timely innovation, facilitating faster access to improved technologies for patients.
Several global resources provide helpful guidance on regulatory reliance, such as: - The WHO Good Regulatory Reliance Practice[16] - The IMDRF Regulatory Reliance Playbook: presents practical guidance and case studies for operationalising reliance across medical device regulatory systems[17] - The GMTA Position Paper: Outlines the global industry's support for advancing convergence and reliance to accelerate patient access[18]		Expedited regulatory pathways are designed to provide a faster pre-market decision for medical devices, including SaMD, as compared to traditional regulatory pathways.	

United States

The U.S. FDA offers expedited regulatory pathways that support early access to innovative medical technologies, including SaMD.

Expedited review pathway: Breakthrough Devices Program and Safer Technologies Program (STeP)

The Breakthrough Devices Program is a voluntary pathway for devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It aims to expedite development, assessment, and review of qualifying devices through interactive and collaborative engagement with the FDA.

The Safer Technologies Program (STeP), modelled after the Breakthrough program, targets devices that are expected to significantly improve the safety of currently available treatments or diagnostics for less serious conditions.

Both programs offer early and frequent interaction with FDA reviewers, senior management engagement, flexible clinical study design options, and priority review for marketing submissions.

Predetermined change management pathway: Predetermined change control plans (PCCP)

2019

FDA first introduced the concept of a **PCCP** specifically in relation to AI/ML-based SaMD in its 2019 discussion paper entitled Proposed Regulatory Framework for Modifications to AI/ML-Based SaMD[20].

2022

Legislation was passed to allow FDA to authorise PCCPs across all premarket pathways and device types.

2023

In October 2023, the U.S. FDA, Health Canada, and the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) have jointly issued guiding principles on PCCP for AI/ML-enabled medical devices (MLMDs)[23] . The key elements medical device manufacturers shall include in a PCCP per the U.S. FDA guidance include:

- Identification of the specific, planned modifications that the manufacturer intends to implement after authorisation. All the planned modifications must be able to be verified and validated and linked to a specific performance evaluation activity within the modification protocol.
- **The Modification Protocol** describes the methods that will be followed when developing, validating, and implementing those modifications, to ensure the device remains safe and effective. The methods described in the Modification Protocol should be consistent with and support the modifications outlined in the Description of Modifications.
- Assessment of the benefits and risks of implementing a proposed PCCP, as well as the plan for risk mitigation.

2024

In August 2024, FDA released a draft guidance document on Predetermined Change Control Plans for Medical Devices[21], which provides recommendations on the information to be included in a PCCP for all medical device types.

Most recently, in December 2024, FDA released a final guidance document on **Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software**[22], which provides recommendations on the information to be included in a PCCP for AI-enabled devices. After manufacturers obtain premarket authorisation for the device with the PCCP, they can then deploy the specified modifications, following the authorised plan, without needing additional FDA marketing authorisation.

PCCPs are intended to be focused and bounded, staying within the device's original intended use. They employ a risk-based approach to ensure that changes are safe, appropriate for the device environment, and do not compromise effectiveness. PCCPs are intended to facilitate more timely patient access to innovative or improved medical devices and are particularly critical for AI-enabled medical devices.

Australia

In late 2024, the Australian Government launched consultations on the safe and responsible use of AI, including its application in medical devices. The outcomes of this review may inform future regulatory pathways for AI-based SaMD.

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Recognition and reliance models

The TGA actively promotes regulatory efficiency through the use of recognition and reliance mechanisms. These models enable faster and more efficient oversight of digital health products, supporting timely patient access while reducing duplicative regulatory efforts.

The TGA has long accepted certification from European notified bodies as evidence of compliance with the conformity assessment procedures, in addition to the conformity assessment certificates issued by the TGA.

Since October 2018, comparable overseas regulators and assessment bodies can include:

- Notified bodies designated by the medical device regulators of European member states, under the medical device regulatory frameworks of the European Union
- The Food and Drug Administration of the United States
- Health Canada
- Medical Device Single Audit Program (MDSAP) Auditing Organisation
- The Ministry of Health, Labour and Welfare and Pharmaceutical and Medical Devices Agency of Japan
- Singapore's Health Sciences Authority (HSA).

This approach aligns with global efforts to reduce regulatory burden on manufacturers while maintaining high standards of safety and performance.

The TGA also participates in international work-sharing and convergence initiatives through:

IMDRF International Medical Device Regulators Forum

ISO International Organization for Standardization

While the TGA's reliance model is well-established, further development of SaMD-specific pathways, particularly to support rapid implementation of significant software modifications, would enhance flexibility and better reflect the iterative nature of software-based technologies.

Japan

Expedited review pathways: SAKIGAKE

Japan's MHLW and the PMDA introduced the **SAKIGAKE Designation System** to accelerate regulatory review for breakthrough devices that address high unmet medical needs. "Sakigake" means "pioneer" in Japanese, reflecting the program's aim to prioritise innovative, first-in-Japan products.

To qualify, a device must meet four criteria:
1. Demonstrated innovativeness
2. Targeting a serious or life-threatening condition
3. High therapeutic efficacy
4. First development plan in Japan

SAKIGAKE Benefits

- Shortened formal consultation timeline (1 month vs. 2–3 months)
- Prioritised and shorter review period (6 months vs. 12 months)
- Option to submit documents in English for pre-review
- Assignment of a dedicated PMDA case manager to oversee the entire approval process

While the program enables faster access to novel therapies, its restriction to Japan-originated technologies is a key limitation. Expanding eligibility to overseas developers could broaden patient access to promising global innovations.

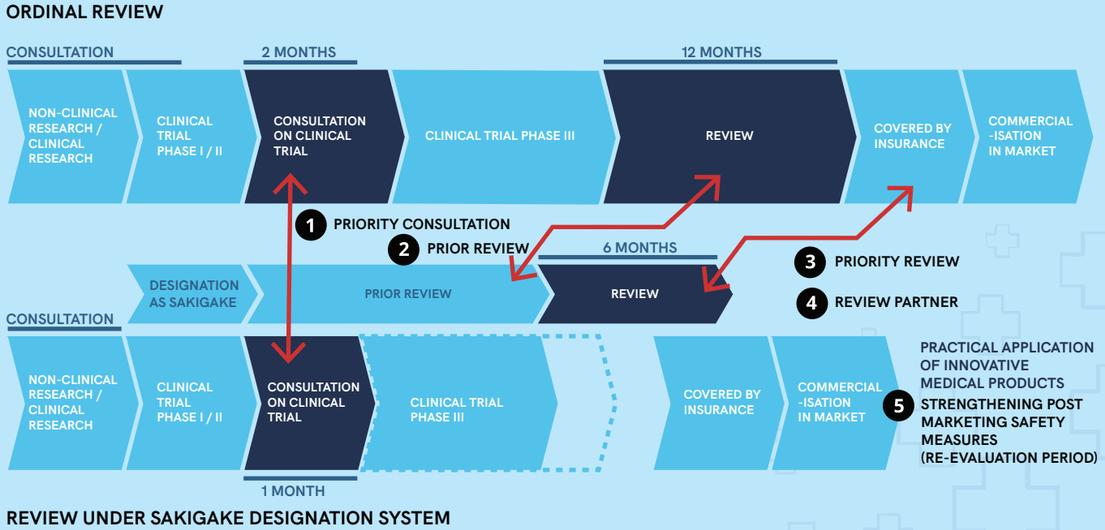


Figure 1: PMDA's 'SAKIGAKE' Designation System

Predetermined change management pathway: IDATEN

Japan's IDATEN framework (Improvement Design within Approval for Timely Evaluation and Notice) was created to facilitate rapid implementation of post-market modifications for medical devices, including SaMD. IDATEN supports two main functions:

1. **Early Realisation of Change Plans:** During premarket review, the Marketing Authorisation Holder (MAH) and PMDA agree on a predefined change plan. Approved changes can later be executed by notification rather than a full amendment, saving time.
2. **Post-Market Lifecycle Management:** IDATEN also supports continuous improvement, particularly for AI/ML-enabled SaMD, by allowing updates under a quality management system without new premarket submissions.

This risk-based approach enables iterative development while maintaining safety and easing the regulatory workload.

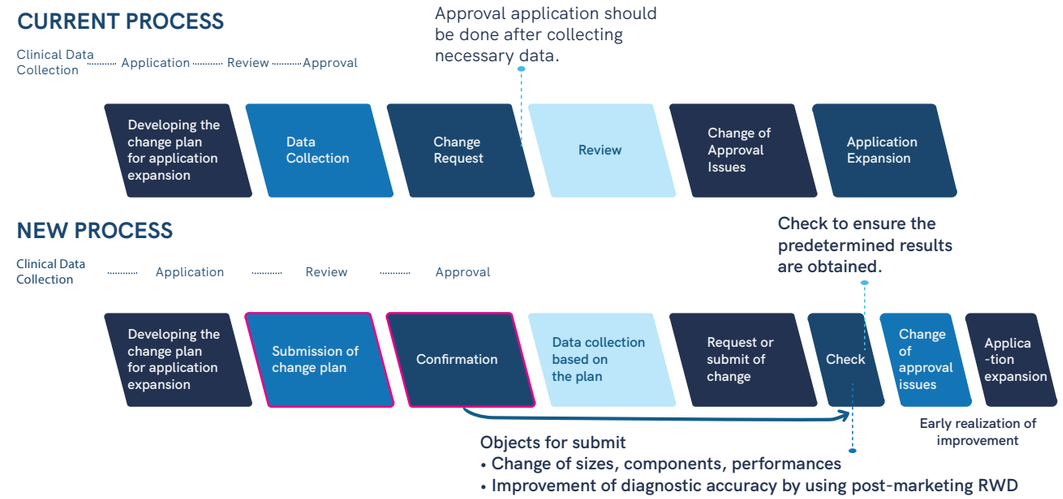


Figure 2: PMDA's IDATEN process

DASH & DASH 2 for SaMD

DASH (2020): Digital Transformation Action Strategies for Healthcare focused on SaMD and broader digital health solutions.

DASH 2 (2023): Builds on DASH by targeting SaMD for general use, encouraging international acceptance of Japanese approvals, and offering funding support for developers.

Japan summary and outlook

Japan's commitment to advancing digital health is evident through its innovative regulatory pathways like **SAKIGAKE and IDATEN**, alongside the strategic **DASH and DASH 2 initiatives.** These frameworks demonstrate a clear forward-looking vision, and we recognise the existing efforts by the Japanese government and related organisations to engage with various stakeholders in the digital health ecosystem. To further enhance the effectiveness and maximise the benefits of these innovative pathways, we respectfully suggest building upon these existing multi-stakeholder dialogues. By fostering more structured and comprehensive discussions, insights from diverse perspectives can be systematically integrated to evaluate the current utilisation of these pathways and brainstorm any refinements needed to optimise their impact based on the evolving inputs and needs from all stakeholders.

Singapore

Singapore's Ministry of Health (MOH) and Health Sciences Authority (HSA) continue to adopt a forward-looking approach to regulating SaMD and AI-enabled technologies.

In October 2023, MOH and HSA jointly issued the **"Artificial Intelligence in Healthcare Guidelines (AIHGLe)"[24],** covering principles such as explainability, data quality, and shared accountability between developers and implementers. The guidance introduces innovative considerations like the use of synthetic data and outlines safety and performance responsibilities across the AI lifecycle.

In March 2024, HSA also updated the **Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach**[11] to include a dedicated section on Artificial Intelligence Medical Devices (AI-MD). It offers much-needed clarity on premarket documentation for AI-MD, including continuous-learning systems and change management. This effort has been welcomed by industry stakeholders for providing actionable and predictable regulatory expectations.

HSA also supports confidence-based regulation through **recognition** and **reliance** models – The evaluation routes for products are set out, according to a confidence-based approach, by leveraging the approvals of HSA's reference regulatory agencies (Australia's TGA, Health Canada, the U.S. FDA, European Union Notified Bodies, and Japan's MHLW) and/or prior safe marketing history of the products. The submission requirements outlined in HSA's "GN-15: Guidance on Medical Device Product Registration"[25] are titrated according to the evaluation routes for which the product qualifies.

Recognition and reliance models

To facilitate expedited review there is provision for:

Abridged Evaluation Route:
Any new product that has been approved by at least one reference regulatory agency is eligible for an abridged evaluation route.

Immediate Class B Registration (IBR) Evaluation Route (Condition 1 or 2):

Condition 1

- Products can be eligible if approved by at least 1 of HSA's independent reference regulatory agencies, and
- A product must be marketed for at least three years in one of the independent reference regulatory agency's jurisdictions, and
- 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, and
- No prior rejection/withdrawal of the medical device by/from any reference regulatory agency/that foreign jurisdiction(s) or HSA/Singapore due to quality, performance/efficacy or safety issues

Condition 2

- Products can be eligible if approved by at least 2 of HSA's independent reference regulatory agencies, and
- No safety issues globally associated with the use of the product in the last 3 years or since market introduction of the product globally, and
- No rejection/withdrawal of the medical device from any of the independent reference regulatory agencies due to quality, performance or safety issues.
- Note on Condition 2: If approved by at least two independent reference agencies, the three-year marketing history is not required, but there must be no safety concerns or prior regulatory rejections

Immediate Class B Registration (IBR) Evaluation Route (Solely for Standalone Medical Mobile Applications):

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

Immediate Class C Registration (ICR) Evaluation Route (Solely for Standalone Medical Mobile Applications):

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

International convergence: HSA is actively engaged in work sharing, information sharing and regulatory convergence activities through international initiatives including:

- The International Medical Devices Regulators Forum (IMDRF).
-
- HSA-Thailand Food and Drugs Administration (FDA) Reliance Pathway.
- HSA- Malaysia Medical Device Authority (MDA) Reliance Pathway.

To further enhance SaMD regulatory efficiency, APACMed recommends the Health Sciences Authority (HSA) continue its proactive and collaborative regulatory approach for managing software-based products.

Expedited review pathway: Priority Review Scheme

The Priority Review Scheme[26] is an alternative regulatory pathway designed to accelerate registration for medical devices manufactured to address critical healthcare needs and submitted through the Full Evaluation Route. It applies to Class B, C, and D devices and excludes Class D devices with a registrable drug in a secondary role.

2 Routes for the Scheme:

Route 1 - The medical device meets both criteria below:

1. It belongs to one of five focused healthcare areas
   A. Cancer
   B. Diabetes
   C. Ophthalmic diseases
   D. Cardiovascular diseases
   E. Infectious diseases
2. It is designed and validated for an unmet clinical need. This means either
   A. It can be used to diagnose and treat a condition which has no other existing treatment
   B. It is a breakthrough technology with an edge over existing technology

Route 2 - The medical device does not meet the above two criteria.
This scheme shortens eligible SaMD products regulatory review and market entry turnaround time by about 35% compared to the standard full evaluation, helping SaMD manufacturers bring innovative software solutions to Singapore market more quickly.

NextGen MD Initiative

The **Next Generation Medical Device (NextGen MD)**[27] **Initiative** is an opt-in program designed to accelerate the registration process for significantly improved medical devices that represent substantial advancements over their predecessors but often cannot use the standard Change Notification pathway and must be submitted via full evaluation route.

To qualify for the HSA NextGen MD Initiative, both the NextGen MD and the original (registered) device must meet specific criteria. The NextGen MD must be a Class B, C, or D device (excluding MD-drug combinations) submitted under the full evaluation route and must be the same product type and leverage identical, previously submitted relevant technical documents.

Concurrently, the original registered device must share the same product owner and registrant, have been registered via the abridged or full route, be actively listed on the **Singapore Medical Device Register (SMDR)** at the time of submission, and any leveraged changes must have been registered via a review or technical change notification.

Predetermined change management pathway: Change Management Program (CMP)

Singapore's HSA introduced the **Change Management Program (CMP)** for SaMD to streamline the regulatory process, ensuring timely implementation of software changes while maintaining safety and efficacy. The CMP provides an optional pathway that reduces redundancy in submissions and accelerates approvals for pre-specified changes.

SaMD under the CMP include standalone software and mobile applications that operate independently. The program ensures quality assurance through pre-specified changes, requiring manufacturers to adhere to standards such as ISO 13485 and IEC 62304. Manufacturers participating in the CMP must submit detailed documentation of changes, implementation protocols, and impact analyses. Once approved, they can implement changes without needing new notifications, significantly simplifying the regulatory process.

The CMP enhances agility by allowing faster response to changes and reducing the regulatory burden through previously approved documentation. HSA plans to evolve the CMP to keep pace with technological advancements, ensuring regulatory effectiveness while fostering innovation in medical technology.

5. Pre-Submission Consultation

Pre-submission consultation (PSC), also known as Q-Sub[28] in the US, is an opportunity to obtain regulator feedback prior to an intended regulatory submission (for example, consultation for a clinical trial design supporting a novel claim). Early interaction with regulators via a PSC may:

1. Improve the quality of subsequent submissions
2. Shorten total review times
3. Facilitate the development process for new devices. Australia's TGA, U.S. FDA, Japan's PMDA and Singapore's HSA have all implemented the PSC scheme.

In Singapore, HSA also encourage researchers, developers and manufacturers of SaMD devices and AI solutions to leverage on the **"Device Development Consultation Scheme"**[29].

In fact, HSA has estimated that 40% of these consultations are related to digital health products[30].

6. Emerging Considerations and Regulatory Guidelines for Advanced Medical Technologies

Digital health has evolved as a broad term encompassing electronically captured data, along with technical and communications infrastructure and applications in the health care ecosystem. Revolutionary advances in digital health are transforming health, medicine, and biomedical science, and redefining and re-engineering the tools needed to create a healthier future.

Developments such as **cloud computing, artificial intelligence, machine learning, blockchain, digitally mediated diagnostics and treatment, telehealth, and consumer-facing mobile health applications** are now routinely used in self-management, health care, and biomedical science.

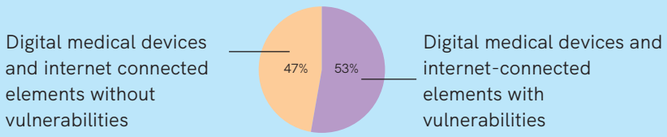
These developments promise to drive earlier diagnoses and interventions, improve outcomes, and support more engaged patients, it also leads to challenges which are multifactorial and overlapping and require updated approaches to ensure safety, effectiveness, and innovation[31].

Within this section, we are exploring two areas, **Cybersecurity** and **Robotics** as an example where both are closely linked to SaMD but present distinct regulatory challenges that warrant further attention.

As healthcare becomes increasingly digitised and interconnected, cybersecurity for medical devices has emerged as a critical concern for patient safety, data privacy, and healthcare operations.

For example, the average U.S. hospital room contains an estimated 15 to 20 connected medical devices. Those numbers are rising due to the accelerated adoption of internet-connected devices to reduce costs for health systems, provide better care to patients, and save clinician time[32].

Cybersecurity risks in medical devices remain a concern, as highlighted in a report from the FBI/American Hospital Association (AHA), which found that 53% of digital medical devices and internet-connected elements surveyed had vulnerabilities[33].



While legacy systems with outdated operating software pose security challenges, the medical device industry has been actively addressing these risks through enhanced security measures, software updates, and adherence to global cybersecurity standards such as IEC 81001-5-1[34] and ISO/IEC 27001[35]. Strengthening collaboration between regulators, healthcare providers, and manufacturers is essential to mitigate threats such as ransomware attacks while ensuring patient safety and data security.

To support safer and more resilient digital health ecosystems, we encourage APAC regulators to **adopt a harmonised, risk-based approach to cybersecurity by integrating internationally recognised standards into their national regulations.**

With this section, we aim to highlight **how cybersecurity can be embedded throughout the entire product lifecycle to ensure robust protection of patient safety, data privacy, and system integrity.** The following are key considerations at each stage:

Design and Development Phase

- Integrate cybersecurity from the outset by adopting **Secure by Design principles** (e.g. threat modelling), implementing defence-in-depth strategies across software, platform, and network layers with multiple, layered security controls (e.g., access controls, encryption, network segmentation), and enforcing robust supply chain risk management for third-party software components (e.g., Software of Unknown Provenance (SOUP)), which could introduce security vulnerabilities.

- Adopt cybersecurity best practices throughout the **Software Development Life Cycle (SDLC)** to mitigate security risks. Ensuring alignment with globally recognised approaches to secure coding, software risk management, and vulnerability assessments enhances compliance with regulatory expectations and strengthens the security of medical device software.

- Ensure traceability between **Secure Software Development Framework (SSDF)** practices and QMS requirements. Regulatory authorities require documentation like threat models, security risk assessments, and vulnerability assessments to demonstrate cybersecurity compliance. Security design and testing are necessary to mitigate risks from inadequate design and implementation.

- Define cybersecurity policies and objectives in a way that ensures consistency across regulatory and healthcare environments, enabling interoperability without compromising patient safety or system integrity. Encouraging alignment with globally recognised cybersecurity principles can help streamline compliance efforts and reduce unnecessary regulatory fragmentation, facilitating a more harmonised approach across markets.

Implementation and Deployment Phase

- Harmonise product security policies imposed by QMS with organisational security policies (e.g., SOC2, ISO 27001) to integrate all necessary measures to mitigate security risks.
- Define responsibilities clearly across the ecosystem, including

Manufacturers:
Security-by-design, monitoring, and patch management

Healthcare providers:
Network controls and infrastructure security

Regulators:
Oversight and alignment with global frameworks

Post-Market and Maintenance Phase

- Stay updated on fast-evolving cybersecurity regulations, standards, and IMDRF technical documents (e.g., N73[25], N70[34], N60[35]) developed by the medical device cybersecurity working group. Understanding and staying current with the latest guidelines is crucial for demonstrating compliance.

- Equip users with clear cybersecurity guidance, including safe device integration into healthcare IT environments, secure configuration and lifecycle maintenance (e.g. patch compatibility testing), transparent disclosure of vulnerabilities, their potential safety or performance impact, and mitigation strategies.

Medical devices are now integrated with computers, software and algorithms which make them more complex than traditional devices. Medical devices can also include AI components, hence the terms AI-enabled, AI-embedded medical devices, **AI-MDs** are used interchangeably across the industry and introduce newer challenges.

For example, **although robotics systems** are not strictly classified as SaMD under IMDRF definitions, software, including AI and ML components, plays an increasingly central role in **robotic-assisted surgical systems.** These complex, integrated platforms often include SaMD-like functionalities such as **data analysis, image processing, and closed-loop control.**

As such, we believe it is important to briefly address **Robotic Assisted Surgical Devices (RASDs)** in this paper as an emerging area that intersects with many of the challenges faced in SaMD regulation.

In recent years, the use of robotics in healthcare, particularly in surgical and interventional procedures, has grown rapidly. When software modules within robotic systems are designed to analyse data, assist with diagnosis or therapy planning, or control actuators based on processed patient inputs, they can exhibit risk profiles and regulatory considerations similar to SaMD.

Stakeholders have noted that the current regulatory frameworks often struggle to accommodate these integrated technologies, particularly when it comes to:

1. AI/ML-based functionalities embedded in robotic systems
2. Software updates that alter device performance post-deployment
3. Validation across different patient populations
4. And interoperability within broader digital health ecosystems.

For example, jurisdictions like Australia and Singapore already apply SaMD-related regulatory expectations to software components within robotic systems, referencing Good Machine Learning Practices (GMLP), local clinical validation, and cybersecurity.

Robotics systems often straddle the boundary between SiMD and SaMD and may involve proprietary hardware-software combinations not easily generalisable. To strike a balance, we suggest the following:

1. Acknowledge that robotics systems should not be classified as SaMD in their entirety, but their embedded or connected software components may qualify as SaMD or raise similar regulatory considerations.

2. Encourage regulators to consider the system-level nature of robotics, particularly when evaluating AI-driven features, real-time decision support, and human-machine interaction.

3. Recommend future policy dialogue or working groups focused specifically on robotics regulation, building upon insights from digital health and SaMD pathways while developing tailored frameworks for robotics.

Ultimately, we believe that the growing role of robotics in healthcare calls for clearer regulatory expectations and more consistent interpretation across markets. While we do not advocate for establishing standalone regulatory pathways for robotics, we recommend that regulatory authorities and stakeholders explicitly consider robotics within ongoing discussions on AI/ML, digital health, and innovative regulatory frameworks.

APACMed encourages the formation of regional and global working groups or policy dialogues that address robotics as part of the broader SaMD and digital innovation ecosystem, ensuring alignment, avoiding duplication, and supporting both safe innovation and timely patient access.

APACMed Recommendations

Based on the challenges and considerations outlined in this paper, we propose the following best practices for establishing fit-for-purpose, risk-based regulatory frameworks for SaMD, including CDSS. These recommendations aim to support timely access, regulatory convergence, and effective oversight across the product lifecycle.

Fit-for-Purpose Qualification and Classification

Define a clear qualification pathway for SaMD
Establish clear criteria for software qualification, ensuring regulation applies only to software with a medical device intended use, consistent with frameworks in the US and Australia.

Apply a structured risk classification model
Use a two-factor model based on: the healthcare situation or condition and the significance of information to the healthcare decision. This should align with IMDRF N12 and N81 (2025).

Apply function-specific oversight for software with multiple functions
Having regulatory oversight only over those functions that meet the medical device definition, based on their intended use and associated risk.

Risk-Based Regulatory Approach for SaMD, Including CDSS

Take a risk-based approach to software regulation
Certain low-risk software, including certain CDSS, should be excluded or exempted from regulatory oversight. Aligning these exemptions and exclusions with other global regulators will help to promote convergence and reduce confusion and unnecessary regulation.

Introduce special controls for higher-risk SAMD and CDSS
Include requirements such as clinical validation, performance testing, post-market monitoring, and human oversight, in line with the U.S. FDA's approach.

Use real-world data for continuous oversight
Encourage the use of real-world evidence and data collection to support ongoing evaluation and improvement of CDSS.

Enabling Speed Through Collaboration and Convergence

Support SaMD regulatory global convergence
Done through the recognition and adoption of internationally recognised guidance documents and standards, such as those developed by IMDRF, GHWP and ISO/IEC.

Establish collaboration among regional health authorities
Foster collaboration to build SaMD assessment capabilities through knowledge-sharing, joint training, and direct communication, while co-developing a common assessment template that enables mutual recognition of regulatory decisions, reduces duplication, and accelerates access to safe and effective products.

Implement reliance frameworks by leveraging regulatory assessments from comparable overseas regulators
This includes exploring various models of reliance and recognition mechanisms to facilitate faster patient access to SaMD products.

Streamline regulatory pathways for the introduction of SaMD products and their modifications
Authorities should consider implementing predetermined change management pathways (such as PCCPs) to support timely and predictable SaMD modifications, collaborate with software developers through Pre-Submission Consultations to align early on regulatory expectations, and offer flexible pathways for breakthrough or emerging technologies.

Ensure regulatory coherence by avoiding fragmented oversight across multiple government agencies
Disjointed or uncoordinated regulatory actions, especially in areas like cybersecurity, AI, and data governance, can lead to duplicative requirements, misaligned expectations, and increased compliance burdens for manufacturers. Close coordination among relevant authorities is essential to create a streamlined, predictable, and innovation-friendly regulatory environment.

Authors and Contributors

APACMed Secretariat:
Cindy Pelou, Lead, Regulatory Affairs
Devya Bharati, Associate, Regulatory Affairs

Authors and Contributors:
James Chan, Varian (a Siemens Healthineers company)
Mahesh Datar, Medtronic
Manan Hathi, Stryker
Mandy Tam, Zeiss
Sangam Biswal, Stryker
Sharad Shukla, Johnson & Johnson
Sheen Wei Wong, Roche Diagnostics
Soeun (Estella) Park, Philips
Victor Tan, Intuitive Surgical
Yasha Huang, Roche Diagnostics

This paper was developed with the contributions and collaborative efforts of the APACMed Digital Health Regulatory Working Group, comprising over 100 individual members, and over 30 companies, from across the industry.

The perspectives offered in this paper should not be construed as those of the individual contributors or the organisations they represent.

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About APACMed

Founded in 2014 and headquartered in Singapore, APACMed represents the medical technology industry in Asia Pacific, including manufacturers and suppliers of medical equipment, devices, services and in-vitro diagnostics. Providing a unified voice for the industry, APACMed works proactively with policy makers, regulators, and stakeholders to demonstrate the value of medical technology, promote innovation, and impact policy that advances healthcare access for patients in Asia Pacific. Visit us online at **www.apacmed.org**