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AI Regulations & Landscape in APAC

26th March 2025
3pm SGT

Webinar

Administrative Details

This webinar will be **recorded**, and materials will be available after the session.

There will be **10 minutes Q&A** session after the presentation. If you have any questions for the presenter, kindly share them via the **Q&A function in Zoom**.

Welcome Address

Devya Bharati
APACMed

Agenda

3.00 PM	Opening remarks	Devya Bharati (APACMed)
3.05 PM	• Key regulatory trends and developments in AI for MedTech across APAC • How regulatory frameworks are evolving and what to anticipate in 2025 • Opportunities for cross-border collaboration and harmonisation of AI regulations	Katherine Wang (Ropes & Gray)
3.50 PM	Q&A	Moderated By: Devya Bharati (APACMed)
3.55 PM	Closing Remarks	Devya Bharati (APACMed)

Presenter

Katherine Wang

Partner at Ropes & Gray LLP

ROPES & GRAY

Overview of AI regulatory Landscape in the Asia Pacific

Katherine Wang
Ropes and Gray

Regulatory Landscape for AI-enabled Medtech

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- Overview of AI
- International Regulatory Frameworks
- Asia Pacific Regulatory Frameworks

Regulatory Landscape for AI-enabled Medtech

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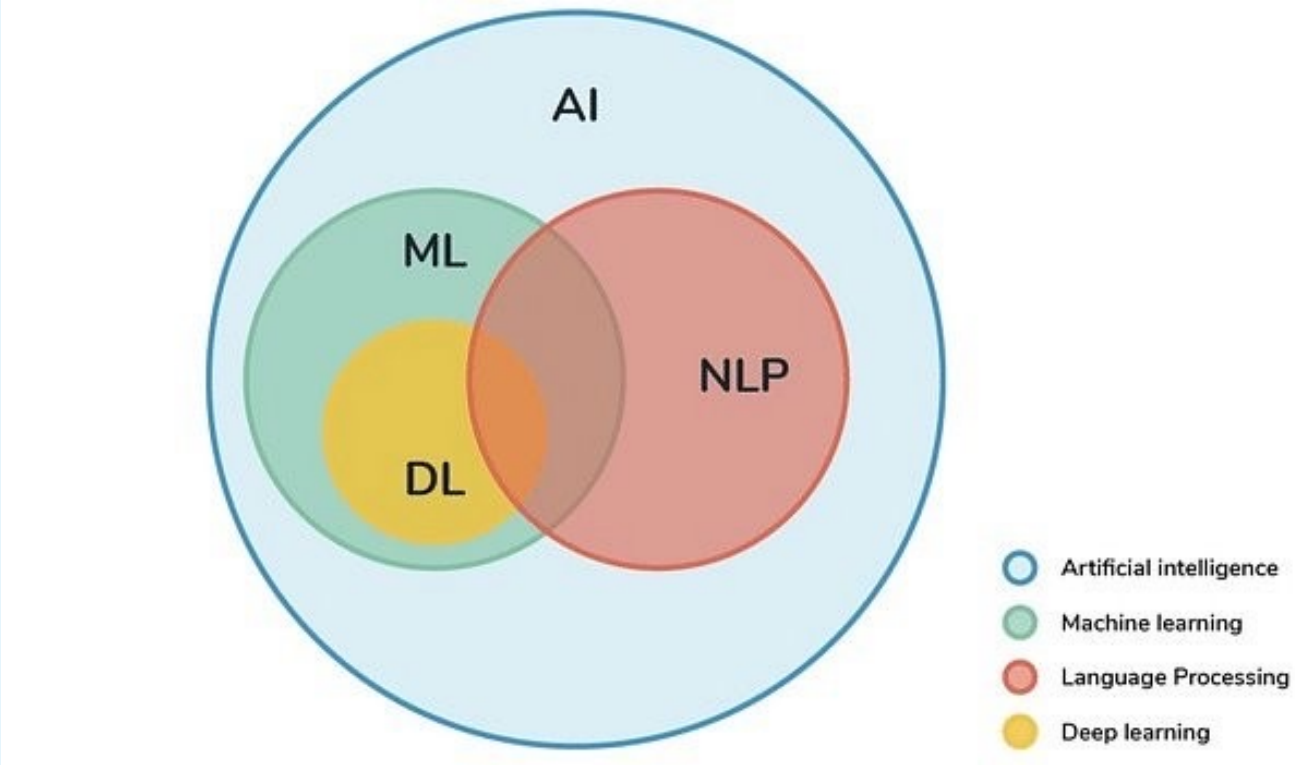
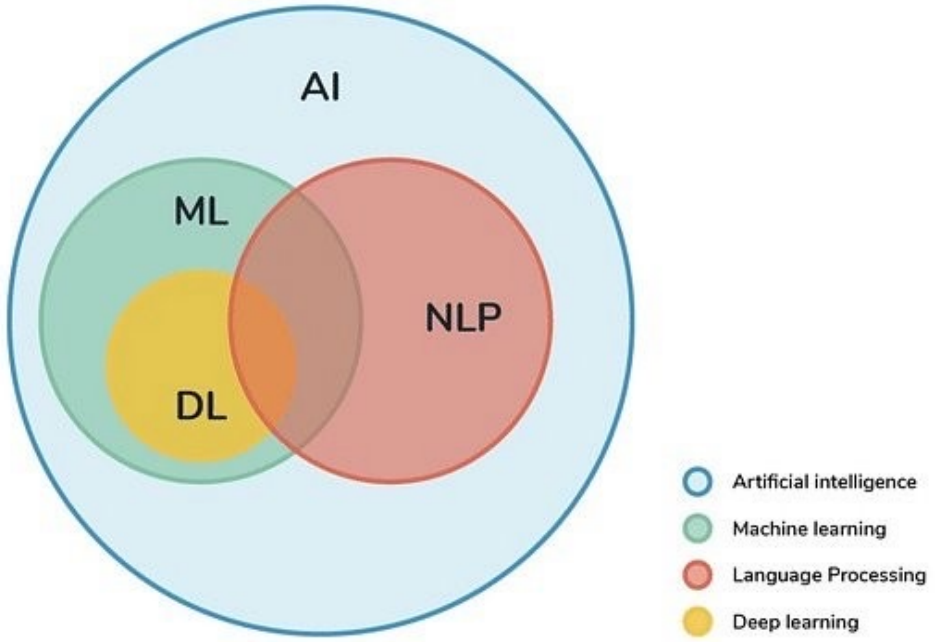
- **Overview of AI**
- International Regulatory Frameworks
- Asia Pacific Regulatory Frameworks

What is AI?


AI
ML
NLP
DL
Artificial intelligence
Machine learning
Language Processing
Deep learning

AI Techniques

- Machine Learning
  - Machine learning is a type of computer program that learns from data
- Deep Learning (Neural Networks)
  - Deep learning programs are a kind of machine learning where the program learns in a way that loosely mimics learning in the brain
- Natural Language Processing
  - Focuses on teaching computers to understand, interpret and generate human language



AI Concerns

1. **Bias and Discrimination**: AI models can learn, and replicate biases and prejudices present in the training data, resulting in discriminatory, unfair, or inaccurate outcomes when models are used in decision-making processes
2. **Misinformation and Fake Content**: AI models can be used to create fake content such as news articles, images, and videos, which can be used to spread misinformation and propaganda
3. **Privacy and Security Concerns**: AI models require access to large amounts of data, which may contain sensitive or personal information. If the data is not properly protected, it could be used for improper purposes or be accessed by unauthorized parties
4. **Ethical Concerns**: AI models can raise ethical questions around the use of technology to replicate or replace human creativity and decision-making and the impact of automation on employment and societal structures
5. **Unintended Consequences**: AI models may generate content that is harmful or offensive or create designs or products that are not feasible or safe

Regulatory Landscape for AI-enabled Medtech

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- Overview of AI
- **International Regulatory Frameworks**
- Asia Pacific Regulatory Frameworks

United States of America

European Union

U.S. : No AI-Specific Law 

- FDA does not have unique legislation or a distinct, established regulatory framework governing AI-enabled medical products.
- If an AI/ML-enabled product meets the definition of “medical device” under the Federal Food, Drug and Cosmetic Act (“FDCA”), FDA regulates such product as “Software as a Medical Device” (“SaMD”) under the traditional FDA regulatory framework for medical devices.
- Under this framework, developers of AI/ML-enabled algorithms must comply with various pre- and post-market requirements including, among other things:
  - Premarket notification or approval;
  - Establishment registration and device listing;
  - Quality System Regulation (“QSR”);
  - Medical device reporting; and
  - Labeling and promotional requirements.

U.S. : An Evolving and Flexible Approach 

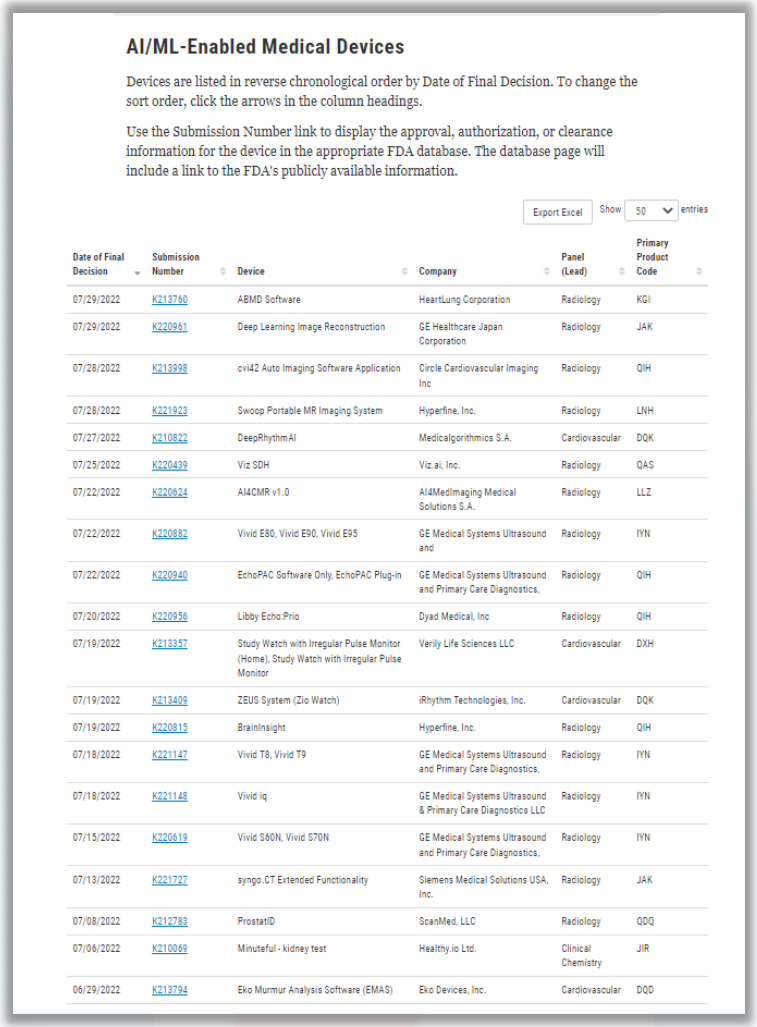
- Because FDA's traditional regulatory paradigm is not designed for adaptive AI/ML-enabled technology, FDA has indicated its intention to engage in regulatory flexibility to enable innovation while balancing safety and effectiveness.
  - FDA has sought significant input from industry and relevant stakeholders to inform the Agency's approach.
- FDA has issued numerous guidance documents, action plans, and papers—as well as a proposed regulatory framework—aimed at addressing considerations specific to AI-enabled medical devices.
- Key aspects of the Proposed Regulatory Framework that FDA published in 2019 for industry consideration include:
  - Good machine learning practices ("GMLP") applied to development;
  - Predetermined change control plan ("PCCP") reviewed with initial marketing application;
  - Some changes will require a new 510(k), while others may just be documented in change history;
  - Transparency about functions and modifications to promote trust; and
  - Real-world performance data monitored to understand product use in real-world and respond proactively to issues that arise.

U.S. : An Evolving and Flexible Approach

- **GMLPs**: FDA has expressed its commitment to developing internationally harmonized GMLPs.
  - In coordination with Health Canada and the United Kingdom's Medicines and Healthcare products Regulatory Agency ("MHRA"), FDA issued 10 guiding principles to inform the development of GMLPs.
- **PCCPs**: PCCPs are plans that describe pre-specified automatic and manual AI/ML-based modifications to device software products that would typically require an additional submission (e.g., PMA supplement, de novo submission, or new 510(k) notification).
  - FDA recommends that developers of AI/ML-enabled medical devices submit PCCPs as part of their marketing submissions in order to avoid the need for re-submission and review when the modification occurs.
  - To avoid the requirement of an additional marketing submission, the modification must be made consistent with the PCCP.
  - Where a pre-specified modification is made consistent with the PCCP, the manufacturer's only obligation is to document the modification in accordance with its quality system.
  - Any modification to an authorized PCCP will generally require a new marketing submission for the device.

U.S. : AI / ML – enabled SaMD

- FDA publishes a list of AI/ML-enabled devices that are legally marketed in the US (via 510(k) clearance, PMA, de novo authorization).
  - The list is not comprehensive.
  - As of March 10, 2025, the list includes 1,016 entries.
    - Shows rapid pace at which devices have been incorporating AI/ML technology in recent years.
  - Earliest entry is from 1995: PAPNET Testing System, which was cleared to aid in the rescreening of cervical pap smears previously reported as negative by detecting evidence of cervical epithelial abnormalities.
  - FDA updates this list on a periodic basis.



AI/ML-Enabled Medical Devices

Devices are listed in reverse chronological order by Date of Final Decision. To change the sort order, click the arrows in the column headings.

Use the Submission Number link to display the approval, authorization, or clearance information for the device in the appropriate FDA database. The database page will include a link to the FDA's publicly available information.

Export Excel Show 50 entries

Date of Final Decision	Submission Number	Device	Company	Panel (Lead)	Primary Product Code
07/29/2022	K213760	ABMD Software	HeartLung Corporation	Radiology	KGI
07/29/2022	K220961	Deep Learning Image Reconstruction	GE Healthcare Japan Corporation	Radiology	JAK
07/28/2022	K213998	cvi42 Auto Imaging Software Application	Circle Cardiovascular Imaging Inc	Radiology	QIH
07/28/2022	K221923	Swoop Portable MR Imaging System	Hyperfine, Inc.	Radiology	LNH
07/27/2022	K210822	DeepRhythmAI	MedicalgorithmicS S.A.	Cardiovascular	DQK
07/25/2022	K220439	Viz SDH	Viz.ai, Inc.	Radiology	QAS
07/22/2022	K220624	AI4CMR v1.0	AI4MedImaging Medical Solutions S.A.	Radiology	LLZ
07/22/2022	K220882	Vivid E80, Vivid E90, Vivid E95	GE Medical Systems Ultrasound and	Radiology	IYN
07/22/2022	K220940	EchoPAC Software Only, EchoPAC Plug-in	GE Medical Systems Ultrasound and Primary Care Diagnostics,	Radiology	QIH
07/20/2022	K220956	Libby Echo:Prio	Dyad Medical, Inc	Radiology	QIH
07/19/2022	K213357	Study Watch with Irregular Pulse Monitor (Home), Study Watch with Irregular Pulse Monitor	Verily Life Sciences LLC	Cardiovascular	DXH
07/19/2022	K213409	ZEUS System (Zio Watch)	iRhythm Technologies, Inc.	Cardiovascular	DQK
07/19/2022	K220815	BrainInsight	Hyperfine, Inc.	Radiology	QIH
07/18/2022	K221147	Vivid T8, Vivid T9	GE Medical Systems Ultrasound and Primary Care Diagnostics,	Radiology	IYN
07/18/2022	K221148	Vivid iq	GE Medical Systems Ultrasound & Primary Care Diagnostics LLC	Radiology	IYN
07/15/2022	K220619	Vivid S60N, Vivid S70N	GE Medical Systems Ultrasound and Primary Care Diagnostics,	Radiology	IYN
07/13/2022	K221727	syngo.CT Extended Functionality	Siemens Medical Solutions USA, Inc.	Radiology	JAK
07/08/2022	K212783	ProstatID	ScanMed, LLC	Radiology	QDQ
07/06/2022	K210069	Minuteful - kidney test	Healthy.io Ltd.	Clinical Chemistry	JIR
06/29/2022	K213794	Eko Murmur Analysis Software (EMAS)	Eko Devices, Inc.	Cardiovascular	DQD

EU: The AI Act

- The AI Act (Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence) is the first overarching AI legislation.
- Applies to all AI systems placed on the market or put into service in the EU.
- Categorises AI systems and their respective obligations into 4 risk categories: (1) prohibited practices/unacceptable risk; (2) high-risk; (3) limited risk; and (4) minimal risk.
  - Medical devices (including in vitro devices) that incorporate AI/ML-enabled device functions will likely be classified as high-risk AI system.
  - AI systems used for certain other purposes deemed high risk such as evaluation of a person's eligibility for essential healthcare services and emergency triage of healthcare are also within scope of the AI Act and may be subject to the regulatory framework for high -risk AI systems even if they do not qualify as a medical device.

EU: AI Act Obligations

- The AI Act sets forth specific obligations for high-risk AI systems, many of which duplicate, and overlap with the conformity assessment procedures already required under Medical Devices Regulation (“MDR”) and In Vitro Medical Device Regulation (“IVDR”).
- Obligations for **high-risk AI systems** include:
  - risk assessment and mitigation systems;
  - systems trained on the basis of training, validation and testing data sets that meet stipulated quality criteria;
  - technical documents sufficient to demonstrate compliance with AI Act requirements;
  - logging of activities (automatic record-keeping);
  - designed to ensure provision of information for deployers on the operation of a high-risk AI system. Information must be sufficiently transparent and be accompanied by instructions for use
  - enable human oversight;
  - perform with appropriate level of accuracy, cybersecurity and robustness.
- To ensure AI systems are developed and used in a manner that is safe, transparent and respects fundamental rights, the AI Act in the EU implements significant penalties for non-compliance of prohibited AI practices. These penalties are up to €35 million or 7% of global turnover for the preceding financial year, whichever is higher. These penalties will apply from 2 August 2025.

EU: SaMD Definition

- Medical device software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a “medical device” in the medical devices regulation or in vitro diagnostic medical devices regulation.

Medical Device Software	In Vitro Medical Device Software
Article 2 (1) of Regulation (EU) 2017/745 – MDR defines when software should qualify as Medical Device Software. The following considerations should apply on the provision of information by software on: a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease b) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, c) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, d) control or support of conception; e) products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and Annex XVI products	Software which provides information according to Regulation (EU) 2017/746 – IVDR Article 2(2) (a) to (f) should qualify as In Vitro Diagnostic Medical Device Software: a) concerning a physiological or pathological process or state (by investigation of this process or state); or b) concerning congenital physical or mental impairments c) concerning the predisposition to a medical condition or a disease; d) to determine the safety and compatibility with potential recipients; e) to predict treatment response or reactions; f) to define or monitoring therapeutic measures.

EU: AI/ML Considerations

- **Clinical trials:** The use of AI/ML within the context of clinical trials should meet applicable requirements in the ICH E6 guideline for good clinical practice (GCP).
- **Precision medicine**: AI/ML can be used to individualise treatment in relation to factors such as disease characteristics, patient genotype, wide-band biomarker panels and clinical parameters. This could include patient selection, dosing, de novo design of product variants and selection from a pre-manufactured library of variants.
- **Product Information**: AI/ML applications used for drafting, compiling, editing, translating, tailoring, or reviewing medicinal product information documents should be used under close human supervision.
- **Manufacturing**: The use of AI/ML in the manufacturing of medicinal products including process design and scale up, process optimisation, in-process quality control and batch release is expected to increase in the coming years. Model development, performance assessment and life-cycle management should follow the quality risk management principles, taking patient safety, data integrity and product quality into account. For human medicines, the principles of ICH Q8, Q9 and Q10 should be considered, awaiting revision of current regulatory requirements and GMP standards.
- **Post-authorisation**: Applications within pharmacovigilance may allow a more flexible approach to AI/ML modelling and deployment, where incremental learning can continuously enhance models for classification and severity scoring of adverse event reports as well as signal detection. However, it remains the responsibility of the MAH to validate, monitor and document model performance and include AI/ML operations in the pharmacovigilance system, to mitigate risks related to all algorithms and models used.
- **Regulatory Interactions**: Applicants and developers are expected to perform a regulatory impact and risk analysis of all AI/ML applications and are recommended to seek regulatory interactions when no clearly applicable written guidance is available. Early interaction on experimental technology is provided by the EMA Innovation Task Force (ITF). Scientific advice and qualification of novel methodologies in medicines development is provided by the Scientific Advice Working Party (SAWP) of the CHMP and the Scientific Advice Working Party (SAWP) of the CVMP.
- **Governance**: SOPs implementing GxP principles on data and algorithm governance should be extended to include all data, models and algorithms used for AI/ML in cases of high regulatory impact or high patient risk. Aspects related to the governance of all components used, the application of data protection and compliance with applicable data protection laws and ethical standards should be documented and regularly reviewed.

Regulatory Landscape for AI-enabled Medtech

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- Overview of AI
- International Regulatory Frameworks
- **Asia Pacific Regulatory Frameworks**

China

Japan

South Korea

Australia

Singapore

China: No Overarching Law on AI

- There is no overarching law governing AI in China.
  - China's National People's Congress has urged the State Council to consider drafting an overarching statute.
- The current regulatory system consists mainly of administrative regulations and standards.
  - Tentative administrative measures on generative AI focuses on legitimacy of data, protection of privacy and safe use of networks.
  - Multiple agencies plan to roll out an integrated system of standards that govern the framework, common technical requirements, core technology, enabling technology, industry applications and risk mitigation of AI in the next five years.

China: Defining SaMD

- SaMD is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.
  - Software in a Medical Device ("SiMD"): embedded software
- Intended medical purposes include:
  - provide **means and suggestions for mitigation of a disease**;
  - **provide information** for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities; or
  - be an **aid** to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.

China: General Considerations for SaMD

- **Lifecycle Management**: Applicants must establish and document the software lifecycle processes, including development, maintenance, and updates.
- **Software Verification and Validation**: Detailed verification and validation activities must be performed to ensure the software meets its intended use and user needs.
- **Risk Management**: Comprehensive risk management activities must be conducted, including risk analysis, risk evaluation, risk control, and residual risk assessment.
- **Clinical Evaluation**: Clinical evaluation is required to demonstrate the safety and effectiveness of the software. This can include clinical trials, literature reviews, and performance comparisons with existing devices
- **Documentation**: Comprehensive documentation must be submitted for approval, including software design specifications, risk management reports, verification and validation reports, and clinical evaluation reports.

China: AI/ML-enabled SaMD

- A SaMD that uses AI technology to process medical device data to achieve its intended use.
  - Medical device data refers to objective data generated by medical devices or general equipment (i.e., mobile devices) for a medical use, including medical images, physiological data, IVD results or cardiovascular disease alerts
- AI/ML-based SaMD is typically approved as an aid to disease diagnosis and predisposition.
  - 11 AI/ML-based SaMD have been approved for cardiovascular, ophthalmology, and respiratory diseases as of December 2024

China: Considerations for AI-ML- based SaMD

- **Algorithm Transparency**: Detailed information about the AI/ML algorithms used, including their type, structure, input/output data, and training methods, must be provided. This includes supervised and unsupervised learning algorithms.
- **Data Quality and Management**: High standards for data quality and management must be maintained, including data collection, preprocessing, and annotation. The data used for training and validation must be representative and free from bias.
- **Performance Evaluation**: The performance of AI/ML algorithms must be rigorously evaluated using appropriate metrics such as sensitivity, specificity, accuracy, and robustness. This includes stress testing and adversarial testing to assess the limits of the algorithm's performance.
- **Clinical Trials for AI/ML Devices**: Clinical trials must be designed to evaluate the diagnostic performance of AI/ML devices. This includes using real-world data and ensuring that the data used in trials is independent of the training data.
- **Post-Market Surveillance**: Continuous monitoring and evaluation of the AI/ML software's performance in the real world are required. This includes collecting and analyzing user feedback, adverse events, and performance data to identify and mitigate any new risks.
- **Regulatory Compliance**: AI/ML software must comply with existing regulations and standards, including cybersecurity requirements, data privacy laws, and quality management system standards.
- **Software Updates**: Any updates to the software, whether algorithm-driven or data-driven, must undergo appropriate verification and validation to ensure continued safety and effectiveness. Major updates require re-evaluation and possibly re-registration.
  - China does not have a scheme for predetermined change control plans. Therefore, it may be burdensome for marketing authorization holders to seek approvals for post-approval changes.

Japan: Regulation of AI/ML

- Japan does not currently have a comprehensive law governing AI. AI regulation occurs at the individual sector level in relevant industries.
- In the healthcare and life sciences industries, there are certain laws that relate to the regulation of AI/ML-enabled tools, including:
  - In 2023, the Next-Generation Medical Infrastructure Act was implemented to facilitate the use of AI in research and development in the medical field and to promote research and development of AI-enabled diagnostic tools.
  - AI/ML-enabled algorithms that meet the definition of "medical device" under the Pharmaceuticals and Medical Devices Act ("PMD Act") are subject to regulation as medical devices under the PMD Act's regulatory framework.
- The Ministry of Health, Labour and Welfare ("MHLW"), the Pharmaceuticals and Medical Devices Agency ("PMDA"), and the Japan Agency for Medical Research and Development ("AMED") have established various committees and commissioned studies and reports to inform the development of rules and regulations specifically targeting AI/ML-enabled SaMD.
  - The Subcommittee on Software as a Medical Device Utilising AI and Machine Learning of the PMDA's Science Board has published reports summarizing key regulatory considerations related to AI-based SaMD.
  - PMDA has sought to organize and publish information on key evaluation and review points (particularly as it relates to safety and efficacy evaluations of AI-enabled SaMD) to assist developers of these technologies and to make the review and approval process more transparent.

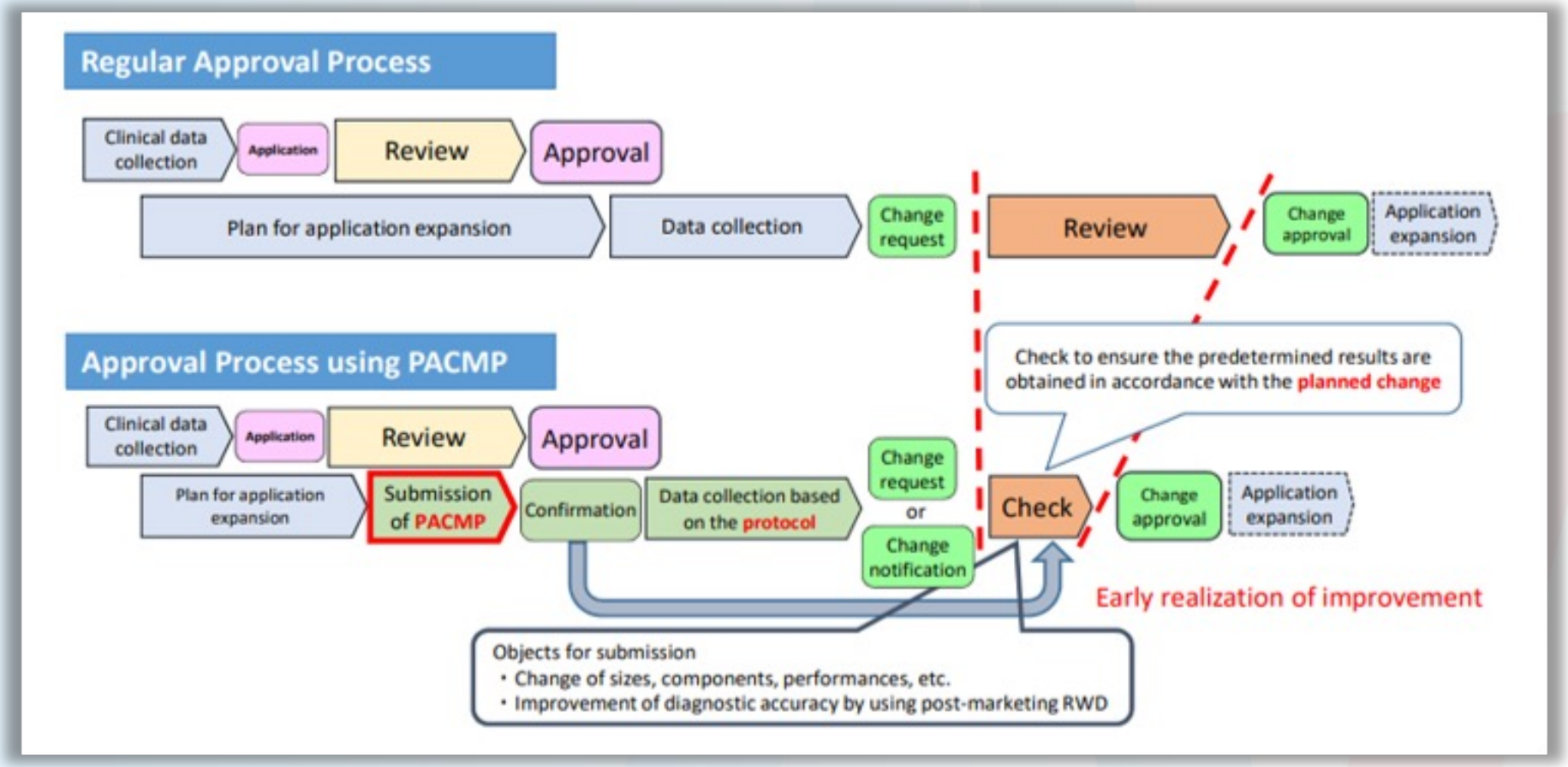
Japan: Regulation of AI under the PMD Act

- The PMD Act requires that, among other things, AI/ML-enabled SaMD obtain approval to be manufactured and sold.
  - Whether an AI-based software constitutes a “medical device” is a case-specific inquiry, but MHLW’s regulatory framework relies on two key questions:
    - How much does the programmed medical device contribute to the treatment, diagnosis, etc., of diseases in view of the importance of the results obtained from the programmed medical device?
    - What is the overall risk, including the risk of affecting human life and health in the event of impairment, etc., of the functions of the programmed medical device?
- While the PMD Act is not specific to AI/ML-enabled products, the law was amended in 2019 to, among other things, accommodate AI/ML-enabled medical devices by establishing the Post-Approval Change Management Protocol (“PACMP”).

Japan: Post-Approval Change Management Protocol

- PACMP was established as an approval review system for medical devices to enable continuous improvement of performance throughout the product lifecycle.
- PACMP anticipates that the marketing authorization holder will develop a process that ensures that the planned changes serve to improve the product, and submit that plan as part of the approval review process.
- PACMPs are also referred to colloquially as “Improvement Design within Approval for Timely Evaluation Notice” (“IDATEN”).

Japan: Post-Approval Change Management Protocol



Japan: Considerations for AI/ML -based SaMD

- **Clinical Trials for AI/ML Devices**: Appropriate clinical evaluation methods that take into account future trends in research and the development of related technologies.
- **Minimization of Bias**: Efforts should be made to scientifically reduce bias, including through the careful use of numerical simulation in the development and study of AI/ML-enabled devices.
- **Post-Market Evaluation**: Developers and regulators must consider whether post-market prospective or randomized clinical trials are necessary to evaluate performance improvement made by post-market learning.

South Korea: Regulation of AI/ML

- On 26 December 2024 South Korea passed the Basic Act on Artificial Intelligence and Establishment of Trust (“Basic AI Act”) which is set to take effect on 22 January 2026.
- The Digital Medical Products Act (DMPA), effective as of January 24, 2025 provides the basis for a regulatory framework governing digital medical devices.
    - The DMPA establishes a regulatory system that reflects the characteristics of digital products. AI/ML-enabled medical devices is subject to the DMPA regarding its approval, quality control and monitoring, compliance with statutory/mandatory performance standards, and the MFDS’s responsibility for implementing a three-year plan to control product risks.

South Korea: Basic AI Act

- Applies to any AI activities that impact the South Korean market, regardless of whether they originate domestically or overseas.
- Classifies AI based on risk:
  - High-impact AI is defined as systems with significant effects on human life, safety, or fundamental rights, such as AI used in healthcare, hiring, loan screening, or biometric analysis.
  - High-impact AI operators must perform impact assessments on fundamental rights and document safety measures and have human oversight.
  - Generative AI systems that mimic input data to generate outputs such as text, sound, images, and other creative content.
- Businesses adopting high-impact or generative AI systems are required to provide users with advance notice if their products or services incorporate AI elements or are artificially created
- Will require AI providers to establish an in-country representative to ensure products comply with prescribed safety and governance requirements.
- The Act introduces fines of up to KRW 30 million (~$20,870) and potential imprisonment for violations, with detailed implementation plans to be developed by the Ministry of Science and ICT.

South Korea: Regulation of SaMD

- MFDS has guidelines to regulate and monitor the use of AI/ML-enabled SaMD that highlight, among other things, the criteria for identification and classification of AI-based SaMD.
- MFDS defines SaMD based on its intended use, the hazard it can cause when it doesn't work as intended and whether the software guarantees the clinical judgment of a medical professional. SaMD includes:
  - Software that diagnoses, predicts, or monitors the possibility of diseases, including the existence of disease and condition, or treats diseases using clinical information; or
  - Software that provides clinical information for diagnosis and treatment by analyzing the medical image, signal from in-vitro diagnostic medical device, and a pattern or signal from the signal acquisition system.
- Medical devices, including AI/ML-enabled SaMD are classified into one of four risk classes based on the degree of risk posed to the patient by using the device.
  - This classification determines the regulatory submission requirements, as well as what other regulatory requirements apply.

South Korea: Change Approval and Certification

- The MDFS previously require pre-approvals and certification for changes that affected safety and effectiveness. Changes that improve the accuracy level of the algorithm through modification and expansion of training data without any design modification of the SaMD would be exempt from change approval and certification requirements.
- The DMPA reflects the IMDRF's latest regulatory consideration of Predetermined Change Control Plan.
  - Marketing authorization applicants can submit a change management plan of their SaMD applications. Once the plan is approved by the MFDS, the manufacturers can implement the predefined changes without seeking additional approvals.

South Korea: Considerations for AI/ML -based SaMD

- **Training Data**: Manufacturers and developers of AI/ML-enabled SaMD should establish policies on data management to consistently maintain the effectiveness of training data.
- **Clinical Validation**: Manufacturers and developers of AI/ML-enabled SaMD must perform clinical studies to establish clinical effectiveness using appropriate measures such as sensitivity, specificity, and positive and negative predictive value.
- **Clinical Studies**: Because retrospective studies can generate results quickly and efficiently, MFDS has introduced the possibility of using retrospective studies, prospective studies, or prospective/retrospective studies where both are conducted in parallel for validation of AI/ML-enabled SaMD. However, because retrospective studies use existing medical data, trials should be designed considering various issues, such as collecting the clinical trial dataset and establishing the primary endpoints.
- **Cybersecurity**: Manufacturers and developers of AI/ML-enabled SaMD must demonstrate that their device is devoid of cybersecurity vulnerabilities, including by recording risk management activities and identifying cybersecurity hazards throughout the total product life cycle.
- **Regulatory Compliance**: AI/ML software will be subject to a desktop GMP review with selective onsite audit. They will also be eligible for exemption of certain provisions of the Medical Device Act (e.g. sales report, standards, renewal or adverse event reporting).

Australia: No Overarching Law on AI

- There is no overarching or specific laws that directly regulate AI in Australia.
- Intention is to implement a principles-based approach or list-based approach (similar to EU) to define “high-risk AI”
- There are two guidance documents which address AI:
  - The AI Ethics Principles (2019)
    - Comprises of 8 voluntary principles for the responsible design, development and implementation of AI
    - These are consistent with OECD principles
  - The Voluntary AI Safety Standard (2024)
    - Comprises of 10 voluntary guardrails that cover aspects such as transparency with other organizations, accountability processes and risk management of AI
    - Practical guidance for Australian organizations to mitigate risks while leveraging the benefits of AI

Australia: Regulation of SaMD

- Software is classified as a medical device if it is intended to be used for one or more of the following purposes:
  - diagnosis, prevention, monitoring, prediction, prognosis or treatment of a disease, injury or disability
  - compensation for an injury or disability
  - investigation of the anatomy or of a physiological process
  - to control conception
  - is an accessory to a medical device
- There is an exemption for Clinical Decision Support Software (CDSS) if it meets all 3 of the below criteria. Exempt CDSS still classifies as a medical device but is not subject to all regulatory requirements.
  1. does not directly process or analyse a medical image or a signal from another medical device (including an in vitro diagnostic device)
  2. 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
  3. does not replace the clinical judgement of a health professional in relation to making a clinical diagnosis or decision about the treatment of patients.
- Digital Therapeutics (DTx) is considered to be health software intended to treat or alleviate a disease, disorder, condition, or injury. It works by generating and delivering a medical intervention that has a demonstrated positive impact on a patient's health. This is regulated as a subset of SaMD.

Australia: Considerations for AI/ML -based SaMD

- **Safety:** must be designed and produced in a way that ensures safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; consequent risks are eliminated or reduced; device is resilient; device provides suitable warnings if relevant; device provides a means for correct operation by user; the integrity and quality of data is maintained; privacy od data or information is maintained.
- **State of the art:** must be developed, produced and maintained having regard to the generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution)
- **Consideration of platforms and external factors:** must be designed and developed taking into account the capability, resources and configuration of the platforms and the external factors (including information technology environments) related to the use of the platforms
- **Instructions:** must provide instructions or information with the device that sets out requirements (including requirements about hardware, software, information technology environments and security measures) necessary to operate the device as intended.
- **Cybersecurity:** must be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device.
- **Data influences:** data that influences the performance of the device must be: (i) representative; (ii) of sufficient quality; (iii) maintained to ensure integrity: and (iv) managed to reduce bias.

Australia: Post-market Considerations

- **Evidence requirements:** Evidence requirements for SaMD continue through the product lifecycle and include robust post-market monitoring practice to ensure continued device performance and model accuracy.
- **Changes to device**: any changes to SaMD may change its regulatory status and may require a Device Change Request or a variation.
- **Registration:** Australian manufacturers of SaMD will also be required to include their medical devices in the ARTG and to comply with the requirements for maintaining the inclusion.
- **Version number and build numbers**: For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device.

Singapore: No Overarching Law on AI

- Currently, there are no specific laws, statutory rules, or regulations in Singapore that directly regulate AI.
- The Singapore government has developed various frameworks and tools to guide AI deployment and promote the responsible use of AI, including:
  - The Model AI Governance Framework: provides detailed guidance to private sector organizations to address key ethical and governance issues when deploying AI solutions
  - AI Verify: an AI governance testing framework and toolkit designed to help organizations validate the performance of their AI systems against AI ethics principles through standardized tests
  - The National Artificial Intelligence Strategy 2.0: outlines Singapore's ambition and commitment to building a trusted and responsible AI ecosystem, driving innovation and growth through AI, and empowering its people and businesses to understand and engage with AI
  - Artificial Intelligence in Healthcare Guidelines: aims to improve the understanding, codify good practice and support the safe growth of AI in healthcare
- The Health Products Act 2007, requires medical devices that incorporate AI technology are registered before they are used.

Singapore: Regulation of SaMD

- Software with an intended use that falls under the definition of a medical device as stipulated in the Health Products Act:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;
  - investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;
  - supporting or sustaining life;
  - control of conception;
  - disinfection of medical devices; or
  - providing information by means of in-vitro examination of specimens derived from the human body, for medical or diagnostic purposes,
- This includes software embedded in medical devices, standalone software, standalone mobile applications and web-based software.

Singapore: Considerations for AI/ML -based SaMD

- **Design verification and validation:** this should include the results of all verification, validation and tests performed in-house and/or simulated user environment for the software prior to its final release and include objective evidence that demonstrates specified requirements are fulfilled and defined software specifications conform to user needs and intended use.
- **Clinical evaluation:** the association between the software output and clinical condition can be substantiated by one or more of the following: (i) referencing existing literature and well-established clinical guidelines; (ii) comparison with similarly established software medical devices in the market and/or; (iii) performing clinical studies for novel claims.
- **Cybersecurity:** minimum necessary requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to ensure the safe use of the software as intended should be implemented.
- **Additional information for submission**: input data and feature attributes used to generate corresponding outputs; source, size and attribution of training, validation and test datasets; AI model selection; test protocol and report for verification and validation of AI medical device ("AI-MD"); performance of AI-MD; clinical association between AI-MD's output and clinical condition; device workflow including how the output result should be used; interval for training data update cycle; software version to be supplied in Singapore and the procedure or plan implemented to trace the software version for subsequent iterations.
- **Continuous learning capabilities:** the learning process should be defined by the manufacturer and appropriate process controls should be put in place to effectively control and manage the learning process. There should be validation processes incorporated within the system to closely monitor the overall learning and the evolving performance of the AI-MD post learning. A robust process control must be in place.

Singapore: Post-market Considerations

- **Risk management**: where changes are made to software, these should be systemically evaluated to determine if any additional risk could arise from these changes. Where necessary, additional risk control measures should be considered.
- **Traceability:** Developers and distributors should establish a process in collaboration with the implementers and users to ensure traceability.
- **Monitoring**: implement mechanisms to monitor and review the performance of the AI-MD deployed in clinical setting. Such monitoring could be in the form of autonomous monitoring embedded in the system.
- **Surveillance model:** a robust surveillance model to ensure that AI-MD especially those with continuous learning algorithms remain accurate and to prevent any concept drifts should be implemented.
- **Change notifications**: The HSA introduced a new optional regulatory pathway to enable pre-specified SaMD software changes post-registration, based on manufacturers' demonstration of robust quality management practices. The change management program and the product application will be reviewed by the HAS concurrently.

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Q&A

https://tinyurl.com/rate-event

Thank you!

If you have any questions or feedback, kindly contact sfong@apacmed.org or devya@apacmed.org