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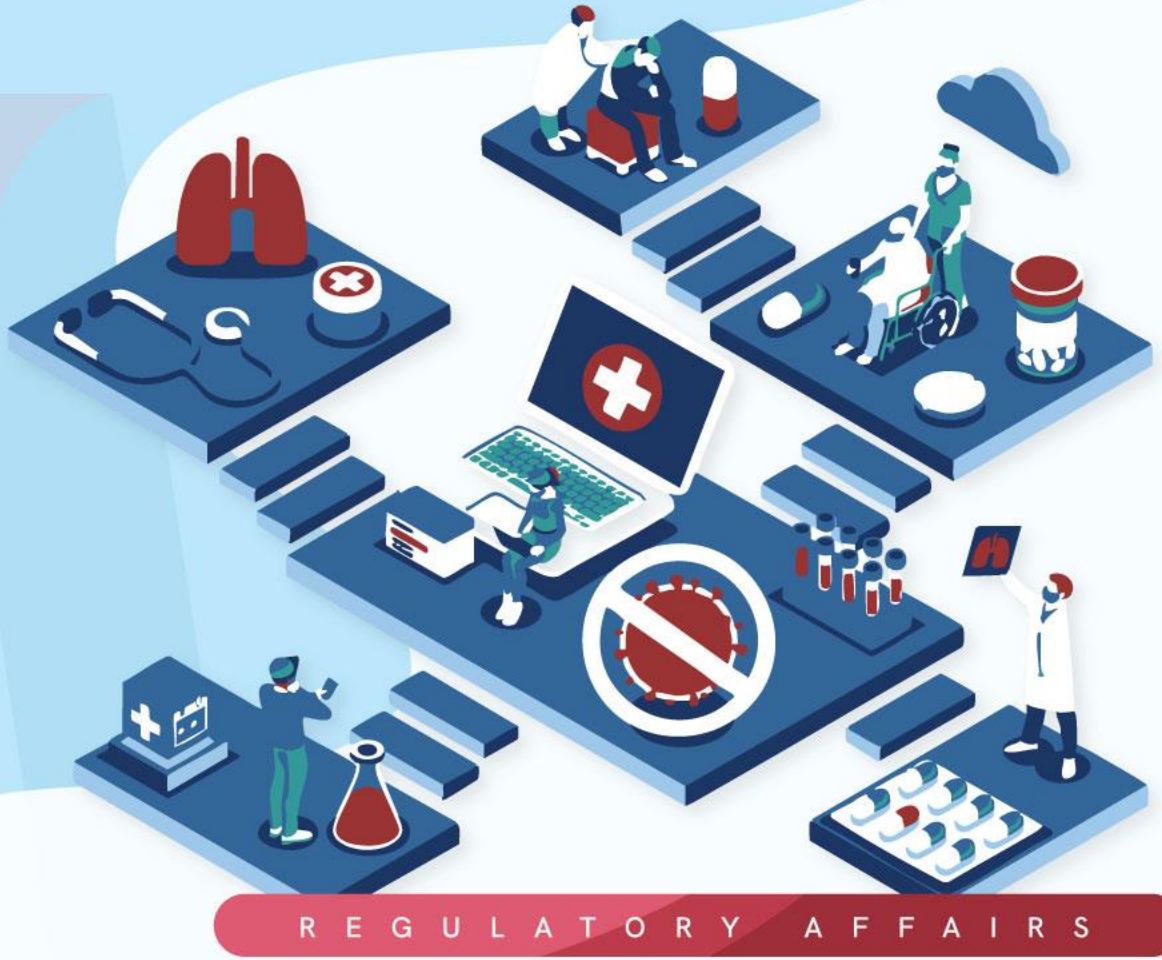
Shaping the Future of SaMD Regulation in Asia-Pacific



TUE | 4 NOV 2025
10.00 AM - 11.00 AM SGT
AVAILABLE ON TEAMS

Agenda

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2’	Closing

Opening Remarks & Introduction

APACMed

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ONE

Voice

The unifying voice for the medical devices, in-vitro diagnostics and digital health industry in APAC.

Mission

To improve the standards of care for patients in APAC through strategic collaborations with MedTech stakeholders.

APACMed Membership – 350 Members

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60 Corporates

160 Start-ups

65 Associates

20 Industry Associations

Our work in the SaMD space

2020
DH Workshop with Singapore HSA and TGA Australia

2023
SaMD Training during AMDC
SaMD Workshop with Thai FDA
SaMD presentation GHWP Shanghai

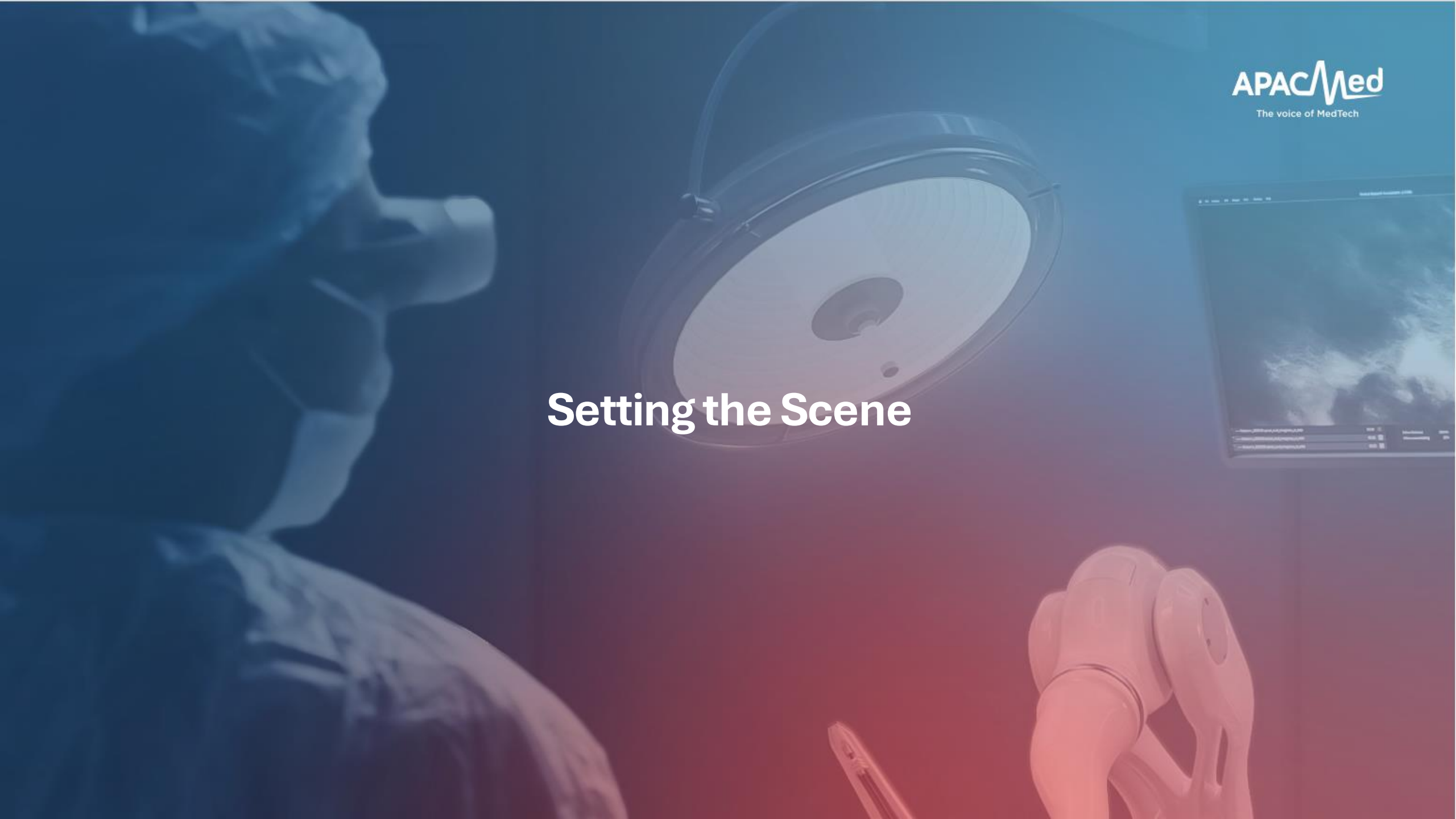
2024
SaMD presentation during GHWP KL and AMDC
SaMD Workshops with Indonesia, Malaysia, Philippines

Sept 2020
Publication of our SaMD Position Papers

2021
DH Workshop with Singapore HSA

2024
Publication of our CM Paper
PCCP Presentation during our RA Forum

2025
CDSCO Updating SaMD
CM/PCCP and AI/ML Trainings with Malaysia MDA
SaMD Workshop with Vietnam IMDA
DH & AI/ML Training during APACMed RA Forum



Setting the Scene

Advancing SaMD Regulations in Asia - Pacific

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What did we set to achieve

Overview of rapidly evolving SaMD landscape & regulatory challenges

Utilise the IMDRF framework and review current regulations in the region (Japan, Australia and Singapore)

Review the IMDRF SaMD Working Group documents and compare them against the existing regulations

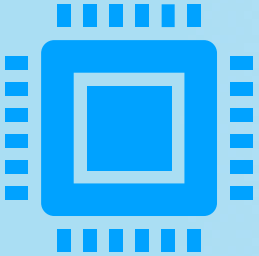
IMDRF

Why Now?

- **Rapid growth of SaMD**
- **Emerging different stakeholders which were not typically part of this ecosystem** (consumers and software developers)
- **Harmonisation will make the SaMD access quicker across the region** and will not be a challenge for new stakeholder groups such as Software Developers

Key Highlights from the SaMD Paper

Qualification: Is it a medical device?



Software applications in Healthcare are varied, with differing levels of risk

Administrative, scheduling, billing algorithms

EMR, data transfer functionality

Clinical Decision support

Diagnostic/therapeutic applications

Regulator resources are limited

Primary mandate, protect public health

Critical to use limited resources to manage software that meets medical device definition

Strategic Recommendation: Focus regulatory oversight on applications that truly meet the definition of a medical device

One Platform, Many Purposes: Rethinking Oversight in a Software-Driven World

- Clinical Decision Support
  - **Regulated**
  - Full qualification and Oversight
- Data Visualization
  - Non-regulated
  - Evaluate for impact only
- Wellness Tracker
  - Consumer Feature
  - No oversight
- Reminder system
  - User engagement
  - No oversight

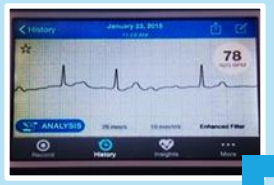
Oversight — Regulatory oversight should focus solely on functions meeting medical device definitions.

Impact — Non-regulated functions must be evaluated only for their impact on regulated components.

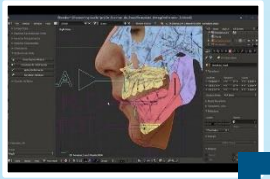
Innovation — This risk-based approach fosters innovation while ensuring public health protection.

Classification: Does all SaMD pose the same risk?

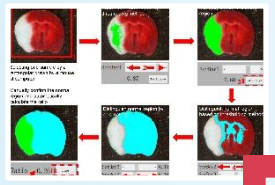
Not all SaMD is created equal—its risk profile can range from benign to life-critical



Evidence Based Suggestions – Physician ultimate Decider



Supports Clinical Insight – used alongside Physician Judgement



Directly suggests Dx or Rx – requires robust validation

Minimal Risk

Just like traditional medical devices, SaMD demands risk-based oversight—because its impact can be as subtle as a nudge or as decisive as a diagnosis

High Risk

Fit For Purpose Regulatory Pathways

Expedited Review Pathways

Designed to provide faster pre-market decisions

- Breakthrough Devices
- Safer Technologies Program (STeP)

- SAKIGAKE Designation System

- Priority Review Scheme
- NextGen MD initiative

Recognition

Recognition: accept regulatory decision of another trusted jurisdiction

- Reliance on USFDA, Japan, Singapore and Health Canada

- Leverages approvals in Australia, USFDA, Health Canada, EU and Japan

Reliance

Reliance: consider / give significant weight to assessments performed by another jurisdiction

Change Management

Allow MFGs to attain preapproval for specific post market changes, with a plan to maintain S&E

- Predetermined Change Control Plan (PCCP)

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

- Change Management Program (CMP)

Presubmission Consultation Matters

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Improved Submission Quality

Early engagement with regulators enhances the quality of submissions by clarifying requirements and expectations efficiently.

Faster Review Timelines

Consulting regulators early helps shorten review times, benefiting manufacturers and regulatory staff alike.

Clearer Regulatory Pathways

Presubmission consultation provides clearer pathways, helping manufacturers avoid pitfalls and ensure robust data requirements.

Global Consultation Schemes

Various international programs, such as FDA's Pre-Submission or PMDA's Consultation, offer structured regulatory advice to manufacturers.

Emerging Considerations

Cybersecurity

- Critical for patient safety, data privacy, and system integrity
- Need for secure by design principles
- Alignment with global standards (ISO/IEC 27001, IEC 81001-5-1)

Robotics

- Increasing integration of software/AI in RASD
- Regulatory frameworks need to evolve
- Complex, system-level risk while supporting innovation

Recommendations

Fit for Purpose

Qualification: Clear criteria for software qualification aligned with intended use

Classification: based on the healthcare situation and significance of information presented – IMDRF N12 and N81

Risk Based approach

Exclude or exempt low risk CDSS– harmonize with global regulators

Special controls for higher risk CDSS and SaMD

Real-World Evidence – for continuous oversight

Tailored Oversight

Ensure regulatory oversight is commensurate with risk

Regulatory oversight focused only on functions that meet device definition

Collaboration

Foster collaboration among regional health authorities

Encourage policy dialogue focused on digital health and SaMD pathways leveraging expertise among regulators and industry partners via APACMed

For more information, read our new position paper

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SCAN ME

https://apacmed.org/wp-content/uploads/2025/06/SaMD-Report_updated.pdf

TGA Reflections on APACMed Paper – Advancing software as a medical device regulations in Asia-Pacific

Gabrielle Harradine
A/g Director Medical Device Software Devices
Specialist Evaluation Section
TGA Australia

HSA Reflections on APACMed Paper – Advancing software as a medical device regulations in Asia-Pacific

Ching Siang Chin
Senior Regulatory Specialist,
Digital Health Branch,
HSA Singapore

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Panel Discussion

Australian Government
Department of Health
Therapeutic Goods Administration

HSA

Gabrielle Harradine
TGA Australia

Chin Ching Siang
HSA Singapore

Sharad Shukla
Johnson & Johnson

Manan Hathi
Stryker

Mahesh Datar
Medtronic

Mandy Tam
Zeiss

Aaditya Vats
Terumo Asia Holdings

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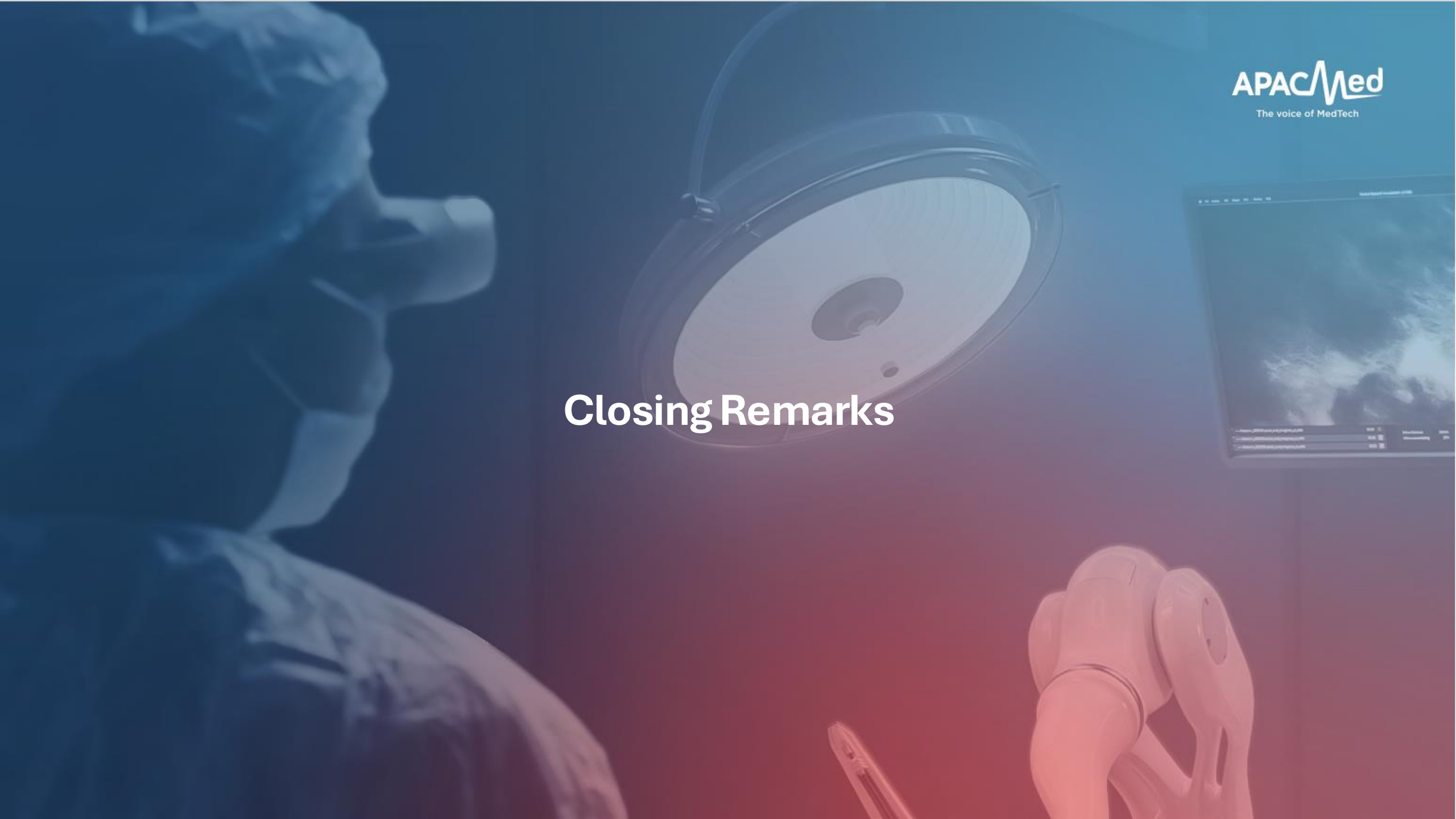

Closing Remarks

Call to Action

For Authorities

Partner with APACMed in upcoming closed-door roundtables to discuss best practices and recommendations

Share your authority's perspective to help shape harmonized SaMD pathways across the region

For Industry & Associations

Activate locally: Work with APACMed and local trade associations to engage authority in your market

Leverage the paper as a reference in internal discussions and external dialogues

Contribute expertise to APACMed's next digital health projects (Change Management, AI/ML, Innovative Pathways, Cybersecurity)

For All Participants

Continue the dialogue: use today's insights to build momentum towards harmonization

Stay engaged: share the recording and resources with your teams and networks

Thank you!

If you have any questions, please reach out to cpelou@apacmed.or