KPMG

APACMed
The voice of MedTech

Realizing the value of AI in MedTech within Asia Pacific

Key considerations to help improve trust, access and adoption of AI in MedTech

—

September 2024

Contents

Executive summary

More than 60 percent of the world's population lives in Asia Pacific.[1] The demand for personalized and efficient healthcare is on the rise and the MedTech industry is booming. But at the same time, the region is faced with an aging population and a growing burden of disease, exacerbated by limited healthcare infrastructure and manpower.

Rapidly aging population

1 in 4 people in Asia Pacific will be aged 60+ by 2030[2]

Limited access to healthcare

Across all age groups in Asia Pacific, 700 million people lack the most basic healthcare support[3]

Growing burden of disease

Chronic disease prevalence and disease-related complications are costing governments **in** Asia Pacific US$250 billion per year[4]

Low healthcare expenditure

Most governments in Asia Pacific spend 5 percent or less of GDP on healthcare vs OECD average of 12 percent[5]

There is enormous potential for the greater use of artificial intelligence (AI) in MedTech in Asia Pacific, a market which is projected to be worth US$250 million, and growing by 50 percent between 2020 and 2028.[6] As both public and private sectors increase their investments in healthcare, how can the region become a world leader in AI and MedTech?

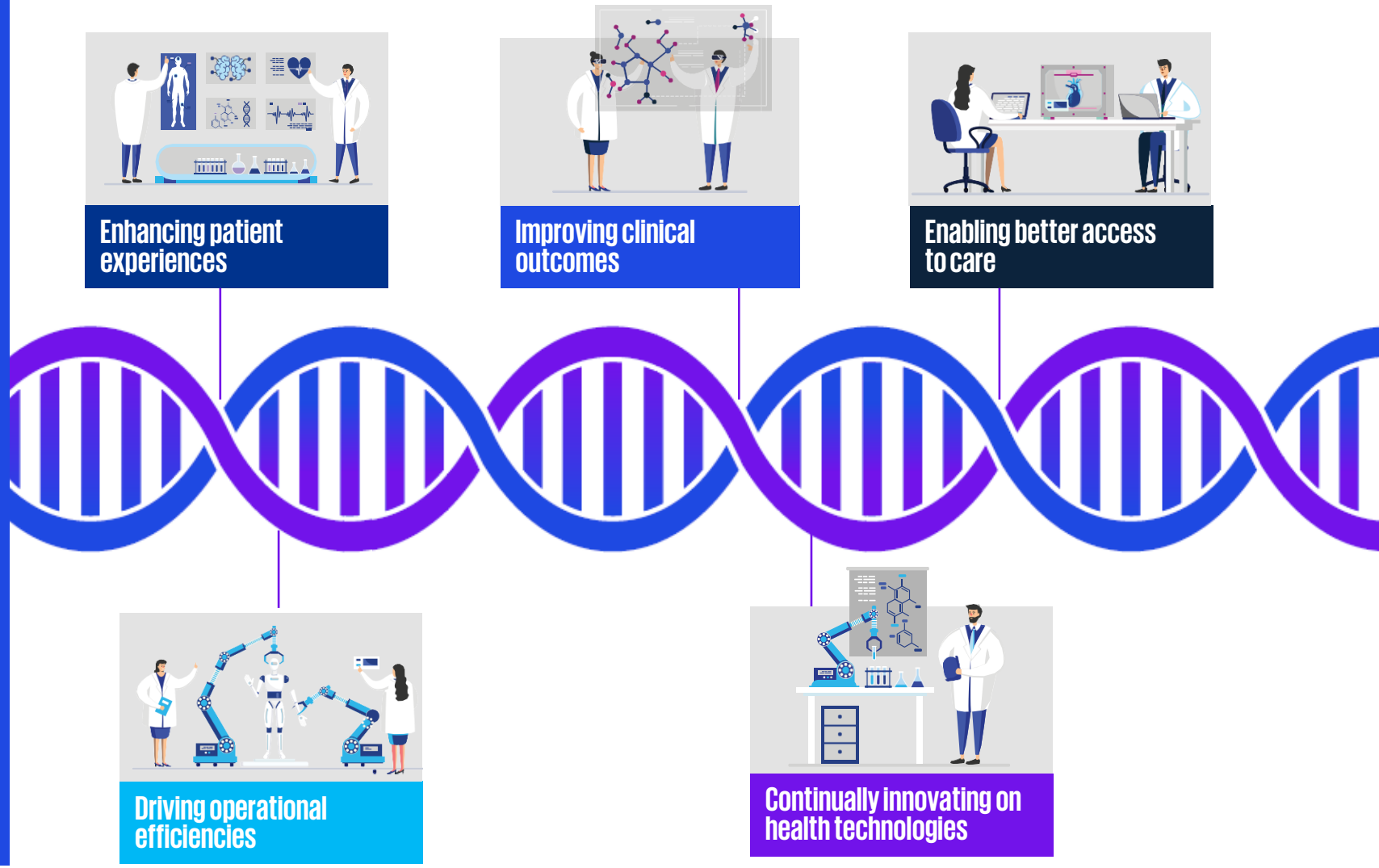
A new era

KPMG, in collaboration with the Asia Pacific Medical Technology Association (APACMed), surveyed global practices in healthcare and consulted with stakeholders in the MedTech industry and beyond to understand key priorities.

The ambition from these stakeholders is resoundingly clear – AI is expected to deliver transformation in the form of next-generation, intelligent healthcare.

The MedTech industry has a critical role to play, therefore, in empowering this transformation, through the following ways (Figure 1).

Figure 1: Ways in which AI in MedTech can empower intelligent healthcare



A-C-T levers enable value realization and adoption of AI solutions in MedTech

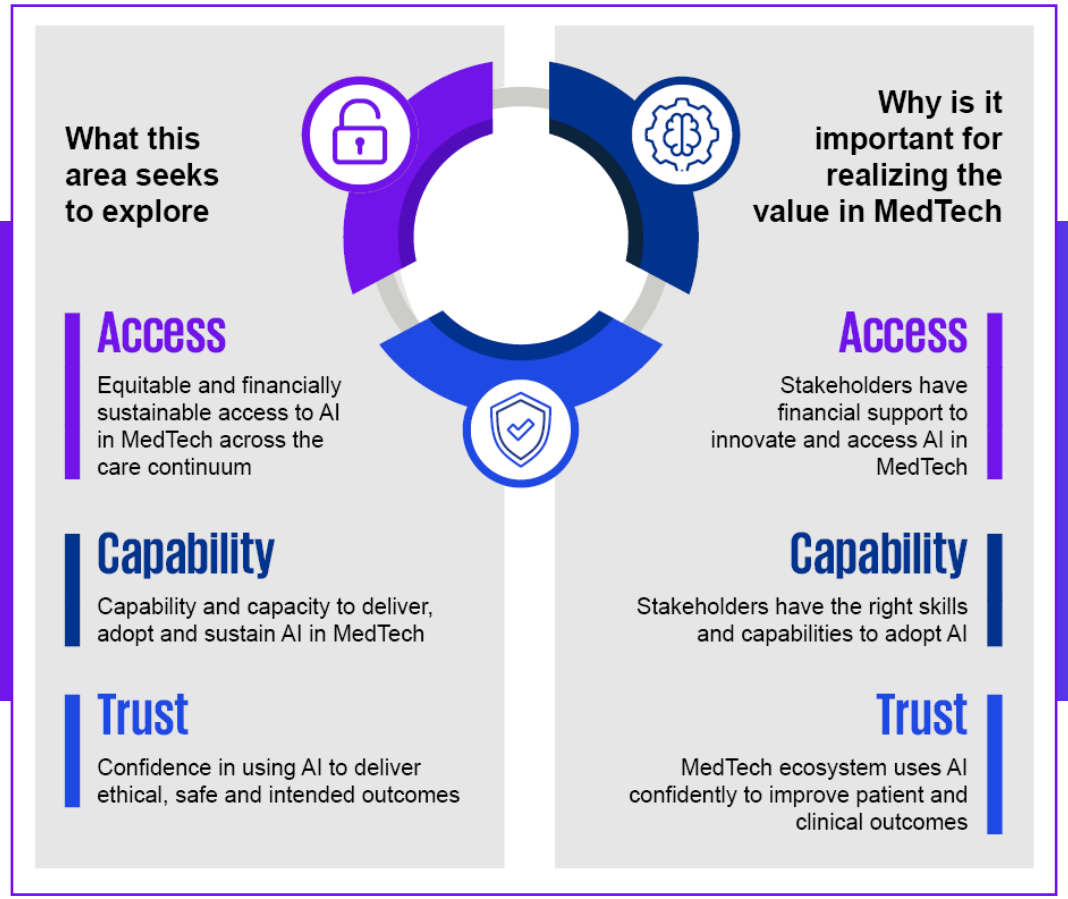


Figure 2: Access-Capability-Trust (A-C-T) framework, outlining levers that enable value realization and adoption of AI solutions in MedTech

While there is immense potential, true value realization lies in translation and adoption of AI for MedTech and healthcare.

This report offers an Access-Capability-Trust (A-C-T) framework (Figure 2) to categorize levers by which the MedTech industry, working hand-in-hand with governments and others in the ecosystem, can address challenges in areas such as regulation, ethics, talent, infrastructure and data, cost and socio-economic disparities.

Introduction

This whitepaper aims to explore key enablers to translate and realize the value of AI in MedTech, with a particular focus on opportunities for stakeholders to address. This section outlines the potential value of AI in MedTech and how it contributes to intelligent healthcare.

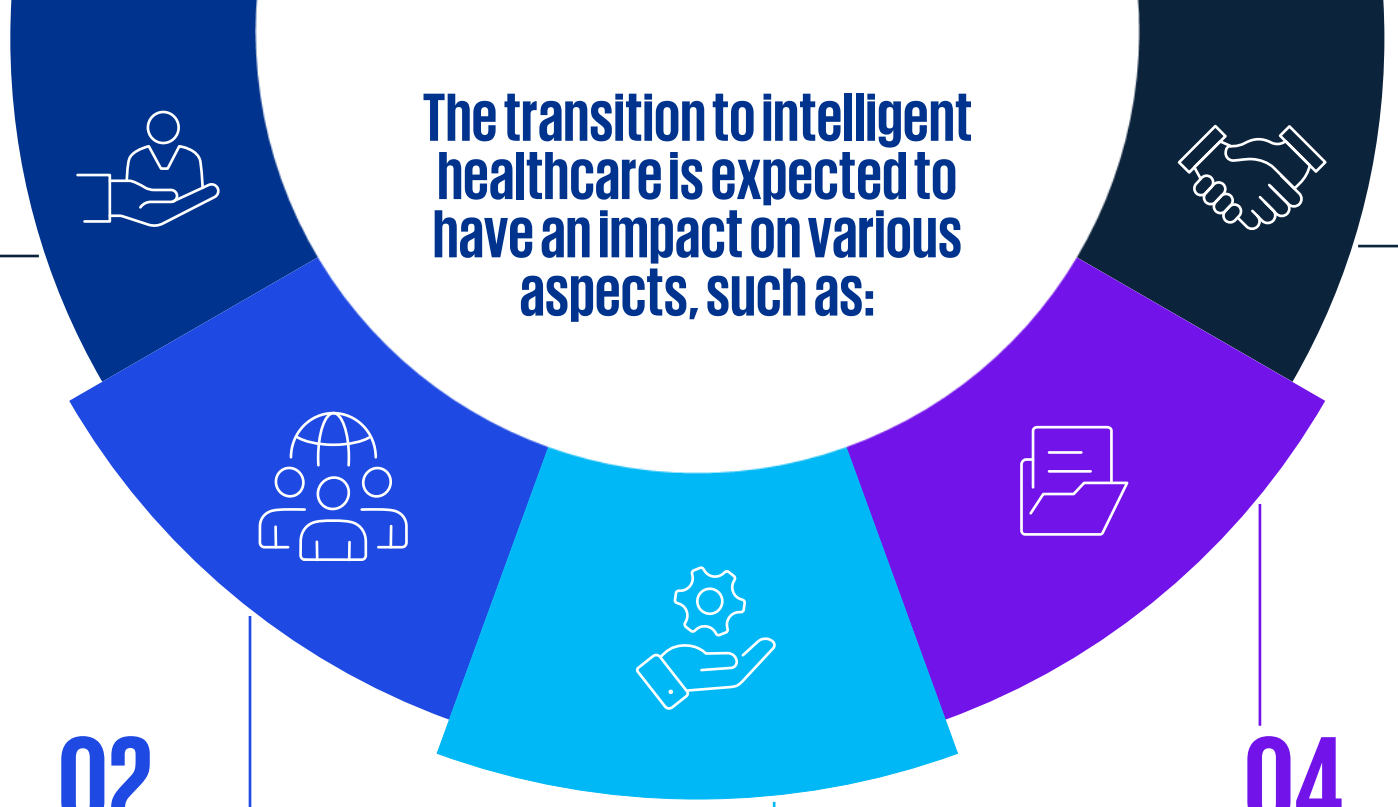
The power of AI in the intelligent healthcare evolution

Intelligent healthcare builds and expands on the 'information age' of digital, data-driven healthcare by integrating AI advancements across the value chain and care continuum to ultimately improve healthcare outcomes. This is defined as the 'next digital evolution' of healthcare, expanding on the latest digital health 'information age'.

Table 1 Evolution of digitally enabled technologies with progression to intelligent healthcare

	Computer power	IT-enablement	E-health	Digital health	Intelligent healthcare
	1950–1960	1970–2000	2000–2020	2020–2023	2023+
What is it	Mainframe computer introduction	Deployment of enterprise IT systems	Electronic Medical Record (EMR) and Electronic Health Record (EHR) implementation	Pervasive use of digital solutions (analytics, robotics, Internet of Things (IoT), Augmented Reality and Virtual Reality (AR/VR)) to provide healthcare insights and information	Electronic Medical Record (EMR) and Electronic Health Record (EHR) implementation
Impact on healthcare	Limited impact on healthcare	Basic IT capability deployed into health systems; Fragmented data	Digital and data connectivity in clinical settings; Information-oriented	Information-based, insight-oriented healthcare, beyond clinical settings	Digital and data connectivity in clinical settings; Information-oriented

The transition to intelligent healthcare is expected to have an impact on various aspects, such as:



01 Roles

The role of healthcare stakeholders (patients, providers, payors, industry) is likely to shift as AI improves operational workflows, accelerates clinical decision-making, helping to alleviate administrative burden. AI literacy will become a basic requisite for all job profiles.

02 Ecosystem

New ecosystem stakeholders are likely to emerge beyond those mentioned above, such as technology firms, telco companies and smart real estate.

03 Models

Care models are expected to transition beyond clinical settings and morph between physical and virtual, with patients and providers equipped with proactive, individualized care intelligence. Business models will integrate AI across all facets of operations to manage the cost, efficiency and effectiveness of care delivery.

04 Portfolio

Intelligent technologies are likely to be integrated along the care continuum, either as purely AI-enabled digital solutions (such as Digital Therapeutics (DTx)) or as AI complements to current technology offerings.

05 Value

Value potential should expand, whereby data becomes a core asset for all stakeholders and a critical component in achieving value from intelligent healthcare.

AI simplifies neuroscience by transforming complex data into accessible and actionable insights, driving innovation and development in MedTech."

Tim Haynes
Co-founder and CEO
Neurofrog

AI in MedTech will be key to delivering and enabling this intelligent healthcare transition.

A mixture of human and machine intelligence could optimize the practice of clinical medicine and streamline operations. intelligent healthcare includes machine learning (ML)-based AI tools that could be valuable as they rely on adaptive learning. This means that with exposure to new data, the algorithms can get better at detecting telltale patterns. Such tools have the potential to transcend the knowledge-absorption and information-retention limits of the human brain because they can be "trained" to consider millions of medical records and billions of data points.

AI in MedTech: Building on digital and data foundations to enable intelligent healthcare

AI in MedTech is a critical component for enabling intelligent healthcare. The World Health Organization (WHO) estimates there are around two million different kinds of MedTech producing data ('information') globally. the introduction of AI, this transforms information-producing devices into intelligent devices – providing proactive and adaptive intelligence at the fingertips of patients, clinicians and carers across the continuum.

AI is not new to MedTech, either with the first AI-enabled medical technology approved by the US Food and Drug Administration (FDA) in 1995. Since then, there have been another 882 approved AI-enabled MedTech to date (as of March 2024). [7] The industry has witnessed the generalization of AI – creating new potential applications, unseen with traditional models.

AI in MedTech expands the power of health data (outlined in APACMed's sister whitepaper 'The Power of Health Data' [8]) by enabling the potential for intelligent and adaptive devices, new data sources and additional use cases along the value chain and care pathways.

Expanding value across the care continuum

The use of AI in MedTech has the potential to expand value across the care continuum – from improving operational efficiency, diagnosis accuracy and treatment speed, to enabling remote health monitoring. Table 2 illustrates examples of potential value-creation use cases across the care continuum.

> Investing in data quality is essential for AI in healthcare, requiring accurate and representative data, complemented by rigorous education and oversight to ensure responsible deployment and governance."
>
> **Shweta Bhardwaj,**
> **Director, Global R&D and Digital Policy**
> **Johnson & Johnson**

Table 2: Examples of AI use cases in MedTech across the care continuum (continued on next page)

Prevention and screening

Proactive accessible screening solutions that allow for earlier preventative interventions

Diagnosis

Intelligent diagnostic solutions that improve accuracy and speed of diagnosis

Treatment

Treatment plans, Digital Therapeutics (DTx), or AI-enabled MedTechs that cater to individual patient needs

Management and surveillance

Adaptive remote intelligence, equipping patients and care teams with social and clinical insights for more effective management

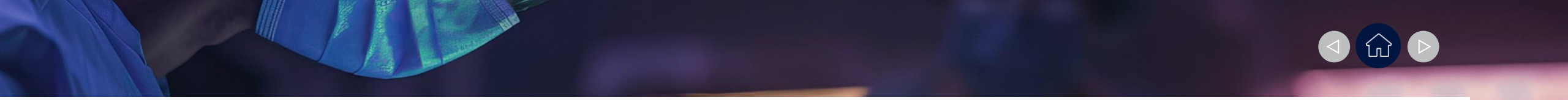


Table 2 (continuation): Examples of AI use cases in MedTech across the care

Prevention and screening:

Device monitoring which provides adaptive intervention and treatments across the continuum

Example tech solution: Boston Scientific's HeartLogic integrates AI into implantable cardioverter defibrillators (ICDs) to monitor heart failure. AI algorithms analyze multiple physiological signals to detect changes indicative of worsening heart conditions. Clinicians receive alerts, enabling early intervention and personalized patient management, thereby improving heart failure outcomes through proactive healthcare strategies.[9]

Treatment:

Disease surveillance solutions that provide intelligence on patient populations for providers (hospital-level) or systems (national-level or regional-level) for preventative care mechanisms and early intervention

Example tech solution: Bluedot uses AI and real-time data to effectively respond to diverse sets of global infectious disease threats, improving the speed of risk assessments and action with 24/7 international coverage. It is able to anticipate the trajectory of outbreaks by providing timely information to mobilize public health interventions.[10]

Diagnosis:

Remote patient management solutions that facilitate intelligent healthcare in patient-preferred care settings

Example tech solution: The Philips eCareCoordinator uses AI for ambulatory health by analyzing patient data in real-time. It predicts health trends, detects abnormalities and alerts healthcare providers, enabling proactive remote interventions. This enhances patient monitoring and management, supporting better outcomes for individuals with chronic conditions outside of traditional clinical settings.[11]

Management and surveillance:

Operational support solutions that leverage AI innovation to alleviate the administrative burden and provide operational efficiencies for clinicians, providers, industry, regulators and policy makers

Example tech solution: AI systems are now used to predictively manage hospital inventory. By analyzing usage patterns, patient inflow, and other relevant data, AI can forecast the demand for medical supplies, medications, and equipment. This capability helps hospitals maintain optimal stock levels, minimize wastage, and ensure critical supplies are available when needed.[12]

Potential benefits to stakeholders

The value created by AI in MedTech across the care continuum has the potential to benefit key healthcare stakeholders across various dimensions (Figure 3).

Figure 3: Potential benefits of AI in MedTech to various stakeholders in the healthcare ecosystem

	Personalized patient care	Improved clinical outcomes	Expanded care models	Operational efficiencies	Medical innovation
Patient	Tailored treatments based on individual health data	Enhanced recovery rates and better health results	Increased availability of services and specialists	Reduced waiting times and streamlined care processes	Access to technologically advanced treatments and solutions
Provider/Clinician	Increased accuracy in patient diagnosis and speed in making treatment decisions	Higher success rates and patient satisfaction	Improved patient outreach (e.g. virtual care, telehealth)	Streamlined workflows and reduced administrative burden	Faster clinical decision-making backed with data and real-world evidence
Health system	Optimized resource allocation and improved patient management	Better population health and reduced hospital readmissions	Improved quality of care	Lower costs and increased resource utilization	Enhanced reputation and competitive edge in the market

Case study #1

Improving outcomes and efficiency of aortic aneurism CT scans

Challenge

Follow-up assessments of aortic aneurysms in Computed Tomography (CT) scans are traditionally time-consuming and challenging due to the need for highly accurate measurements. There is also significant variability between different radiologists in measuring the diameter of aortic aneurysms.

Actions

Siemens Healthineers introduced AI assistance through the AI-Rad Companion Chest CT to streamline the process of aneurysm follow-up assessments.

Outcomes

Improved clinical outcomes
The use of AI resulted in a notable reduction of 42.5 percent in inter-reader variability when measuring the diameter of aortic aneurysms in CT scanner follow-ups. This indicates improved consistency and accuracy in measurements, potentially reducing diagnostic discrepancies.[13]

Operational efficiencies
The AI-Rad Companion Chest CT reduced the radiologist's reporting time for aortic aneurysm follow-up assessments by 63 percent, decreasing it from more than 13 minutes to less than five minutes. This efficiency improvement led to quicker treatment decisions and enhanced patient care.

Case study #2

Analyzing Operating Room for efficiency and physician learning

Challenge

In the Operating Room (OR), there is a need for documenting surgical videos to provide insights, learning, and quality improvement strategies to physicians.

Actions

Johnson & Johnson MedTech has a portfolio of digital solutions for the OR, including the Polyphonic™ digital ecosystem, that uses AI algorithms during procedures practically in real time to share surgical videos with residents and peers, offering valuable post-case analysis.

Outcomes

Improved clinical outcomes
The wealth of data coming from surgical procedures is analyzed to learn the behaviours, tactics and movements that create positive and negative outcomes during surgery and improve the experience of patients, doctors, and hospitals alike.[14]

Case study #3

Accelerating tumor diagnosis in biopsy tissues

Challenge

47 percent of the world's population lacks access to basic diagnostics. Traditional diagnostic methods are often slow, inefficient and not widely accessible, particularly in underserved areas.

Actions

Leveraging advanced AI and ML algorithms, Qritive, a Singapore-based MedTech start-up, introduced QAi Prostate. This AI-powered diagnostic tool helps pathologists accurately identify prostatic adenocarcinoma regions and classify malignant and benign tumor areas in biopsy tissue. AI identifies patterns and anomalies in imaging data that may be overlooked by the human eye, leading to more accurate and thorough diagnoses.

Outcomes

Operational efficiencies
AI-driven diagnostics providing timely diagnostic services in underserved areas and enable efficiency improvements, enhancing the patient experience and overall public health management.[15]

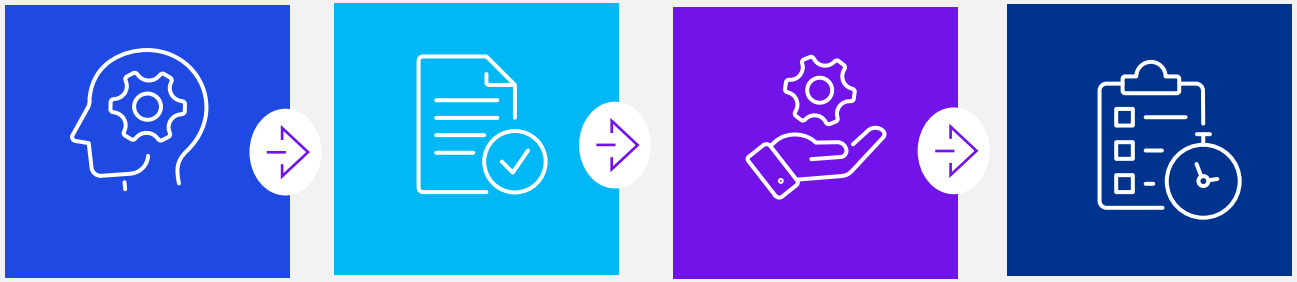
Improved clinical outcomes
QAi Prostate enables more accurate diagnosis of prostate cancer, reducing analysis time and allowing for quicker decision-making which improves healthcare accessibility and scalability.

Approach

Insights and recommendations from this whitepaper have been formulated based on a secondary review of peer-reviewed publications, whitepapers and other literature. This was complemented with a series of diverse, qualitative stakeholder consultations, including with industry, policymakers, regulators, payors, academia and other associations. Research and insights were focused on six Asia Pacific markets: Singapore, South Korea, Japan, China, India and Australia. Three key enablers (Access, Capability and Trust) were identified and broken down into sub-categories to identify and analyze challenges in translating and realizing the value of AI in MedTech. Considerations and opportunities to address these challenges were then developed and validated through further consultations with contributing parties (Acknowledgments).

Objectives

Informed by the potential value of AI in MedTech identified above, this whitepaper aims to:



Understand key enablers for translating and realizing the value of AI in MedTech

Identify and categorize key challenges and barriers in translating and realizing value

Suggest key considerations and propose opportunities to improve the value realization of AI in MedTech

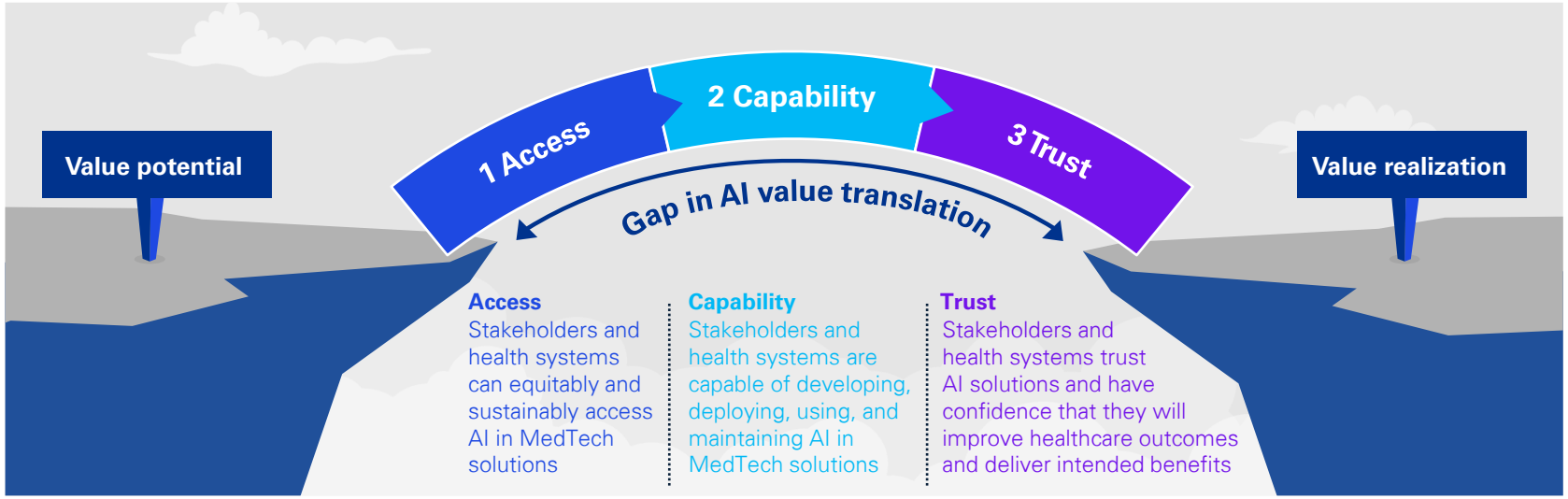
Share a call-to-action for key stakeholders to address suggested considerations

Overview of challenges for translating and realizing the value of AI in MedTech

> AI will continue to shape the future of healthcare. With AI-enabled connected devices, the technology infrastructure is poised to advance the world of health and to benefit patients and caregivers."
>
> **Legal Counsel multinational medical device company**

Despite the potential, challenges persist in the translation and realization of AI in MedTech value, diminishing benefits to patients, providers and health systems. Figure 4 illustrates the current gap or 'chasm' between value potential and value realization; three key enablers (Access, Capability and Trust – the 'ACT' framework) are identified as critical in helping to realize the value of AI in MedTech.

Figure 4: Representation of the chasm between value potential and value realization, bridged by 'ACT' enablers



The following sections of the whitepaper explore these barriers to 'ACT' further and propose opportunities for stakeholders to address together.

Access considerations for AI in MedTech

Financial and equitable access to AI in MedTech is critical for adoption. Reimbursement plays an important role in incentivizing timely access and reducing financial barriers for care providers and patients. Additionally, addressing disparities in patient populations across Asia Pacific is vital for equity in delivering on the promise of healthcare outcomes offered by AI in MedTech (Table 3).

> The importance of equitable access to healthcare can never be overstated, so as the implementation of AI in MedTech becomes more mainstream, we must be aware that this innovation may in fact exacerbate existing care disparities, even create new ones. Access considerations also play a critical role in ensuring that AI in MedTech is implemented in a way that respects patient privacy and data protection the laws."

Peter Liddell
Global Operations Centre of Excellence Lead,
Head of Life Sciences Asia Pacific
KPMG

Overview of key barriers and considerations for improving access to AI in MedTech

Table 3: Overview of key barriers and considerations for improving access to AI in MedTech

	A. Financial access – Reimbursement	B. Financial access – Delivery and deployment costs	C. Equitable Access – ESG
BARRIER	Lack of clarity and coherence on reimbursement mechanisms for AI in MedTech	High cost of design and deployment of AI in MedTech	Disparities across Asia Pacific markets in access to digital infrastructure (Technological disparities) Disparities across Asia Pacific markets in AI literacy, readiness and investment (Social, economic and political disparities). Limited awareness and understanding of digital sustainability in AI for MedTech
CONSIDERATION TO IMPROVE ACCESS	A.1 Expand and align on government-led reimbursement frameworks MedTech	B.1 Explore alternate funding mechanisms for AI development and deployment	C.1 Establish a regionally aligned equity and governance framework for AI in MedTech C2. Invest in regional AI readiness C.3 Develop guidelines and recommendations for digital sustainability for AI in MedTech

A. Financial access – reimbursement

As evidenced by APACMed efforts in recent years, reimbursement of digital health solutions is crucial to bringing high-quality care to the market.[16] Reimbursement is the mechanism by which to incentivize patients and clinicians to receive and provide timely access to care and treatments but this is challenging.

Reimbursement barriers - Lack of clarity and coherence on reimbursement mechanisms for AI in MedTech

What is it

There is a lack of clear and consistent reimbursement guidelines and frameworks for AI in MedTech in the Asia Pacific region, and globally.

What is the impact

This creates friction and complexity for the MedTech industry when developing AI solutions and for care providers when utilizing these solutions in healthcare settings. As AI rapidly evolves, so do regulations and reimbursement mechanisms, creating uncertainty about financial funding coverage. A lack of reimbursement impacts stakeholders from potentially adopting, integrating and utilizing AI, when comparing the financial viability of these solutions to the current standard of care and reimbursed alternatives. Additionally, this can impede innovation development in AI in MedTech, as the industry may be unsure if developed and invested solutions will be reimbursed and thus adopted.

Evidence and examples

- **Changing Preferences:** With healthcare IT implementation failures reaching as high as 70 percent and significant hesitance among providers to adopt and integrate AI technologies, there is a marked preference for existing reimbursed tools over forward-thinking solutions.[17]
- **Uptake of AI in MedTech:** A recent New England Journal of Medicine article analyzed the real-world uptake of medical AI based on payer claims data and identified reimbursement as one of the key drivers in facilitating widespread adoption of medical AI solutions.[18]

A. Financial access – reimbursement

Reimbursement

A.1 Expand and align on government-led reimbursement frameworks for AI in MedTech

Why is it important

Clarity on reimbursement models and value-based guidelines incentivize care providers to integrate AI-enabled tools when providing care to patients. This in turn, promotes innovation viability to invest in and develop innovative AI in MedTech solutions.

What is it

Alignment on appropriate value assessment and reimbursement frameworks for AI in MedTech for Asia Pacific.

How to address

Facilitate multi-stakeholder sharing and alignment on reimbursement strategies across Asia Pacific for AI in MedTech. This could include establishing a regional working group between industry, payors and other key stakeholders to facilitate regional knowledge sharing and alignment on regional reimbursement strategies, value assessment and framework(s) that support the adoption of AI in MedTech for Asia Pacific. One strategy could be to expand upon the existing Digital Health Reimbursement Working Group, established by APACMed in 2020, to include focus on AI in MedTech.[19]

Evidence and examples

- **Regional example:** South Korea's national health insurance has started to provide reimbursement of AI-based imaging technology.[20] This helps to lower the financial barriers for MedTech providers by covering the cost to design, develop, adopt and integrate AI into clinical practice.
- **Global example:** The CPT coding system in the US financially supports healthcare providers who use AI technologies. Timely updates to the CPT coding system and accurate clinical coding enable reimbursement for AI adoption in clinical settings.

B. Financial access – delivery and deployment costs

AI in MedTech becomes more accessible when there are ways to pay for the costs of delivering and deploying it. Currently, MedTech innovators and industry are confronted with high Research and Development (R&D) costs of AI in MedTech innovation. This is coupled with commercial risk and unclear Return on Investment (ROI) given the lack of clear reimbursement mechanisms. For care providers, there is the additional cost of integrating AI-enabled solutions into the health system infrastructure. Therefore, a need exists to support financial access for innovation and integration of AI in MedTech solutions.

Delivery and deployment barriers - High cost of design and deployment of AI in MedTech

What is it

The costs involved in the design, development, deployment and integration of AI-enabled solutions present barriers to access for AI innovators, healthcare providers and other researchers. This financial burden can be further exacerbated by challenges in the fast-evolving AI regulatory environment and the limited availability of AI capability and talent.

What is the impact

High costs of design and deployment may make it financially challenging for the MedTech industry to sustain AI innovation, especially if the development costs significantly outweigh the potential return.

Additional costs involved in introducing new AI-enabled solutions in clinical care may disincentivize hospitals and other healthcare providers from integrating AI into delivery systems.

> Novel ways of reimbursement need to be adopted which do not disadvantage digital solutions and create a level playing field with other therapeutic interventions – like medication."

Chief Clinical Officer
Digital health transformation company

B. Financial access – delivery and deployment costs

Delivery and deployment of AI in MedTech considerations

B.1 Explore alternate funding mechanisms for AI development and deployment

Why is it important

Promoting financial coverage for the design, development and deployment of AI solutions in MedTech improves the viability of ongoing innovation for stakeholders. Financial funding enables healthcare providers to integrate and utilize AI in MedTech into clinical practice.

What is it

Funding mechanisms, such as grants, subsidies, crowdfunding and private insurance, to help lower the high upfront and fixed costs, including expenses related to R&D, integration and infrastructure.

How to address

Work with payors and policymakers to build and expand upon a range of funding mechanisms for AI development and deployment. Explore both public and private access channels such as financial service providers, private health insurance and insurance technology (InsurTech), accounting for variations across countries/territories, stakeholders and specific use case archetypes.

Evidence and examples

Various funding mechanisms exist across the Asia Pacific region already (Table 4) (see next page).

> We cannot diagnose everyone; those who can afford AI get a diagnosis early. Those who cannot afford it might not even know (the disease) they are suffering from."

Bruno Occhipinti
CEO
Qritive

Table 4 Summary of alternative financial mechanisms for AI in MedTech in Asia Pacific

Alternative financial mechanisms (grants, policies, mutual funds)	
Singapore	The Healthcare Translation Partnership between SingHealth and the Agency for Science, Technology and Research (A*STAR) will provide US$5.9 million (SGD8 million) in funding support to accelerate the translation, deployment and commercialization of projects focused on medical AI.[21] The National Research Fund (NRF) in Singapore has set up the Health Technologies Consortium to help companies translate research outcomes into products and services, with a focus on health analytics and AI. NRF has set aside funding of US$1.1 million (SGD1.5 million) over three years to support the activities of the consortium.[22]
Australia	The government has awarded approximately US$20 million of grants to harness the power of AI in the healthcare system.[23]
China	Cities in China, such as Shanghai and Hangzhou, have started to develop and release plans for AI R&D (including medical AI) at estimated investment levels of about US$1.4 billion each.[24] Beijing supports private companies to accelerate medical AI development. For instance, a state-owned finance institution has provided US$1.5 billion to a biotechnology company to expand its R&D platforms, including for the purposes of adopting AI
Japan	The Japanese government is investing heavily in AI in healthcare through its shift towards "Society 5.0." The annual budget in 2019 for science and technology increased from US$24.7 billion (2002-2017) to US$26.1 billion, supporting Japan's investment in the development and application of digital technologies.[25]
India	The government of India launched the Ayushman Bharat Digital Mission in September 2021 to develop the backbone necessary to support the integrated digital health infrastructure in the country. This increased the use of AI/ML and sensor technologies in areas of early detection of diseases, disease management and treatment.[26]
South Korea	The Ministry of Science and ICT is investing an estimated US$585 million in domestic AI research and development to develop next-generation core technologies, including medical AI.[27] South Korea is placing emphasis on digital transformation in hospitals, uplifting infrastructure and the integration of AI technologies. In March 2023, Samsung Medical Center became the world's first healthcare provider to achieve the highest possible stage for the Healthcare Information and Management Systems Society (HIMSS)[28] Digital Imaging Adoption Model scale, which measures capabilities for secure delivery of medical imaging and associated processes to improve quality of care, patient care and organizational efficiency in hospitals and diagnostic centers.[29] In May 2023, HIMSS signed a Memorandum of Understanding (MoU) with the Korean Hospital Association in South Korea to advance digital transformation in the healthcare sector.[30]

C. Equitable access - ESG

Disparities between patient populations (such as by geographic locations, access to technology, social demographics) and ecosystems (such as by maturity of existing AI capability, AI readiness, level of AI literacy) impact equitable access to AI in MedTech across Asia Pacific. Fostering equitable access can help populations, regardless of socio-economic status, to benefit from advanced healthcare technologies.

Social and governance barriers - Disparities across Asia Pacific markets in access to digital infrastructure (technological disparities)

What is it

There are disparities in the maturity of digital and data infrastructure across Asia Pacific. For example, the strength of connectivity (internet and mobile coverage) and compute power differ regionally.

What is the impact

Disparities in access and maturity of AI infrastructure, such as internet access, can create barriers for AI integration and adoption into healthcare systems. This can exacerbate existing health digital health inequities.

Evidence and examples

- **Connectivity levels:** Approximately a third of the population in Asia Pacific remained unconnected in 2023.[31]
- **Resource distribution:** An example of uneven distribution of medical resources can be observed across states and provinces in China. Patients residing in remote areas pay out-of-pocket for travel to hospitals in megacities, such as Beijing and Shanghai, for diagnosis and treatment. Adequate government spending is key to enabling equitable access to healthcare in rural and remote areas.[32]

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Social and governance barriers - Disparities across Asia Pacific markets in AI literacy, readiness and investment (social, economic and political disparities)

What is it

The Asia Pacific region is home to varied social, economic and political environments, with differing levels of capacity to invest in AI infrastructure, AI capability and, therefore, differing levels of AI—and digital—literacy.

What is the impact

Existing socio-economic disparities in the region can potentially increase gaps in healthcare access as the capacity and capability for countries and territories to adopt AI in MedTech solutions could vary.

Evidence and examples

- **AI readiness:** AI readiness levels across Asia Pacific vary significantly (Table 5).
- **Government investment in AI:** Governments are ramping up AI capabilities with investment – Australian governments' investment of US$27 million (AU$41.2 million)[33] to support the responsible deployment of AI and US$1 billion in Singapore (Singapore National AI strategy 2.0).[34]

Table 5: Overview of Asia Pacific AI Readiness Index

Global position	Jurisdiction	Overall AI readiness 2023 score[35]
2	Singapore	81.97
7	South Korea	75.65
9	Japan	75.08
12	Australia	73.89
16	China	70.94
40	India	62.58

C. Equitable access - ESG

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Social and governance barriers - Limited awareness and understanding of digital sustainability in AI for MedTech

What is it

Digital sustainability is making its way into the environmental, social and governance (ESG) agenda. However, this is at an early stage and there is limited understanding of initiatives to implement, and the metrics required to measure AI performance in the context of potential environmental impact.

What is the impact

A limited understanding of digital sustainability means there may be misalignment on appropriate environmental measures to promote the sustainability of AI in MedTech solutions. Additionally, a lack of clear environment metrics may impede the value demonstration and adoption of AI in MedTech solutions.

Evidence and examples

- **Lack of information on environmental impacts:** As with many other MedTech innovations, there is a significant gap in information regarding the environmental impacts of AI.[36]
- **Ecological impact of AI in MedTech:** The significant environmental impacts of AI – with its high use of energy, material and other resources – may be overlooked in the health sector, where the immediate goal of saving lives can overshadow potential long-term ESG risks.[37]

> Some countries may not have well-developed IT infrastructure and internet speeds suitable for AI adoption in healthcare organizations."

US & LATAM Business Development Manager
South Korean healthcare AI company

C. Equitable access

ESG considerations

C.1 Establish a regionally aligned equity and governance framework for AI in MedTech

Why is it important

Equitable and sustainable access to AI in MedTech innovation fosters universal translation of health outcomes that can help address and improve current regional health disparities.

What is it

An aligned and harmonized governance framework should consider the specific socio-economic needs, cultural needs, local capabilities, infrastructure maturity and population literacy of Asia Pacific demographics when adopting AI in MedTech.

How to address

There are several existing global and regional frameworks and papers published on governance and equity for AI and healthcare. Industry, policymakers and regulators should collaborate to align and adopt a clear framework. This could be specific to MedTech or integrated into broader AI and healthcare governance frameworks in the region.

Evidence and examples

- **WHO:** WHO underscores health equity as the absence of unfair, avoidable, or remediable differences among groups,[38] highlighting the critical need for equitable access to AI-driven MedTech. Additionally, WHO's 'Ethics and Governance of Artificial Intelligence for Health'[39] outlines key ethical considerations and mechanisms with specific governance guidance on using the appropriate large language models (LLMs) in healthcare.
- **UNESCO:** UNESCO has introduced a global standard on AI ethics, known as the 'Recommendation on the Ethics of Artificial Intelligence'. This landmark initiative outlines 10 core principles that prioritize human rights in ethical AI. It also offers policy recommendations specifically tailored to AI solutions in healthcare, guiding ethical practices in the development, deployment and governance of these technologies.[40]

C. Equitable access

ESG considerations

C.2 Invest in regional AI readiness

Why is it important

Preparing the region for AI adoption can help all countries and territories be sufficiently able to provide access to AI in MedTech.

What is it

Investment in AI readiness means preparing, equipping and supporting the region so that markets have the right infrastructure in place to adopt and integrate AI technologies into MedTech and healthcare. Important factors to consider include quality of infrastructure, digital maturity, availability of quality data, skills and capability in AI, investment and financing mechanisms, and policies and governance in AI.

How to address

There are several existing global and regional frameworks and papers published on governance and equity for AI and healthcare. Industry, policymakers and regulators should collaborate to align and adopt a clear framework. This could be specific to MedTech or integrated into broader AI and healthcare governance frameworks in the region.

Evidence and examples

- **Australia:** In Australia, there is an effort to draw further collaboration by sharing leading practice materials, as recently demonstrated at the Digital Health Festival[41] in May 2024.
- **Singapore:** Singapore is investing in infrastructure and initiatives to develop AI capabilities. An example of this is the announcement of the Committee of Supply Debates 2024. The Singapore Ministry of Communications and Information announced AI initiatives to power Singapore's next bound of economic growth, including investment of over USD 370 million (SGD 500 million) to secure high performance computing resources for AI innovation and capability building.[42]

C. Equitable access

ESG considerations

C.3 Develop guidelines and recommendations for digital sustainability for AI in MedTech

Why is it important

Developing guidelines and recommendations for digital sustainability for AI in MedTech can help guide the implementation and monitoring of sustainability practices, facilitating the long-term viability and ethical responsibility of AI innovations in MedTech.

What is it

Develop practices that monitor and improve energy efficiency, optimize resource usage and reduce environmental footprint and production of energy waste related to AI in MedTech.

How to address

Develop guidelines for the digital sustainability of AI in MedTech for Asia Pacific. This could include providing recommendations on initiatives and metrics that promote energy efficient LLMs and AI innovation in MedTech. By fostering collaboration among stakeholders, these guidelines may drive the adoption of sustainable AI practices and potentially contribute to the reduction of the carbon footprint in healthcare technology. Furthermore, existing channels could be explored including building on APACMed's strategic focus on ESG and demonstrating industry leadership by expanding the APACMed ESG dashboard to identify and include potential AI-relevant ESG metrics.[43]

Evidence and examples

- **Growing focus on sustainability in Asia Pacific:** AI usage is causing a significant spike in power usage. There are efforts to promote the sustainable growth of data centers — for example, the Green Data Centre Roadmap launched in Singapore.[44] Sustainability is expected to be of increasing focus from an ESG perspective for many companies and their Boards.
- **Sustainable AI:** Issues in global healthcare transformation related to sustainability have previously been discussed by the Federation of European Academies of Medicine (FEAM). A framework has since been proposed by FEAM for sustainable AI in healthcare, outlining key strategies for integrating AI technologies to improve patient treatments, aid drug discovery, reduce costs and enhance accessibility. There is also an emphasis on the importance of ethical considerations and data privacy in the development and use of AI in healthcare.[45]

Capability considerations for AI in MedTech

To maximize the value of AI in MedTech, it is essential that the ecosystem is capable of using, adopting and integrating AI across the value chain and care continuum. A lack of AI talent, skills and awareness continues to be a primary barrier for the successful adoption of AI. This section explores such barriers and considerations for improving AI capability in MedTech (Table 6).

> Intelligent healthcare requires healthcare intelligence. Only by ensuring all stakeholders across the healthcare ecosystem are empowered with the right capability - including skills, systems, strategies - can we then realize the future promise of AI in healthcare."

Anastasia Miros
Director, Healthcare and Life Sciences Asia Pacific
KPMG

Overview of key barriers and considerations for improving AI capability in MedTech

Table 6 Overview of key barriers and considerations for the enablement of AI in MedTech

	D. Talent and skills	E. Data, interoperability and integration	F. Collaboration and partnership
BARRIER	Disparities in the current country and stakeholder capabilities. Limited alignment on approach to developing future AI capabilities and skills required.	Disparities in availability, accessibility, quality and integration of health system technologies and infrastructure. Lack of availability, interoperability and homogeneity of health data.	Lack of awareness, understanding and acceptance across healthcare ecosystem stakeholders on the use of AI in MedTech. Asynchronous levels of stakeholder engagement across the AI value chain for policy and regulation development. Fragmentation of channels and collaboration for AI MedTech translation across the Asia Pacific region.
CONSIDERATIONS TO IMPROVE ACCESS	D.1 Explore risk-based approaches to the regional regulation of AI in MedTech. D.2 Explore regional recognition and reliance models to promote convergence of AI in MedTech. D.3 Facilitate regional engagement in AI regulation development.	E.1 Explore regional harmonization of interoperable data standards and guidelines. E.2 Facilitate regional and local digital and data maturity development. E.3 Facilitate access to regionally representative use-case-based datasets for AI in MedTech.	F.1 Facilitate collective, consistent awareness and understanding of AI in MedTech solutions across the healthcare ecosystem. F.2 Promote early engagement for designing and updating regulation, reimbursement and other policies relating to AI in MedTech. F.3 Explore existing and new collaborative mechanisms to facilitate AI MedTech adoption.

D. Talent and skills

Ensuring that stakeholders possess the necessary skills and capabilities is crucial for the successful integration of AI in MedTech. Many policymakers are developing and promoting initiatives aimed at supporting both current and future efforts to upskill and enhance AI capabilities. These are essential to enable healthcare ecosystem stakeholders to effectively utilize AI technologies and drive innovation.

AI talent and skill barriers - Disparities in current country/territory and stakeholder capabilities

What is it

The healthcare ecosystem, including MedTech, is experiencing a notable gap in awareness, understanding and expertise in AI.

What is the impact

The pressure from the divergence in AI capability and maturity, coupled with the lack of necessary skills, is affecting the entire value chain – from AI design and deployment to utilization and governance (regulatory, policy, security). This results in skills gaps in the AI workforce, thereby impacting the capability and capacity of the ecosystem to translate, protect and sustain AI value in MedTech.

Evidence and examples

- **Reference to skills in the Global AI Adoption Index:** Executives in multinational corporations find the scarcity of AI skills and expertise a barrier to AI adoption in enterprises.[46]
- **Talent availability:** Only one in every 1,000 job candidates in the Asia Pacific region is fully equipped to handle AI tasks.[47]

D. Talent and skills

Ensuring that stakeholders possess the necessary skills and capabilities is crucial for the successful integration of AI in MedTech. Many policymakers are developing and promoting initiatives aimed at supporting both current and future efforts to upskill and enhance AI capabilities. These are essential to enable healthcare ecosystem stakeholders to effectively utilize AI technologies and drive innovation.

AI talent and skill barriers - Limited alignment on approach to develop future AI capabilities and skills required

What is it

Frameworks and approaches for developing future-ready AI skills for the MedTech and the healthcare ecosystem vary both between and within countries/territories. Current learning opportunities for the next generation of clinicians and wider healthcare ecosystem stakeholders are lacking in many universities and educational institutions during formative training. A misaligned approach may result in varying prioritization and investment, creating workforce imbalances that limit the scalability of AI solutions.

What is the impact

Without regional alignment on skills requirements and a consistent approach, AI talent and capability is likely to be inconsistent across the region and stakeholders, resulting in limitations to the development, deployment and adoption of AI in MedTech.

Evidence and examples

- **Training program divergence:** Preparing the current and future health workforce for AI is increasingly important as AI applications grow. However, there is no consensus among educators on what should be taught or how learning should be supported and assessed.[48]

D. Talent and skills

AI upskilling considerations

D.1 Develop educational programs for talent development

Why is it important

With 40 percent of global jobs likely to be complemented or replaced by AI,[47] AI education pathways are integral to equipping the workforce of the future with AI competencies across the value chain. Identification and alignment on AI skills and capabilities provide the future workforce with the appropriate technical and business capability for AI in MedTech and promotes a sustainable talent pipeline for continued industry innovation and value delivery.

What is it

Regionally aligned and integrated education programs are designed to build both fundamental AI competencies and role-based competencies, across various educational levels — secondary, tertiary and workplace.

How to address

Develop adaptable, AI-centric educational programs tailored to key functions across the MedTech value chain, integrated into the curricula and professional roles of stakeholders in regulation, policy, engineering and business. Programs should be adaptable to the dynamic AI landscape and emerging trends. This could include exploring innovative development options such as micro-credentials to enable ongoing workforce upskilling and futureproofing.

Evidence and examples

- **Asia Pacific AI education and workforce development initiative examples:** Table 7 (see next page).

> From the perspective of the public sector, specialized workforce education programs [are a potential opportunity for incentivizing AI innovation and improving market access]. We need more education and training programs to develop professionals with knowledge in both medical domains and AI technology, collaborating with educational institutions to offer specialized degree programs in medical AI."
>
> **Government R&D Grants Manager**
> **South Korean medical device company**

Table 7 Examples of current education and workforce development initiatives in Asia Pacific (continued on next page)

Country	Education – future workforce development	Capability development – current workforce development
Singapore	• National Digital Literacy Programme: By Singapore's Ministry of Education (MOE) in 2020 for schools of higher learning. To help students strengthen their digital literacy.[50] • Infocomm Media Development Authority (IMDA) investment of US$14.8 million (SGD20 million) in the next three years: To increase the number of AI-related digital scholarships and overseas internship AI roles. [51]	• AI Singapore (AISG) – LearnAI and AI Apprenticeship Programme: To develop Singaporean AI talent and enhance career opportunities in AI-related roles.[52] • SG Government x Google Cloud: 100 solutions in 100 days – GenAI Sandbox with Google Cloud to enhance GenAI capabilities in the public and private sector.[53] • Human Health and Potential Roadmap: By the Research, Innovation and Enterprise 2025 envisions a diversified base of high-quality research and innovation, and enterprise talent for the adoption of innovations.[54] • Duke NUS: Integrated an AI-centric curriculum framework to medical students, supporting medical professionals in developing robust clinical reasoning skills alongside substantial AI literacy.[55]
Australia	• Next Generation AI Graduates Program: By Commonwealth Scientific and Industrial Research Organization (CSIRO) – US$6 million (AUD9 million) to fund 162 scholarships equipping students with key skills to drive innovation in AI and emerging technologies.[56]	• National AI Centre and CSIRO AI courses: Provides micro skill courses for AI related training and upskilling.[57]
China	• Smart Education of China Platform (2022): A digital education database with more than 44,000 courses for primary and secondary, and 27,000 online courses for higher education.[58]	• 14th Five Year Plan (2021-2025) for National Informatization: By Central Commission for Cybersecurity and Informatization China to improve talent evaluation and create big data job certifications. It also supports certain third parties to provide on-the-job training and certifications.[59]

Table 7 Examples of current education and workforce development initiatives in Asia Pacific (continuation)

Country	Education – future workforce development	Capability development – current workforce development
Japan	• GIGA School Program: By Japan Ministry of Education, Culture, Sports, Science and Technology (MEXT) – US$4.4 billion plan to digitalize primary and secondary school education across the country to equip students with techniques to master digital tools.[60]	• Kwansei Gakuin University AI Talent Development Program: Virtual Learning Edition (KGAI-VL) together with IBM Japan July launched the program in 2021 as a paid service for companies, local governments, and universities to create AI talent.[61]
India	• National Education Policy 2020: By the Government of India MOE. Emphasizes the integration of technology into education, aims to revamp the education system to make it more AI-ready.[62] • YUVAi – Youth for Unnati and Vikas with AI program: Plans to equip students from classes 8 to 12 across the nation with relevant mindsets and skill sets and empower them to become human-centric designers and users of AI.[63]	• INDIAai Portal: The Indian government launched a one-stop digital platform for AI-related developments. It will host a section for online learning, skills development and AI job opportunities.[64] • NASSCOM (National Association of Software and Service Companies): Offers AI courseware and certifications under the FutureSkills Initiative to equip learners with essential skills for the evolving digital landscape.[65] • The Centre of Excellence in Artificial Intelligence (CoEAI) at IIT Kharagpur is a hub for AI and ML innovations, dedicated to transforming industries and society. The center emphasizes four key areas: groundbreaking research, advanced teaching, collaborative industry projects and dynamic entrepreneurship.[66]
South Korea	• AI-powered public education: The South Korean government will inject US$70 million into improving digital infrastructure and develop digital textbooks at public schools.[67]	• 6th National Informatisation Master Plan for an Intelligent Information Society: This is a plan for the shift in the use of information technology towards an intelligent hyper-connected information-based nation, with fostering and educating active workers to lead the intelligent information society.[68]

D. Talent and skills

AI upskilling considerations

D.2 Invest in upskilling the current workforce

Why is it important

AI and big data are becoming key focus areas for skills training in the current workforce as organizations are increasing their investment in these domains. However, there is a shortage of AI skills in the current MedTech and healthcare workforce. This impedes value translation of AI in MedTech, spanning limitations in MedTech design and delivery processes for producers, to challenges in integration for care providers and payers, and to issues with utilization for clinicians and patients.

What is it

Organizations should focus on both general AI literacy and role-based technical training to support a workforce with wide-ranging and specialized AI skills. By enhancing AI capabilities across levels, the MedTech industry can effectively integrate AI technologies, and improve the design, delivery and utilization of AI.

How to address

Collaborate to deliver role-based workforce retraining and upskilling programs as well as organizational capability building by co-designing initiatives across stakeholder groups and regional borders to facilitate best practice sharing.

The MedTech industry should look at opportunities to lead internal talent development and promote upskilling.

Evidence and examples

- **General upskilling:** Singapore's LearnAI and India's NASSCOM courseware under FutureSkills initiative can help with immediate upskilling in the workforce.
- **Role-based upskilling:** Duke NUS integrated AI-centric curriculum framework for medical students supports medical professionals in developing robust clinical reasoning skills alongside AI literacy.

D. Talent and skills

AI upskilling considerations

D.3 Promote awareness and co-design of AI MedTech in Asia Pacific

Why is it important

Research has shown that insufficient stakeholder involvement, such as clinicians in AI development, can hinder AI adoption.[69] There must be collaboration to foster a balanced and well-educated workforce that is equipped with regionally aligned fundamental skillsets. This includes collaboration between small start-up technology organizations and large global MedTech firms, partnerships with AI technology leaders, and co-designing with clinicians, patients and governments to help develop wider ecosystem talent across the care continuum.

What is it

Collaborative environments, such as technologically enabled innovation sandboxes and awareness-building innovation challenges, facilitate the practical application of AI. This approach can streamline AI integration, foster confidence and create an environment that supports collective learning, innovation and upskilling.

How to address

Explore strategies and channels that encourage early dialogue and engagement among stakeholders. This can range from individual interactions (such as between MedTech companies and hospitals) to broader discussions at national or regional levels (such as in policy and regulatory development). Incorporating innovation sandboxes can facilitate this process by providing a controlled environment for testing and refining AI applications.

Evidence and examples

- **Google and government:** The Singapore government's partnership with Google Cloud launched a generative AI sandbox to develop 100 Generative AI (GenAI) use cases in 100 days in September 2023. This initiative fostered a coordinated whole-of-society approach to enhance regional GenAI capabilities cohesively. It addressed healthcare challenges by facilitating learning and skills development while providing an opportunity for collaboration and ecosystem engagement.[70]
- **Indian Institute of Technology (IIT) Kharagpur and Hyderabad:** IIT has flagship courses on the use of AI in MedTech and collaborations with research facilities for a well-rounded education. The center offers a dual-degree ("MTech") program in AI, ML and applications for students, established in 2018.[71]
- **Singapore investment into AI development:** Singapore will allocate more than US$ 741 million (SGD1 billion) into AI development over the next five years. The aim is to fuel the AI talent pool, developing a workforce that is sufficiently equipped with a digital skillset.

E. Data, interoperability and integration

Translating AI innovation in MedTech into clinical settings requires infrastructure integration and data interoperability. High data quality, representativeness and availability are integral for the delivery of AI in MedTech outcomes. As is frictionless infrastructure integration, which allows for interfacing among clinical teams, applying AI outputs in meaningful clinical contexts[72], engaging end users effectively and continuously monitoring for issues and improvements.

Data, interoperability and integration barriers - Disparities in availability, accessibility, quality and integration of health system technologies and infrastructure

What is it

We have observed disparities in the availability, accessibility, and quality of digital health infrastructure across Asia Pacific. Examples observed range from disparities in digital infrastructure at the national level down to digital readiness in community-based care settings, among various other disparities in between.

What is the impact

Translating AI innovation in MedTech into clinical settings is dependent on the availability, suitability and level of integration with health system infrastructure. Limitations here can affect the reliability and efficacy of AI applications, ultimately impacting patient outcomes and healthcare efficiency.

Evidence and examples

- **Clinical integration challenges:** Some clinicians may experience difficulties in integrating AI and ML into their routines. Currently, AI models are not yet integrated into clinical workflows to improve care, creating a divide between users and implementers, which poses a significant challenge for those responsible for clinical use. Thus, AI systems should be user-friendly and congruent with existing workflows.[73]
- **Infrastructure challenges:** Nearly one in four (23 percent) of Asia Pacific's healthcare leaders cite technical infrastructure limitations as a factor hindering their ability to use data effectively.[74]

E. Data, interoperability and integration

Translating AI innovation in MedTech into clinical settings requires infrastructure integration and data interoperability. High data quality, representativeness and availability are integral for the delivery of AI in MedTech outcomes. As is frictionless infrastructure integration, which allows for interfacing among clinical teams, applying AI outputs in meaningful clinical contexts[72], engaging end users effectively and continuously monitoring for issues and improvements.

Data, interoperability and integration barriers - Lack of availability, interoperability, and homogeneity of health data

What is it

The integration of AI technologies in Asia Pacific faces challenges due to the heterogeneity of data and systems. This includes variations in clinical workflows, infrastructure and data standards, interoperability, availability, definitions and preferences.

What is the impact

Siloed systems and heterogeneous data standards across the Asia Pacific healthcare ecosystem present barriers to consistent and timely AI integration and adoption in MedTech solutions.

Evidence and examples

- **Data silos:** 73 percent of Asia Pacific healthcare leaders report that data silos significantly limit data utilization,[75] with 97 percent of hospital-produced data remaining unused.[76]
- **Availability:** Even in Singapore, which has maintained a central repository for patient health records since 2011, participation by private providers was only at 15 percent as of October 2023.[77]

E. Data, interoperability and integration

Data, interoperability and integration considerations

E. 1 Explore the regional harmonization of interoperable data standards and guidelines

Why is it important

The success of AI-driven outcomes in MedTech depends critically on having timely access to data that is of high quality and representative.

What is it

Enhance local and regional interoperability standards and guidelines across Asia Pacific. Develop aligned and consistent leading practices for managing healthcare data both within the region and globally (summarized in Table 8. Facilitate awareness and alignment on standards, principles and use case applications.

How to address

Flexible, voluntary, consensus-driven standards should be developed through active collaboration with the industry. This initiative should also be supported by civil society, government and academia. Given the industry's leadership in developing and deploying AI solutions for cutting-edge use cases, it should play a pivotal role in shaping these standards. The industry's development of technical talent, specifically tailored for AI, positions it uniquely to drive foundational research and establish leading practices.

Evidence and examples

- **Sandboxes:** Initiatives such as regional and local interoperability sandboxes can support early testing and refining of interoperability standards and applications, contributing to more harmonized efforts.
- **APACMed Health Data Committee:** The Committee collaborates with stakeholders across healthcare and IT to shape policies for developing a common set of standards to optimize health data use for innovation and improved patient outcomes, and creating harmonized, robust cybersecurity frameworks to protect healthcare data against evolving threats in a connected ecosystem.[78] APACMed has contributed to the field with position papers and related initiatives such as capability development workshops, working with ASEAN governments to promote interoperability and health data standards.

Table 8 Examples of interoperability initiatives in the Asia Pacific

Country	Data & interoperability initiatives
Singapore	• Singapore-Australia Digital Economy Partnership Development: By Singapore's Ministry of Trade and Industry (MTI) to enhance digital trade agreements between Singapore and Australia, with the development of compatible and interoperable data transfer mechanisms for personal data as a key feature.[79] • IMDA-Google Privacy Enhancing Technology (PET) Sandbox: A safe space to trial PETs to foster personal data protection and data privacy while increasing data collaboration, cross-border data flow and data collection for AI development.[80]
Australia	• National Healthcare Data Interoperability Plan 2023-2028: By the Australian Digital Health Agency to share consumer health information in a safe, secure and seamless manner by focusing on identity, standards, information sharing, innovation and measuring benefits.[81]
Japan	• Data free flow with trust: By Digital Agency – Japan, aims to promote the free flow of data while ensuring trust in privacy, security and intellectual property rights. It provides guidelines for the cross-border flow of data, facilitating international collaboration and data exchange.[82]
China	• China Standards 2035: The Chinese government released a new plan in 2020 to influence how the next generation of technologies such as AI will work, and their interoperability globally.[83]
India	• Biological Data Storage, Access and Sharing Policy of India: By the Department of Biotechnology of India – guidelines for sharing data generated by scientists using advanced biotechnological tools to enhance the collective utility of health and biological data responsibly.[84] Additionally, guidelines on Electronic Health Record standards are provided by the Ministry of Health & Family Welfare, underscoring the government's commitment to promoting data standards and interoperability.[85]
South Korea	• Standards on the exchange of core data for interoperability: South Korea's Health Data Standardization Taskforce revised standards for healthcare data to promote interoperability of its healthcare institutions. The taskforce developed specific standards for technical exchange methods, including data formats.[86] • Korea-Singapore digital partnership agreement: An initiative of the Ministry of Trade, Industry and Energy (South Korea) and MTI Singapore, which has been designed to deepen bilateral cooperation in the digital economy between the two countries. By establishing forward-looking digital trade rules and norms, the agreement aims to promote interoperability between digital systems, enable more seamless cross-border data flows and build a trusted and secure digital environment for businesses and consumers.[87]
Regional and Global	• Health IT sandboxes: Multiple vendor sandboxes from leading healthcare IT companies allow developers to build, test and demonstrate applications without affecting production systems. • WHO Go.Data: A platform designed for disease outbreak response and investigation, featuring tools for visualizing transmission chains and facilitating secure data exchange. Efforts are currently underway to enhance its interoperability, in preparation for a global rollout.[88] • APACMed Health Data Workshop – e-Health interoperability and IHE training: Aims to work with Association of Southeast Asian Nations (ASEAN) governments to promote interoperability and international health data standards across the region, starting from nationwide health information exchange, then establishing relevant frameworks to enable easier, more secure governance and processes.[89]

E. Data, interoperability and integration

Data, interoperability and integration considerations

E.2 Facilitate regional and local digital and data maturity development

Why is it important

Interoperability and integration of AI in MedTech into health systems is crucial for deploying and adopting solutions in clinical settings. Harmonizing efforts across the ecosystem can help accelerate regional maturity by sharing knowledge, skills and practices across borders. This should enable AI in MedTech solutions to be deployed and scaled.

What is it

Developing specific indexes or leveraging those already available for digital, data and AI health maturity in Asia Pacific can address specific country data needs and the sharing of learnings and industry best practices, uplifting regional digital and data maturity.

How to address

Explore opportunities to align on a common framework for digital, data and AI maturity for health systems across the region. There are many digital and data maturity assessments available globally that can be complemented by the growing presence of AI readiness benchmarks to define an appropriate, Asia Pacific-wide digital, data and AI maturity benchmark.

Evidence and examples

- **AI Readiness Index:** Singapore is the leader in AI readiness, followed by South Korea, Japan, Australia, China, and India (Table 5).[90] With numerous such AI readiness indices available, there are opportunities to align on and anchor around a common framework.

E. Data, interoperability and integration

Data, interoperability and integration considerations

E.3 Facilitate access to regionally representative use-case-based datasets for AI in MedTech

Why is it important

The Asia Pacific region presents novel demographics and a diverse patient pool. Training and maintaining AI algorithms using accurate and representative data sets for the intended population is crucial.

What is it

Promoting the accessible, representative and high-quality Asia Pacific datasets that are available and utilized throughout the AI in MedTech lifecycle.

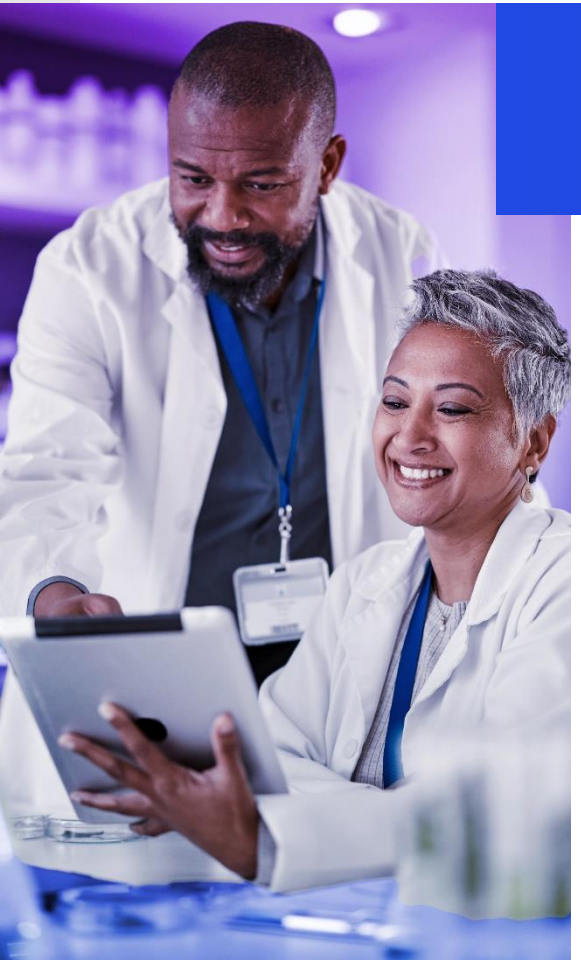
How to address

Explore and implement initiatives to promote industry practices for data standards. These include training AI algorithms with data that is representative of their intended use and integrating these industry practices into health data standards. Additionally, facilitate the availability and improvement of local and regional datasets related to patient health populations and priority disease areas, including for secondary use in research and development by academia, industry and innovators in Asia Pacific.

Evidence and examples

- **India:** The Ayushman Bharat Digital Mission, launched in 2021, aims to strengthen the digital health ecosystem by developing and integrating health data records and registries, thereby making systems more interoperable. It is envisaged to provide a dataset of every clinical encounter, generating a plethora of health information available to citizens, hospitals and insurance firms.[91]

F. Collaboration and partnership



Collaboration and partnership are critical to the successful adoption and realization of value from AI in MedTech. By working together, stakeholders can harness the full potential of innovative technologies.

Collaboration and partnership barriers - Lack of awareness, understanding and acceptance across healthcare ecosystem stakeholders on the use of AI in MedTech

What is it

There are varying levels of acceptance, awareness and understanding of AI across the healthcare ecosystem.

What is the impact

Lack of familiarity and awareness can hinder stakeholder acceptance and adoption of AI in MedTech. This creates numerous friction points and impacts AI integration into organizations, products, clinical workflows, regulations and policies.

Evidence and examples

- **AI acceptance and training:** A recent review of acceptance of AI in healthcare identifies fear of loss of professional autonomy and clinical workflow as the hindering factors for adoption in clinics. However, training on the uses of AI seemed to facilitate acceptance.[92]

F. Collaboration and partnership

Collaboration and partnership are critical to the successful adoption and realization of value from AI in MedTech. By working together, stakeholders can harness the full potential of innovative technologies.

Collaboration and partnership barriers - Asynchronous levels of stakeholder engagement across the AI value chain for policy and regulation development

What is it

Strategies, regulations and policies are still in development, broadly in healthcare and general practice, and more specifically for AI in MedTech. Engagement levels and formats vary significantly across organizations, countries and territories.

What is the impact

Varying engagement levels can hinder the effective understanding and application of policies and regulations. This can diminish the effectiveness of policy and regulation, as well as relevance for industry, operational and clinical use cases, further impeding policy and regulation execution and adoption. It can also result in policy or regulatory inefficiencies across the region, affecting the access and scale of AI in MedTech solutions.

Evidence and examples

- **Importance of stakeholder engagement in AI policymaking:** The New South Wales AI Advisory Committee in Australia has helped shape comprehensive AI assurance and ethics frameworks. Australia simultaneously announced a complete review of its governance mechanisms for the use of AI, including stakeholder feedback through public and stakeholder consultations.[93]

F. Collaboration and partnership

Collaboration and partnership are critical to the successful adoption and realization of value from AI in MedTech. By working together, stakeholders can harness the full potential of innovative technologies.

Collaboration and partnership barriers - Fragmentation of channels and collaboration for AI MedTech translation across the Asia Pacific region

What is it

The current channels and forums for facilitating discussions, dialogue and collaboration on AI in MedTech are fragmented. This disparity can lead to fractured (and even divergent) strategies, policies, regulations, collaborations and partnerships.

What is the impact

When industry best practices, advancements and educational resources are not uniformly distributed throughout Asia Pacific, it can result in uneven adoption of AI technologies in healthcare. Limited access to information may also result in slower awareness, access to knowledge and adoption rates, or even resource duplication and innovation delays.

Evidence and examples

- **Siloed players due to lack of collaboration:** The pace of R&D in Asia Pacific has slowed down due to segregation in the healthcare sector and the lack of communication between different players in the field. MedTech companies and academic institutions often conduct research in isolation. Thus, there is limited sharing of results, data and findings in their discoveries.[94]

F. Collaboration and partnership

Collaboration and partnership considerations

F.1 Facilitate collective, consistent awareness and understanding of AI in MedTech solutions across the healthcare ecosystem

Why is it important

Knowledge sharing and collaboration are important for AI adoption and value realization as they facilitate the exchange of success stories, lessons learned and troubleshooting experiences among different stakeholders.

What is it

Current collaborative efforts can take many forms, from forums and events to larger consortiums and partnerships. These can be specific to AI in MedTech or healthcare, or more generally promoting a shared understanding of AI.

How to address

There are numerous forums and consortiums dedicated to discussing, collaborating on and shaping the future of AI. However, this diversity risks a lack of coherence that may push AI in MedTech in varying or even conflicting directions, leading to fragmented outcomes. The Asia Pacific MedTech industry should look at avenues to integrate into or leverage existing global and regional forums to foster effective representation of AI in MedTech.

Evidence and examples

See examples of Asia Pacific regional and global forums for promoting leading healthcare practices on next page.

F. Collaboration and partnership

Collaboration and partnership considerations

F.1 Facilitate collective, consistent awareness and understanding of AI in MedTech solutions across the healthcare ecosystem

Evidence and examples

- **Investment focus:** A primary investment focus for Asia Pacific countries and territories in 2024 is to enhance knowledge management. This includes refining processes for information sharing to support companies in adopting and effectively using AI technologies.
- **Asia Pacific regional forums that are useful for promoting leading practices in healthcare and demonstrating the impact of Public-Private Partnerships (PPPs) in advancing MedTech innovation include:**
  - **The AI Summit Series (Singapore):** Run by Asia Tech x Singapore, this is a key event that brings together AI professionals, business executives, investors and stakeholders to foster discussions and forge partnerships aimed at advancing AI technology and applications.[95]
  - **Digital Health Symposium:** By APACMed, this conference highlights leading practices in digital health and facilitates the exchange of knowledge and innovations.[96]
  - **Asia Pacific MedTech Forum:** Discusses and shapes regulations impacting medical technology, including AI applications in healthcare in Asia Pacific.[97]
- **Global forums that are useful for promoting leading practices in healthcare include:**
  - **AI for Good Global Summit:** Organized by ITU, convenes expert stakeholders from around the world.[98]
  - **Global Forum on the Ethics of Artificial Intelligence:** By UNESCO, this forum is focused on policy development, with members sharing their experiences and expertise.[99]

F. Collaboration and partnership

Data, interoperability and integration considerations

F.2 Promote early engagement for designing and updating regulatory, reimbursement and other policies relating to AI in MedTech

Why is it important

Knowledge sharing and collaboration are important for AI adoption and value realization as they facilitate the exchange of success stories, lessons learned and troubleshooting experiences among different stakeholders.

What is it

Early engagement with healthcare stakeholders – including clinicians, patients, payors and industry representatives – in the development of policies and regulations for AI in MedTech can result in more effective and appropriate policies.

How to address

APACMed can help foster these ecosystem partnerships and collaboration.

Evidence and examples

Table 9 Examples of global collaborations and partnerships in the Asia Pacific and globally (see next page).

Table 9 Examples of global collaborations and partnerships in the Asia Pacific and globally.

Country	Collaboration & partnerships
Singapore	• **IMDA-Google:** PET x Privacy Sandbox: A secure environment to trial Privacy Enhancing Technologies. Aims to enhance personal data protection and privacy while fostering data collaboration, cross-border data flow and data collection for AI development.[100] • **Digital Economy Partnership Agreement:** The agreement between Chile, New Zealand and Singapore facilitates trusted data flows and promotes cross-border digital trade by developing frameworks for personal data protection, expanding access to open government data, and supporting forward-thinking data-driven businesses through regulatory sandboxes. [101] • **IMDA GenAI x Digital Leaders:** Leverages partnerships with tech experts to enhance organizations' understanding of GenAI, guiding them from identifying impactful projects to implementing solutions. These collaborations offer advisory support and leading practices in AI governance, along with grant support, to encourage early adoption and accelerate the deployment of GenAI technologies.[102] • **Digital Forum of Small States (Digital FOSS) AI Governance Playbook:** To help small states harness AI. Singapore and Rwanda are developing the Digital FOSS AI Governance Playbook. This guide will address the secure design, development, evaluation and implementation of AI systems, tailored to the unique challenges small states face.[103]
Australia	• **Victorian All-Party Parliamentary Group on Artificial Intelligence:** Established to facilitate informed discussions among Victorian parliamentarians about the transformative nature and potential of AI. It includes collaborating with experts of AI to enhance understanding of AI among lawmakers and guide policy development.[104] • **Singapore-Australia Digital Economy Partnership Development:** Enhance digital trade agreements between Singapore and Australia with developing compatible and interoperable data transfer mechanisms for personal data as a key feature.[105] • **New South Wales AI Ethics Framework and NSW AI Advisory Committee:** By Digital NSW, consisting of the NSW Advisory committee which is a collaboration of AI experts informed by industry standards.[106] They played a crucial role in advising and the formation of the NSW AI Ethics Framework in efforts to demystify AI and build trust.[107]
Japan	• **EU-Japan Economic Partnership Agreement**: In 2023, EU and Japan concluded a landmark deal to make doing business online easier. This agreement lays the foundation for a common approach on digital trade with a focus on cross-border data flow.[108]
India	• **US-India Artificial Intelligence Initiative:** A platform to discuss opportunities, challenges and barriers in bilateral AI research development and developing an AI workforce.[109] • **Quad Tech partnerships:** This includes India, Australia, Japan and US.[110] • **Indo-German Science and Technology Centre:** India and Germany have set up a joint AI initiative allowing India's Department of Science and Technology and Germany's Federal Ministry of Education and Research to forge partnerships in research and development programs focused on healthcare and sustainability to promote the sharing of leading practices and ethical frameworks.[111]
South Korea	• **Korea-Singapore Digital Partnership Agreement:** By The agreement between the two countries seeks to bilateral cooperation in the digital economy. The aim is to establish forward looking digital trade rules and norms to promote interoperability between digital systems to enable more seamless cross-border data flows and build a trusted and secure digital environment for businesses and consumers. [112]
Regional and global	• **OECD Council recommendations on AI:** Supports governments by measuring and analyzing the economic and social impacts of AI technologies and applications and engaging with stakeholders to identify good practices for public policy.[113] • **ASEAN Medical Device Directive (AMDD):** ASEAN established the AMDD to harmonize regulatory requirements across member states, allowing for mutual recognition of MedTech approvals among them, thereby speeding market entry and approvals.[114]

F. Collaboration and partnership

Data, interoperability and integration considerations

F.3 Explore existing and new collaborative mechanisms to facilitate AI MedTech adoption

Why is it important

Establishing and strengthening collaborative mechanisms can streamline the introduction of new technologies, including AI, in MedTech. Greater understanding, awareness and confidence among key stakeholders along the care continuum can accelerate AI adoption. Moreover, new collaborative frameworks can facilitate a quicker translation of AI capabilities into practical MedTech applications.

What is it

Expansive partnerships between startups, established MedTech and technology companies and healthcare providers, along with PPPs, can help foster knowledge and capability sharing.

How to address

Facilitate and support partnerships, collaboration and co-design with current and emerging AI in MedTech and wider healthcare stakeholders. This could be in the form of co-design with clinicians, partnerships with tech firms and/or PPPs. Organizations such as APACMed can play a crucial role by connecting diverse stakeholders together, MedTech organizations and beyond.

Evidence and examples

- **Market access and seamless AI integration:** Qritive is working with a European life sciences multinational company to commercialize MedTech hardware with embedded AI applications. The European life sciences multinational company is commercializing a slide scanner that can capture and display scanned biopsies on a digital interface. This is combined with Qritive's AI modules which can provide AI insights about the interpretation of the slide as a clinical decision support system for pathologists. Partnerships between MedTech hardware providers and software startups create opportunities for startups to access the MedTech market and for seamless AI integration in healthcare.
- **Operations and regulatory efficiency:** Partnerships between startups and specialized Contract Development and Manufacturing Organizations (CDMOs) can be highly beneficial. CDMOs provide critical resources and expertise that a smaller (or even mature) MedTech firm might lack internally, such as equipment for manufacturing or assistance with certification and regulatory approvals. These relationships can help in ensuring that datasets are clean and robust and strengthen regulatory alignment, potentially speeding up the clearance and approval processes for new MedTech.[115]
- **Investments from MNCs:** US$28 million (SGGD$38 million) MedTech Catapult national initiative hosted of by A*STAR aims to accelerate the development of MedTech products in Singapore.[116]

Trust considerations for AI in MedTech

Clinician and patient trust in AI are essential for the integration of AI in the provision of care in hospital settings and the adoption of AI-enabled smart devices in out-of-hospital community settings. Confidence in using AI for disease diagnosis, patient treatment and health monitoring is built by having effective regulations, protection and risk mitigation mechanisms in place to serve as guardrails, thereby cultivating safe and ethical AI use. This section of the whitepaper explores some of the key barriers and considerations for trust in AI in MedTech (outlined in Table 10).

> Trust is the catalyst for outcomes when it comes to AI in MedTech. With trust comes confidence. With confidence comes utilization. With utilization comes outcomes."

Anastasia Miros
Director, Healthcare and Life Sciences Asia Pacific
KPMG

Trust considerations for AI in MedTech

Table 10 Overview of key barriers and considerations for improving trust in using AI in Asia Pacific

	G. Regulation	H. Protection	I. Ethics
BARRIER	Lack of clarity and coherence of AI device regulation in MedTech.	Lack of clarity and consistency in data protection mechanisms for AI MedTech. Lack of coherence and expectations on patient data fair use definitions. Lack of clarity on addressing novel risks introduced by AI in healthcare settings.	Lack of consistency, availability and alignment on ethical principles and guidelines for AI in MedTech.
CONSIDERATION TO IMPROVE ACCESS	G.1 Explore risk-based approaches to the regional regulation of AI in MedTech. G.2 Explore regional recognition and reliance models to promote convergence of AI in MedTech. G.3 Facilitate regional engagement in AI regulation development.	H.1 Establish regional cybersecurity standards for AI in MedTech. H.2 Establish guidelines on the fair use of patient data. H.3 Develop controlled environments and settings for early testing of protection mechanisms.	I. Establish regional and aligned ethical principles and guidelines for AI in MedTech.

G. Regulation

Regulations in MedTech govern AI development and adoption by ensuring tech solutions meet stringent patient safety standards. The following sub-sections explore existing barriers in AI regulation and considerations for improving future regulation development.

Regulation barriers - Lack of clarity and coherence of AI device regulation in MedTech

What is it

Across Asia Pacific, there are varied regulatory approaches for AI in MedTech between jurisdictions.

What is the impact

Limited coherence and clarity on AI regulation developments and updates for AI in MedTech can create friction, uncertainty and delays in the deployment and adoption of AI in MedTech across Asia Pacific. Additionally, localized frameworks and regulations pose further challenges for cross-border sharing of data (i.e. data silos are reinforced in attempts to comply with local data protection regulations) and scalability of solutions.

Evidence and examples

- Variations in the regulatory approach adopted by markets across Asia Pacific are summarized in Table 11 (see next page).

> The region lacks a coordinating body to oversee harmonized policy implementation. ASEAN is a possible option, but its oversight is not sufficient."

Alistair Lang
Consultant and Researcher
Center for Asia-Pacific Resilience and Innovation

Table 11 Overview of regulatory approaches adopted by Asia Pacific markets

Market	Regulatory approach adopted			
	Guiding principles approach	Balanced approach	Prescriptive approach	Key AI Acts, Laws, Regulations and Policies
Australia	✓			• Therapeutic Goods Administration Guidance on Software as a Medical Device[117] • Australia's Artificial Intelligence Ethics Framework[118] • Digital Health Cooperative Research Centre Initiatives[119]
Japan	✓			• Medical Device Program by the Pharmaceuticals and Medical Devices Agency[120] • Next Generation Medical Infrastructure Act[121] • AI Health and Medical Strategy by the Ministry of Health, Labor and Welfare[122]
Singapore	✓			• Health Sciences Authority Regulatory Guidelines for AI in Healthcare[123] • Singapore's National AI Strategy[124] • AI Governance Framework by the Personal Data Protection Commission[125]
China			✓	• National Medical Products Administration Principles for the Classification Defining of AI-Based Medical Software Products[126] • New-Generation Artificial Intelligence Development Plan[127] • Cybersecurity Law[128]
India		✓		• Digital Personal Data Protection Bill[129] • National Digital Health Blueprint[130] • ICMR's Ethical Guidelines for Application of AI in Biomedical Research and Healthcare[131] • National Strategy for AI (NITI Aayog)[132]
South Korea			✓	Digital Bill of Rights[133] National Strategy for AI[134] Personal Information Protection Act[135]

Regulatory approach: The frameworks and principles adopted by authorities to ensure the safe, effective and ethical use of AI technologies in medical applications range from providing non-enforceable guidance and recommendations (guiding principles) to implementing strict legal requirements specific to AI applications (prescriptive) to adopting a middle ground that incorporates elements of both (balanced approach)

Guiding principles approach: Guidance and recommendations are provided without enforcing strict laws

Prescriptive approach: Implementation of legal requirements specific to a particular type of AI application

Balanced approach: Middle ground between the guiding and prescriptive approach

G. Regulation

Regulation considerations

G.1 Explore risk-based approaches to regional regulation of AI in MedTech

Why is it important

Adopting a risk-based approach to AI regulation across the Asia Pacific region can significantly reduce regulatory burden, enhance regulatory efficiency and promote compliance.[136]

What is it

An AI framework that stratifies AI solutions by use-case risk level can help support tech solutions that are fit to comply with regulations.[137] The potential benefits of a risk-based AI framework are two-fold: it can facilitate resource efficiency for regulatory bodies by focusing more effort and oversight on high-risk solutions and it can help streamline the approval process to accelerate speed in bringing new products to market. A regionally coordinated regulatory approach to AI regulation development can help build confidence in the safety and efficacy of AI technologies.[138]

How to address

To create a risk-based AI framework for MedTech in Asia Pacific, there is a need for engagement between regulators themselves – as well as between them and the industry to define a set of criteria that determines the classification of AI products based on their potential associated risks to users and defines the process and requirements for AI product certification. There are opportunities for the industry to actively facilitate these discussions through existing channels such as APACMed's Regulatory Committee.

Evidence and examples

- **EU's Medical Device Regulations (EU MDR):** The EU MDR adopts a risk-based approach in regulating MedTech by considering potential risks that MedTech poses to humans (such as duration of contact with body, device invasiveness and potential toxicity). Additionally, it mandates new MedTech to undergo and pass a conformity assessment to demonstrate products meet safety and performance standards before they are launched in market.[139]

G. Regulation

Regulation considerations

G.2 Explore regional recognition and reliance models to promote convergence of AI in MedTech

Why is it important

Sector-specific AI regulations provide clear accountability and ensure compliance requirements for AI in MedTech are met before products are launched in the market. Convergence in AI regulations streamlines cross-border sharing and scale, expediting access to AI-enabled MedTech products.

What is it

Regulators across Asia Pacific can explore mechanisms, such as recognition and reliance models specific to the MedTech industry, to provide clear compliance requirements. In a recognition model, one regulator accepts another's approval as sufficient evidence of compliance. In a reliance model, on the other hand, one regulator acknowledges another's approval and expedites the market entry process. These harmonized approaches can benefit healthcare providers and patients by promoting timely access to safe and effective technologies, while balancing resources and expertise across the region based on the capacity and capability of local regulators.

How to address

Explore potential regulatory harmonization models such as recognition or reliance. To implement mechanisms such as MedTech industry-specific recognition and reliance models, there should be expedited regulatory pathways for the review of AI products already approved by another acknowledged, trusted institution(s), as well as streamlined pre-market review processes for AI products with certifications that demonstrate quality in product development.[140]

Evidence and examples

- **Australia:** The Therapeutic Goods Administration (TGA) in Australia has Mutual Recognition Agreements with the EU.[141]
- **Singapore:** Singapore's Health Sciences Authority acknowledges approvals from multiple international regulators, including TGA Australia, Health Canada, US FDA, and EU Notified Bodies.[142]

G. Regulation

Regulation considerations

G.3 Facilitate regional engagement in AI regulation development

Why is it important

Engaging key stakeholders in the regional MedTech ecosystem facilitates timely, appropriate development and updates to AI regulations, also improving compliance, transparency, trust and the effectiveness of AI regulations.

What is it

A regional consortium that can facilitate industry dialogue with policymakers from different jurisdictions. This enables proactive anticipation of regulatory needs and draws on industry expertise to support AI regulations that are practical, well-understood and adhered to.

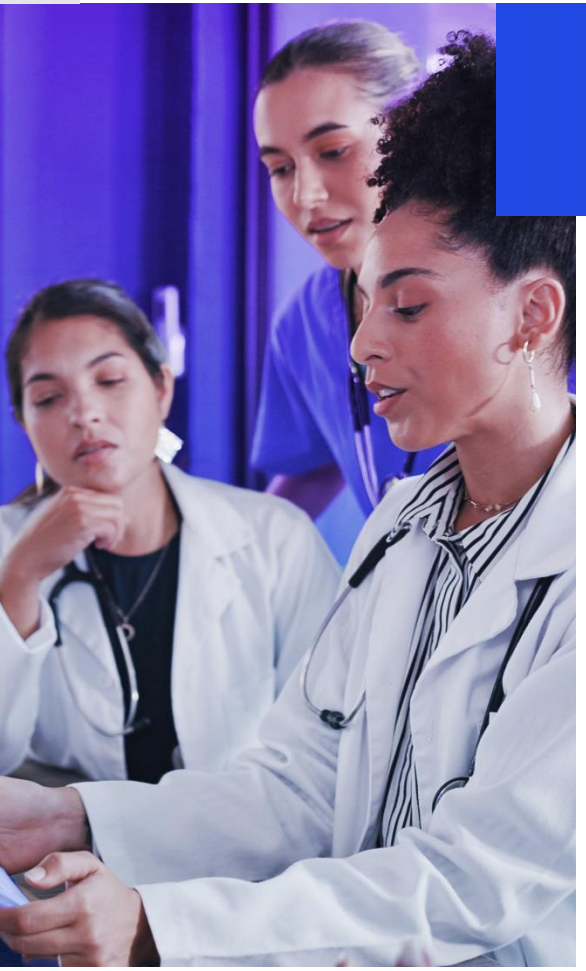
How to address

Establish a regional consortium with representative members from key stakeholder groups in the MedTech ecosystem. Engage with members from the regional consortium through a public consultation process during the early stages of policy and regulation development to develop effective, well-accepted AI regulations that can keep up with the evolving landscape of AI innovation. This can moreover integrate with recommendation F.2 to align channels for early and ongoing engagement regarding proactive dialogue between MedTech companies and regulators.

Evidence and examples

- **APACMed:** The Digital Health Committee – Regulatory Working Group[143, 144] has been impactful in elevating industry perspectives on global leading practices in digital health regulation, including those related to AI, through webinars[145], thought leadership and position papers. 'Digital Health Regulation in Asia-Pacific: Overview and Best Practices', one such position paper, calls for cross-ecosystem partnerships through industry associations and private-public consortiums to share leading practices to facilitate safe, effective and timely delivery of forward-thinking solutions.
- **Singapore:** Singapore's Ministry of Health Singapore conducts public consultations to iteratively inform its AI regulations, forging health cooperation MoU with other regional countries such as Australia.[146]

H. Protection



The adoption of AI in MedTech comes with heightened cybersecurity and patient data confidentiality risks and concerns for the healthcare system. Stakeholders expect solutions and data to be protected, before engaging with and utilizing AI in MedTech solutions.

Cybersecurity and data protection barriers - Lack of clarity and consistency in data protection mechanisms for AI MedTech

What is it

Trusted use and adoption of AI in MedTech requires protective mechanisms embedded across the AI development lifecycle to safeguard personal patient data. Jurisdictions globally and regionally in Asia Pacific do have AI-related cybersecurity regulations and policies in place (outlined in Table 12); however, there are limitations and variations to the extent of protection mechanisms and expectations.

What is the impact

The healthcare industry is vulnerable to cyber-attacks because health data is often housed in legacy or siloed data infrastructure, and healthcare providers are likely to pay ransoms in the event of such a cyber-attack (i.e. high attack profitability). With the rise of home-based care and telemedicine, health records have become less centralized and thus, more susceptible to cyber-attacks.

Evidence and examples

- **Financial impact:** Cyber breaches can cost over US$400 per exposed patient record and the average breach in the healthcare sector can cost US$6.45 million.[147] Between 2005 and 2019, 249.1 million individuals were affected by healthcare data breaches globally, with 157.4 million of these breaches occurring between 2015 to 2019 alone, highlighting the growing risk of cyber-attacks.[148]
- **Data Availability:** With the rise of home-based care and telemedicine, health records have become less centralized and thus, more susceptible to cyber-attacks.[149]

H. Protection

Table 12 Summary of AI-related cybersecurity regulations in global and Asia Pacific markets

Market		AI-related cybersecurity regulations	Scope and limitations
Global	US	• Health Insurance Portability and Accountability Act[150] • Health Information Technology for Economic and Clinical Health Act[151] • National Institute of Standards and Technology (NIST) Cybersecurity Framework[152]	• Protection of patient health information, data privacy and security requirements for healthcare providers and businesses • Guidelines and leading practices for managing cybersecurity risks
Global	EU	• General Data Protection Regulation (GDPR) [153] • EU AI Act[154]	• Comprehensive data protection and privacy for individuals, including health data • Aims to regulate AI applications with a focus on high-risk sectors including healthcare
Regional	Australia	• Privacy Act 1988[155] • My Health Records Act 2012[156]	• General data protection and privacy principles • Digital health records, data privacy and security • Does not cover AI-specific regulations
Regional	Japan	• Act on the Protection of Personal Information[157] • The Basic Act on Cybersecurity[158]	• General data protection principles, including personal and sensitive data • National cybersecurity policy framework • Does not cover AI-specific regulations

H. Protection

The adoption of AI in MedTech comes with heightened cybersecurity and patient data confidentiality risks and concerns for the healthcare system. Stakeholders expect solutions and data to be protected, before engaging with and utilizing AI in MedTech solutions.

Cybersecurity and data protection barriers - Lack of coherence and expectations on patient data fair use definitions

What is it

Varying definitions of fair data use for primary (evidence generation) and secondary (research and innovation) purposes across Asia Pacific markets can lead to data misuse and undermine public trust.[159]

What is the impact

Patients may not have a clear awareness of how their health data is used for AI model development as consent rates for secondary uses vary significantly. While sharing data for primary purposes like EHR is generally accepted, there is a lack of public understanding about the importance of data sharing for secondary research, including activities such as clinical trials and reimbursement processes.

Evidence and examples

- **Consent rates:** According to a meta-analysis of 2,109 studies, consent rates for secondary purposes ranged from 98 percent to as low as 10 percent, indicating a gap in public understanding and trust.[160]

> I would think the real opportunity is to build new social contract (trust) around data and AI usage."

Steve MacFeely
Director of Data & Analytics
WHO

H. Protection

The adoption of AI in MedTech comes with heightened cybersecurity and patient data confidentiality risks and concerns for the healthcare system. Stakeholders expect solutions and data to be protected, before engaging with and utilizing AI in MedTech solutions.

Cybersecurity and data protection barriers - Lack of clarity on addressing novel risks introduced by AI in healthcare settings

What is it

The expansion of traditional AI into LLMs introduces novel risks such as hallucinations, accountability, ingestion, data representation and bias, data currency, transparency and memory.

What is the impact

As AI technology continues to emerge and evolve, including the risks therein, this results in varying degrees of understanding of appropriate mitigation measures relating to AI adoption in MedTech.

Evidence and examples

- **Hesitation and comprehension of AI:** A 2024 survey of 1,490 experts across academia, business, government and the international community found that 53 percent identified AI-generated misinformation and disinformation as risks likely to cause a material crisis on a global scale. Additionally, 39 percent pointed to cyber-attacks as posing significant risks.[161]
- **Lack of up-to-date training:** The advancement of GenAI can help propel organizations but also leave them open to risks that need to be addressed, such as the risk of leaking private data into the public realm. In a KPMG survey about GenAI adoption in Canada, 18 percent of users revealed they had entered proprietary data about their company into a prompt.[162]

H. Protection

Cybersecurity and data protection considerations

H.1 Establish regional cybersecurity standards for AI in MedTech

Why is it important

With the limited availability of cybersecurity measures specific to AI in MedTech, the ecosystem currently leverages broader frameworks like ISO/IEC 27001, the NIST Cybersecurity Framework and GDPRF. These may not fully address the heightened cybersecurity risks introduced with AI in the specific nuances of healthcare and MedTech. Regionally aligned standards and guidelines can help cultivate trusted and safe integration of AI solutions into healthcare settings across Asia Pacific.

What is it

Clear and aligned cybersecurity standards and guidelines for AI in MedTech are crucial for consistency in safeguarding patient data and facilitating trust in AI in MedTech.

How to address

Develop regionally aligned standards which define measures inclusive of considerations for authentication, access controls, data minimization and anonymization, federated learning and data encryption, along with guidelines for continuous monitoring, assessment and audits of AI databases.

Evidence and examples

- **APACMed:** The Digital Health Committee – Cybersecurity Working Group is devoted to facilitating private-public collaborations in Asia Pacific to increase and share knowledge on MedTech cybersecurity and to advocate for harmonized policy frameworks.[163]

H. Protection

Cybersecurity and data protection considerations

H.2 Establish guidelines on the fair use of patient data

Why is it important

Promoting clear guidelines on the fair use of patient data fosters transparency and trust between patients, clinicians, industry, academia and government.

What is it

Clear guidelines for the fair use of patient data, including opt-in/opt-out options to control data use and storage.

How to address

Facilitating a unified approach and developing clear regional guidelines and communication protocols for data use is essential. Providing education on primary and secondary use of data, including regarding opt-in/out sharing decisions, in the MedTech industry can build trust among the public that personal data used in AI systems is being handled safely, securely and ethically.

Evidence and examples

- **Willingness to share:** A survey revealed that 71 percent of respondents are willing to share de-identified medical data, emphasizing the importance of trust in their decision to share such records.[164]
- **Singapore:** Singapore's Personal Data Protection Act allows the use of personal data for research under specific conditions (provided the research has a clear public benefit and results are anonymized).[165]

H. Protection

Cybersecurity and data protection considerations

H.3 Develop controlled environments and settings for early testing of protection mechanisms

Why is it important

Controlled environments and settings for early testing enable stakeholders to collectively build, test and iterate control measures of AI solutions, in nearly real-time. This supports early testing and adoption of controls by MedTech companies, collaboration between stakeholders on control appropriateness in a 'risk-reduced' environment and can inform future policies and regulations which account for potential AI in MedTech innovation use cases.

What is it

Provisioning of controlled digital environments and toolsets through mechanisms such as evaluation toolkits and sandbox environments (with AI labeling).

How to address

Implement thorough approaches that enable safe testing and iteration. These include benchmarking AI control systems, collaborating to develop and test new cybersecurity measures, and conducting early-stage integration tests within clinical workflows.

Evidence and examples

- **AI Verify Foundation's Project Moonshot:** Integrates benchmarking, labelling, adversarial testing and baselines to promote safe and efficient AI deployment. As one of the world's initial LLM evaluation toolkits, it assesses AI systems across various competencies, fostering overall model safety and performance.[166]
- **Singapore:** Singapore's Cybersecurity Labelling Scheme for Medical Devices rates MedTech/consumer smart devices based on their cybersecurity provisions. This encourages manufacturers to adopt security-by-design practices and empowers consumers and healthcare providers with informed decision-making capabilities regarding device use, thereby enhancing overall cyber hygiene and security standards. APACMed has been active in working alongside Singaporean government agencies through roundtable discussions, leveraging industry expertise in MedTech for the roll-out of the scheme.[167]

I. Ethics

Ethical principles are fundamental to cultivating transparency and to achieving greater security, safety and accountability of AI solutions in MedTech.

Ethical AI barriers - Lack of consistency, availability and alignment on ethical principles and guidelines for AI in MedTech

What is it

While many Asia Pacific countries/territories have already, for the most part, begun to tailor their existing ethics guidelines for AI, common themes which remain open for discussion include protecting human interests, promoting fairness, transparency and improving health outcomes, all crucial for fostering trust in AI within MedTech.

What is the impact

A lack of clear and aligned principles risks fragmentation of ethical uses of AI, impacting patient outcomes and potentially allowing for unethical practices to damage trust in AI solutions in MedTech.

Evidence and examples

- **Ethical frameworks:** There are numerous AI ethical guidelines now available from leading supernational organizations which emphasize: human rights and democratic values, transparency and explainability of AI systems, robustness, security, safety and accountability.

I. Ethics

Ethical AI considerations

I.1 Establish regional and aligned ethical principles and guidelines for ai in MedTech

Why is it important

Adopting the Responsible AI Code of Ethics embeds principles, safeguards and guidelines across stages of the AI development lifecycle, thereby enhancing transparency, accountability and public confidence.[168] Responsible AI processes can take three years on average to establish and implement, underscoring the importance of timely intervention.[169]

What is it

Ethical frameworks accounting specifically for AI considerations in MedTech. In particular, accounting for different use cases and ethical implications (for example, traditional AI versus LLMs) and patient-level versus system-level ethical implications (for example, over-estimation, over-reliance and healthcare pay-walls).

How to address

Leverage the globally available ethical frameworks that can serve as the baseline for translation and alignment on ethical principles tailored toward the needs of AI in MedTech in Asia Pacific.

Evidence and examples

- **WHO:** WHO's guidance on 'Ethics and Governance of Artificial Intelligence for Health'.[170]
- **WEF:** World Economic Forum's 'PRISM Framework for Responsible AI in Social Innovation'. [171]
- **US:** NIST's 'AI Risk Management Framework'.[172]
- **US-EU Trade and Technology Council:** Voluntary AI code of conduct.[173]

Call-to-action

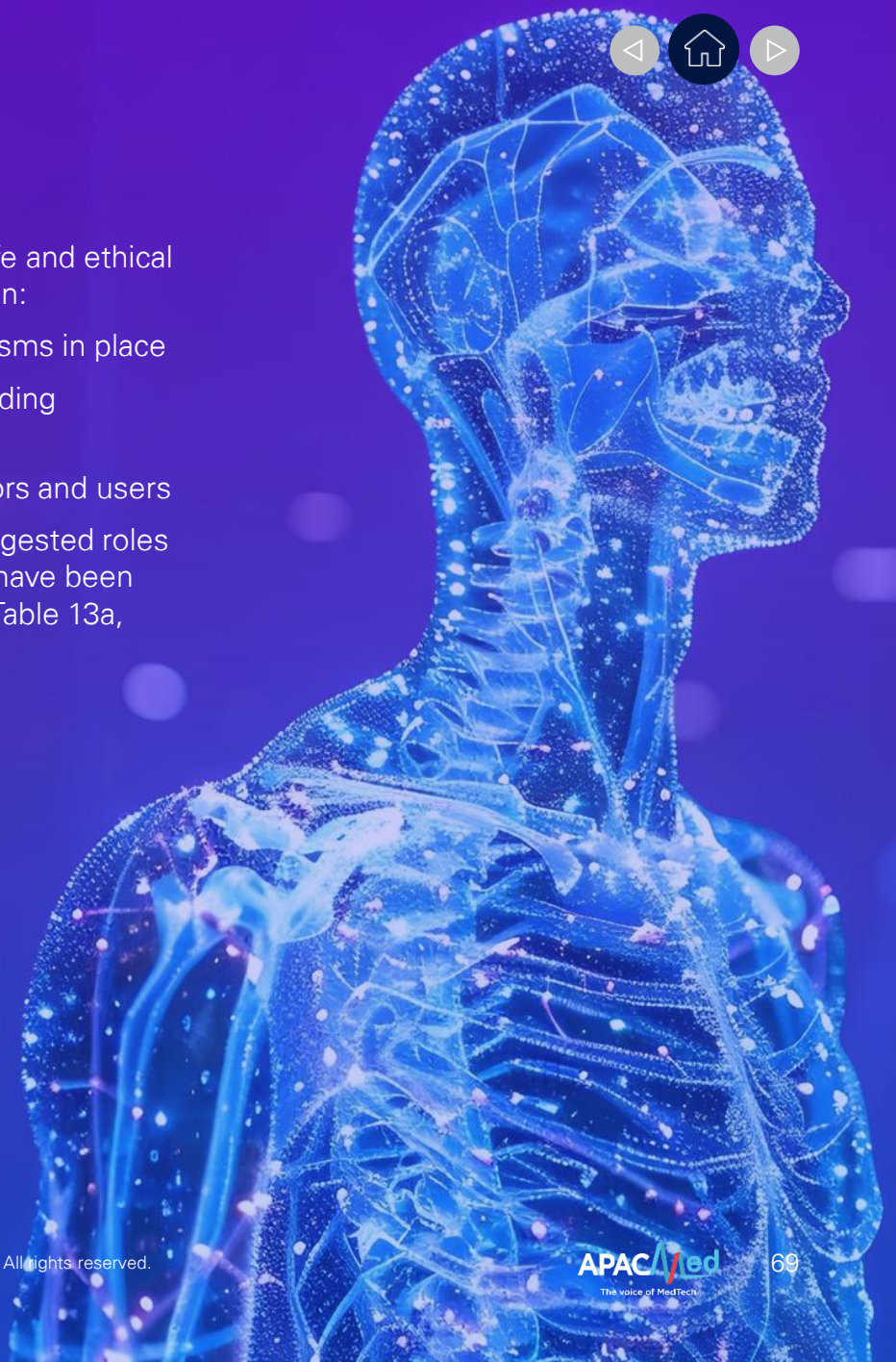
The consensus view gathered through interviews and research for this whitepaper is that safe and ethical development and adoption of AI innovation in MedTech and healthcare can be optimized when:

- Trust is created by having effective regulations, cybersecurity and data protection mechanisms in place
- The MedTech ecosystem is equipped with the right talent, data and AI infrastructure, including mechanisms for knowledge mindshare
- Barriers in financial and social inequity are lowered to make AI more accessible to innovators and users

Finding ways to overcome these described barriers will be a multi-stakeholder endeavor. Suggested roles and actions of key healthcare ecosystem stewards in facilitating the use of AI in Asia Pacific have been identified, particularly from a MedTech perspective. The following list in the next few pages (Table 13a, 13b), is by no means exhaustive, but rather seeks to act as foundation for future discussion.

> AI needs a clear regulatory infrastructure region-wide. As AI technologies develop across the region, differing regulatory frameworks (especially on data security and privacy) from country to country will hamper the penetration of AI solutions across different markets. Not all countries in the region will adopt EU, US, or Chinese standards, which may make it difficult for the scalability of solutions."

Caroline Fried
Interim Director of Research,
Center for Asia-Pacific Resilience and Innovation



Summary of considerations associated with Access-Capability-Trust

Table 13a Summary of considerations associated with Access-Capability-Trust

Levers	Themes	Considerations for APACMed
Access	**A.** Financial Access – Reimbursement	**A.1** Expand and align on government-led reimbursement frameworks for AI in MedTech.
	B. Financial Access – Delivery and deployment	**B.1** Explore alternate funding mechanisms for AI development and deployment.
	C. Equitable Access – ESG	**C.1** Establish a regionally aligned equity and governance. framework for AI in MedTech **C.2** Invest in regional AI readiness. **C.3** Develop guidelines and recommendations for digital sustainability for AI in MedTech.
Capability	**D.** Talent and skills	**D.1** Develop educational programs for talent development. **D.2** Invest in upskilling the current workforce. **D.3** Promote awareness and co-design of AI MedTech in Asia Pacific.
	E. Data, Interoperability and Integration	**E.1** Explore regional harmonization of interoperable data standards and guidelines. **E.2** Facilitate regional and local digital and data maturity development. **E.3** Facilitate access to regionally representative use-case-based datasets for AI in MedTech.
	F. Collaboration and Partnership	**F.1** Facilitate collective, consistent awareness and understanding of AI in MedTech solutions across the healthcare ecosystem. **F.2** Promote early engagement for designing and updating regulation, reimbursement and other policies relating to AI in MedTech. **F.3** Explore existing and new collaborative mechanisms to facilitate AI MedTech adoption.
Trust	**G.** Regulation	**G.1** Explore risk-based approaches to the regional regulation of AI in MedTech. **G.2** Explore regional recognition and reliance models to promote convergence of AI in MedTech. **G.3** Facilitate regional engagement in AI regulation development.
	H. Protection	**H.1** Establish regional cybersecurity standards for AI in MedTech. **H.2** Establish guidelines on the fair use of patient data. **H.3** Develop controlled environments and settings for early testing of protection mechanisms.
	I. Ethics	**I.1** Establish regional and aligned ethical principles and guidelines for AI in MedTech.

Call-to-action for the Asia Pacific MedTech ecosystem

Table 13b Summary of considerations associated with Access-Capability-Trust

- **Policymakers can:** Develop regional directives and macro policies in AI that aim to maintain policy effectiveness and relevance to the evolving MedTech industry.
- **Regulators can:** Define the rules of operations for AI in MedTech by developing micro policies that are harmonized with regional, macro policies. Topics may include AI regulations, governance, cybersecurity, data privacy and protection.
- **Payors can:** Design and implement clear funding frameworks, mechanisms and models to enable AI development, deployment and equitable patient access to AI in healthcare settings.
- **Hospitals can:** Guide the use of AI-enabled MedTech innovation to improve patient and clinical outcomes.
- **Academic institutions can:** Integrate AI into higher education curricula to promote AI literacy and prepare future workforces to use AI responsibly.
- **MedTech and technology organizations can:** Demonstrate safe, responsible and ethical development and use of AI in MedTech to deliver effective, high quality and personalized healthcare to patients.
- **Global and regional consortia can:** Democratize knowledge in AI for MedTech across the Asia Pacific by facilitating industry dialogues on the development of AI regulation, talent, capability and innovation.

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APACMed

Founded in 2014 and headquartered in Singapore, APACMed represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations and other key stakeholders associated with the medical technology industry in Asia Pacific.

Providing a unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of medical technology and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia Pacific.

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