Towards Responsible Health AI in Asia Pacific

ACCESS HEALTH INTERNATIONAL

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This report aims to provide an objective analysis of the current responsible Health AI policy-to-practice landscape and offers recommendations for strengthening Health AI ecosystems in APAC. It aims to inform policy discussions and implementation strategies in balancing patient safety with innovation that improves healthcare outcomes and supports industry growth.

1. Executive Summary

The use of artificial intelligence technologies for health ("Health AI"), widely hailed as transformative for the healthcare sector, has consistently dominated news headlines, healthcare conferences, and stakeholder discussions worldwide over the past two years.[1,2,3] While Health AI isn't new -- with the first use of AI for healthcare dating to the 1970s -- the current pace of Health AI innovation is unprecedented.[6] Healthcare AI patents have quadrupled since 2018, and the healthcare industry has seen a rapid proliferation of generative AI in healthcare startups in the past year globally.[5] A significant catalyst for this surge has been the rise of generative AI, particularly through large language models (LLMs) -- a type of AI designed to process, understand, and generate human language. LLMs are a subset of generative AI, and their public accessibility has drawn significant attention. The launch of ChatGPT in November 2022, a well-known LLM, marked a pivotal moment, ratcheting both excitement and concerns around the use of LLMs in healthcare.[6] Since their launch, the number of LLMs have grown exponentially, with the LLM market expected to grow from $6.4 billion in 2024 to $36.1 billion by 2030.[7]

Impact of Health AI: Examples

	Country	AI Application	Impact
	JAPAN	Stroke classification and treatment support system AI (SCTSS-AI)[8]	Improved patient outcomes by enhancing stroke diagnosis and reducing time to treatment by 20%.
	SINGAPORE	AI-powered deep learning software (SELENA+) for eye image analysis[9]	Reduced workload of medical professionals by up to 50%, allowing patient results in minutes; enabled cost savings of approximately 20% in operational costs related to eye care services.
	CHINA	AI image-assisted diagnosis system for lung cancer screening[10]	A real-world study at West China Hospital evaluated AI-assisted diagnosis in lung cancer screening among 23,336 patients. The AI system demonstrated a significantly higher detection rate for malignant pulmonary nodules compared to manual interpretation, with a positive screening rate of 97.2% versus 86.4% for physicians.
	USA	AI-driven antibiotic discovery (halicin)[11]	MIT researchers developed a deep-learning model that discovered halicin, a powerful new antibiotic effective against many drug-resistant bacteria. Laboratory and animal tests showed it could eradicate severe infections, including those caused by strains resistant to all known antibiotics.

Large language models (LLMs) represent just a small subset of the broader Health AI landscape, where AI is already driving impact in areas like medical imaging, diagnostics, clinical workflow optimization, and drug discovery. Across these applications, AI is enhancing diagnostic accuracy, streamlining administrative processes, personalizing patient care, and boosting overall efficiency and decision-making.

As with any other technology of significance, there may arise risks associated with Health AI -- such as the potential for deepening existing human biases or generating inconsistent outputs. These concerns have prompted proposals for new regulations in the region. However, with Health AI adoption still in its early stages and the technology evolving rapidly, there is currently limited evidence to support the need for new or additional legislation over existing digital health regulations. If not considered carefully, regulations may have the unintended effect of stifling innovation and preventing access to useful applications. Instead, this report emphasizes the importance of combining regulatory measures with complementary strategies to promote the Responsible use of Health AI while fostering innovation and introduces a corresponding framework to assess the readiness of the Asia Pacific region's Health AI ecosystem in ensuring Responsible Use of Health AI.

We define the **Responsible Use of Health AI**, aligning with the International Standards Organization's (ISO) definition of Responsible AI, as the practice of developing and using Health AI solutions in ways that benefit society while minimizing the risk of negative outcomes. Additionally, in line with our Responsible Health AI Readiness framework, this study maps the landscape of Responsible Health AI initiatives across 12 Asia-Pacific countries and offers recommendations to strengthen the Health AI ecosystem in the region.

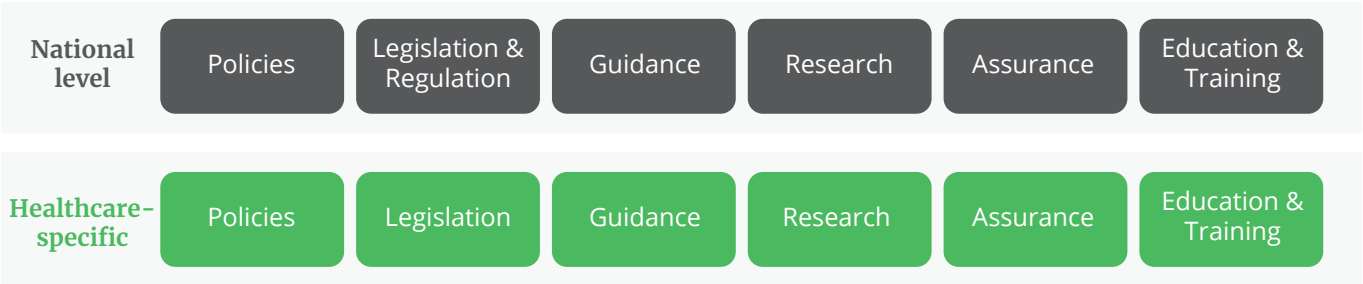
Furthermore, while many countries are adopting a risk-based approach to AI regulation, this risk-based approach often classifies the bulk of healthcare use-cases in AI as high-risk, impacting both innovation in Health AI and its adoption. To address the need for more nuanced discussions on what responsible use of AI in healthcare encompasses, this report through Chapter 6, also provides guidance for users on assessing the risk of a Health AI solution through a use-case based approach. Annex 2 provides further considerations for mitigating Health AI-associated risks.

Methodology

We began our analysis by identifying the key components that influence the safe and ethical use of Health AI at a national level. Based on our research and expert interviews, we identified six components: Policy and Strategy; Legislation and Regulations; Guidance on Responsible Use; Assurance Mechanisms; Research; and Education and Training. Each building component includes both national level initiatives and healthcare-sector-level initiatives influencing the use of AI. We then identified indicators within each component against which we assessed the corresponding policies and mechanisms for each of the 12 countries. We carried out detailed literature reviews and interviewed 22 Health AI policy and regulatory experts from the 12 countries and across the region. We interviewed policymakers, regulators, academic experts on Health AI regulation, industry leaders, Health AI startup regulatory leads and founders to understand the extent of Health AI adoption in their countries; the current state of national-level and Health AI policies and regulations; and other key Health AI initiatives within the 6 components.

The graphic below illustrates the 6-component framework which guides the findings and proposed recommendations presented in this report.

Key Components of Responsible Health AI



To analyze our findings holistically and glean deeper insights, we classified the 12 countries into three groups based on their income as we observed that the status of Responsible AI adoption had correlations with the countries' gross domestic product (GDP).

High income ("Group 1"):
Australia, Japan, New Zealand, Singapore, South Korea, Taiwan

Upper-middle income ("Group 2"):
Thailand, Malaysia

Lower-middle income ("Group 3"):
India, Indonesia, Philippines, Vietnam

Key Findings

The following are the key findings across the 12 countries within each component of Responsible AI. The report also includes detailed findings by country in Annex 1.

Countries have either developed new AI-specific policies and legislation or chosen to adapt existing technology-neutral laws to include AI-specific risks in a context-specific manner.

Policy and Strategy

Countries are advancing in national AI strategies and responsible AI policies, particularly in APAC, where regulators aim to balance AI adoption with safeguards. All countries have established national AI policies. All Group 1 countries have also established Health AI policies except for Taiwan, whose Health AI policy is undergoing development. Group 2 countries have Health AI policies in development. In Group 3, Indonesia and Vietnam have established Health AI policies while the Philippines is working on theirs.

Assurance Mechanisms

Assurance mechanisms such as audits, certifications, and third-party assessments can be useful in evaluating Health AI solutions that are considered high-risk. They can also increase trust in the use of AI in healthcare. All Group 1 countries, apart from New Zealand, have national mechanisms for evaluating AI safety. Group 2 countries' assurance mechanisms are in development. In Group 3, countries like the Philippines, India, and Indonesia are working on national validation mechanisms, while others are focusing on guiding principles and self-assessments.

Legislation and Regulations

Countries have taken different approaches to AI regulation. South Korea is the only country among the 12 to have signed into law its AI Basic Act. Japan, Taiwan, Malaysia, Thailand, India, Indonesia, the Philippines, and Vietnam have initiated or drafted baseline AI laws pertaining to public safety, trust, and innovation. However, timelines for enactment are unclear. In Group 3 countries like the Philippines, India, and Vietnam, digital health laws are being updated and are expected to also address AI considerations. Four out of 12 countries – Singapore, South Korea, Philippines, and Vietnam, have introduced AI-specific provisions in data privacy regulations, while a few others have indicated that similar developments are in progress.

Ensuring that regulations and guidelines are fit for purpose is crucial, as demonstrated by the widespread or ongoing adoption of risk-based categorization approaches in both national and Health AI policies for most countries.

Research

Nine out of 12 countries have appointed national research institutes to carry out research into the responsible use of AI or are planning to do so (New Zealand). However, when it comes to research on the responsible use of AI in healthcare, only five countries – all Group 1 – have appointed research institutes with this mandate or are funding research on this topic.

Guidance on Responsible Use

Group 1 countries have robust national-level guidance on generative AI, ethical use of AI, and AI-SaMD in healthcare, with Australia and South Korea issuing guidance on generative AI in healthcare. Group 2 and 3 countries have less well-developed guidance, although India's AI ecosystem is more advanced among the group 3 countries.

Education and Training

Most countries have developed national AI safety and/or ethics programs and have also initiated national-level upskilling programs on AI. However, when it comes to the healthcare sector, less than a quarter of the countries have initiated AI safety awareness for healthcare workers and Health AI-related upskilling programs.

Note: These findings are as of February 15th, 2025.
Expert interviews were carried out between June to August 2024.

Recommendations

Building on our findings and analysis, we recommend strategies to strengthen the Health AI ecosystem across four key areas: policies, regulatory capacity, regulatory processes, and sustainability. Recommendations accompanied by the symbol ***LMICs & UMICs*** indicate that these recommendations are more relevant to Lower-Middle Income Countries (LMICs) and Upper-Middle Income Countries (UMICs).

R1: Strengthen healthcare policies, if required, to ensure the responsible use of Health AI. ***LMICs & UMICs***

1.1 Develop or update AI in health policies to address the responsible use of AI in healthcare.

1.2 Consider appointing an existing authority (or authorities) to increase trust in Health AI and promote its responsible use facilitated by fit-for-purpose and technology-neutral regulations, practical guidance on ethical use, assurance mechanisms for high-risk use cases, research, and capacity building.

R2: Review and update Health AI regulatory frameworks, if required, to be fit-for-purpose and technology-neutral to ensure patient safety, protect individual and collective human rights, and promote Health AI adoption

2.1 Amending existing regulations should be prioritized over adding new regulations where applicable to avoid increasing the compliance burden and stifling innovation, especially for Small & Medium Enterprises (SMEs). Empower/direct an existing regulatory body to evaluate and determine whether existing consumer patient protection legislation, regulatory frameworks, guidance, and enforcement mechanisms sufficiently cover the use of AI.

2.2 Ensure that relevant stakeholders, including industry, are consulted when reviewing or introducing new regulations or guidelines.

2.3 Develop sectoral guidance that is fit-for-purpose, incorporates a risk-based approach, is use-case specific, and is aligned with international standards and best practices.

2.4 Ensure that medium-to-low-risk use cases can be deployed with minimal regulatory approvals.

2.5 Monitor technological advances to ensure regulations and guidance remain effective and relevant.

2.6 Consider collaborating with healthcare institutions and clinical colleges to offer education and provide clarity on liability in existing legal and regulatory guidelines to users and organizations.

2.7 Ensure data governance and cybersecurity policies and regulations are risk-based and fit-for-purpose.

R3: Strengthen regulatory capacity building through intra- and inter-governmental collaboration

3.1 Establish and/or strengthen participation in international, regional, and bilateral mechanisms for collaboration, research, and regulatory capacity building.

3.2 Promote intra-government collaboration to ensure that regulatory frameworks are interoperable.

R4: Streamline regulatory processes to be more adaptive and agile in keeping up with rapidly evolving technology

R5: Promote sustainable Health AI with a focus on workforce readiness and consideration of environmental impact

5.1 Develop policies and programs that focus on upskilling and training healthcare workers to successfully adopt and manage AI-enabled healthcare, addressing job displacement fears through proactive workforce development initiatives.

5.2 Consider the long-term environmental impact of AI use and align with national AI sustainability policy.

Responsible Health AI ecosystems are pivotal for healthcare transformation. By enhancing diagnostic accuracy and enabling personalized care, they improve patient outcomes while easing administrative burdens and optimizing resources. At the same time, these systems prioritize ethical integrity, addressing privacy, security, and bias through strong governance and adaptable, risk-based regulatory frameworks. Above all, Responsible Health AI serves as a powerful tool for advancing equitable healthcare innovation—leveraging technology and data sharing to bridge disparities and empower healthcare professionals. Aligned with the UN's 2030 Agenda, Responsible Health AI ecosystems stand poised to ensure healthier lives and well-being for all.[12]

2. How AI Is Transforming Healthcare

Artificial Intelligence (AI) has emerged as a transformative technology with wide-ranging applications across various industries. Its ability to process vast amounts of data, recognize patterns, and make predictions has made it an invaluable tool in many fields, including healthcare, finance, education, and manufacturing. Common ways AI can transform current systems include:

- Increased efficiency and productivity
- Enhanced decision-making capabilities
- Automation of repetitive tasks
- Pattern recognition and prediction
- Improved accuracy and precision
- Personalized user experiences

2.1 Health AI Use Cases are Varied—and Rapidly Expanding

With regards to healthcare, AI has enormous potential for improving health outcomes and helping countries achieve universal health coverage[13]. Health AI is being used to improve clinical care, patient outcomes, and healthcare system efficiency (see examples below).

Health AI can be classified into six main categories: Direct Clinical Care, Clinical R&D, Patient Coordination, Health Surveillance and Promotion, Hospital Operations, and Health System Optimization (Fig. 1). This classification is based on an evaluation of both the aggregated health risk of the AI and the type of AI, which will be further addressed.

Figure 1: AI in health applications categorized by type

<table>
<tr><th>Clinical Practice</th><th>Biomedical Research</th><th>Public Health</th><th>Healthcare Administration</th></tr>
<tr><td rowspan="2">Direct Clinical Care:
1. Therapeutic interventions
2. Medical imaging & diagnosis
3. Patient monitoring
4. Treatment planning
5. Risk prediction
6. Clinician co-pilots</td><td>Direct Clinical Care:
1. Clinical trials</td><td>Health Surveillance and Promotion:
1. Disease surveillance
2. Health promotion</td><td>Patient Coordination:
1. Chatbot
2. Patient navigation
3. Scheduling</td></tr>
<tr><td>Clinical R&D:
1. Post-market monitoring
2. Pre-clinical development
3. Drug discovery</td><td>Health System Optimization:
1. Workforce allocation
2. Supply chain allocation</td><td>Hospital Operations:
1. Medical records management
2. Healthcare audits
3. Insurance</td></tr>
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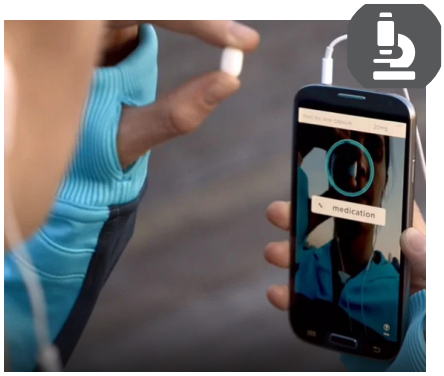
2.2 Common Use Cases of Healthcare AI

The following real-world case studies illustrate the breadth and practical implementation of Health AI across a diverse range of applications.

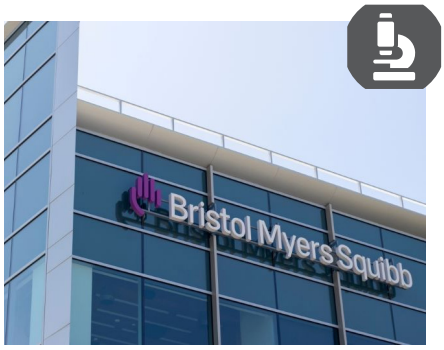


Clinical Trials

AiCure

AiCure uses AI and computer vision to enhance clinical trial adherence

AiCure is an AI and advanced data analytics company based in New York. AiCure leverages AI to monitor patients through mobile devices during clinical trials. The technology uses computer vision and AI to ensure medication adherence, providing real-time insights into patient behavior. By remotely verifying medication intake and offering personalized engagement, AiCure helps improve trial outcomes, reduce risks, and increase patient retention. Their solution enhances trial efficiency by delivering reliable data without the need for in-person monitoring.[14]



Drug Discovery

Bristol Myers Squibb

Bristol Myers Squibb accelerates drug discovery using cloud technology

Bristol Myers Squibb is a global biopharmaceutical company with headquarters in New Jersey, and, in collaboration with Accenture, leverages AWS and SAP S/4HANA to enhance its drug discovery process. By migrating its operations to the cloud, Bristol Myers Squibb improves data analysis, enabling more accurate insights into clinical outcomes. This infrastructure transformation allows for better collaboration and faster decision-making, driving innovation in their drug discovery efforts and enhancing patient outcomes.[15]

Medical Imaging & Diagnosis

aidoc

Aidoc accelerates medical imaging analysis with AI

Established in 2016, Aidoc initially focused on supporting radiologists in reducing turnaround time and increasing the quality of diagnosis scans.[16] Aidoc utilizes AWS to power its AI solutions for medical imaging, enhancing diagnostic accuracy and speed. Built on the cloud, Aidoc's AI models analyze medical images in real-time, assisting radiologists in identifying critical conditions like strokes or pulmonary embolisms. This solution enables faster and more accurate diagnoses, improving patient outcomes and operational efficiency in hospitals.[17]

Risk Prediction

careMonitor

CareMonitor enhances risk prediction and patient monitoring with AI

Australian healthtech startup CareMonitor was created to improve telehealth and remote patient monitoring. As an AI-driven platform, CareMonitor enables real-time risk prediction and remote patient monitoring. By integrating various health data sources, CareMonitor's AI models can predict and manage health risks, especially for patients with chronic conditions. The platform helps clinicians make proactive decisions, reducing hospitalizations and improving patient care through continuous monitoring and timely interventions.[18]

Risk Stratification

ClosedLoop.ai

ClosedLoop.ai uses AI to enhance patient risk stratification

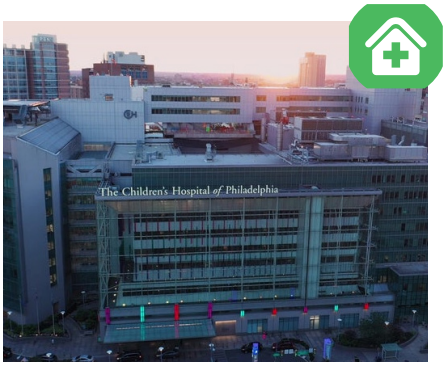
ClosedLoop.ai is a data science platform that uses AI models to analyze vast amounts of health data to predict patient outcomes and identify those at higher risk for chronic conditions or adverse events. This allows healthcare deployers to prioritize care interventions, improve outcomes, and reduce costs by focusing resources on patients with the highest need for proactive management.[19]

Clinical Documentation

SOPRIS HEALTH

Sopris Health enhances clinical documentation with voice-enabled AI

Sopris Health is a startup utilizing AWS to power its AI-driven, voice-enabled clinical documentation assistant. This AI solution captures and automates note-taking during patient interactions, significantly reducing the administrative burden on healthcare deployers. By automatically generating and organizing clinical documentation, Sopris allows doctors to focus more on patient care, improving workflow efficiency and reducing the likelihood of errors in medical records.[20]



Clinical Documentation

Children's Hospital of Philadelphia

Children's Hospital of Philadelphia (CHOP) enhances internal data sharing for improved decision-making using AWS cloud

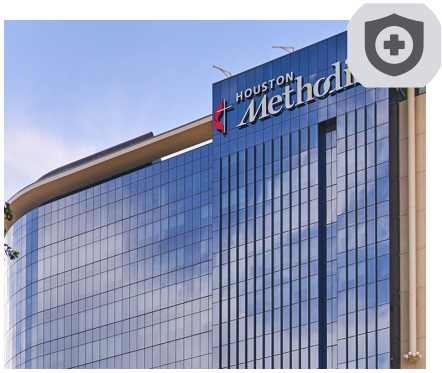
CHOP leverages AWS to securely share clinical data across multiple research and healthcare institutions. By using AWS' cloud infrastructure, CHOP facilitates the seamless exchange of data, accelerating research collaboration and clinical innovation. This allows researchers and clinicians to analyze large datasets in real-time, improving insights into pediatric care and enabling more efficient data-driven decisions for patient treatments.[21]

Health Monitoring

electronic caregiver

Electronic Caregiver builds augmented-reality health monitoring using Amazon Sumerian

Electronic Caregiver is a technology leader in connected health and safety monitoring devices. Electronic Caregiver's AI-based health monitoring solutions platform provides real-time health assessments and remote patient management, particularly for elderly and at-risk individuals. By leveraging connected devices and machine learning, Electronic Caregiver enables continuous monitoring of vital signs and health conditions, allowing caregivers to intervene early in case of abnormalities. This system helps improve patient outcomes and reduces hospital visits.[22]



Clinical Workflow

Houston Methodist enhances clinical workflows with its hands-free voice assistant

Houston Methodist is an eight-hospital system that develops digital health solutions to better care for patients in the Greater Houston area. Houston Methodist developed a hands-free voice assistant that allows healthcare deployers to interact with patient data through voice commands. This AI-powered system helps clinicians access real-time information and manage tasks without using their hands, improving efficiency in sterile environments and streamlining clinical operations.[23]

Patient Engagement & Recovery

Force Therapeutics improves patient engagement and recovery

Force Therapeutics is a healthcare technology company founded in 2010 that leverages AWS to build a digital care platform that enhances patient engagement during surgery recovery. Using machine learning and data analytics, the platform delivers personalized recovery plans, tracks patient progress, and provides clinicians with real-time insights. This system helps reduce readmissions, improves outcomes, and empowers patients to take a more active role in their recovery journey.[24]

Radiology Automation

Rad AI enhances radiology reporting

Rad AI is a startup that aims to use AI to streamline radiology workflows and enhance patient care. Headquartered in Berkeley, California, Rad AI harnesses AWS to automate radiology reporting, significantly reducing the time radiologists spend on documentation. The AI-driven solution analyzes medical imaging reports, suggesting edits and auto-generating follow-up recommendations. By improving efficiency and accuracy, Rad AI helps radiologists focus on image interpretation and patient care, streamlining workflows and reducing burnout.[25]

Personalized Health Management

Cambia Health Solutions enhances personalized healthcare with Journi

Cambia Health Solutions is a family of companies headquartered in Portland, Oregon.[26] Using AWS, Cambia Health Solutions developed Journi, a digital platform that provides personalized health management. The platform uses AI to analyze individual health data and deliver tailored healthcare recommendations. By offering a unified view of medical records, medications, and care options, Journi empowers users to make informed decisions about their health while enhancing patient engagement and care coordination.[27]

3. Why Is Responsible Use of AI in Healthcare Important?

The International Standards Organization (ISO) defines Responsible AI as **the practice of developing and using AI systems in a way that benefits society while minimizing the risk of negative consequences.**

There are several guiding principles and frameworks to ensure the responsible use of Health AI ("Responsible Health AI") including the United States Blueprint for an AI Bill of Rights[28], Singapore's Model AI Governance Framework[29] and the OECD AI principles[30] that largely overlap with the following WHO ethical principles for Health AI.[31]

WHO's ethical principles for the use of AI for health

1. **Protect autonomy**
2. **Promote human well-being, human safety, and the public interest**
3. **Ensure transparency, explainability and intelligibility**
4. **Foster responsibility and accountability**
5. **Ensure inclusiveness and equity**
6. **Promote AI that is responsive and sustainable**

This section examines two types of possible hazards that currently exist in Health IT and digital health solutions, and may also arise in the use of Health AI solutions: Use-case-based/service level hazards and product-level hazards. As the names indicate, while product-level hazards are applicable to all use cases of the Health AI product or solution, the service-level hazards applicable to a use case and their severity may vary with each service or use case the product provides.

The majority of these hazards are not unique to AI: bias and clinical inaccuracy in healthcare, for example, are long-standing issues in conventional medicine and healthcare delivery, however, AI can potentially magnify some of these existing hazards and may give rise to some new hazards such as alignment risks and automation bias. More details on each of these hazards can be found below.

Refer to Annex 2 to understand in more detail how users of Health AI solutions can mitigate the risks arising from each of these hazards.

A. Use-Case Dependent Hazards:

Given the diversity of Health AI use cases and consequently the varied degree to which these use cases impact patient's health outcomes, a nuanced understanding of these hazards is require to ensure Responsible Use.

Use Case-Based Hazards

Hazard & Definition	Non-AI Examples	AI-Specific Examples	What ensuring responsible use could look like:
Clinical Accuracy & Reliability Risks *Inaccurate or inconsistent outputs may lead to incorrect medical diagnoses or treatment recommendations.*	A malfunctioning blood pressure monitor that consistently provides incorrect readings.	A machine learning-based clinical assistant may provide incorrect treatment recommendations due to poor-quality training data.	• Adopting robust validation processes for systems. • Implementing continuous monitoring of performance. • Ensuring clinical expert oversight in decision-making. • Complying with regulatory standards for system deployment.

Hazard & Definition	Non-AI Examples	AI-Specific Examples	What ensuring responsible use could look like:
Bias *Disparities in predictions or decisions leading to unfair treatment of certain patient groups.*	Clinical guidelines developed from a limited clinical trial dataset that is unrepresentative of the population applied to.	A hospital's AI system, biased by historical data, may lead to AI models underperforming and providing suboptimal health outcomes for such groups.	• Ensuring diverse and representative data collection. • Ensuring representative training data and algorithm design for AI models. • Regularly auditing deployed systems for biased outputs. • Implementing transparent processes for monitoring and adjusting algorithms post-deployment. • Providing continuous training for staff on identifying and addressing bias, especially in AI-driven decisions.
Alignment Risks *Misalignment between a system's objectives and clinical goals may result in outputs that fail to support desired patient outcomes.*	A triage protocol focused on efficiency over urgency may delay critical care for severely ill patients, compromising health outcomes.	Remote-monitoring AI might flag non-urgent patient data as critical due to overly sensitive thresholds, causing unnecessary strain on healthcare deployers and diverting attention from high-risk patients.	• Ensuring that system objectives are clearly defined and aligned with clinical goals before deployment. • Involving clinical stakeholders in the selection, customization, and ongoing monitoring of systems. • Regularly assessing system outputs to confirm they support desired patient outcomes and adjust the system as needed. • Establishing a clear framework for continuous evaluation and optimization of systems to maintain alignment with clinical needs.
Automation Bias *Overreliance on recommendations by healthcare deployers, potentially overlooking clinical judgment or contrary evidence.*	A clinician relies solely on an automated blood test analyzer's result, dismissing clear physical symptoms that suggest a different diagnosis.	An AI-driven prescription system suggests a dosage that the pharmacist believes is incorrect based on the patient's medical history, but the pharmacist defers to the AI, resulting in adverse drug effects.	• Promoting a balanced approach where AI or machine recommendations support, but do not replace, clinical judgment. • Training healthcare providers to critically assess system outputs and incorporate clinical expertise in decision-making. • Establishing protocols requiring verification of AI or machine suggestions, especially in complex or high-risk scenarios. • Regularly auditing system-driven decisions to ensure minimizing overreliance and appropriately integrating clinical judgment.

Hazard & Definition	Non-AI Examples	AI-Specific Examples	What ensuring responsible use could look like:
Liability Risks *The potential for legal responsibility and financial consequences arising from adverse outcomes associated with deploying new solutions in healthcare.*	A hospital adopts a new surgical instrument without thorough staff training. If a patient is harmed due to improper use, the hospital may face legal action and financial penalties.	An AI-driven healthcare claims-processing system may wrongfully deny coverage for necessary treatments based on automated decisions, leading to disputes and accountability issues for the healthcare provider.	• Implementing clear accountability frameworks to define roles and responsibilities in AI or machine-related decisions. • Ensuring comprehensive documentation of system deployment processes and decisions for legal transparency. • Securing robust liability insurance to mitigate financial consequences from potential adverse outcomes. • Conducting regular training on risks, risk assessments, and compliance checks to minimize legal exposure and safeguard patient outcomes.

B. Health-IT Product-Level Hazards:

The product-level hazards associated with Health AI solutions are the same as those associated with a typical Health IT solution with some AI-specific considerations.

Health-IT Product-Level Hazards

Product-Level Hazards & Definitions	Non-AI Considerations	AI-Specific Considerations	What ensuring responsible use could look like:
Data Privacy *Unauthorized access, use, or disclosure of sensitive patient data handled by systems, compromising patient confidentiality.*	Healthcare workers accessing patient data without a legitimate reason or sharing it inappropriately could lead to breaches of patient privacy.	Health AI systems require large datasets, often including sensitive patient information, for training.	• Implementing strong data anonymization techniques. • Ensuring informed patient consent processes. • Adopting data governance frameworks to monitor data access and usage.
Data Security *Breaches or attacks on systems that jeopardize the integrity, availability, or confidentiality of healthcare data.*	Sending patient data over unsecured communication channels, such as email, can expose it to interception by malicious actors.	The proprietary nature of AI algorithms and the sensitive data used in training require measures to prevent unauthorized access to both data and models, as well as protect against manipulation of AI behavior.	• Using encryption for both data storage and transmission. • Regularly updating security protocols to counter emerging threats. • Employing access control measures to restrict data and model access.

Product-Level Hazards & Definitions	Non-AI Considerations	AI-Specific Considerations	What ensuring responsible use could look like:
Software Change Management Risks *The potential for disruptions or errors when updating or modifying systems in healthcare settings.*	System updates or modifications that are not properly tested can result in bugs or unforeseen issues, resulting in incorrect data entry or loss of important medical information.	Continuous updates and retraining of AI systems may introduce performance issues.	• Implementing version control and validation procedures for system updates. • Continuously testing system performance post-update to detect any issues. • Ensuring transparency and traceability in system modifications.
Integration & Interoperability Risks *Risks ensuing from systems being unable to seamlessly work with existing healthcare technologies and data sources.*	New systems that cannot communicate with existing systems may lead to fragmented data across multiple platforms, making it difficult for healthcare providers to access complete information.	AI systems integrate diverse data sources and healthcare environments, requiring robust handling of unstructured data and seamless interoperability with other systems.	• Developing standard data formats and protocols to ensure compatibility. • Ensuring ongoing system testing and monitoring to confirm successful integration. • Collaborating with stakeholders to ensure smooth data exchange across platforms.
User Skill Gaps *Risks ensuing from healthcare providers lacking the necessary training or expertise to effectively use new technologies.*	Healthcare providers who are unfamiliar with new electronic health record (EHR) systems may enter patient data incorrectly, causing errors in patient care or treatment plans.	Healthcare professionals need adequate training to understand and effectively use AI-driven insights. This includes interpreting AI recommendations, understanding their limitations, and integrating AI outputs into clinical decision-making processes.	• Providing regular training programs on new tools and their applications. • Enhancing user interfaces to simplify interactions with systems. • Establishing clear guidelines for interpreting system outputs and recommendations.

4. The Landscape of Responsible Health AI in APAC

4.1 Overview of Global & Regional Initiatives

The Landscape of Responsible Health Initiatives in Asia-Pacific

The Asia-Pacific region is home to a diverse range of countries, each with unique challenges and opportunities in the development and deployment of Artificial Intelligence (AI). Recognizing the transformative potential of AI, these nations have initiated comprehensive strategies and frameworks to ensure that AI is developed and used responsibly. This infographic highlights the general and health-specific AI initiatives across key APAC countries, along with significant international partnerships and guidelines that shape the responsible AI landscape in the region.
The initiatives aim to foster innovation while upholding ethical standards, transparency, and the protection of human rights, ensuring that AI contributes positively to societal progress.

International Initiatives

OECD AI Principles (2019)
The OECD AI Principles are the first intergovernmental standards on AI, adopted by 42 countries in 2019. These principles promote AI that is innovative and trustworthy, respecting human rights and democratic values. They serve as a global benchmark for AI policy and regulation.

ASEAN Guide on AI Governance and Ethics (2024)
The ASEAN Guide on AI Governance and Ethics, adopted in 2024, provides a regional framework for responsible AI development in SEA. It includes principles for transparency, fairness, and accountability.

APEC AI Principles (2022)
APEC's AI Principles were established to guide member economies in the responsible development and use of AI.

IEEE AI Ethics (2021)
The IEEE AI Ethics framework provides comprehensive guidelines for the ethical design and implementation of AI systems, emphasizing principles like transparency, accountability, and privacy.

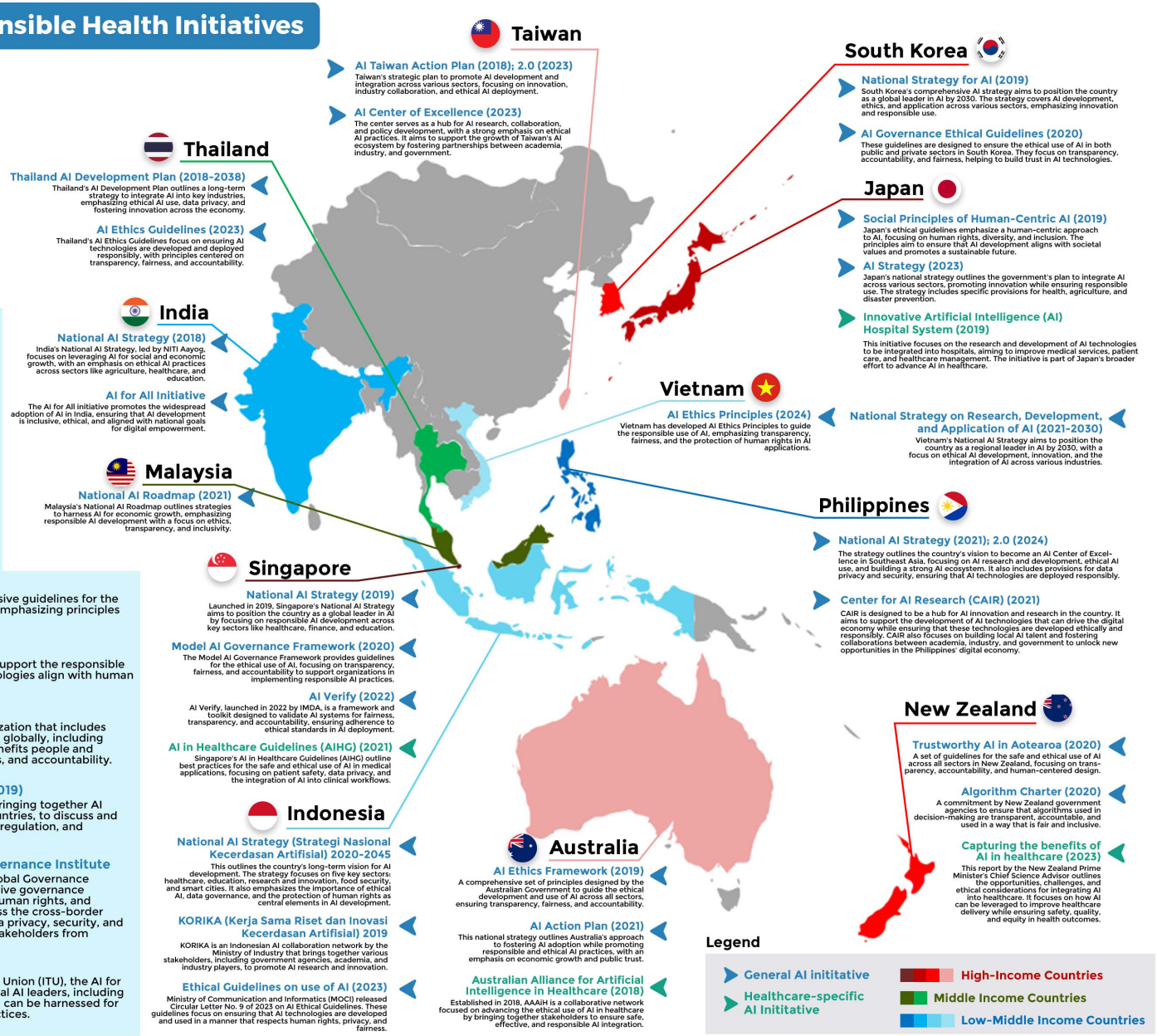
Global Partnership on AI (GPAI)
GPAI is an international collaboration that aims to support the responsible development and use of AI, ensuring that AI technologies align with human rights, inclusion, diversity, and innovation.

Partnership on AI (2024)
The Partnership on AI is a multi-stakeholder organization that includes governments, companies, and research institutions globally, including APAC countries. It focuses on advancing AI that benefits people and society, with an emphasis on transparency, fairness, and accountability.

OECD Network of Experts on AI (ONE AI) (2019)
ONE AI is a global forum facilitated by the OECD, bringing together AI experts from around the world, including APAC countries, to discuss and shape policies and practices surrounding AI ethics, regulation, and implementation.

AI and Global Governance of the Global Governance Institute
It is an international initiative established by the Global Governance Institute. The AIGGC works to develop comprehensive governance frameworks for AI, focusing on ethical standards, human rights, and global cooperation. The commission aims to address the cross-border challenges posed by AI technologies, including data privacy, security, and ethical deployment, and it actively engages with stakeholders from various regions, including APAC countries.

AI for Good Global Summit (ITU) (2017)
Organized by the International Telecommunication Union (ITU), the AI for Good Global Summit is an annual event where global AI leaders, including those from APAC, come together to discuss how AI can be harnessed for the benefit of humanity, focusing on ethical AI practices.



As of August 15, 2024

Health-Specific AI International Initiatives

Global Initiative on AI for Health (GI-AI4H):
Launched in July 2023, under WHO, International Telecommunication Union (ITU), and the World Intellectual Property Organization (WIPO), the GI-AI4H aims to enable, facilitate, and implement AI in healthcare.

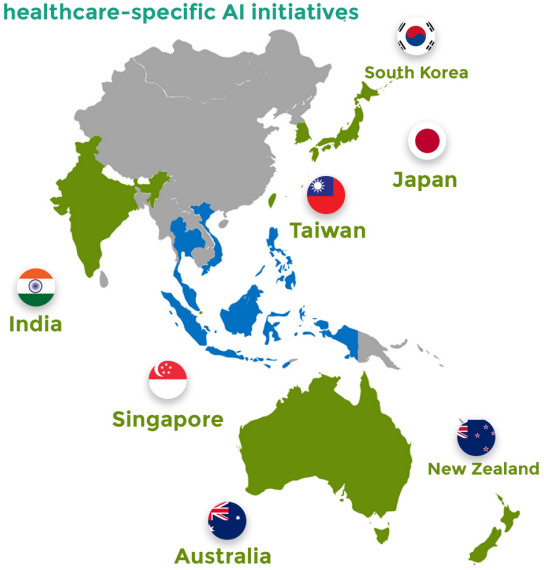
Coalition for Health AI (CHAI) (2022)
The Coalition for Health AI (CHAI) brings together leaders from healthcare, technology, academia, and policy to establish standards and best practices for the ethical use of AI in healthcare, ensuring that AI technologies enhance patient care and improve health outcomes.

International Medical Device Regulators Forum (IMDRF) AI Working Group (2022)
The IMDRF AI Working Group includes medical device regulators from around the world, including APAC countries, focused on creating guidelines for the regulation of AI and machine learning in medical devices, ensuring safety, effectiveness, and ethical use.

Artificial Intelligence for Health by the World Health Organization (AI4Health WHO) (2022)
AI4Health is a WHO initiative that involves global collaboration on developing AI tools for health, particularly in low- and middle-income countries, with contributions from APAC countries to improve public health and health system efficiency.

HealthAI (2023)
Originally established as The International Digital Health and AI Research Collaborative, the Global Health AI Agency (HealthAI) was rebranded in 2023 to better align its mission with the evolving needs of countries and the global health community.

APAC Countries that have healthcare-specific AI initiatives



A Timeline of Responsible Health AI Developments

2017

- **FDA approves first AI-Powered Device for Operating-Room Use** — September 2017

2018

- **Australian Alliance for Artificial Intelligence in Healthcare (AAAiH) was formed** — 2018
- **South Korea's Healthcare Special Committee released a plan which aimed to put AI at the forefront of the nation's health strategy** — 2018

2019

- **FDA Approves First AI-Powered Device for Cancer Diagnosis** — February 2019
- **FDA approves deep-learning algorithm for Brain MRI Interpretation** — October 2019

2020

- **A global guide for the use of AI in healthcare was released in South Korea** — August 2020
- **COVID-19 Pandemic and AI was utilized in predictive modeling, drug discovery, and diagnostics.** — 2020
- **Taiwan AI Labs launched a federated machine learning alliance with Taiwan's MOHW NHI, NTUH, TVGH, and other medical centers to innovate AI applications in healthcare.** — December 2020

2021

- **WHO released Guidance on Ethics and Governance of AI for Health** — 2021
- **Singapore published AI in Healthcare Guidelines (AIHGle)** — October 2021
- **A Roadmap for AI in Healthcare for Australia was published by AAAiH** — December 2021

2022

- **Launch of ChatGPT by OpenAI, based on GPT-3, and quickly became one of the fastest-growing applications, reaching 100 million users within two months.** — November 2022
- **International Medical Device Regulators Forum (IMDRF) AI Working group was established** — May 2022
- **Coalition for Health AI (CHAI) was established** — May 2022
- **AI for Health by the World Health Organization (AI4Health) was established** — 2022

2023

- **HealthAI was established, rebranded from the International Digital Health and AI Research Collaborative to align with evolving needs in healthcare** — 2023
- **Innovative Artificial Intelligence Hospital system in Japan, an initiative to leverage AI in improving hospital management and patient care** — April 2023
- **New Zealand published a report on capturing the benefits of AI in healthcare** — December 2023

2024

- **India released ethical guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare** — 2023
- **A National Policy Roadmap for Artificial Intelligence in Healthcare was published by Australia's AAAiH** — November 2023

Sources: U.S. Food and Drug Administration (2017, 2019), Australian Government (2018, 2021, 2023), South Korean Government (2018, 2020), World Health Organization (2020, 2021, 2022), Taiwan Ministry of Health and Welfare, Singapore Ministry of Health (2021), OpenAI (2022), International Medical Device Regulators Forum (2022), Coalition for Health AI (2022), Japanese Government (2023), Government of India (2023), New Zealand Government (2023).

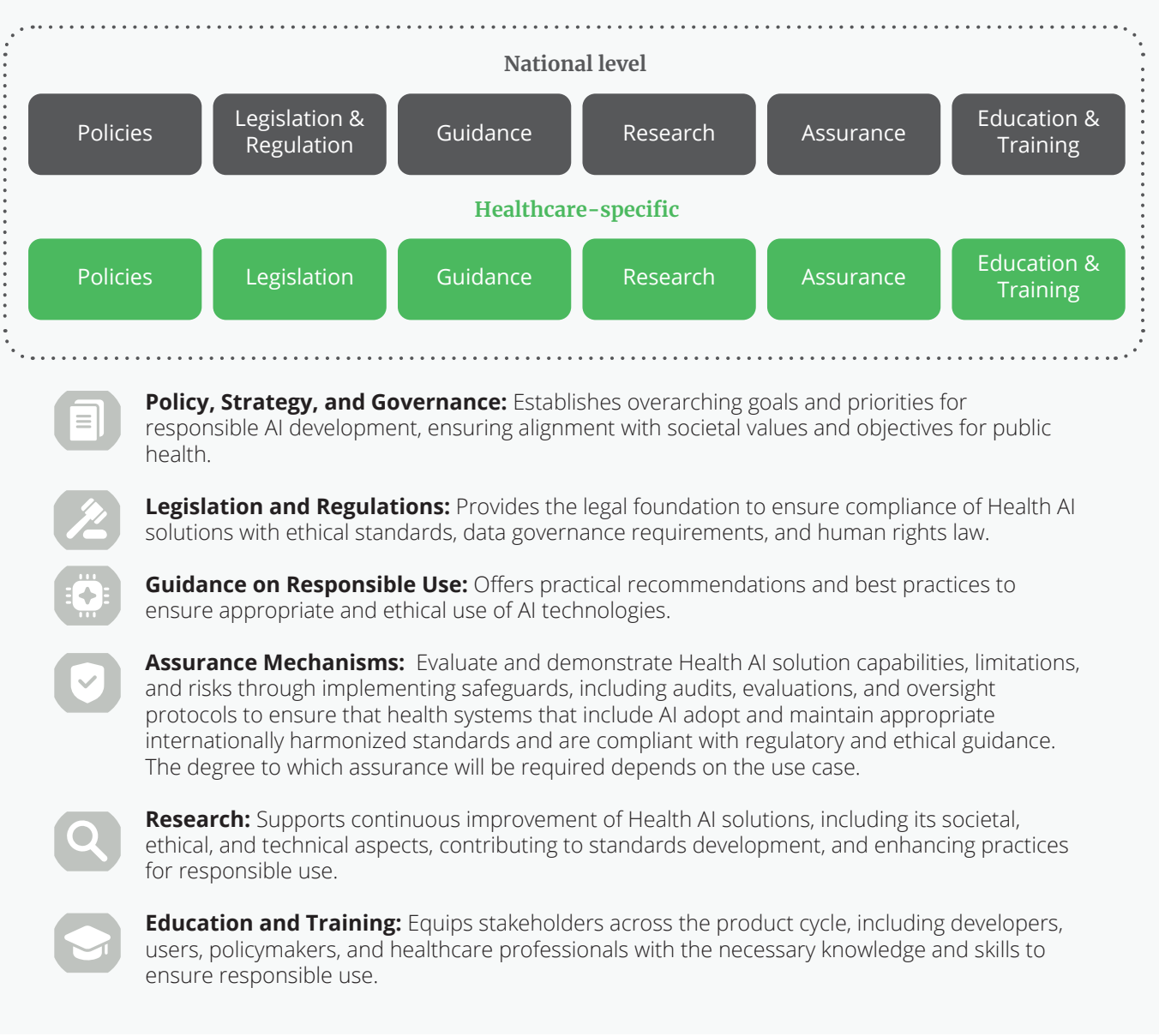
As of August 15, 2024

4.2 Key Components of a Responsible Health AI Ecosystem

To evaluate the Responsible Health AI ecosystems landscape in the 12 countries, a framework was drawn up based on interviews with regulatory experts and insights from literature reviews.

Based on these insights, this report posits a 6-component framework for a Responsible Health AI ecosystem. Collectively, the 6 components guide the development of a Responsible Health AI ecosystem, ensuring that these systems are safe and ethical for use. Each component represents a fundamental component of building and maintaining reliable AI technologies.

Figure 2: **Framework: Key Components of a National Responsible Health AI Ecosystem**



These are influential both horizontally at the national level and vertically within the healthcare sector.

The table below provides an overview of indicators included in our mapping of countries' Responsible Health AI initiatives. While most of these indicators highlight initiatives that explicitly address AI, they are not meant to be exhaustive. In all focus countries, there are existing policies, legislation, and regulations, that may not address AI specifically but apply to Health AI solutions and promote its responsible use with varying relevance and scope.

Components of Responsible AI	National Level	Health-Sector Specific
Policy, Strategy, and Governance	• Availability of national AI policies and/or strategy. • Availability of policies and programs addressing responsible AI. • Adopts a risk-based categorization approach to AI use in policies.	• Availability of AI in health policies and/or strategy. • Availability of policies and programs addressing responsible Health AI. • Adopts a risk-based categorization approach to AI use in policies.
Legislation & Regulations	• Cybersecurity legislation. • Data protection and data privacy legislation. • Existence of an AI Act. • Provides framework for classifying high-risk AI to inform liability. • Provides framework for assessment of risk.	• Healthcare data protection and privacy legislation. • SaMD regulations/regulatory guidance.
Guidance on Responsible Use	• Generative AI guidance issued on adoption at a national level. • Practical guidance issued includes practical ethics or regulatory guidance on AI adoption and implementation. • Issued technical guidance on AI adoption.	• AI in health ethics guidance issued. • Introduced AI SaMD regulatory guidance or guidelines. • Generative AI in healthcare guidelines issued.
Research on Responsible AI	• Appointed research body to look into responsible use of AI or funding research on responsible use of AI.	• Has research programs on integrating and leveraging responsible AI use in clinical trials, drug discovery and development, and other use cases of Health AI.
Assurance Mechanisms	• Encourages the adoption of international standards. • Encourages the use of risk and impact assessments or algorithmic impact assessments. • Establishment of national/state level mechanisms for sandboxing/evaluation/validation/testing/compliance with and/or compliance with international standards. • Requires or encourages organizations to carry out ethics impact assessments. • Appointed an organization or body for oversight of AI safety.	• Health AI solutions are required to be compliant with technical standards, e.g., ISO standards. • Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions.
Education & Training	• Developed AI ethics or safety or regulatory awareness programs. • Has national technical education or upskilling programs related to AI (including safety, data privacy, data protection).	• Has awareness program for AI in health safety for the healthcare workforce • Developed programs for technical education or upskilling for AI in health programs

4.3 Findings from Evaluation of APAC Countries

Health AI Context in the 12 Countries

This section aims to evaluate the strength of the 12 countries' digital infrastructure and readiness for Health AI looking at their Universal Health Coverage Index, AI Readiness Index Rank, E-government Development Index, E-participation Index, UN ICT Development Index, and Digital Competitiveness Ranking.

Figure X summarizes existing metrics that assess how ready countries are across various indicators for technology adoption in terms of AI specifically (AI readiness index); digital governance maturity (E-government development index); e-participation mechanisms for public information dissemination and policy formulation that are deployed by the government (E-participation index); digital infrastructure availability and reach, digital literacy and technology adoption (UN ICT development index); appetite for digital adoption (digital competitiveness ranking) and commitment to handling cybersecurity threats (global cybersecurity index). The Universal Health Coverage (UHC) index indicates how strong or fragmented the overall health system of a country is. UHC is assessed in terms of service capacity and financial protection with scores from 0 to 100. Higher scores indicate health systems with better quality, availability, accessibility and affordability of key services. Numbers below the global average (68 as of 2021) indicate more fragmented systems the lower the score gets.

The UHC index is included in this table as more fragmented health systems may have challenges in adoption and risk management that are different from those with more robust health systems. In presenting the results, countries have been grouped in order of income: high income countries (group 1); upper-middle income countries (group 2) and lower-middle income countries (group 3).

Looking at the three groups of countries based on their income, our findings show:

- Health AI readiness is highly dependent on countries' national incomes.
- Group 1 index rankings and scores are higher than Group 2 and then Group 3. Within the first group, the five countries, Australia, Japan, Singapore, South Korea, and Taiwan, score higher than New Zealand in the readiness factors.
- Group 2 countries Malaysia and Thailand are fairly similar in their scores.
- Among Group 3 countries, India, Indonesia and Vietnam's scores and rankings are significantly ahead of the Philippines.

Figure 3: Health AI Readiness Factors for the 12 Countries

Components	Group 1 Countries						Group 2 Countries		Group 3 Countries			
	AUS	JPN	NZ	SGP	SK	TW	MYS	THA	IND	IDN	PHIL	VNM
Universal Health Coverage Index (2021)[i] (out of 194 countries; max score of 100)	87	83	85	89	89	NA*	76	82	63	55	58	68
AI Readiness Index Rank (2023)[ii] (out of 193 countries)	73.9	75.1	60.2	82.0	75.7	70.3	68.7	63.0	62.6	61.0	52.0	54.5
E-government Development Index[iii] (2022) (out of 193 countries; max score of 1)	0.90	0.90	0.94	0.91	0.95	NA	0.77	0.77	0.59	0.72	0.65	0.68
E-participation Index (2022)[iv] (out of 193 countries; max score of 1)	0.99	1.00	0.95	0.98	0.94	NA*	0.68	0.78	0.59	0.72	0.49	0.53

Components	Group 1 Countries						Group 2 Countries		Group 3 Countries			
	AUS	JPN	NZ	SGP	SK	TW	MYS	THA	IND	IDN	PHIL	VNM
UN ICT Development Index [v] (out of 157 countries)	95.1	93.2	90.3	97.8	94.4	NA*	95	91	NA	82.8	74.4	85
Digital Competitiveness Ranking[vi] (out of 193 countries)	16	32	25	3	6	9	33	35	49	37	59	NA
Global Cybersecurity Index[vii] (out of 194 countries)	97.5	97.8	84.0	99.0	98.5	NA*	98.1	86.5	97.5	94.9	77.0	94.6

Figure 4 maps the responsible Health AI landscape for each of the 12 countries in line with the framework outlined above. The 12 countries are grouped based on their income (high-income countries on the left, followed by upper-middle-income countries and then low-income countries) to highlight the correlation between countries' gross domestic product (GDP) and the status of responsible AI adoption. Indicators are grouped under six components: Policy and Strategy, Legislation and Regulations, Guidance on Responsible Use, Assurance Mechanisms, Research, and Education and Training.

Each building component includes both national-level initiatives and healthcare-sector-specific efforts influencing the responsible use of AI. 'Y' and 'N' signify the presence and absence correspondingly of a policy or the implementation of a related mechanism, 'IP,' indicates that it is under development. These symbols reflect the current status of initiatives as of February 15, 2025, and are meant to provide an objective, high-level overview of the country's responsible AI policy-to-practice landscape. **'Y'** does not always imply adequacy, as a policy or mechanism may not fully address a country's unique needs, while **'N'** does not always imply a gap and may reflect a lack of relevance. A more detailed analysis requires considering each initiative within the country's political, legal, and regulatory context.

Figure 4: Mapping the Responsible Health AI Initiatives Landscape

National Level Health Sector Level

COMPONENT	AREA OF FOCUS	GROUP 1						GROUP 2		GROUP 3			
		AUS	JPN	NZ	SGP	SK	TW	MYS	THA	IND	IDN	PHIL	VNM
AI Policy	National/Sector-agnostic policies issued	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	AI in health policies or strategic plans issued	Y	Y	Y	Y	Y	IP	IP	IP	N	Y	IP	IP
	National AI policy covers responsible use of AI	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Health AI policy covers responsible use of AI	Y	Y	Y	Y	Y	IP	N	IP	N	Y	IP	N
	National AI policy adopts a risk-based categorization approach	Y	Y	Y	Y	Y	Y	IP	IP	Y	IP	Y	Y
	Health AI policy adopts a risk-based categorization approach	Y	Y	Y	Y	Y	N	N	N	N	N	N	N
Legislation	Established cybersecurity legislation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Established data protection and data privacy legislation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Has an AI act	N	IP	N	N	Y	IP	IP	IP	IP	IP	IP	IP
	Provides framework for assessment of risk	Y	Y	Y	Y	Y	Y	Y	IP	N	N	IP	IP
	Availability of AI-specific provisions in data privacy laws	N	N	N	Y	Y	IP	N	IP	IP	IP	Y	Y
	Availability of AI-specific provisions in cybersecurity legislation and regulations	N	N	N	IP	Y	IP	IP	IP	N	N	Y	IP
	Provides framework for classifying high-risk AI to inform liability	Y	IP	IP	IP	Y	IP	N	Y	N	N	N	IP
	Established healthcare data protection and privacy legislation	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
	Established SaMD regulations or regulatory guidance	Y	Y	IP	Y	Y	Y	Y	Y	Y	Y	Y	Y
Guidance	AI in health ethics guidance issued	Y	Y	Y	Y	Y	Y	N	Y	Y	N	N	N
	Introduced AI SaMD regulatory guidance or guidelines	Y	Y	IP	Y	Y	Y	N	Y	IP	N	N	N
	Generative AI in healthcare guidelines	Y	N	N	N	Y	IP	N	N	N	N	N	N
	Generative AI guidance issued on adoption at a national level	Y	Y	Y	Y	Y	N	IP	Y	N	N	N	N
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation	Y	Y	Y	Y	Y	Y	IP	Y	Y	Y	IP	Y
	Issued technical guidance on AI adoption	Y	Y	Y	Y	Y	Y	N	Y	IP	IP	IP	Y

COMPONENT	AREA OF FOCUS	GROUP 1						GROUP 2		GROUP 3			
		AUS	JPN	NZ	SGP	SK	TW	MYS	THA	IND	IDN	PHIL	VNM
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development	Y	Y	IP	Y	Y	Y	IP	N	IP	N	N	N
	National AI safety institute appointed or funding research into AI safety	Y	Y	IP	Y	Y	Y	Y	N	Y	N	Y	N
Education & Training	Developed AI ethics or safety or regulatory awareness programs	Y	Y	Y	Y	Y	Y	IP	IP	IP	Y	Y	N
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)	Y	IP	IP	Y	Y	Y	IP	IP	IP	Y	Y	Y
	Has awareness programs for AI in health for the healthcare workforce	Y	N	IP	Y	Y	N	IP	Y	N	Y	N	N
	Developed programs for technical education or upskilling for AI in health programs	Y	Y	IP	IP	IP	N	IP	Y	IP	IP	Y	N
Assurance	Establishment of national/state level or funding support for sandboxing/ evaluation/validation/testing and/or compliance with international standards	Y	Y	IP	Y	Y	Y	IP	IP	Y	IP	IP	N
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards	Y	Y	IP	Y	Y	Y	Y	Y	N	IP	N	IP
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N	IP	IP	Y	IP	IP	IP	IP	N	N	N	N
	Requires or encourage organizations to carry out ethics impact assessments	Y	N	Y	Y	Y	N	Y	IP	N	N	N	N
	Appointed an organization or body for oversight of AI safety	Y	Y	Y	Y	Y	Y	Y	Y	IP	N	IP	N
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y	Y	Y	Y	Y	Y	Y	IP	Y	N	Y	IP

A. Overall Findings

The following are the key findings across the 12 countries within each considered regulatory factor. For detailed information by country, refer to Annex 1.

Note: These findings are as of February 15th, 2025.

1. Policies

National AI policies: All 12 countries have national AI policies and/or strategies. For five countries out of these twelve, i.e. Taiwan, Malaysia, Thailand, Philippines, and Vietnam, dedicated national Health AI policies or plans are under development. While healthcare was identified as a key sector of focus in India's National Strategy for AI (2018), there is no dedicated AI in healthcare policy yet.

Responsible use of AI: Countries are moving toward national AI strategy and responsible AI policies. A strong inclination of regulators in APAC to enable the use of AI while putting in place guardrails is observed. All countries have highlighted the responsible use of AI in their national AI policies. Policies related to the responsible use of AI for health are in development in Taiwan, Thailand, and the Philippines.

Risk-based approach: Most countries with national and Health AI policy approaches have incorporated a risk-based approach, while a few countries have indicated their intention to do so.

2. Legislation & Regulations

AI laws & regulations: Countries have adopted varied approaches toward regulating AI. Korea's AI Basic Act was signed into law on January 21, 2025. About half the countries – Japan, Taiwan, Thailand, India, Indonesia, the Philippines, and Vietnam have drawn up or initiated the drafting of baseline AI laws to establish regulatory frameworks to govern the use and development of AI systems. However, for most, there is no timeline yet for their enactment. In Group 3 countries such as the Philippines and Vietnam, where digital health laws are still being drafted, these are being updated to address AI-related considerations.

AI-SaMD regulations: When it comes to the regulation of Health AI specifically, most Group 1 countries and Thailand have addressed AI regulation by issuing regulatory guidance on AI-SaMDs. Countries have also introduced policies or regulatory amendments to enable AI innovation and adoption in healthcare: Japan has amendments to regulations that streamline approval of new technology while addressing the risks of plasticity once deployed, while South Korea introduced a five-year plan that facilitates market entry for innovative technologies like AI and digital solutions in the medical devices sector.

Risk-based framework: Most Group 1 countries have announced efforts to develop a risk-based framework to inform AI regulations. However, a risk-based approach often classifies the bulk of healthcare use cases in AI as high-risk, creating a need for more nuanced discussions on how risk mitigation of AI in healthcare can be operationalized while maintaining an enabling approach to AI adoption in healthcare.

AI-specific data governance: While all countries have data privacy and cybersecurity legislation in place, more than half the countries have developed AI-specific provisions or are in the process of doing so.

3. Guidance on Responsible AI

Generative AI national guidance: Most Group 1 countries have moved more quickly than Group 2 and Group 3 countries in terms of guidance issued at the national level on generative AI, ethical and technical guidance, and within the healthcare sector – on the ethical use of AI, AI-SaMD responsible use guidance, and generative AI in healthcare. When looking at the guidance issued at the national level in Group 3 countries, India has made more progress.

With the exception of Australia and South Korea, most countries have yet to provide regulatory guidance on generative AI in healthcare.

4. Research

AI safety institutes: A majority of Group 1 countries have established AI safety institutes, while Group 2 and Group 3 countries have yet to do so. However, nearly all countries have either appointed AI safety institutes or have funded research into ensuring responsible use of AI.

National Health AI safety research programs: Five out of six Group 1 countries (Australia, Japan, Singapore, and South Korea) have instituted or funded national AI research programs focused on the responsible and safe use of AI in healthcare.

5. Education and Training

AI safety awareness and education: Most Group 1 countries have initiated national AI safety awareness programs, while Group 2 countries are developing similar programs. Within Group 3, Indonesia and the Philippines have initiated national AI ethics and regulatory educational programs.

Technical education on AI safety: Four Group 1 countries have developed technical education programs on AI safety, while the remaining Group 1 and Group 2 countries are developing similar programs. In Group 3 countries, Indonesia and the Philippines have announced similar initiatives, with India reported to be developing its own technical education program.

Health AI safety awareness and education: Half of Group 1 countries have launched Health AI safety awareness programs. In Group 2, Thailand has developed both safety and technical education programs, while Malaysia is developing a Health AI ethics awareness program. In Group 3, Indonesia has initiated Health AI safety programs, and India is developing technical education programs.

6. Assurance

National oversight bodies for AI safety: All Group 1 countries have designated new or existing committees or bodies to develop AI governance mechanisms and oversight. In Group 2 countries, Thailand has set up an AI governance clinic, while Malaysia has plans to appoint an oversight committee. Of the Group 3 countries, the Philippines and India have reported plans to do so as well.

AI safety and evaluation: All Group 1 countries have established national-level mechanisms for evaluating AI safety, except for New Zealand. Group 2 countries, Thailand and Malaysia, are still developing their national assurance processes, while most Group 3 countries are in the early stages, with limited mechanisms and a focus on guiding principles and self-assessments. India, however, has announced a number of evaluation and validation tools that are being developed at various national research institutes toward ensuring safe use of AI tools while the Philippines now requires organizations processing personal data using AI solutions to carry out Privacy Impact Assessments.

Healthcare-specific AI governance: Group 1 countries have national-level oversight for Health AI through regulatory bodies, with Japan and South Korea having specific evaluation mechanisms and Singapore providing a national platform. In Group 2, Thailand and Malaysia are focused on AI-SaMDs with existing medical device regulations, and Thailand is developing platforms for AI evaluation. Group 3 countries do not have national mechanisms for Health AI validation and cover only conventional SaMDs; Indonesia and Vietnam are developing technical requirements.

Regulatory sandboxes: Group 1 countries Singapore, Japan, South Korea and Taiwan, and Group 2 country Malaysia have introduced sandboxes with reduced regulatory and operational constraints for AI solution testing and development. New Zealand, Thailand, and Group 3 countries India, the Philippines, and Vietnam are currently developing theirs.

5. Strengthening Responsible Health AI Ecosystems in APAC: Policy Recommendations

The set of recommendations proposed in this section focuses on enhancing the governance, regulation, and sustainability of Health AI to ensure its responsible adoption and use in healthcare.

The recommendations cover four key areas:

1. AI safety, ethics, and governance | **2. Regulatory capacity building** | **3. Optimizing regulatory processes** | **4. Sustainability**

5.1 Overview of Recommendations

R1: Strengthen healthcare policies, if required, to ensure the responsible use of Health AI. ***LMICs & UMICs***

1.1 Develop or update AI in health policies to address the responsible use of AI in healthcare.

1.2 Consider appointing an existing authority (or authorities) to increase trust in Health AI and promote its responsible use facilitated by fit-for-purpose and technology-neutral regulations, practical guidance on ethical use, assurance mechanisms for high-risk use cases, research, and capacity building.

R2: Review and update Health AI regulatory frameworks, if required, to be fit-for-purpose and technology-neutral to ensure patient safety, protect individual and collective human rights, and promote Health AI adoption

2.1 Amending existing regulations should be prioritized over adding new regulations where applicable to avoid increasing the compliance burden and stifling innovation, especially for Small & Medium Enterprises (SMEs). Empower/direct an existing regulatory body to evaluate and determine whether existing consumer patient protection legislation, regulatory frameworks, guidance, and enforcement mechanisms sufficiently cover the use of AI.

2.2 Ensure that relevant stakeholders, including industry, are consulted when reviewing or introducing new regulations or guidelines.

2.3 Develop sectoral guidance that is fit-for-purpose, incorporates a risk-based approach, is use-case specific, and is aligned with international standards and best practices.

2.4 Ensure that medium-to-low-risk use cases can be deployed with minimal regulatory approvals.

2.5 Monitor technological advances to ensure regulations and guidance remain effective and relevant.

2.6 Consider collaborating with healthcare institutions and clinical colleges to offer education and provide clarity on liability in existing legal and regulatory guidelines to users and organizations.

2.7 Ensure data governance and cybersecurity policies and regulations are risk-based and fit-for-purpose.

R3: Strengthen regulatory capacity building through intra- and inter-governmental collaboration

3.1 Establish and/or strengthen participation in international, regional, and bilateral mechanisms for collaboration, research, and regulatory capacity building.

3.2 Promote intra-government collaboration to ensure that regulatory frameworks are interoperable.

R4: Streamline regulatory processes to be more adaptive and agile in keeping up with rapidly evolving technology

R5: Promote sustainable Health AI with a focus on workforce readiness and consideration of environmental impact

5.1 Develop policies and programs that focus on upskilling and training healthcare workers to successfully adopt and manage AI-enabled healthcare, addressing job displacement fears through proactive workforce development initiatives.

5.2 Consider the long-term environmental impact of AI use and align with national AI sustainability policy.

5.2 Detailed recommendations with examples

This section expands on the high-level recommendations presented earlier, offering a deeper dive into each with specific sub-recommendations and examples. These detailed insights are intended to guide implementation, providing actionable steps to address challenges and ensure alignment with the broader strategic objectives. The examples in this section are drawn both from the healthcare sector and the national sector-agnostic level as this is still an emerging area and examples in healthcare remain limited.

AI Safety, Ethics, and Governance

R1: Ensure deployment of AI is enabled through robust policies to maintain trust and responsible use of AI in healthcare.

1.1 Develop or update AI in health policies to address the responsible use of AI in healthcare. ***LMICs & UMICs***

A. To address the responsible use of Health AI, it is recommended that national digital health policies:
- are underpinned by principles that support the equitable, ethical, and safe use of Health AI.
- incorporate a risk-based approach to regulation and promote regulatory flexibility.
- address robust data governance to protect sensitive health information.
- enforce interoperability standards to ensure seamless data exchange.
- establish training programs for healthcare professionals to effectively use AI tools.
- establish mechanisms for ongoing monitoring and evaluation to assess AI's impact on patient outcomes and mitigate emerging risks.

The WHO identifies the following principles for the ethical use of AI in healthcare: 1) protect autonomy; (2) promote human well-being, human safety, and the public interest; (3) ensure transparency, explainability, and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; (6) promote AI that is responsive and sustainable.

B. To develop inclusive and well-rounded policies, consider appointing an AI in the health task force or panel that gathers input on the responsible use of Health AI from all relevant stakeholders – policymakers, developers, deployers, healthcare organizations, patients, civil society organizations, the pharma industry, medicine, and health tech; medical, and public health research institutes.

Example: In April 2021, the New South Wales government established the AI Review Committee, comprising a diverse group of experts to provide guidance on ethical AI implementation. The committee developed the AI Assurance Framework, requiring agencies to evaluate AI projects for performance, reliability, robustness, and audibility, ensuring compliance with NSW Ethical AI Principles.[32]

1.2 Consider appointing an existing authority (or authorities) to increase trust in Health AI and promote its responsible use facilitated by fit-for-purpose and technology-neutral regulations, practical guidance on ethical use, assurance mechanisms for high-risk use cases, research, and capacity building. ***LMICs & UMICs***

> **Example:** Singapore's designated national AI oversight agency, the Infocommunications Media Development Authority of Singapore (IMDA), has established the AI Verify Foundation, which is a community that develops AI testing tools for responsible AI and promotes best practices and standards for AI.[33] The AI Verify Foundation launched Project Moonshot in 2024, one of the world's first LLM Evaluation Toolkits, designed to integrate benchmarking, red teaming, and testing baselines.

The appointed body could take on the initiatives listed below.

A. Establish fit-for-purpose, standardized approaches for the evaluation and reporting of Health AI in line with international best practices and guidance.

> **Example:** International collaborations comprising experts from the fields of medicine, computer science, and regulatory science have led to the development of the CONSORT-AI, INSPIRE-AI, and DECIDE-AI international standards recommended for AI evaluation in clinical trials and reporting. It should be noted that these are yet to updated for the use of generative AI.[34]
>
> **Example:** The WHO has issued AI ethics and governance guidance for large multi-modal models that can be referred to and adapted to the country's context.[35]

B. Consider providing **training or guidance to procurement teams** to carry out AI risk and ethics impact assessments; evaluating vendors and working with them to mitigate identified risks; and monitoring performance.

> **Example:** While not a healthcare-specific guide, the Singapore Model AI Governance Framework provides detailed guidance and tools for organizations to assess and validate their AI systems against ethical principles.[36] Similarly, the United Nations Educational, Scientific and Cultural Organization (UNESCO) has also issued a tool for Ethical Impact Assessment, which considers the entire process of designing, developing, and deploying an AI system, allowing for assessment of the risks before and after the system is released to the public.[37]

C. Develop **national technical education programs** for developers related to AI safety and ethics in healthcare (including patient safety, data privacy, and cybersecurity).

> **Examples:**
>
> - The Institute of Electrical and Electronics Engineers (IEEE), launched in 2023, is a program offering free access to global socio-technical standards in AI Ethics and Governance. It provides guidance and considerations for ensuring trustworthy AI.[38]
> - **Singapore released Artificial Intelligence in Healthcare Guidelines (AIHGle), which share best practices for developers and implementers of Health AI.[39]**
> - The WHO course on Ethics and Governance of AI for Health includes comprehensive guidance on building responsible Health AI solutions with a dedicated module to enhance developers' capabilities.[40]

"Government regulators should provide incentives to developers to identify, monitor and address relevant safety- and human rights-related concerns during product design and development and should integrate relevant guidelines into precertification programmes." -- Ethics and Governance of Artificial Intelligence for Health; WHO Guidance

D. **Establish risk-tiered regulatory requirements and post-market surveillance systems for SaMDs with elements such as early warning systems, periodic safety updates, and incident reporting systems.**

Examples:

- Australia, Singapore, South Korea, and Japan use a risk-based medical device classification to assess the level of regulation required.
- "The Taiwanese government now institutionalizes annual, continuous monitoring and evaluation of the accuracy [of Health AI solutions]" – Senior leader and CMIO of a leading national hospital in Taiwan.

E. **Consider appointing an existing national research institute or body to carry out research on the use of AI, including AI ethics and safety, risk assessment and mitigation within the healthcare sector, and develop capacity-building programs for healthcare practitioners and patients.**

The designated institute could research the value of AI's application in healthcare and the potential risks associated with new models across the lifecycle. It could also **drive foundational AI safety research** and function as a collaborative knowledge-sharing platform for stakeholders from the industry, government, and academia on incidents and vulnerabilities, as well as provide technical support.

Examples:

- Taiwan's Ministry of Science and Technology (MOST) established the **Artificial Intelligence Biomedical Research Center** at National Cheng Kung University, where research focuses on integrating AI with ethics and humanity in healthcare solutions.[41] Singapore launched the **Digital Trust Centre (DTC)** to lead AI safety research and development, with initial research areas including model design, testing, and governance, supported by $50 million in funding.[42] Similarly, the Philippines set up the **Centre for AI Research (CAIR)** in July 2024 as part of its National AI Strategy Roadmap.[43]
- The United States National Institute of Standards and Technology (NIST) has launched the **Assessing Risks and Impacts of AI (ARIA) program**, aimed at helping organizations and individuals evaluate AI technologies for validity, reliability, safety, security, privacy, and fairness with ARIA focusing on assessing large language models.[44]

F. **Consider building standardized datasets as digital public goods to strengthen Health AI validation.** ***LMICs & UMICs***

Building standardized anonymized datasets and pseudonymized datasets as digital public goods is the first step toward strengthening Health AI tools' validation, particularly for high-risk use cases. With robust data governance in place, incorporating datasets comprising identified data can further improve the accuracy and reliability of Health AI solutions.

Examples:

- Japan's 2017 Next Generation Medical Infrastructure Act facilitates the collection and anonymization of medical data for research while protecting patient privacy. The 2023 amendment allows for pseudonymized data collection, expanding its use for medical research.[45]
- India's Medical Imaging Data Sets (MIDAS) project, a collaboration between the Indian Institute of Science (IISc) and the Indian Council of Medical Research (ICMR), aims to centralize medical imaging data across India. It uses a hubs-and-spokes model, with IISc as the nodal center and the AI and Robotics Technology Park (ARTPARK) providing the technological backbone. The project adheres to gold-standard data collection practices to ensure the datasets are representative of the Indian population, advancing AI-driven healthcare innovation.[46]
- The UK Biobank is a significant biomedical resource combining de-identified genetic, lifestyle, and health data from 500,000 participants, making it instrumental in developing AI models for disease prevention, diagnosis, and treatment.[47]
- The European Health Data Space (EHDS), announced in 2022 and expected to include all European Union (EU) members by 2025, aims to create a unified health data ecosystem. Its two pillars – MyHealth@EU for patient data exchange and HealthData@EU for secondary research use – enhance data accessibility and promote cross-border healthcare, all while ensuring strict privacy compliance.[48,49]

R2: Review and update Health AI regulatory frameworks, if required, to be fit-for-purpose and technology-neutral to ensure patient safety, protect individual and collective human rights, and promote Health AI adoption.

2.1 Amending existing regulations should be prioritized over adding new regulations where applicable to avoid increasing the compliance burden and stifling innovation, especially for Small & Medium Enterprises (SMEs). Empower/direct an existing regulatory body to evaluate and determine whether existing consumer patient protection legislation, regulatory frameworks, guidance, and enforcement mechanisms sufficiently cover the use of AI.

Example: The Law Reform Committee of the Singapore Academy of Law formed a Subcommittee on Robotics and Artificial Intelligence in 2021 to evaluate and provide recommendations regarding the legal application of robotic and AI systems.[50]

Example: The Australian government released the Safe and Responsible AI discussion paper in 2023, presenting an overview of existing governance and the country's regulatory framework along with providing an overview of international developments and inviting feedback from the public on whether further governance and regulatory responses are needed in Australia.[51]

2.2 Ensure that relevant stakeholders, including industry, are consulted when reviewing or introducing new regulations or guidelines

2.3 Develop sectoral guidance that is fit-for-purpose, incorporates a risk-based approach, is use-case specific, and is aligned with international standards and best practices.

2.4 Ensure that low-to-medium-risk use cases can be deployed with minimal regulatory approvals.

2.5 Monitor technological advances to ensure regulations and guidance remain effective and relevant.

A. **Guidance on the use of AI in medical devices (AI-MD) and generative AI should be developed and made available to all key stakeholders.**

> **Example:** Regulatory authorities across several countries have issued guidelines on the use of AI in medical devices. In 2023, Australia's Therapeutic Goods Administration provided guidance on generative AI and large language models, while Singapore's Health Sciences Authority released AI-MD guidelines in 2022.[52,53] Taiwan's Food and Drug Administration issued technical guidance for AI/ML-based software in 2021, and the WHO released a framework in 2021 outlining evidence-generation requirements for AI-based medical devices, focusing on training, validation, and evaluation.[54,55]

B. **Regularly review and update user-level guidance where needed to ensure it remains fit for purpose and aligned with current developments.**

2.6 Consider collaborating with healthcare institutions and clinical colleges to offer education and provide clarity on liability in existing legal and regulatory guidelines to organizations and users.

2.7 Ensure data governance and cybersecurity policies and regulations are risk-based and fit for purpose.

A. **Clear data governance policies and principle-based regulatory frameworks must be adopted to ensure risk-appropriate governance** based on internationally recognized standards.

> **Example:** Japan's Next Generation Medical Infrastructure Act aims to boost medical research by setting policies for the use of anonymized data. It establishes "Certified Anonymized Medical Data Agents" as secure third-party holders of such data. The act introduces an opt-out system, allowing medical institutions to share data with these agents unless patients explicitly opt-out after being informed. Unlike the EU's GDPR, this model doesn't require consent for data transfer, which may enhance research and public health. Its recent amendment for pseudonymization ensures data can't be linked to individuals without separate, securely stored information.[56]
>
> **Example:** ISO/IEC 4200:20231 is the first international standard for Artificial Intelligence Management Systems (AIMS), designed to guide organizations in the ethical, secure, and transparent management of AI technologies throughout their lifecycle. It emphasizes principles such as transparency, accountability, risk management, bias mitigation, and data protection. The standard requires organizations to integrate AI governance into their business strategies, promote continuous improvement, and ensure compliance with relevant regulations.[57]

B. **Encourage public sector organizations to periodically carry out AI privacy** and **cybersecurity impact assessments and review policies and regulations** in line with evidence generated.

C. **Establish open standards for data interoperability and data exchange supported by the implementation of electronic medical records and cloud-based data exchange infrastructure. This will ensure a secure, patient-centered, connected healthcare system and more inclusive, reliable, and accurate AI solutions.** ***LMICs & UMICs***

Interoperability standards such as HL7 FHIR and open EHR help standardize data formats and terminologies, reducing errors associated with data entry and interpretation and increasing the reliability of the AI solution. With established open standards, healthcare organizations can more easily comply with regulatory requirements regarding data sharing and patient privacy.[58,59,60]

Regulatory Capacity Building

R3: Strengthen regulatory capacity building through intra- and inter-governmental collaboration

3.1 Establish and/or strengthen participation in international, regional, and bilateral mechanisms for collaboration, research, and regulatory capacity building.

A. For the development of harmonized ethical principles, regulatory guidelines, and technical standards, collaborate with organizations such as the World Health Organization (WHO), the Global Harmonization Working Party (GHWP), the International Organization for Standardization (ISO), the International Medical Device Regulators Forum (IMDRF), the Global Partnership on Artificial Intelligence (GPAI), and the Artificial Intelligence Safety Institute Initiative.

Example: The International Telecommunication Union (ITU)/WHO Focus Groups on AI for Health (FG-AI4H) were established in July 2018 to develop international evaluation standards for AI solutions in health. Its overall objective is to tap this network of international expertise to create (a) guidelines for the evaluation of AI for health and (b) to create an online platform and complementary tools for the benchmarking of AI for health.[61]

Example: IMDRF is a voluntary group of international medical device regulators working toward building on the foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims to accelerate international medical device regulatory harmonization and convergence.[62]

3.2 Promote intra-government collaboration to ensure that regulatory frameworks are interoperable.

Optimize Regulatory Processes

R4: Streamline regulatory processes to be more adaptive and agile in the face of rapidly evolving technology in line with international guidelines and best practices

The regulatory authority should consider working closely with the designated AI Safety Research institute and the private sector to stay up to date with the latest research on AI Safety and Ethics. It can consider adopting mechanisms and approaches to improve agility such as recognition and reliance models, accelerated approval channels, conditional approvals, predetermined change control modifications, and modular regulations.[63,64] The regulatory authority could also enable controlled experimentation and testing of Health AI solutions through regulatory sandboxes and pilots that provide an enabling environment for local innovation.

Example: The Ministry of Health, Labour, and Welfare (MHLW) of Japan developed DASH 2 (Development Approval System for Health software) for SaMD (Software as a Medical Device), a strategy to streamline the approval process for AI-based medical software.[65,66]

Example: Singapore's Institute of High-Performance Computing (IHPC) has partnered with a healthcare cluster to create an AI sandbox – the Clinical Sandbox provides anonymized clinical data sets for AI developers to validate their models' applicability and generalizability to the Singapore population. There is also a Technical Sandbox designed specifically for clinical-tested algorithms (e.g., FDA or HSA-approved) to be tested in a simulated environment, ensuring seamless integration with existing systems and deployment readiness.[67] Given the variety of use cases of AI-MD, Singapore's Health Sciences Authority encourages developers to engage early under their pre-market consultation scheme for specific guidance on individual AI-MD.[68]

Sustainability

R5: Promote sustainable Health AI with a dual focus on workforce readiness and environmental impact

5.1 Develop policies and programs that focus on upskilling and training healthcare workers to successfully adopt and manage AI-enabled healthcare, addressing job displacement fears through proactive workforce development initiatives.

A. In the short term, it would be beneficial for all healthcare stakeholders if the government considers establishing a platform for collaborative dialogue, providing education and awareness on the benefits of AI use, and designing and providing incentives for upskilling and re-skilling. .

B. The healthcare ministry may consider tapping into national research capacity to evaluate the long-term societal and economic implications of AI potentially replacing specific medical roles to proactively address job displacement and design the healthcare workforce of the future.

Example: The European Union's European Institute of Technology (EIT) Health, in collaboration with McKinsey, produced a report on the impact of AI in healthcare, including the impact on employment.

5.2 Develop national policies to address the long-term environmental impact of AI use.

Example: The Global Partnership on AI (GPAI) provides recommendations on the sustainable use of AI.[69]

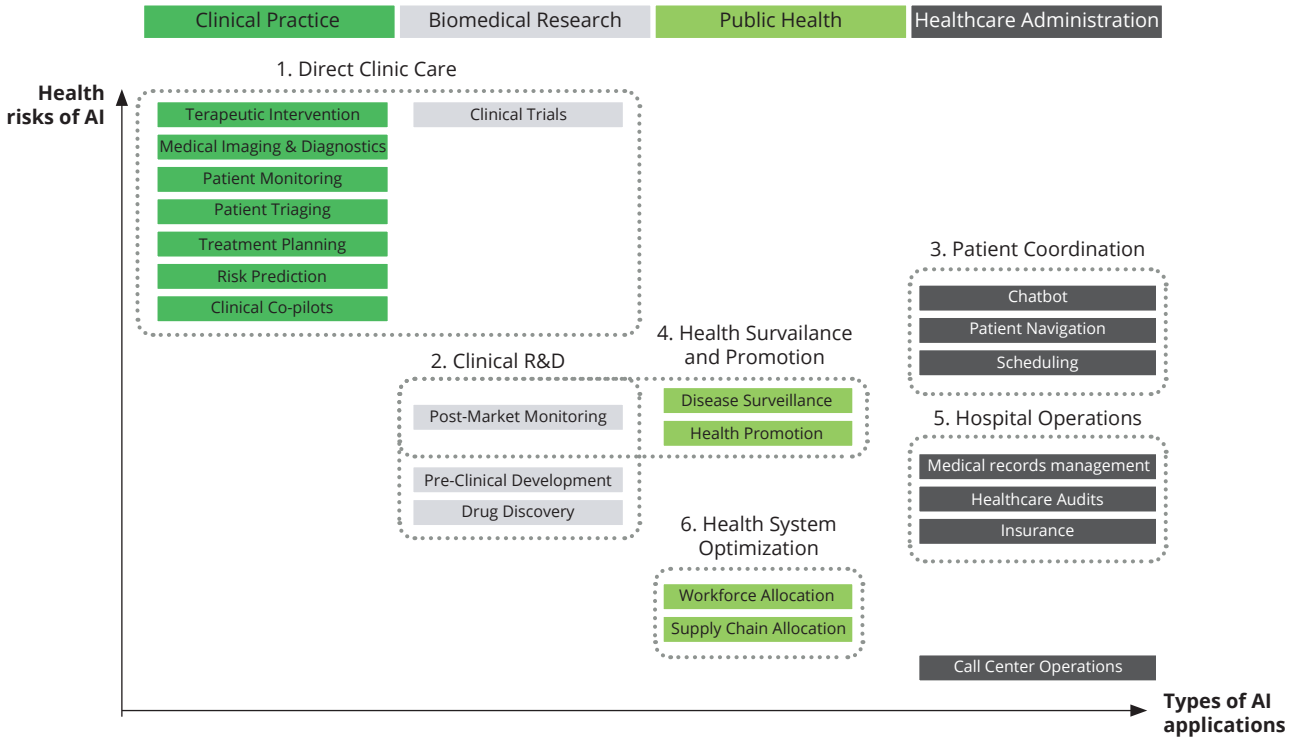
6. A Risk-based Approach Towards Responsible AI Deployment in Healthcare

6.1 Overview

AI promises to have great application potential in the healthcare setting, subject to the acceptability of its' integration into existing processes by Hospitals, Software vendors, Ministries of health and other payers. Despite its benefits and existing healthcare-specific safeguards, AI is seen to pose several risks of which most are pre-existing threats that could be exacerbated or facilitated with greater ease with the use of AI. In the context of healthcare, pre-existing issues such as marginalised groups' access to healthcare services, racial or gender discrimination and biases could be reproduced by AI due to the way models are designed or trained.[70]

The level of risk involved in AI's use in healthcare depends on the potential outcome severity from unmitigated risks and the likelihood of such events occurring. Ultimately, such events could be mitigated by evaluating specific risks at a user use-case level and monitoring and reporting incidents, re-assessing risk after implementing mitigation strategies and having an incident reporting mechanism that feeds into the greater regulatory ecosystem to respond and be reflexive.

Figure 5: **AI in health applications clustered according to type of AI application and health risks posed by AI**



AI is seen as having greater risk where the decision impacts patients directly, as compared to more distally (see *Figure 5*). For instance, clinical practice (which includes treatment, medical imaging and diagnosis, patient monitoring, triaging, risk prediction) and clinical trials in biomedical research pose more severe impact to patient health if risks are unmitigated than from drug discovery, preclinical development or post-market monitoring in clinical R&D pathways. AI uses in public health surveillance, health promotion and health system optimization such as workforce allocation or supply chain allocation pose much lower risks. Similarly, healthcare administration roles may pose higher risks when it comes to patient coordination roles as compared to hospital operations roles.

6.2 Effective Management of Health AI Risks by Institutional Users

Institutional and individual users, developers, and deployers (see *table 1*) have roles to play in identifying risks during specific phases of the development and implementation of AI solutions. Institutional users in this context are healthcare organizations. Technology-based organizations can be solely developers or deployers or organizations that are both. Table 1 outlines the responsibilities in risk identification for each of these roles. This section then delves more closely into the role of healthcare organizations as the institutional user.

Table 1: Roles and Responsibilities of Key Actors in Risk Management

Role	Responsibilities in risk identification and mitigation
Developer Designers of AI solution	Document internal efforts to evaluate and mitigate potential risks and share such documentation with customers – so that customers can make informed decisions about how to deploy the AI system.
Deployer Deployers include third-party companies that provide AI as a service and incorporate AI-powered tools and capabilities into user systems.	Identifying risk in AI performance when integrating AI into healthcare solutions, including reliability, accuracy, and fault tolerance levels.
Institutional & individual users (Users) This includes public and private healthcare institutions, academic institutions, and pharmaceutical companies that use AI for clinical, preclinical, public health, and healthcare administration needs.	Identifying risks to patients from integrating AI into decision-making processes that may result in severe patient outcomes; risks to clinical trial participants from AI use in preclinical drug discovery; unfair or unequal access to health services; and misrepresentation of potential health threats or health gains at population levels.

Note: In some cases, a healthcare institution may assume the role of a deployer or act as both user and deployer.

Section 3 introduced the two main types of hazards with Health AI solutions: baseline Health AI hazards and use-case-specific hazards. The tables below recaps both types.

Figure 6: The two types of hazards associated with Health AI solutions

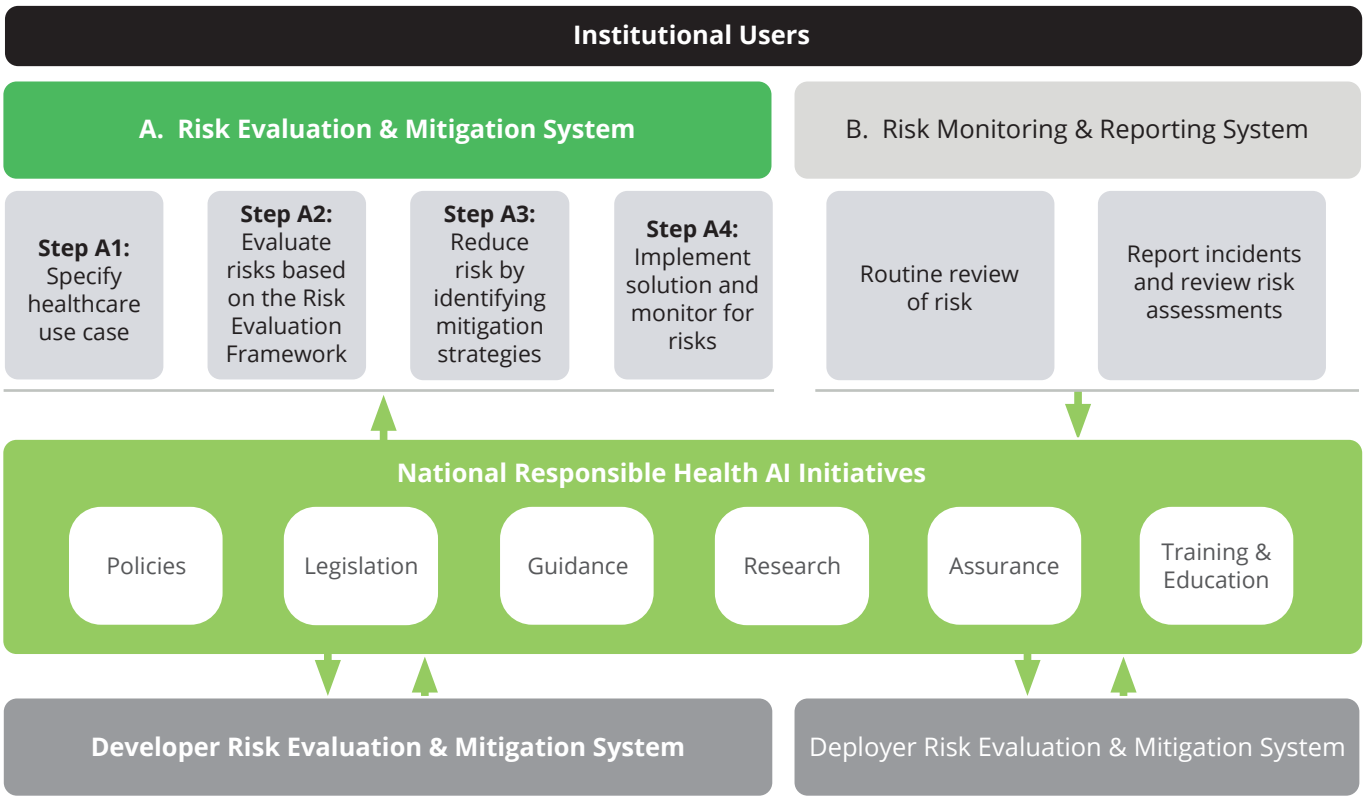
Use-Case Specific Variable Hazards
Lack of clinical accuracy and reliability
Bias
Alignment risks
Automation risks
Liability risks

Health-IT Product-Level Hazards
Data privacy
Data security
Software change management risks
Integration and interoperability risks
User skill gaps

Institutional users can assess and bring down risks by evaluating hazards for their specific use case, implementing risk control measures, and routinely reviewing these risk assessments, as well as having a robust incident management system.

This framework (see *Figure 7*) provides a broad overview of how institutional users could evaluate and monitor risk and how developers and deployers' risk evaluation and mitigation could inform institutional users' risk evaluation by increasing transparency to support the organization's decision to select a specific AI solution. The various risk mitigation strategies and reporting of incidents by developers, deployers, and institutional users will feed off and into each country's specific regulatory ecosystem in a continuous process.

Figure 7: Effective Management of Health AI Risks in the Healthcare Ecosystem



The following sections provide more details on how institutional users ("users") can manage evaluate and manage Health AI risks.

A. Institutional Users Risk Evaluation and Mitigation System

Institutional users may consider including an AI Safety in Health (AISH) team at an organizational level. These AI safety officers will require training to assess risks in consultation with clinicians, public health specialists, health administrators and researchers for specific AI use cases; set up and oversee departmental incident monitoring and reporting mechanisms, conduct internal safety audits, routine risk assessment reviews, and liaise with relevant regulatory bodies regarding organization-level regulatory approval management for AI use.

Each AISH team could include the organization's existing Data Protection Officer (DPO) to be involved in the development, procurement or use phase of the AI system to:

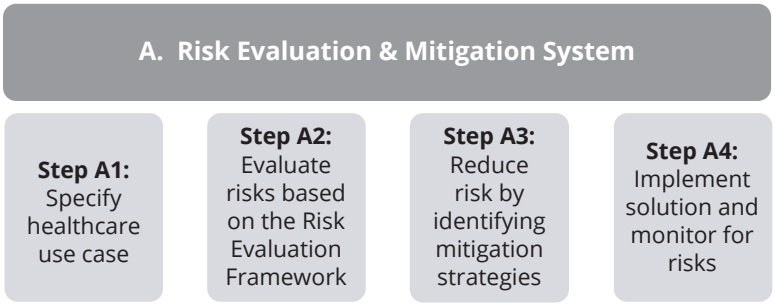
1. Ensure privacy-by-design in technology during and privacy by default (e.g. encryption, pseudonymisation and anonymisation) during procurement processes.[71]

2. Oversee mechanisms for data processing (including role-based access controls for accessing data and implement mechanisms for logging data access and modification).[72]

3. Oversee data minimization (reducing time and types of personal data required based on use case).[73]

Organizations could provide specific training to existing cybersecurity and data security personnel to ensure they are capable of applying their responsibility appropriately to data systems that incorporate AI. Such responsibilities could also include ensuring the developer of the AI system has provided information about likely security threats to the system and account for deployment environment security requirements when developing contracts for AI system products or services. Additionally, cyber security officers with appropriate Ai skills could provide users with guidelines to evaluate and monitor AI systems and ensure the supply chain is evaluated to ensure that standards and risk management has been adhered at all stages; ensure application programming interfaces are secured with authentication requirements, actively monitoring unauthorized changes to the model's architecture, conduct penetration testing and run routine security tests.[74]

Stepwise Overview of the Risk Evaluation and Mitigation System for Institutional Users

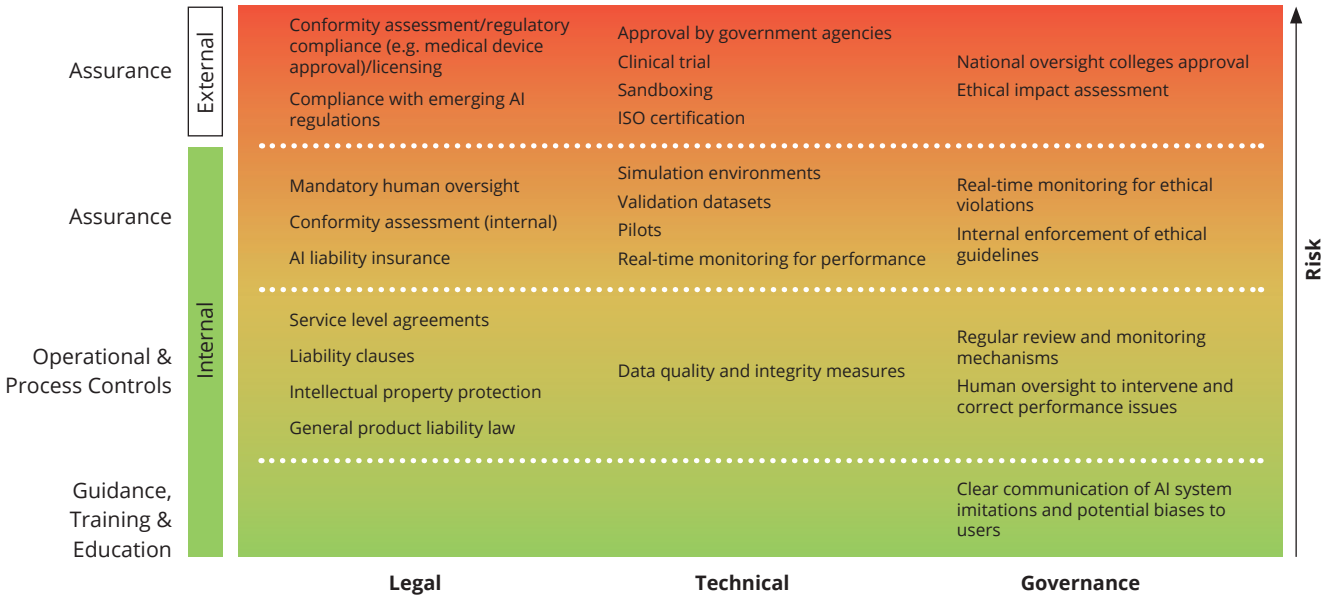


Step A1: Specify Healthcare Use case: Ideally, risks from specific hazards will have to be mitigated at the use-case level within each healthcare setting.

Step A2: Evaluate Risks based on the risk evaluation framework: Evaluate risks using a risk evaluation template where specific hazards are identified for the use case; the severity of the outcome scored based on each hazard and the likelihood of such an incident happening factored in to arrive at an overall risk score per hazard. *Refer to section 1.3 on risk evaluation methodology.*

Step A3: Reduce risk by identifying risk mitigation strategies: Mitigation strategies are meant to address the hazards posed by either eliminating them or providing an understanding of when they may occur or through means of monitoring them to ensure they can be intercepted through external controls. Risk mitigation measures come in the form of internal and external assurance mechanisms supplemented with the required operational and process controls as well as guidance, education, and training. Assurance mechanisms can be legal, technical, or related to governance. *Refer to Section 1.3 for a worked example illustrating how controls can bring down the risk score.*

Figure 8: Hierarchy of risk mitigation measures



Risk Mitigation measures that will need to be employed by institutional users control the risk of each hazard can be viewed as a hierarchy of control measures.

The higher the risk, the greater the number of control strategies required. Outlined below are the mitigation strategies from the top tier (level 4, for highest risk) down to level 1 for lowest risks.

Level 1 (Internal) training and guidance: this is the baseline risk mitigation measures for the lowest levels of risk. This includes clear communications of AI system limitations and potential biases to users as well as routine training for users.

Level 2 (Internal) operation and process controls: operational and process controls include intellectual property protections, general product liability laws under legal measures; data quality and integrity measures under technical measures. Regular review and monitoring mechanisms and human oversight to intervene and correct performance issues are two governance measures under this level of control.

Level 3 (Internal) assurance mechanisms: consider including at the organizational level conformity assessments, mandated human oversight, liability insurance that has provisions for AI and service level agreements on the legal end. Organization level pilots, simulation environments and validation data sets before rolling out A solutions are some technical mitigation strategies. Under internal governance measures, institutional users could utilise real time monitoring of ethical violations and internal enforcement of ethical guidelines.

Level 4: (External) assurance mechanisms: the highest risks may require assurances that are external to the user organization. This could include conformity assessments or regulatory compliance, for instance medical device approvals or licensing under legal measures, clinical trials or sandboxing and ISO certification under technical measures and ethical impact assessments or national oversight college approvals under governance measures. *See Annex 3 for more details on hazard-based mitigation strategies.*

Step A4: Implement solution and monitor risks: once the risk assessments have been conducted and mitigation strategies identified and put in place, these strategies must be monitored and documented in a continuous process.

B. Institutional User Risk Monitoring and Reporting System

The institutional user Risk Monitoring and Reporting System in Health AI ensures real-time tracking and analysis of AI system performance, promptly identifying and reporting potential risks to patient safety. By continuously monitoring data and outcomes, it enhances the reliability and accountability of AI-driven health interventions.

Healthcare users could consider designating dedicated trained personnel from the safety team to handle risk monitoring and incident reporting. The personnel could be the primary contact person linking users to the wider regulatory incident management ecosystem at the country level that will inform research and in turn inform future regulatory needs.

Overview of the Risk Monitoring and Reporting System for Institutional Users

Routine review of risks: The risk assessment documentation could be maintained by each department for every use case as a safety management system. In the absence of incidents, risk assessments could be reviewed periodically (at a fixed period). These risk assessment documents serve as important legal documents for user liability at an organization level.

Incident-based risk assessment and reporting: The risk monitoring system functions as a feedback loop for organizations to review and address low impact and high impact events in a proportionate manner.

- Organizations could monitor incidents and **report incidents that are deemed low impact within the organisation** for internal monitoring and review and then fine-tune clinical processes that integrate AI solutions reflexively to minimize risks.
- Incidents with **serious impact to patient outcomes** could be reported at a country-level to a regulatory body that oversees and monitors incidents in the healthcare sector —this could be an existing body appointed by the Ministry of Health or related regulatory agency for oversight.
- Incident reporting at both levels could be followed by risk re-evaluation and improved mitigation.

6.3 Considerations for developers and deployers

It is important that developers and deployers of A solutions for healthcare conduct their own risk assessments for hazards relevant in their contexts. For instance, for developers, use case risk assessments may include bias as a hazard where robust training data sets are the mitigation strategy to bring down such risks, inclusion of white box documentation and providing licencing in the case of A when used in medical devices are some of the strategies that Deployers will need to assess how AI is integrated into standalone healthcare solutions that they may provide institutional users and assess for risks to the wider healthcare system that such solutions are being integrated into. Particularly, deployers may consider the importance of human factors and user interface design in the evaluation of AI-powered devices, ensure that devices are intuitive, user-friendly, and accessible to individuals with diverse abilities to enhance usability and reduce the risk of user errors. These evaluations will need to be documented clearly.

Together, both developer and deployer documentation of mitigation strategies will provide useful upstream information for institutional users to assess their own risk mitigation strategies when selecting AI solutions and implementing them.

Hazard-based risk evaluation methodology for specific use cases

This section explains the methodology for a hazard-based risk evaluation for two use cases as illustrated in Example 1 and Example 2 below.

Example 1: Risk assessment template and scoring for use case 1 before implementing mitigation strategies

Figure 9: Illustration of the Risk Assessment Template for Use Case 1

Use case: Health AI solution provides diagnosis on bladder cancer for oncologist to review
Preliminary risk assessment: High
GenAI use (Y/N): No

Health AI-specific hazards	Impact of hazard on patient outcomes (A)	Likelihood of occurrence (B)	Risk score per hazard (A) x (B)
(1) Clinical inaccuracy or unreliability	5	4	20
(2) Bias	3	4	12
(2) Automation bias	3	2	6
(3) Alignment risks	1	1	1
(4) Liability risks	2	2	2

1 Non-serious	1 Very low (1-19%)	Low (1 to 8)
3 Serious	2 Low (21%-40%)	Medium (9-16)
5 Critical	3 Medium (81%-100%)	High (17-25)
**See annex*	4 High (61%-80%)	
	5 Very high (81%-100%)	

To arrive at this assessment, we follow the stepwise process outlined in the previous section. The first step is to identify the use case.

Step 1: Specify Healthcare Use case
In this use case, the health AI solution provides automatic tumour detection, staging, and grading, bladder wall segmentation, as well as prediction of recurrence, response to chemotherapy, and overall survival.

Step 2: Evaluate risks based on the risk evaluation framework
Before integrating this AI application into the oncologists' existing workflow, the AI Safety in Health (AISH) team could conduct a preliminary risk assessment in consultation with the oncologist to assess the potential outcome severity to patients for each potential hazard in this use case. Each hazard's impact on a negative outcome to patients is assessed by the AI safety officers and oncologist.

The impact on patient outcomes is scored based on the type of disease treated for and the range of outcomes tied to this treatment. At baseline, an oncology clinic will have a higher severity range than a GP clinic reviewing routine flu cases. For each hazard, the impact of the hazard on patient outcomes is calculated, and a rating of non-serious (1) to serious (3) to critical (5) is accorded in see column A.

Patient outcome type	Outcome Description
Critical	Death, long-term disability, or other serious health deterioration. • Sometimes time-critical, depending on disease/condition progression • Also relevant for fragile target population (e.g., pediatrics, high-risk)
Serious	Results in unnecessary interventions (e.g., biopsy) and/or long-term irreversible consequences in a curable moderate disease/condition
Non-serious	May lead to minor complications, worsening of symptoms, or unnecessary interventions in a slow-progression predictable disease

The impact of hazard on patient outcomes is then multiplied by the frequency or likelihood of such a hazard occurring. If the likelihood is less than 20%, a rating of 1 is given, verses a very high likelihood of 80% or more which is given a score of 5. The risk score for this hazard is then calculated by multiplying A x B.

Impact of hazard on patient outcomes (A)	Likelihood of occurrence (B)	Risk score per hazard (A) x (B)

For the first hazard, **Clinical Inaccuracy or Unreliability,** the total risk score for clinical inaccuracy was assessed to very high at 20.

Health AI-specific hazards	Impact of hazard on patient outcomes (A)	Likelihood of occurrence (B)	Risk score per hazard (A) x (B)
(1) Clinical inaccuracy or unreliability	5	4	20

Risk scores of 17 and above are high (red), while 9-16 score medium (orange) and low or acceptable risk is from scores of 1 to 8 (green). Risk scores that are high or medium require additional mitigation strategies that can bring down the score to an acceptable level of 1 to 8.

Low (1 to 8) Medium (9-16) High (17-25)

The same evaluation process is followed for each of the other use-case-specific hazards: bias, automation bias, alignment risks, and liability risks.

Health-IT Product-Level Hazards' Risk Assessment

In addition to specific hazards, AI solutions must be risk assessed for data protection, privacy and cybersecurity risks that are covered by regulatory requirements across the board and address the ethical considerations of transparency, confidentiality and patient privacy. Other baseline hazards such as user skill gaps, integration and interoperability risks, and software change management risks could also be evaluated.

Step 3: Reduce Risk by Identifying Risk Mitigation Strategies

In the above example, while the risk scores of hazards 3 to 5 are acceptable (green), the scores for Hazard 1 and Hazard 2 are high and medium, respectively. Mitigation strategies could be employed to bring down risk proportionately.

The risk assessment is reviewed after implementing mitigation strategies until the risk column is within the acceptable range. For detailed risk mitigation tools and mechanisms, refer to Annex 3.

Step 4: Implementation of Risk Mitigation Strategies:

After implementing mitigation strategies, risk is re-evaluated.

Figure 10: Risk assessment template and scoring for use case 1 after implementing mitigation strategies

Use case: Health AI solution provides diagnosis on bladder cancer for oncologist to review
Preliminary risk assessment: High
GenAI use (Y/N): No

Health AI-specific hazards	Mitigation Strategies	Impact of hazard on patient outcomes (A)	Likelihood of occurrence (B)	Risk score per hazard (A) x (B)
(1) Clinical inaccuracy or unreliability	Human in the loop, Pilots, Conformity Assessments, Guidelines and Training	5	1	5
(2) Bias	Audits, Model Evaluation, & Training	3	1	3
(2) Automation Bias	Human-in-the-loop	3	1	3
(3) Alignment risks	Guidelines	1	1	1
(4) Liability risks	Education and training	1	1	2

1 Non-serious	1 Very low (1-19%)	Low (1 to 8)
3 Serious	2 Low (21%-40%)	Medium (9-16)
5 Critical	3 Medium (81%-100%)	High (17-25)
	4 High (61%-80%)	
	5 Very high (81%-100%)	

While the outcome severity remains unchanged for the hazard, mitigation strategies reduce the likelihood of occurrence, thus bringing down overall risk. Hazard 1 and Hazard 2 are now within an acceptable risk range by implementing a variety of strategies that fall under a hierarchy of controls (refer to section 1.4) and all other hazards have been improved upon by employing the simplest strategies.

Different use cases may score impact on patient outcomes differently for each hazard as can be seen in the following example.

Example 2: Here is another use case where a GenAI solution uses clinician notes to predict billing codes for review by a healthcare administrator. As can be seen, while the same hazards apply for this use case, the impact to patients is much lower in this context. Risks are all within acceptable ranges.

Figure 11: Risk assessment template and scoring for use case 2

Use case: Health AI solution provides diagnosis on bladder cancer for oncologist to review
Preliminary risk assessment: High
GenAI use (Y/N): No

Health AI-specific hazards	Impact of hazard on patient outcomes (A)	Likelihood of occurrence (B)	Risk score per hazard (A) x (B)
(1) Inaccuracy or unreliability	1	2	2
(2) Bias	1	1	1
(2) Automation Bias	1	2	2
(3) Alignment risks	1	1	1
(4) Liability risks	1	2	2

1 Non-serious	1 Very low (1-19%)	Low (1 to 8)
3 Serious	2 Low (21%-40%)	Medium (9-16)
5 Critical	3 Medium (81%-100%)	High (17-25)
**See annex*	4 High (61%-80%)	
	5 Very high (81%-100%)	

Annex 1. Detailed Findings

This section is an expansion of the findings on the responsible AI landscape from Section 4. Taking each of the responsible Health AI components in turn, this section focuses on highlighting the 12 countries' progress against the indicators identified under each essential component. The countries are divided into groups based on their national

Group 1:	Group 2:	Group 3:
Australia, Japan, New Zealand, Singapore, South Korea, Taiwan	Thailand, Malaysia	India, Indonesia, Philippines, Vietnam

Note: These findings are based on public data and expert interviews as of February 15th, 2025.

1. Policies

National level	**1. All Group 1 countries have either developed or are developing policies that address responsible AI and adopt a risk-based categorization approach.** • Australia, Japan, Singapore, South Korea, and Taiwan's policies address the responsible use of AI through provisions around data governance and data privacy; technical guidance and compliance requirements for responsible AI; research on AI safety (in progress for New Zealand, South Korea); governance mechanisms such as oversight bodies for AI safety (except Taiwan); and AI safety awareness and education. • All six Group 1 countries' national AI policies adopt a risk-based categorization approach. • Only Australia and New Zealand's policies plan to address the environmental impact of AI. **2. Both Group 2 countries have developed policies to address consumer protection, data governance, and data security** • Both Group 2 countries are developing a risk-based categorization approach for their national AI policy. • Both Group 2 countries – Thailand and Malaysia – have established research programs on integrating and leveraging the safe and ethical use of AI. • Malaysia is working to appoint a national AI safety institute or equivalent. • Malaysia has implemented national-level approval of AI solutions through sandboxing, evaluation, validation, and/or safety testing. Thailand is working to have such mechanisms. **3. Group 3 countries are in the early stages of developing responsible AI policies** • With the exception of India, which launched its national AI plan in 2018, the other Group 3 countries launched their national AI strategies between 2020-2021. As such, while most Group 3 countries do address the responsible use of AI at a high level, they have yet to issue specific policies to address other building blocks. However, except for Indonesia, all Group 3 countries are adopting a risk-based categorization approach to their national AI policies.

Healthcare-specific	**Group 1** **1. With the exception of Taiwan, five Group 1 countries – Australia, Japan, New Zealand, Singapore, and South Korea – have AI in health policies or strategic plans that address responsible AI use.** **2.** The risk-based approach national AI policies are built on also applies to Health AI policies for five Group 1 countries (in progress for Taiwan). **3. Japan, Singapore, and South Korea's policies more comprehensively address responsible Health AI through provisions on technical guidance for Health AI;** ethical and regulatory guidance, technical compliance requirements for Health AI safety; Health AI safety awareness and education; and AI in SAMDs. **4.** National generative AI guidance has been issued in all Group 1 countries except for New Zealand. **Only Australia and South Korea have issued guidance that addresses the use of generative AI in health.** **Group 2** **1. Malaysia and Thailand have yet to develop a national AI in health policy. However, Thailand is reported to be developing one. Each country has addressed some aspects of responsible Health AI in their health policies.** • Thailand addresses the responsible use of AI-SaMDs in its health policies, and Malaysia is developing policies that address guidance on ethics and regulatory considerations for Health AI. • Malaysia's health policies address governance mechanisms for Health AI safety and national-level validation of Health AI solutions. • Thailand is developing policies that address technical compliance requirements for Health AI safety and is also working on developing policies that address Health AI safety awareness and education. • Both countries are developing AI ethics, safety, and regulatory awareness programs for AI use. **Group 3** **1. Across Group 3 countries, there has been varying progress in developing AI in health policies, with Indonesia addressing a number of key aspects of responsible Health AI in its policies.** Two out of four countries – Indonesia, Vietnam, with the Philippines in progress, have issued AI in health policies or strategic plans, and the same countries have policies addressing ethical and regulatory guidance, research on Health AI safety, capacity building for regulators, and Health AI safety awareness and education. • However, no country has yet issued guidance on generative AI in health, though the Philippines is reported to be developing the same. • All four countries are working on policies toward developing technical guidance, technical compliance requirements, and national-level approval of Health AI products, including addressing the development of policies for AI in Software as a Medical Device (SaMD).

2. Legislation & Regulations

National level	**Group 1** 1. Among the Group 1 countries, **South Korea** has signed its AI Basic Act into law, while **Japan and Taiwan have a draft AI Act.** • Australia has introduced voluntary AI safety standards and a proposed framework to mandate these standards in high-risk settings. **2. Four of the six Group 1 countries are working on a framework for classifying high-risk AI to inform liability** – Australia, South Korea, Japan, and Singapore. 3. Apart from mobilizing existing laws to govern AI, some Group 1 countries have introduced AI-specific provisions in SaMD regulations and already have or are developing AI-specific cybersecurity and data privacy provisions. 4. All six of the Group 1 countries provide a framework for assessing the risk of AI technologies. 5. Singapore and South Korea have developed AI-specific provisions in data privacy laws. Taiwan is developing similar provisions. 6. Similarly, Singapore and Taiwan are working to establish AI-specific provisions in cybersecurity legislations and regulations, while South Korea has already done so. **Group 2** **1. Malaysia mobilizes existing laws to govern AI while Thailand has additionally also added AI-specific provisions to its data privacy and cybersecurity laws.** Thailand has also developed a draft Royal Decree and a Draft AI Act, with the first **using a risk-based approach for regulation** and the second providing mechanisms and legal instruments to support AI development and consumer protection 2. Both Group 2 countries are developing a framework for risk assessment of AI technologies. 3. Thailand is in the process of developing AI-specific provisions in both data privacy and cybersecurity legislation and regulations. **Group 3** **1. All Group 3 countries are using existing laws and regulations to govern AI products.** All four are in the process of evaluating and drafting legislation for AI. 2. Vietnam is the only Group 3 country in the process of developing a risk assessment framework for AI technologies. 3. Among the Group 3 countries, the Philippines has developed AI-specific privacy and cybersecurity provisions, while Vietnam has AI-specific provisions in its data protection laws. Indonesia has reported the development of AI-specific provisions in data privacy laws.
Healthcare-specific	**All countries have data protection and cybersecurity laws in place that are applicable to the healthcare sector, with Group 1 countries having more healthcare-specific data protection legislation.** **All countries have SaMD regulations. However, in countries where AI-SaMD guidance had not been issued (Taiwan, Malaysia, and Group 3 countries), experts expressed the need for more clarity in applying existing regulations and guidelines to AI-SaMDs.**

3. Guidance

National level	**Group 1** 1. **All six Group 1 countries have issued practical ethics or regulatory guidance on AI adoption and implementation and** have issued technical guidance on AI adoption. **Group 2** 1. **Thailand has issued** practical ethics or regulatory guidance on AI adoption and implementation, while **Malaysia is developing** such guidance. 2. **Both Group 2 countries have not issued any guidance for generative AI adoption.** **Group 3** 1. **Three of four Group 3 countries have issued practical ethics or regulatory guidance on AI adoption and implementation** – India, Indonesia, and Vietnam (in development for the Philippines). 2. India and the Philippines are also developing technical guidance on AI adoption.
Healthcare-specific	**Group 1** 1. **Four of six Group 1 countries have issued AI in health, ethical, or regulatory guidance** – Japan, New Zealand, Singapore, and South Korea (in development for Australia and Taiwan). 2. Except for New Zealand, all Group 1 countries have issued AI-SaMD ethical or regulatory guidance. 3. **Three of six Group 1 countries are working to develop guidance for generative AI in health** – Australia, Singapore, and Taiwan. **Group 2** 1. Thailand has issued ethical or regulatory guidance on AI in health as well as guidance on AI-SaMDs. **Malaysia has not issued any guidance** in this area. **Group 3** 1. India has issued ethical or regulatory guidance for Health AI and is **reported to currently have AI-SaMD guidance in development.** 2. None of the four Group 3 countries have guidance on generative AI in health in development.

4. Research on Responsible AI

National level	**Group 1** 1. While **Japan, Singapore, South Korea, and Taiwan have appointed AI safety institutes** or funded research into the responsible use of AI, New Zealand has yet to do so. **Group 2** **2. Only Malaysia has announced plans to set up an AI safety institute.** **Group 3** 3. India and the Philippines have announced national research programs looking into the responsible use of AI.
Healthcare-specific	**Group 1** **1. Five out of six Group 1 countries** – Australia, Japan, Singapore, and South Korea – **have national AI research programs** looking into the responsible use/safe use of Health AI. **Group 2** **1. Neither Malaysia nor Thailand** have AI research programs that specifically focus on the responsible and safe use of Health AI. **Group 3** 1. Similar to Group 2 countries, **none of the four Group 3 countries** have national research programs looking into the responsible use of Health AI. However, India has laid out plans to do so.

5. Education & Training

National level	**Group 1** 1. **All Group 1 countries except for New Zealand have initiated national AI safety awareness and education programs.** New Zealand is currently developing such programs. 2. **Four of six Group 1 countries have initiated national technical education programs** related to AI safety – Australia, Singapore, South Korea, and Taiwan (in progress for Japan and New Zealand). **Group 2** 1. **Both Group 2 countries** – Malaysia and Thailand – **are in the process of developing** national educational programs and technical education programs on AI safety. **Group 3** 1. **Indonesia and the Philippines have initiated** national AI ethics and regulatory education and awareness programs. India is currently developing such programs. 2. Similarly, **Indonesia and the Philippines have introduced national technical education programs related to AI safety.** India is working to develop similar programs.
Healthcare-specific	**Group 1** 1. **Three of six Group 1 countries** have initiated national Health AI safety awareness and education programs – Australia, Singapore, and South Korea (in progress for New Zealand). 2. **Australia and Japan have initiated national technical education programs related to AI safety in healthcare** (in progress for New Zealand). **Group 2** 1. **Thailand has initiated both** national Health AI safety awareness and technical education programs related to AI safety in healthcare. • **Malaysia is developing** national Health AI ethics and regulatory awareness education programs. **Group 3** 1. **Indonesia has initiated** national Health AI safety education and awareness programs. 2. **India is developing** technical education programs related to AI safety in healthcare. Vietnam focused its national annual cybersecurity education program for government agencies on AI-related cybersecurity risks.

6. Assurance

National level	**Group 1** **1. All Group 1 countries have designated a specific body or committee to oversee the governance of AI.** 2. All countries, with the exception of New Zealand, have established mechanisms for evaluating and testing AI safety at the national level. **3. While adherence to identified ethical guidelines is prescribed by all six countries,** only Singapore and South Korea have introduced and encouraged voluntary adoption of ethics impact assessments, with South Korea's focus being on the public sector. **4. All countries encourage the use of risk and impact assessments or algorithmic impact assessments.** **Group 2** **1. Both Thailand and Malaysia are in the process of establishing national-level assurance processes.** • Thailand's Electronic Transactions Development Agency (ETDA) currently operates an AI governance clinic to evaluate risk levels, provide recommendations, and oversee AI-related projects. It is also in the process of drafting generative AI governance guidelines for developers to help them prevent AI hallucinations and avoid intellectual property violations. • Malaysia's Ministry of Science, Technology, and Innovation is planning to create a specialized Policy and Regulation Committee with a specific focus on overseeing AI. • Both countries are in the midst of developing more robust frameworks to encourage the use of risk and impact assessments. **Group 3** **2. All Group 3 countries are in the early stages of governing AI with limited mechanisms for assurance.** Most have issued or adopted recommended guiding principles for the responsible use of AI and encourage organizations to carry out self-assessments based on these principles. • The Philippines, India, and Indonesia are developing mechanisms for national-level validation of AI solutions • The Philippines and India are also reportedly working toward appointing a designated body to oversee AI safety. • Among the Group 3 countries, India currently encourages the use of risk and impact assessments or algorithmic assessments. The Indian government has developed a Risk Identification and Assessment Tool to help AI-led enterprises adopt and implement effective risk management strategies by visualizing potential risks that may arise. Vietnam is developing mechanisms to support such assessments. The Philippines also requires organizations processing personal data through AI-based solutions to carry out Privacy Impact Assessments.

Healthcare-specific	**Group 1** 1. **Oversight of Health AI safety in most Group 1 countries is mainly at the national level and within the healthcare sector through regulatory bodies governing medical products and medical devices.** 2. **Japan and South Korea have established mechanisms for national/state-level evaluation of Health AI solutions for AI-SaMDs,** while **Singapore has a national-level platform** that is also applicable to Health AI solutions. 3. **Four out of six Group 1 countries** – Australia, Japan, Singapore, and Taiwan – have issued guidelines requiring Health AI solutions to comply **with certain technical requirements,** such as ISO standards and IMDRF medical device guidelines for quality management and other key design and manufacturing principles. **Group 2** 1. **Thailand and Malaysia's governance measures for Health AI are limited to AI-SaMDs,** which will have to comply with existing medical device requirements. 2. Similar to Group 1 countries, oversight of Health AI products mainly concerns AI-SaMDs and is overseen by the Ministry of Public Health and the Healthcare Regulatory Authority, apart from national-level oversight. 3. Thailand is in the early stages of developing national-level platforms for AI evaluation and testing. **Group 3** 1. **None of the Group 3 countries** – India, Indonesia, the Philippines, and Vietnam – **have established national/state mechanisms for the validation of AI solutions; these** are available only for conventional SaMDs. In most of these countries, national SaMD guidelines remain to be updated in line with the latest technology and developments in healthcare. However, these are **reportedly under development in India, Indonesia, and Vietnam.** 2. Indonesia and Vietnam are reportedly developing technical compliance requirements for Health AI. 3. None of the four Group 3 countries have issued any requirements for organizations to carry out ethics impact assessments for Health AI.

Annex 2.
Responsible Health AI Readiness — Country Profiles

Australia

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[75]	87
AI Readiness Index Rank (2023)[76]	73.89
E-government Development Index[77] (2022)	0.9002
E-participation Index (2022)[78]	0.9886
UN ICT Development Index[79]	95.1
Digital Competitiveness Ranking[80]	16
Global Cybersecurity Index[81]	97.5

Overview of Health AI Use

- Australia has comprehensive universal health coverage in terms of access to affordable health services, including maternal, newborn, and child health and infectious diseases, although a somewhat lower coverage for non-communicable diseases.[82]
- Australia has highly developed e-governance structures, ranking second globally in the E-Participation Index and maintaining a strong position in digital development.[83]
- Australia needs to enhance its future readiness by improving business agility, entrepreneurial risk-taking, and cybersecurity preparedness to remain competitive in the digital economy.[84]
- In Australia, AI is being used for medical imaging analysis and diagnosis of diseases such as cancer and retinal conditions.[85] AI is also being used in clinical decision support systems to predict patient outcomes and create personalized treatment plans.[86]

Assessment of Responsible Health AI Initiatives: Key Findings

- Australia's approach includes **sector-agnostic AI policies and a risk-based approach** that emphasizes the safe and ethical use of AI without stifling innovation. The **AI Action Plan** provides clear regulatory frameworks to support responsible AI deployment across various sectors.[87] On 5 September 2024, Australia released **voluntary AI Safety Standards** and a **proposed mandatory framework to regulate high-risk AI settings** where the same voluntary standards will be mandatory for developers and deployers.
- Australia has implemented frameworks like the **AI Ethics Framework** and indirect regulations such as data privacy laws, cybersecurity measures, and sector-specific guidance.[88,89]
- Legislative efforts are ongoing to adapt existing laws, like the **Privacy Act**, to better accommodate AI technologies. Although there is **no dedicated AI Act yet**, the AI Action Plan highlights ongoing efforts to create a supportive legislative environment for AI innovation.[90] Australia is **developing a proposed three-tiered system** to classify AI tools as low, medium, or high risk to inform future liability and regulation.[91,92]
- Australia is developing guidelines under the **National Policy Roadmap for Artificial Intelligence in Healthcare** to integrate AI into existing SaMD regulations overseen by the Therapeutic Goods Administration (TGA). These guidelines will ensure that AI-enabled SaMDs meet rigorous safety and performance standards, addressing the unique challenges of AI in medical devices.[93,94]
- The **AI Ethics Framework** offers various types of guidance, including technical examples like the **AI Adopt Program, which provides specific guidelines for responsible AI adoption**. Key features of this framework include a focus on transparency, accountability, and inclusivity, ensuring AI technologies align with Australian values through practical and ethical standards.[95]
- Australia supports AI research through national institutes and funding programs, fostering safe and ethical AI integration in healthcare and other sectors. Educational initiatives focus on upskilling the workforce and raising awareness about AI ethics and regulations.[96] Australia's current AI framework for health lacks dedicated national-level programs for safety testing, validation, and ethics impact assessments, highlighting areas for improvement. However, it does **enforce compliance with international technical standards like ISO,** ensuring a baseline of quality and safety for AI health solutions.[97,98]

"As a regulator, the approach is not to regulate the AI model itself but rather to focus on its use case. We evaluate how the technology is applied, assessing the risks and benefits within that specific context, ensuring that regulation is tied to the outcomes produced by the AI in its particular use scenario." — Health AI expert, leading national research institute

"We are still concerned with risks with AI, especially GenAI, because it is rapidly changing and deployed on a large scale, which is why we need specific laws rather than waiting for general laws or existing laws to be effective...we want to put in safeguards. And healthcare is a high-risk field." — Academician and expert in AI regulation

Mapping Australia's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Japan

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[121]	83
AI Readiness Index Rank (2023)[122]	75.08
E-government Development Index[123] (2022)	0.902
E-participation Index (2022)[124]	1.000
UN ICT Development Index[125]	93.2
Digital Competitiveness Ranking[126]	32
Global Cybersecurity Index[127]	97.8

Overview of Health AI Use

- Japan has good provision of essential health services and financial coverage of such services to ensure affordability and accessibility.
- Japan has well-developed E-governance structures, is the global leader in terms of E-participation, and has a high rate of universal internet coverage that is affordable and accessible. However, Japan lags behind other advanced economies in Asia and globally in terms of digital competitiveness in terms of knowledge, technology, and future readiness.
- Japan ranks high in global cybersecurity in terms of legal, technical, and organizational measures, capacity development, and cooperation.
- Japan is among the top three countries for AI readiness in Asia, behind Singapore and South Korea.[128]
- At present, in Japan, AI is being used for medical image analysis and in the diagnosis of diseases such as cancer.[129]
- AI is also being used to predict patient outcome prediction and create personalized treatment plans.[130]

Assessment of Responsible Health AI Initiatives: Key Findings

- Japan's approach has been regulation of and for AI, meaning that Japan focuses **on balancing risk control without stifling innovation** and is revising existing regulations across sectors to enable AI adoption. Japan is committed to complying with international guidelines and ensuring appropriate AI procurement and use by the government.[131]
- Japan is discussing introducing a draft act, the **"Basic Act on the Advancement of Responsible AI."**[132] This is poised to introduce a more robust regulatory framework for AI in Japan, focusing on high-risk applications and ensuring safety and compliance through legally binding measures.
- Japan has a comprehensive framework that addresses the management, quality, privacy, and ethical considerations of data used in Health AI systems through the **Next Generation Medical Infrastructure Act, Act on Protection of Personal Information (APPI)**, and Medical Information Guidelines, Ethical and Regulatory Guidance. Japan has various **regulatory reforms** to facilitate **AI adoption in healthcare**, including the introduction of pseudonymized medical data through an amendment in May 2023 to the **Next-Generation Medical Infrastructure Act,**[133] **DASH,** a strategy for AI in SaMDs that includes amendments to the **Pharmaceuticals and Medical Devices Act (PMD Act)** to **streamline approval** of new technology while **addressing the risks of plasticity** once deployed.[134]
- While Japan's APPI lays a foundation for data protection, existing data privacy and cybersecurity legislation do not have AI-specific provisions.
- Japan is addressing risk in several ways: Japan's draft AI Act in development would require companies involved in **high-risk AI to conduct internal or external safety verifications and share risk assessments** with the government, and system maintenance requirements with the government being able to intervene and evaluate non-compliance.[135] Japan is also collaborating internationally with G7 countries on the **Hiroshima AI Process** to discuss AI regulation and safety.
- Japan has several awareness and training initiatives in place: the **Clinical AI Human Resources Development Program**[136] across 12 universities for upskilling health professionals in AI has **established an AI Safety institute,**[137] **developed Machine Learning Quality Management Guidelines,**[138] **AI Guidelines for Business139 and Operator guidelines**[140] **for developers, deployers, and users.**
- In terms of assurance measures, Japan has implemented a regulatory sandbox[141] approach to promote innovation in various sectors, including healthcare, which includes guidance for regulatory review of AI-based SaMDs,[143] and requires AI technology to comply with international standards. **However, Japan has not mandated national-level ethics impact assessments for AI and does not require pre-clinical or clinical trials for AI in health products.**

"Japan is focused on genomic medicine, diagnostic imaging support, diagnosis and treatment support, drug development, nursing care and dementia, and surgery support. As for diagnostic imaging support, it has been included in medical fees since 2022, and implementation is progressing."— Researcher at the Tokyo Foundation for Policy Research

"AI should be regulated according to the purpose of use, using a risk-based approach like the EU. However, Japan is still at the stage where it has not accumulated enough use cases."
— Researcher at the Tokyo Foundation for Policy Research

Mapping Japan's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

New Zealand

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[174]	85
AI Readiness Index Rank (2023)[175]	60.18
E-government Development Index[176] (2022)	0.9432
E-participation Index (2022)[177]	0.9545
UN ICT Development Index[178]	90.3
Digital Competitiveness Ranking[179]	25
Global Cybersecurity Index[180]	84

Overview of Health AI Use

- New Zealand has high universal health coverage, with financial access achieved through a mostly publicly funded, regionally administered delivery system.[181]
- With a high e-government development and participation index (ranked 4th and 6th out of 193 countries, respectively), this puts New Zealand as the region leader when it comes to e-government development, indicating the government's dedication to building up human capital, telecommunication infrastructure, and online services. New Zealand's high e-participation index reflects the country's commitment to including public input in government decisions through a partnership approach.
- New Zealand's high Global Cybersecurity Index shows that the country is committed to cybersecurity issues at a global level.
- The country's digital competitiveness ranking is impacted by the availability of STEM talent to support innovation in AI and develop programs to implement AI within systems.[182]
- New Zealand's AI Readiness Index rank is impacted by the cautious approach the government has taken toward AI, with a limited number of AI strategies released in comparison to other high-income countries.[183]
- Currently, AI has been used in medical imaging of mammograms within a handful of private clinics in New Zealand, utilizing AI to support radiologists with the identification of breast cancer through a mammogram.[184]

Assessment of Responsible Health AI Initiatives: Key Findings

- Currently, there are no AI-specific laws in New Zealand, with the **Algorithm Charter** being the only AI-specific policy for government agencies to assess the risks of decisions made with AI.[185] New Zealand is taking a cautious approach toward AI and is currently in consultations with various stakeholders to develop their National AI strategy that aligns with Māori principles. New Zealand has released a strategic report, **"Capturing the benefits of AI in healthcare for Aotearoa New Zealand,"** to highlight the principles needed to establish policies regulating AI within the country.[186] The Public Service AI Framework, developed by the Government Chief Digital Officer (GCDO), provides structured guidance for the responsible and safe deployment of AI, including generative AI, across government agencies.[187,188]
- New Zealand adopts a risk-based categorization approach in its national AI strategy, which extends to healthcare and encourages the use of Algorithmic Impact Assessments (AIA) by providing an AIA user guide by the Algorithm Charter.[189,190]
- Existing data privacy, governance, and cybersecurity laws extend to AI with a published set of guidelines, "AI and the Information Privacy Principles," which outlines how information privacy principles apply to AI, training data, data use, and purpose. GenAI is covered within this set of guidelines.[191] Similarly, the **Artificial Intelligence Use Policy** provides guidelines for the responsible and trustworthy use of AI within the country, with AI tools requiring an approved privacy impact assessment or privacy threat assessment before these tools can be used.[192]
- A **national AI and algorithm expert advisory group (NAIAEAG)** has been established to oversee AI safety. The advisory group is responsible for reviewing proposals to develop or put into practice any new models of AI in our national health services. Various voices are represented within the advisory group, including experts in AI, ethics, clinical, research, Māori health, data, digital, privacy, law, and innovation. Proposals are considered against an assessment framework that considers various themes and perspectives.[193]
- Despite the recent repeal of the **Therapeutics Product Act 2023,**[194] new proposals for regulating therapeutic uses of AI and software as a medical device will be presented to the Cabinet by the end of November 2024, with expected impacts on the implementation of AI in healthcare[195] and existing laws such as the **Medicines Act 1981** still stand.[196]
- New Zealand has practical ethics guidance on AI adoption and the implementation of **"Artificial Intelligence Guidance"**[197] as well as **"The Privacy, Human Rights and Ethics (PHRaE)**[198] **framework"** to help guide companies looking to use AI technology in their business operations. New Zealand is supporting the development of international AI standards, including ISO/IEC 42001:2023, through Callaghan Innovation, a government agency.[199] National programs for technical upscaling and to raise regulatory awareness are in the works. The Artificial Intelligence Researchers Association is the current leading association for AI research within the country.[200]

"At present there is no regulation of SaMD in New Zealand, and risk-proportionate regulation is currently being considered by Government. Health Technology Assessment processes for new technology such as AI are being established, which will ensure any investment provides good value"— Chief Science Advisor, Ministry of Health

"NZ has been doing social investment in AI for years by looking at who is more likely to experience harm. Guidelines-based, voluntary approach to regulating AI and in an ethical manner. This approach helps us to better allocate resources, mitigate harm and identify people who better need help."— Prof. James Maclaurin, Director, Centre for AI and Public Policy, The University of Otago

Mapping New Zealland's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Singapore

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[234]	89
AI Readiness Index Rank (2023)[235]	81.97
E-government Development Index[236] (2022)	0.9133
E-participation Index (2022)[237]	0.9773
UN ICT Development Index[238]	97.8
Digital Competitiveness Ranking[239]	3rd
Global Cybersecurity Index[240]	99

Overview of Health AI Use

- Singapore has good coverage of basic health services with an efficient health finance system and regional health clusters serving dedicated communities.[241]
- Singapore is a global leader in governance, data, infrastructure,[242] and active e-participation, leading in the Asia-Pacific region, behind world leaders Japan and South Korea.[243] Singapore's population is well-covered in digital access, with 98.8% of individuals owning mobile phones and 100% of individuals using the Internet, ranks 3rd globally for digital competitiveness and ranks 2nd in Asia-Pacific behind South Korea for cybersecurity with strong legal measures, capacity development, and cooperative measures.[244]
- Singapore is known to have one of the highest AI adoption rates among global countries[245] and is pioneering in testing AI treatment solutions in trials.[246]
- Singapore leverages AI for medical imaging, clinical research, patient support services, and remote patient monitoring.[247]
- Singapore is also developing multimodal AI, GenAI/LLM, and machine learning for models and platforms that perform predictive disease detection and diagnosis and precision medicine.[248]

Assessment of Responsible Health AI Initiatives: Key Findings

- Singapore's **National AI Strategy 2.0** adopts a risk-based approach and aims to draw together different sectors and stakeholders across industries, government, and research for full AI integration for the public good.[249] However, it does not have a standalone AI Act or Law.
- Singapore's Ministry of Health (MOH), Health Sciences Authority (HSA), and Infocomm Media Development Authority (IMDA) together developed a **Model AI Governance Framework** that provides AI safety guidelines and guiding ethical principles for organizations.[250] **Use cases, practical tools, and best practices**[251] are shared along with the framework to foster collaboration and facilitate the implementation of responsible and safe AI.
- Singapore has brief market approval and liability guidelines in standalone guidelines for GenAI and AI-based SaMDs, ensuring data privacy through its updated **Personal Data Protection Act**[252] with a specific guide on the Use of Personal Data in AI Recommendation and Decision systems.[253]
- National guidelines for AI in both ethics and regulatory[254] as well as technical aspects exist, including **Evaluation Toolkits and an Evaluation Sandbox.** It also has **GenAI-specific ethical and technical guidelines**[255] that address additional risks, provide standardized model safety evaluations, and recommend safeguards.
- Singapore is conducting national AI safety awareness education through AI Verify Foundation and AI safety technical education through AI Verify's Testing Toolkits,[256] is establishing a physical space for the AI community[257] (RAISE.SG) for AI upskilling, attracting talent, and strengthening research and activities.
- Singapore's **AI in Healthcare Guidelines (AIHGIe)** provides ethical and regulatory guidance for Health AI on key risks in responsibilities, development lifecycle, implementation, ethical concerns, and risk monitoring and evaluation.[258] It offers **Healthcare Cybersecurity Essentials (HCSE), which** covers issues concerning health data use, cybersecurity, and transparency.[259]
- Singapore's Health Sciences Authority (HSA) has issued **Regulatory Guidelines for SaMDs – A Lifecycle Approach** and **Guidelines on Risk Classification**, aligning with international standards set by the IMDRF.[260] A **risk-based classification system** for SaMDs is enforced. The Regulatory Guidelines for SaMDs also provide a list of existing regulations that cover additional regulatory measures for the provision of healthcare services, professional responsibilities, product safety, and data protection.
- Singapore has **national AI testing toolkits,**[261] **data regulatory sandboxes,**[262] **and national-level research and safety institutes**[263] so that the government and experts can help AI systems benchmark and validate their data and outputs. Singapore's **AI Verify Foundation is a national collaborative platform for boosting AI testing capacities and assurances.**

"Singapore is at the forefront of prospective validation of AI and digital medicine, with actual treatment taking place under trial. Very few places are doing so. This shows SG is quite agile." — Director, The N.1 Institute for Health, Singapore

"For Singapore, IMDA has general guidelines. For healthcare-specific guidelines, look at MOH. However, guidelines are only high-level policy. For implementation, you would usually talk with doctors to get an understanding, particularly for public hospitals."— CEO, Milkiway.AI

Mapping Singapore's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

South Korea

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[293]	89
AI Readiness Index Rank (2023)[294]	75.65
E-government Development Index[295] (2022)	0.9529
E-participation Index (2022)[296]	0.9432
UN ICT Development Index[297]	94.4
Digital Competitiveness Ranking[298]	6th
Global Cybersecurity Index[299]	98.5

Overview of Health AI Use

- South Korea's Universal healthcare is administered through the National Health Insurance Service (NHIS), with co-payments required for healthcare services. Payments beyond the annual limit (determined by income) will be reimbursed by the NHIS.[300]
- South Korea's high e-government development index ranks it 3rd out of 193 countries. It has a very high E-participation rate and cybersecurity index, putting the nation as a region leader when it comes to utilizing information technology to promote access and inclusion of its people, and it is safe from misuse or external threats.
- Korea is ranked 6th for its digital competitiveness and has an AI readiness Index score of 75.65. This is backed by its high spending in R&D combined with the availability of digital infrastructure to support AI implementation, such as the availability of 5G infrastructure and open data, as well as a generally positive attitude toward the adoption of emerging technology.[301]
- South Korea has deployed AI in medical imaging and is utilizing AI to create treatment plans for patients using predictive models. A joint project at the Healthcare Innovation Park with the Korea Institute of Science and Technology Information (KISTI) and the European Council for Nuclear Research (CERN) is using remotely located supercomputers to analyze data and secure the transfer of medical big data.[302] An AI Internet of Things project utilizing screen-based AI speaker technology is being used to assist mobility-challenged senior citizens in accessing healthcare services.

Assessment of Responsible Health AI Initiatives: Key Findings

- **The 1st Comprehensive Plan for Development and Support for the Medical Devices Industry (2023~2027)** aims to facilitate market entry for innovative technologies like AI and digital solutions in the medical devices sector.[303] The government has collaborated with experts from the UK and Singapore to release a global guide for the use of artificial intelligence in medical care.[304] This guide serves as a benchmark for the responsible use of AI and adopts a risk-based approach to enhance clarity and standards for technological applications in healthcare.
- South Korea signed into law the **AI Basic Act** on January 21, 2025, which is set to take effect on January 22, 2026. The **AI Basic Act** establishes a national AI governance system, supports industry growth through R&D and data infrastructure, and sets safeguards for high-risk and generative AI to mitigate societal risks. The bill places new requirements on some categories of AI systems. High-impact AI – such as those used in essential services, health care, employment, and hiring – needs advanced user notification, and deployers need to have risk management plans and ensure human oversight is included in its use. Large-scale AI needs to have a risk management system in place.[305] South Korea's **Digital Medical Products Act (DMPA)**, passed on January 23, 2024, regulates digital health technologies, ensuring the safety, efficacy, and oversight of digital medical products. Most provisions take effect in 2025.[306] The primary organization overseeing AI safety in healthcare is the **Ministry of Food and Drug Safety (MFDS)**. The MFDS regulates AI-based medical devices, ensuring their safety and efficacy through a comprehensive review process that includes clinical validation and documentation requirements. Currently, no other forms of validation beyond clinical validation are required for AI-based medical devices.[307] Impact assessments have been introduced, but they are limited to society and the public sector and are voluntary.[308]
- The **Personal Information Protection Act (PIPA)**, South Korea's primary data privacy law, was updated with AI-specific provisions allowing pseudonymized data use for research and public records without consent under strict safeguards. The **Personal Information Protection Commission (PIPC)** issued the Policy Direction for Safe Use of Personal Information in the Age of Artificial Intelligence to ensure AI accountability.[309]
- On January 24, 2025, South Korea's **Ministry of Food and Drug Safety (MFDS)** released the world's first guideline for reviewing generative AI-based medical devices. It sets standards for safety, efficacy, and risk management, requiring compliance with technical and global standards like ISO 13485 and ISO/IEC 27001.[310] When it comes to ethical standards in healthcare AI, the Korean National Institutes of Health (KNIH) published the "Research Ethics Guidelines for AI Researchers in Healthcare" in Aug 2023.[311] National efforts related to AI safety education and safety have been made with the aim of setting up an **AI safety institute** that may potentially cover healthcare.[312]
- South Korea is taking steps toward AI education and safety by aiming to adopt AI education in its national curriculum by 2025,[313] publicizing guidelines on the safe use of publicly available personal information by generative AI model developers and deployers.[314] South Korea's **Five-Year AI Healthcare Roadmap** (2025) focuses on increasing R&D investment, addressing labor shortages, and reducing the tech gap with leading countries like the US.[315]

"The current regulations, policies, guidelines, and guidance issued in South Korea are considered sufficient for the safe and ethical development of Health AI solutions. However, this is a controversial topic. At the industry level, these regulations are deemed adequate for ensuring safety and effectiveness. Nonetheless, patient groups have expressed concerns about their use."— Professor Jack Wong, CEO and Founder of Asia Regulatory Professionals Association; CEO, RNAscence

Mapping South Korea's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Taiwan

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[360]	NA*
AI Readiness Index Rank (2023)[361]	70.25
E-government Development Index[362] (2022)	NA
E-participation Index (2022)[363]	NA*
UN ICT Development Index[364]	NA*
Digital Competitiveness Ranking[365]	9th
Global Cybersecurity Index[366]	NA*

Overview of Health AI Use

- Taiwan has achieved 99.9% financial coverage and has good coverage and access to essential services.[367]
- Taiwan's digital competitiveness ranks 9th globally out of 193 countries, with strengths in technology and business agility and use of big data and analytics in Future Readiness.[368]
- Taiwan's AI Readiness Index, particularly in the technology pillar, ranks competitively both regionally and globally.
- Currently, Taiwan's hospitals mainly utilize AI to support clinicians in imaging analysis and diagnosis. Taiwan has 105 SaMD and machine-learning AI applications for healthcare use up till Jan 2024.
- Taiwan has been traditionally strong in producing hardware for the ICT sector, and it is investing more in supporting AI initiatives and AI R&D,[369] including using Health AI.

*Taiwan lacks several Index scores due to its exclusion from the World Health Organization (WHO) and related global health assessments and non-participation in certain international organizations, leading to a lack of officially reported data in these areas stemming from its unique political status.

Assessment of Responsible Health AI Initiatives: Key Findings

- Taiwan has made significant strides in establishing AI policies at the national level. The country has issued national/sector-agnostic policies that guide AI development across various sectors. Additionally, **AI is integrated into health policies and strategic plans,** marking ongoing efforts to incorporate AI into healthcare frameworks. However, the focus is broader and not exclusively on healthcare AI.[370] On October 5th, the Ministry of Health and Welfare (MOHW) announced the establishment of three new AI centers for healthcare: the "Responsible AI Execution Center," the "Clinical AI Certification and Verification Center," and the "AI Impact Research Center." These centers aim to address the key challenges of AI application in clinical settings – implementation, certification, and reimbursement – through cross-hospital collaboration across multiple levels and systems.
- Taiwan lacks Health AI-specific legislation; however, Taiwan has issued **AI/ML-based SaMD guidelines, which provide certification according to risk classification and give licensing of Quality System Documentation (QSD)**. It further outlines guidelines for Clinical Performance Verification and that its data is applicable for its intended use, requires provision of clinical data, and specifies quality requirements for the data used for training.[371]
- Currently, Taiwan is developing **"Taiwan Artificial Intelligence Action Plan 2.0 (2023-2026),"** which aims to develop AI technology across various sectors, enhance AI talent cultivation, and establish international AI innovation hubs. Its draft AI Basic Act (2023) aims to legalize AI ethical principles and mandates the development of an AI risk classification framework aligned with international standards.[372,373,374]
- Taiwan's National Science and Technology Council (NSTC) is seeking **public consultation for the draft Basic Act for Developments of Artificial Intelligence**, which will establish core principles for regulating AI development and application, including transparency, privacy, autonomy, fairness, cybersecurity, sustainable development, and accountability.[375]
- **Taiwan adopts a "guidance-before-legislation" strategy to navigate the evolving AI legal landscape.** This approach emphasizes issuing non-binding guidelines first, enabling agencies to adapt before formal laws are established.[376] Taiwan is actively working on developing a legal framework to include AI-specific provisions in data privacy and cybersecurity laws, particularly through the Basic Law on Artificial Intelligence.[377]
- Taiwan shows progress in developing AI ethics and regulatory awareness programs at the national level but lacks specialized programs for Health AI. There are no national-level technical education or upskilling programs specifically targeting AI safety in healthcare, indicating a gap in the educational infrastructure needed to support AI adoption in this sector. According to experts, **post-market retraining and revalidation need to be enforced as AI develops.[378]**
- **Taiwan has robust sandboxing for AI solutions. However, the country lacks comprehensive compliance requirements for Health AI, ethical impact assessments, and post-market retraining measures.**

"...when we develop the product, we need to look at the longer timeline and see if the product is truly useful and worthwhile. How much healthcare costs can it save? How much time can it save? For Taiwan's MOHW, they've been actively considering the evaluation of the economic aspect of healthcare products." — Anonymous expert, Taiwan

"Taiwan doesn't have regulations on whether the AI model should be allowed to be commercially exchanged. This concerns data ownership. If the AI model is trained on your data and sold commercially, should you be notified? Patients don't know that their data is being used to train AI models that are for business use."— Health AI expert, National Health Data Network, Taiwan

Mapping Taiwan's Responsible Health AI Initiatives[379]

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[380]	Y
	AI in health policies or strategic plans issued[381,382]	IP
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	N
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	N
Legislation	Established cybersecurity legislation[383]	Y
	Established data protection and data privacy legislation[384]	Y
	Has an AI act[385]	IP
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[386]	IP
	Availability of AI-specific provisions in cybersecurity legislation and regulations[387]	IP
	Provides framework for classifying high-risk AI to inform liability	IP
	Established healthcare data protection and privacy legislation[388]	Y
	Established SaMD regulations or regulatory guidance[389]	Y
Guidance	AI in health ethics guidance issued[390]	Y
	Introduced AI SaMD regulatory guidance or guidelines[391]	Y
	Generative AI in healthcare guidelines issued	IP
	Generative AI guidance issued on adoption at a national level[392]	N
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[393]	Y
	Issued technical guidance on AI adoption[394]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[395]	Y
	National AI safety institute appointed or funding research into AI safety	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[396]	Y
	Has awareness programs for AI in health for the healthcare workforce	N
	Developed programs for technical education or upskilling for AI in health programs	N
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards[397]	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[398]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	IP
	Requires or encourage organizations to carry out ethics impact assessments	N
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Malaysia

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[399]	76
AI Readiness Index Rank (2023)[400]	68.71
E-government Development Index[401] (2022)	0.7740
E-participation Index (2022)[402]	0.6818
UN ICT Development Index[403]	95
Digital Competitiveness Ranking[404]	33rd
Global Cybersecurity Index[405]	98.1

Overview of Health AI Use

- Malaysia has achieved effective UHC through tax-funded public provision of healthcare.
- Malaysia is above the region's average for E-governance for online services, human capital, and telecommunication infrastructure. E-participation is slightly higher than the region's average, but more can be done by the government when it comes to promoting citizens' e-participation in the policy-making process.
- Malaysia has well-developed ICT structures and connectivity combined with a high global security index, putting it in a favorable position to adopt AI technology. Malaysia's AI readiness Index Rank puts it at 23rd out of 64 other countries due to limited broadband quality, data governance, and lack of open data.[406]
- AI has been used to identify potential hotspots for COVID-19 infections and[407] AI-assisted quantitative medical image analysis is also being installed in local hospitals to aid healthcare deployers in screening computed tomography images to help speed up diagnosis.[408]

Assessment of Responsible Health AI Initiatives: Key Findings

- The National AI Office (NAIO) serves as the central authority to champion Malaysia's AI agenda and coordinates the continuity of strategies and implementation of AI through the AI Technology Action Plan 2026–2030, which aims to increase the innovation and competitiveness of Malaysia's AI ecosystem.[409]
- Malaysia is planning to enact a comprehensive AI Bill.[410] For now, existing legislation, including the law of torts, **Consumer Protection Act 1999 ("CPA") ,**[411] **Personal Data Protection Act 2010 ("PDPA"),**[412] **Sale of Goods Act 1957 ("SGA"),**[413] **and Contracts Act 1950 ("CA")**[414] are applicable. Similarly, **the Standards of Malaysia Act 1996** is used to establish standards and regulations for various industries to ensure quality and compliance.[415] The **Cybersecurity Bill** impacts AI systems that handle or process sensitive data, especially those used in critical infrastructure, and outlines how cybersecurity threats and incidents to the Critical National Information Infrastructure should be managed.[416]
- The **Ministry of Science, Technology and Innovation (MOSTI)** developed the National Guidelines on AI Governance & Ethics (AIGE) outlining seven key principles to ensure ethical AI deployment across various sectors, including healthcare. The guidelines support a risk-based approach to AI governance, aligning with emerging global consensus and emphasizing the establishment of AI risk management systems as part of its strategic objectives. This involves identifying high-risk applications, particularly in sensitive sectors like healthcare, and applying stricter oversight and testing measures to ensure safety and reliability. It expects to launch an AI Safety Institute soon.[417,418] Malaysia's Ministry of Health launched a single-door mechanism, managed by MAHTAS, and a HealthTech Hub to streamline health technology innovation, assessment, and adoption while ensuring safety, effectiveness, and accessibility.[419]
- MOSTI also aims to create **a specialized Policy and Regulation Committee** for the responsible development of AI in Malaysia, including the implementation of Risk Management Systems by 2024. **This will form part of the AI Coordination and Implementation Unit, which will be the central hub for all things related to AI.**
- **The Malaysian Medical Device Authority (MDA) has released guidelines on the registration of AI medical devices, but there is no specific guideline for cloud-based AI technology.** Under the Current Act, clinical evidence is required during conformity assessment before the technology can be approved for use.[420]
- NAIO is tasked with bridging gaps in AI education and workforce training. It collaborates with educational institutions to integrate AI-related modules into curricula, focusing on ethics, safety, and data protection.[421,422]

"Malaysia's approach to introducing AI in healthcare, I think it has been very cautious, but progressive. And when you look into the Malaysia context, AI has been integrated into the broader digital health transformation efforts." — National Digital Health Policy Advisor, Malaysia

"Important for us to maintain flexibility in regulations to accommodate rapid technological advancements. I think the critical elements for us to focus on is data government, governance and privacy, algorithm transparency and explainability." — National Digital Health Policy Advisor, Malaysia

Mapping Malaysia's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Thailand

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[450]	82
AI Readiness Index Rank (2023)[451]	63.03
E-government Development Index[452] (2022)	0.766
E-participation Index (2022)[453]	0.784
UN ICT Development Index[454]	91.0
Digital Competitiveness Ranking[455]	35
Global Cybersecurity Index[456]	86.5

Overview of Health AI Use

- Thailand has high universal health coverage overall with very high service capacity and access rates, good coverage for infectious diseases, and maternal and child health with more moderate coverage for non-communicable diseases.[457]
- Thailand has well-developed E-governance structures, with well-balanced human capital, telecommunication, and online service provision, although fixed broadband is lagging. E-participation rates are higher than the global and regional averages.[458]
- Thailand's AI readiness score is comparable to other countries in the region, such as Malaysia and Indonesia, with strengths in governance and infrastructure but lagging in AI innovation capacity and maturity.[459]
- Thailand's adoption and use of AI is still in its initial stages in Thailand, with multiple initiatives that indicate great potential to harness Health AI(1).[460]
- AI is currently being used to assess the risk of stroke caused by heart disease[461] (1) and transfer real-time data from ambulances ("smart ambulance") to doctors in the hospital.[462] (2) (1,3)

Assessment of Responsible Health AI Initiatives: Key Findings

- The healthcare and medical sector is one of the key target sectors as part of phase 1 (2022-2023) of the **National AI Strategy and Action Plan (2022–2027).**[463]
- Thailand is developing a comprehensive regulatory framework for AI. The **Draft Royal Decree on Business Operations** aims to implement control and prevention measures based on the level of risk assessment of AI systems.[464] (4) The **Draft Act on the Promotion and Support of AI Innovations** will provide mechanisms and legal instruments to support the development of AI in Thailand and include provisions to protect consumers[465] (4). In 2022, the Digital Economy and Society (DES) Ministry spearheaded the approval of a new set of mandatory standards governing AI development and use. These standards categorize AI into three tiers: low, medium, and high-risk. Organizations creating or deploying high-risk AI systems will undergo substantial auditing and review processes, including algorithmic bias testing, evaluations of data quality and security protections, assessments of transparency and explainability, and more. The goal is to minimize the dangers of inaccurate, discriminatory, or otherwise faulty AI.[466] DES of Thailand, in collaboration with the Electronic Transactions Development Agency (ETDA), has launched the "Guidelines for the Application of Generative AI with Good Governance for Organizations." This new framework, developed through the AI Governance Center (AIGC), aims to provide comprehensive guidance for Thai businesses and government entities using generative artificial intelligence (AI). It emphasizes principles of good governance to ensure AI is deployed safely, responsibly, and effectively across sectors.[467]
- Thailand is mobilizing existing medical product regulations to govern AI products, particularly in the context of Software as a Medical Device (SaMD), based on a four-class risk classification system. All medical device software AI processes are required to include the review of a human clinician or technician. Also required are expert reviews by a third-party expert (excluding technology from Singapore), change notifications, documentation, and labelling.[468] Thailand's data privacy legislation, particularly the **Personal Data Protection Act (PDPA),**[469] includes consent, minimization, purpose limitation, Data Protection Officers in some contexts, and incident response plans to address management, quality, and ethical aspects of data collection and use.[470] Thailand's cybersecurity framework, particularly the **Cybersecurity Act (2019)** and **National Cyber Security Committee (NCSC) notifications** establishes security requirements for critical healthcare infrastructure and data. This includes risk assessment, minimum standards, and regulatory oversight to protect sensitive health data and AI systems from cyber threats.[471]
- Thailand's Civil and Commercial Code governs general liability principles, including tort liability. However, there are currently no specific laws addressing AI product liability. Product liability laws could be applied to AI products in principle, but AI's unique challenges may complicate the assessment of liability.
- Thailand has issued **AI ethics guidelines**[472] that include considerations relevant to the healthcare sector, regulatory guidance for SaMDs by the Thai FDA,[473] and practical and technical guidance at a national level but has not provided Generative AI guidance at national or healthcare levels thus far.
- Thailand has no standalone Safety Institute or awareness programs. National awareness and technical upskilling programs are in development.[474]
- Thailand is establishing an AI sandbox under the requirements of the AI Promotion Law, allowing for the waiver of certain laws and regulations for AI testing when deemed necessary by the ETDA.[475] AI use in healthcare requires adherence to stringent pre-clinical and clinical trial standards.[476] The Thai FDA mandates compliance with international standards such as **ISO 13485,** which is specific to quality management systems for medical devices.[477] Thailand does not require impact assessments to be carried out.

"The high cost of regulatory compliance is a significant challenge for Thailand, a middle-income country, and regulators face financial constraints in implementing stringent AI regulations."— Dr. Supharerk Thawillarp

"AI technologies from English-speaking countries face challenges in non-English speaking countries like Thailand. Voice recognition and text-based AI require significant adjustments to handle local language and accents effectively."
— Dr. Supharerk Thawillarp

Mapping Thailand's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

India

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[509]	63
AI Readiness Index Rank (2023)[510]	62.58
E-government Development Index[511] (2022)	0.5883
E-participation Index (2022)[512]	0.5909
UN ICT Development Index[513]	NA
Digital Competitiveness Ranking[514]	49th
Global Cybersecurity Index[515]	97.5

Overview of Health AI Use

- At present, in India, AI is being used for medical diagnostics in radiology and mainly for delivering primary health care services.[516]
- AI adoption is not yet integrated into the healthcare system. Most pilots are in the early demo phase, with examples such as X-rays for tuberculosis screening, cough sound analysis for respiratory illnesses like TB and COPD, and disease prediction.[517]
- India was not evaluated as a part of UN ITU's 2024 report on the development of the Information and Communication Technology sector.[518] In 2017, India ranked 121 out of 157 countries in ICT Development Rankings.[519]
- India ranks 49th globally in digital competitiveness, lacking in terms of trade-offs between economic growth and sustainability, Foreign Direct Investment, and developing skilled workforce, etc.[520]
- India ranks 10th globally and 1st among LMICs in global cybersecurity, with areas of strength in Legal, Cooperative, and Capacity Development Measures.[521]

Assessment of Responsible Health AI Initiatives: Key Findings

- India has a **National Strategy for AI,**[522] focusing on promoting innovation while identifying, governing, and mitigating risks, but no specific health sector policy is in place. Multiple Indian states have also announced their own AI strategies, with some indicating a healthcare focus. The country also announced a US $1.2 billion investment into IndiaAI mission, an initiative to accelerate India's AI innovation, governance, and ecosystem development. Several tools for building and evaluating the ethical use of AI are being developed under the 'Safe and Trusted AI Pillar.'[523,524] The government also launched an AI Centre of Excellence for healthcare that will be led by IIT Delhi and the All India Institute of Medical Sciences (AIIMS).[525]
- The Indian Ministry of Electronics and IT (MeitY) released a report on AI Governance Guidelines Development, proposing an India-specific regulatory framework for AI. The report emphasizes a whole-of-government approach, advocating for inter-ministerial coordination, an AI governance committee, and a Technical Secretariat to track AI harms. It explores multiple regulatory strategies, including principle-based, techno-legal, and activity-based approaches, but retains a focus on voluntary commitments. MeitY also conducted a multi-stakeholder consultation in conjunction with UNESCO, employing the latter's AI Readiness Assessment Methodology toward creating an India-specific AI policy and governance strategy.[526]
- In January 2025, the Indian government released the draft Digital Personal Data Protection (DPDP) Rules for public comment. The **Proposed Digital India Act 2023**[527] will enhance data security legal frameworks enforced under the **National Cybersecurity Reference Framework.**[528]
- India's national think tank, NITI Aayog, and Ministry of Electronics and Information Technology (MeitY) have practical ethical and regulatory guidelines for Responsible AI, including **Principles for Responsible AI,**[529] **Operationalizing Principles for Responsible AI,**[530] and a series of **Artificial Intelligence Reports and Guidance.**[531] India is drafting technical standards for AI adoption with some emerging developments by an AI committee under The Bureau of Indian Standards (BIS).[532]
- The India Medical Research Council (IMRC) has existing **Ethical Guidelines for the Application of Artificial Intelligenc**e in healthcare that provide ethical principles and recommendations for data privacy.[533] India has not yet issued **technical guidance for GenAI or guidelines specific to its use in healthcare and AI-SaMDs.**
- While India does not yet have a national institute for AI safety, IndiaAI is working with various technology and institutional partners to support AI development, research, and education,[534] and **project AIRAWAT** is launching an initiative to promote collaboration among researchers, businesses, academicians, and AI professionals to enable secure data storage and processing.[535] India's AI development agency, ArtPark, is implementing **MIDAS (Medical Imaging and Information Datasets for India)** to develop a national standardized database for AI for dataset validation and training, starting with data in AI-based medical imaging.
- Safety ethics, regulatory awareness, and technical education programs are under development. IndiaAI, a national AI ecosystem initiative, provides indigenous upskilling and awareness education and enables industry collaboration.[536] India does not yet have national healthcare AI safety ethics and regulatory awareness programs, but it is developing **Healthcare AI technical education** with Leadingindia.ai,[537] which aims to equip faculty members and students with industry-driven AI and deep-learning tools that can be applied to various fields, including healthcare.
- India does not require ethics impact assessments to be conducted for the use of healthcare AI.

"The space of AI solutions requires more deliberation and thoughtful mechanisms which are actively being developed in India. For example, MIDAS (Medical Imaging and Information Datasets for India) is an effort involving ICMR to define standards for creating datasets for AI research and validation."— CEO, AI & Robotics Innovation Hub, India

"India should bring in more AI and AI-SaMD specific regulations and be more stringent on AI products for the market. It would be highly appreciated if India has similar regulations where it is a little more stringent for AI manufacturers or SAMD manufacturers to make sure that India receives only quality products available in the market."— Doctor at Qure.ai India, a global Healthcare AI developer

Mapping India's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Indonesia

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[555]	55.0
AI Readiness Index Rank (2023)[556]	61.03
E-government Development Index[557] (2022)	0.7160
E-participation Index (2022)[558]	0.7159
UN ICT Development Index[559]	82.8
Digital Competitiveness Ranking[560]	37/193
Global Cybersecurity Index[561]	94.9

Overview of Health AI Use

- Indonesia's progress to achieving adequate service coverage for essential medical services is slow, although it has improved service affordability through the introduction of national health insurance.
- Indonesia has a reasonably well-developed E-governance structure, high E-participation, and a high rate of universal internet coverage that is affordable and accessible.
- The country scores reasonably in comparison with other countries in the region for digital competitiveness in terms of technology but is still progressing in terms of knowledge and future readiness.
- Indonesia ranks high in global cybersecurity on legal, technical, and organizational measures, capacity development, and cooperation.
- Among LMICs in the region, Indonesia is the most AI-ready and is marginally behind Malaysia and Thailand.[562]
- The Indonesian government plans to have AI play a crucial role in healthcare by processing big data from individual medical records and sharing it with healthcare deployers to determine the most appropriate medical treatment for each individual.[563]

Assessment of Responsible Health AI Initiatives: Key Findings

- Indonesia has included AI in health into its national strategic plan, the **National Strategy for Artificial Intelligence (Stranas KA) 2020-2045**, as well as the **Ministry of Health's Strategic Plan 2020-2024,**[564] **and is looking at drafting new AI regulations**, which may be codified in a Presidential Regulation.[565] Indonesia is one of the first countries to adopt and complete UNESCO's diagnostic tool on Readiness Assessment Methodology for AI.[566]
- Although it currently lacks a regulatory framework, the Ministry of Communication and Information (Kominfo) is currently preparing regulations regarding the **Governance of Artificial Intelligence (AI) Technology horizontally via the Information and Electronic Transactions Law, Personal Data Protection Law, and the Circular Letter of the Minister of Kominfo concerning AI Ethics** as well as sector-specific laws.[567]
- Indonesia does not have AI-specific regulations for AI in medical devices at present.
- Data privacy in Indonesia does not include considerations of data used in Health AI systems[568] at present, an upcoming law in October 2024 might mandate a Personal Data Officer for every hospital to ensure no misuse of health data.[569]
- Indonesia has existing cybersecurity measures in place via its National Action Plan for Health Security.[570]
- **While there are no specific liability laws for AI, AI is regulated as an Electronic Agent under Law No. 11 of 2008 EIT** (Electronic Information and Transactions) Law under which, and along with the implementing law GR 71/2019, the operator is held liable except in the case of negligence where liability lies with the user.[571]
- Indonesia currently does not have a framework for classifying high-risk AI to inform liability.
- There are no specific guidelines for AI in healthcare or generative AI. **The Kominfo Circular Letter Number 9 of 2023 addresses the Ethics of Artificial Intelligence** and general guidelines on the values, ethics, and control of AI use.[572] The MOH is preparing guidelines on what kind of data will be used by whom and who will be responsible.[573]
- Indonesia does not have a dedicated national safety institute or equivalent at present.
- Kominfo has initiated various awareness programs on AI safety, ethics, and regulations.[574] The **"Indonesia AI Healthcare Course"** featured on-site training courses and specialized lectures in the field of AI healthcare and tuberculosis diagnosis.[575]
- Currently, no regulatory sandboxes or ethics impact assessments are required. Indonesia has collaborated with Australia's Harrison.ai and Google Cloud to conduct clinical trials on the safe implementation of AI and test responsible AI innovation in healthcare, respectively.[576,577]

"Involve industry as much as possible and as early as possible during the development of regulation"— Digital Transformation Officer, Ministry of Health on critical policy enablers for AI in healthcare regulations in LMICs

"We might also focus on specific diseases, i.e. cardiovascular, that have a high burden on our health financing. We might push based on the specific outcome of the disease. We are looking at the population health outcomes."— Digital Transformation Officer, Ministry of Health on considerations for a risk-based approach for AI deployment in healthcare

Mapping Indonesia's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Philippines

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[590]	58
AI Readiness Index Rank (2023)[591]	51.98
E-government Development Index[592] (2022)	0.652
E-participation Index (2022)[593]	0.489
UN ICT Development Index[594]	74.4
Digital Competitiveness Ranking[595]	59th
Global Cybersecurity Index[596]	77

Overview of Health AI Use

- The Philippines has moderate universal health coverage, faring better in service coverage for non-communicable diseases and maternal, reproductive, and child health than infectious diseases.[598]
- The Philippines fares moderately but has a low E-participation rate and is lower than the regional average. It has good ICT infrastructure and fares well in terms of cybersecurity but is lagging behind regional leaders in digital competitiveness.
- The Philippines has a lower AI readiness score compared to advanced economies but is ahead of less developed countries in the region.[599]
- A prominent hospital chain in the Philippines, The Medical City, has partnered with Lunit, a company specializing in Health AI solutions, to integrate AI into its mammography and chest X-ray services.[600] The Philippines' National Health Institute has also initiated several projects that leverage Health AI, such as early liver cancer detection and screening for COVID-19.[601]

Assessment of Responsible Health AI Initiatives: Key Findings

- Philippines' National Artificial Intelligence Strategy Roadmap 2.0 (NAISR 2.0)[602] aims to position the Philippines as a leader in AI research and development while harnessing the potential to improve the economy and the quality of life for its citizens through fostering an ethical AI ecosystem.[603] The government has launched the **Center for AI Research** to drive the digital transformation of industries and ensure the responsible use of AI.[604]
- The Philippines currently has no legislation that directly addresses or regulates AI.[605] The NAISR 2.0 seeks to address critical challenges hindering AI adoption in the country, including limited use cases of AI, limited human and physical resources within industries, the difficulties faced by enterprises in developing data strategies, and the uncertainties surrounding AI regulation and legal frameworks.[606] The proposed Artificial Intelligence Act (HB 10944) includes provisions for risk assessment and compliance monitoring of AI systems. The Philippines is working on a regulatory framework for AI, which is expected to include risk assessment guidelines. This framework may be proposed to ASEAN in 2026 when the Philippines chairs the organization.[607]
- Health policies for AI are still under consideration. The existing regulatory framework for SaMD, which will apply to AI in SaMD products provided by Circular No. 2021-001-A, provides a four-tier risk classification and requires pre-assessment of risk category and conformity assessments for licensing.[608] Philippines' Data Privacy Act of 2012 (Republic Act No. 10173) includes provisions that address management, quality, privacy, and ethical considerations of data used in Health AI systems in terms of scope, data processing principles, rights of data subjects, security measures, and ethical considerations.[609,610] Data Privacy Act of 2012 and the Cybercrime Prevention Act of 2012 have provisions that require healthcare organizations to obtain consent, implement security measures, and report breaches. The Philippine National Privacy Commission (NPC) has released an official advisory outlining the application of the Data Privacy Act of 2012 (DPA) to artificial intelligence (AI) systems that process personal data.[611] The National Privacy Commission Advisory No. 2024-04 in December 2024 recommended that personal information controllers (PICs) conduct **Privacy Impact Assessments (PIAs)** for AI systems processing personal data. The Philippines is developing a regulatory sandbox on privacy-enhancing technologies.[612]
- The Philippines has a general framework for **product liability** under **the Civil Code and the Consumer Act,** which can apply to AI products.[613] While there are no specific AI liability regulations yet, the Consumer Act, **E-Commerce Act,** and **Internet Transactions Act** collectively provide a framework for holding companies accountable for defective products, unfair practices, and data privacy violations related to AI systems after they are deployed,[614] but there is no risk framework that informs liability tailored to AI.
- There is no guidance for ethical AI use in health, SaMD regulatory guidance for AI or Generative AI guidance at present. However, practical guidance at the national level for regulations and AI adoption is in development.[615] The NPC conducts various awareness programs and initiatives on AI ethics and data privacy.
- In early 2025, the Philippines government allocated PHP70 million ($1.2 million) to support TESDA's digital transformation, funding three key projects: an AI-powered **Technical and Vocational Education and Training (TVET)** Course Builder to standardize training materials, an IoT Training System to equip students with industry-ready skills, and an AI-driven Labor Market Information System to provide workforce insights. There are no health-specific AI training or upskilling programs.[616]

"It is important to consider the local context in AI deployment, including accessibility, affordability, relevance, and capacity building particularly for developing countries. These should be considered upfront and not as afterthoughts."— Former Director, National Telehealth Centre

"Lower middle-income countries need to focus on building robust health systems and data ecosystems first before adopting AI. An incremental approach of gradually introducing AI into healthcare once foundational issues are resolved should be taken." — Assistant Professor from the Department of Computer Science, University of the Philippines Diliman

Mapping the Philippines' Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Vietnam

Health AI Readiness at a Glance

Universal Health Coverage Index (2021)[642]	68.0
AI Readiness Index Rank (2023)[643]	54.48
E-government Development Index[644] (2022)	0.6787
E-participation Index (2022)[645]	0.5341
UN ICT Development Index[646]	85.0
Digital Competitiveness Ranking[647]	NA
Global Cybersecurity Index[648]	94.6

Overview of Health AI Use

- Vietnam is still progressing slowly toward achieving strong health service coverage, including service capacity and access to infectious and non-communicable diseases, while having made significant improvements in maternal and child health needs.[649]
- Although Vietnam is in the nascent stages of AI adoption in healthcare, there are ongoing pilots to detect breast cancer and other diseases like COPD and Tuberculosis.[650]
- Experts see that diagnostics will be the major area for AI adoption, along with post-diagnosis patient management in terms of drug monitoring and follow-up scheduling.[651]
- Vietnam's E-governance and E-participation are relatively good, ranking higher than the world and regional averages.[652]
- Vietnam has better ICT development than the regional average and of those in other similar economies overall and in terms of universal connectivity and affordability.
- Vietnam ranks high in global cybersecurity on legal, technical, and organizational measures, capacity development, and cooperation.[653]
- Vietnam is progressing toward AI readiness but lags in terms of adequate infrastructure, human capital, innovation capacity, adaptability, and market maturity.[654]

Assessment of Responsible Health AI Initiatives: Key Findings

- Vietnam has a national AI strategy655 and a master plan on AI development as well as studies on AI use in the healthcare sector launched by the Ministry of Science and Technology in 2017656 and is **currently drafting a new "Law on Digital Technology" where AI is specifically addressed** and prohibits specific AI practices.[657]
- Vietnam is actively developing a framework for risk assessment for AI as well as a comprehensive legal framework to specifically address AI. **The draft Digital Technology Law was published and is expected to be adopted in May 2025.** The draft law introduces important definitions of AI and distinguishes between different types of AI systems: High-risk, high-impact, and standard AI systems.[658] In February 2025, the Law on Data was enacted and will take effect on July 1, 2025, which establishes a comprehensive legal framework for data usage in Vietnam's digital landscape with stringent regulations on personal data processing and cross-border data transfers. **A Personal Data Protection Law is also being developed.**[659]
- Vietnam has regulations for medical devices that include software but does not at present mention AI specifically.[660] Vietnam regulates Software as a Medical Device (SaMD) under its broader medical device regulatory framework. The **regulation of SaMD in Vietnam is governed by Decree No. 98/2021/ND-CP,** which came into effect on January 1, 2022.[661]
- Cybersecurity laws and regulations mandate security measures for all information systems, including those used in healthcare.[662] There are no specific regulations addressing data quality, privacy, and ethics for Health AI at present. **Vietnam's 2007 Law on Product and Goods Quality and the 2015 Civil Code[663] could be applied to AI products,** but it does not specifically address issues of opacity, complexity, and semi-autonomous behavior, which are unique to AI.[664]
- Vietnam does not have a standalone AI safety institute but has several pilot projects and collaborative research projects ongoing to test and study the risks and benefits of AI applications in healthcare.[665] The Ministry of Science and Technology has organized workshops and seminars on AI ethics and safety and released guidance on ethical principles for responsible AI development. In Dec 2024, the Vietnam Software and IT Services Association (VINASA) announced the formation of the **AI Ethics Committee.**[666,667]
- AI upskilling programs are yet to be developed, and none exist specifically for healthcare at present.[668] Vietnam does not have healthcare-specific guidance or generative AI-specific guidance at present. Guidelines for the ethical development of AI have been issued.[669] Vietnam launched the **ASEAN Computer Incident Response Team (ACID) 2024** exercise, which focused on AI-driven cyber threats. The event gathered 450 Vietnamese technical staff and international teams from ASEAN and key partners to strengthen regional cybersecurity and incident response capabilities.[670]
- Vietnam is developing a regulatory sandbox for AI solutions, but it is not yet fully operational. There are no regulations for AI to adhere to international standards, although medical devices are expected to. Impact assessments are not mandatory in Vietnam for AI, although organizations are encouraged to adhere to ethical principles and consider potential impacts on patients and society.[671]

"The use of local data to train AI is very important. Our pilot results on a mammography image detection study shows a difference in the reliability of the AI detection technology when trained on local Vietnamese data compared to data collected from the Asian population living in Australia. Sensitivity is higher when locally trained." — Policy researcher, Vietnam

"There needs to be a motivating factor to increase AI adoption in public healthcare, and this depends on the financing mechanism as AI adoption is expensive, whereas there is greater incentive for the private sector as the fee is not limited by affordability." — Policy researcher, Vietnam

Mapping Vietnam's Responsible Health AI Initiatives

National Level | Health Sector Level | Yes | In progress | No

Mechanism	Area of focus	Status
AI Policy	National/Sector-agnostic policies issued[99]	Y
	AI in health policies or strategic plans issued[100]	Y
	National AI policy covers responsible use of AI	Y
	Health AI policy covers responsible use of AI	Y
	National AI policy adopts a risk-based categorization approach	Y
	Health AI policy adopts a risk-based categorization approach	Y
Legislation	Established cybersecurity legislation[101]	Y
	Established data protection and data privacy legislation[102]	Y
	Has an AI act	N
	Provides framework for assessment of risk	Y
	Availability of AI-specific provisions in data privacy laws[103]	N
	Availability of AI-specific provisions in cybersecurity legislation and regulations[104]	N
	Provides framework for classifying high-risk AI to inform liability[105]	Y
	Established healthcare data protection and privacy legislation[106]	Y
	Established SaMD regulations or regulatory guidance[107]	Y
Guidance	AI in health ethics guidance issued[108]	Y
	Introduced AI SaMD regulatory guidance or guidelines[109]	Y
	Generative AI in healthcare guidelines issued[110]	Y
	Generative AI guidance issued on adoption at a national level[111]	Y
	Practical guidance issued include practical ethics or regulatory guidance on AI adoption and implementation[112]	Y
	Issued technical guidance on AI adoption[113]	Y
Research	Has research programs on integrating and leveraging safe and ethical use in clinical trials, drug discovery, and development[114]	Y
	National AI safety institute appointed or funding research into AI safety[115]	Y
Education & Training	Developed AI ethics or safety or regulatory awareness programs[116]	Y
	Has national technical education or upskilling programs related to AI safety (including safety, data privacy, data protection)[117]	Y
	Has awareness programs for AI in health for the healthcare workforce[118]	Y
	Developed programs for technical education or upskilling for AI in health programs[119]	Y
Assurance	Establishment of national/state level or funding support for sandboxing/evaluation/validation/testing and/or compliance with international standards	Y
	Health AI solutions required to be compliant with technical standards, e.g. ISO standards[120]	Y
	Availability of national/state-level mechanisms for evaluation and testing of Health AI solutions	N
	Requires or encourage organizations to carry out ethics impact assessments	Y
	Appointed an organization or body for oversight of AI safety	Y
	Encourages the use of risk and impact assessments or algorithmic impact assessment	Y

Annex 3. Risk Mitigation Strategies for Institutional users ("users")

The following sections detail how **users** can mitigate each of the hazards introduced in Section 3. Based on the risk assessment, in most cases, not all of these mitigations will be required for each application. These are some measures that can be considered on a case-by-case basis to manage the risks assessed.

Health-IT Product-Level Hazards

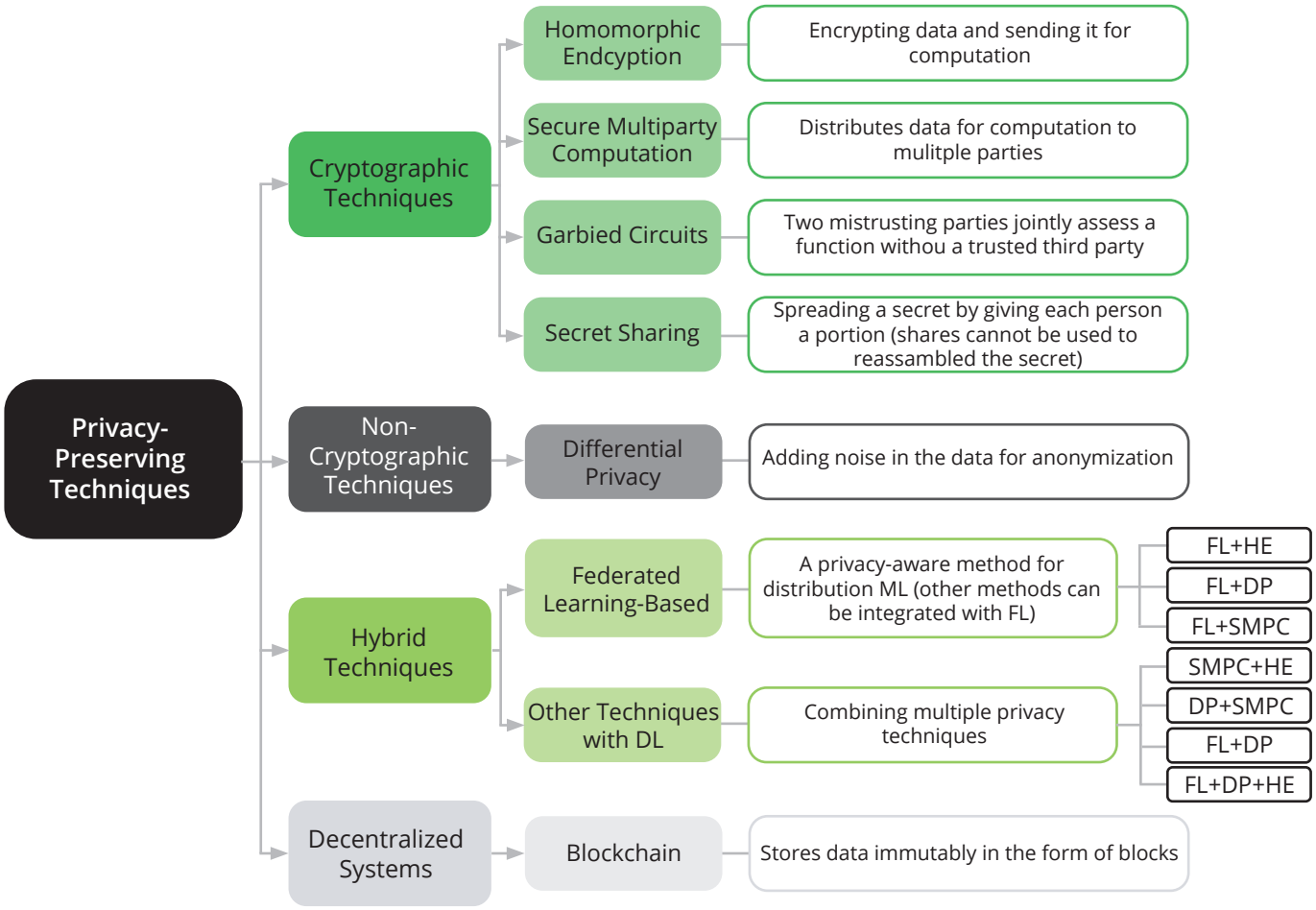
1. Data Privacy

Data privacy refers to unauthorized access, use, or disclosure of sensitive patient data handled by AI systems, compromising patient confidentiality.

1. **Conduct Impact Assessments and Comply with Regulations:**
   Users can conduct Privacy Impact Assessments (PIA)[688] and ensure that AI technologies comply with relevant regulations before deployment. PIAs identify privacy risks and how said risks have been mitigated. It is important to safeguard data if the processing of personal information is likely to result in a high risk to individual rights and freedom. PIAs can also evaluate whether existing data privacy protections are sufficient. Here is a *link* to a PIA guide by the Office of the Privacy Commission of New Zealand.

2. **Employ Privacy Preserving AI Techniques[689]:**
   Users can leverage AI models such as federated learning, differential privacy, and cryptographic techniques to preserve data privacy. Federated learning[690] involves decentralized data training by training AI models across various devices or servers that store local data, minimizing the risk of leaking sensitive information. Differential privacy[691] enhances data protection by adding small changes to individual data to minimize the risk of exposing individual data points while preserving group patterns. Cryptographic techniques[688] secure information through codes and by obscuring transmitted information, ensuring that only authorized parties can access or understand the data. Using a combination of all three methods can help to enhance data privacy in the use of healthcare AI. However, it should be noted that employing privacy-preserving techniques comes at a trade-off with accuracy and typically requires huge computing capacity. Users should consider the suitability and appropriateness of such measures before employing privacy-preserving technologies. The figure[692] below provides an overview of privacy-preserving techniques.

Figure 12: Overview of Privacy-preserving Techniques



3. **Implement Technical and Organizational Measures[691]:**
Users must adhere to the instructions for use and implement technical and organizational measures to protect data privacy. Such measures include controlling access to AI models through encryption and secure key management; consistently monitoring, evaluating, and debugging AI software to detect and address potential threats to data privacy that may arise; and maintaining a continuous, iterative risk management system throughout the AI system's lifecycle.[693]

2. Data Security

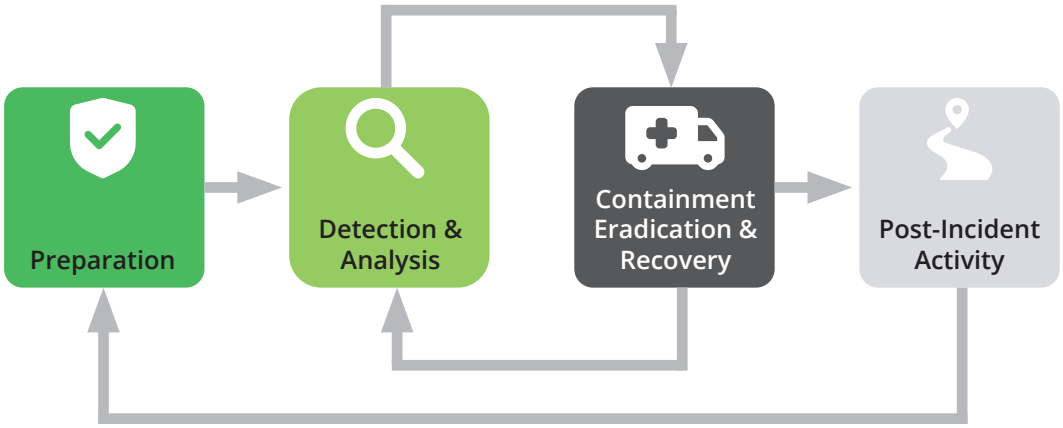
Data security refers to breaches or attacks on AI systems that jeopardize the integrity, availability, or confidentiality of healthcare data.

1. **Data Encryption and Access Controls[694]**
Strategies that can enhance data security include implementing strong end-to-end encryption (E2EE)[695] to protect data at every juncture – at rest, in transit, and in use to ensure that the data remains unreadable to unauthorized users. Additionally, establishing Role-Based Access Control (RBAC)[696] to limit data access to only authorized personnel minimizes the risk of data exposure. Implementing Multi-Factor Authentication (MFA)[697] creates an added layer of security by requiring multiple forms of verification before granting users access to data. MFA minimizes risks due to human error, helps companies protect organizational and user data, and facilitates early detection of cyberattacks, enhancing overall data security.

2. **Establish Robust Incident Response and Disaster Recovery Plans[698,699]**
To minimize the impact of potential data breaches, users should consider developing and regularly updating an incident response plan through comprehensive risk assessments. The incident response plan should detail

processes for identifying, managing, and mitigating data breaches. Clear roles and responsibilities should be defined to allow personnel to respond to incidents systematically. Disaster recovery solutions should be implemented and regularly tested to ensure that data can be restored promptly in the event of a breach. The incident response life cycle is illustrated in the figure below.

Figure 13: Overview of the Incident Response Lifecycle



3. **Education and Training on Security Protocols**[700,701]
   Providing regular training and refresher courses for users on data security best practices, including recognizing phishing attempts and secure data handling procedures, can significantly reduce the risk of data breaches, given that human error is a common cause of data security incidents.

4. **Data Minimization and Anonymization**
   Collecting excessive amounts of sensitive data increases the risk of data security breaches.[702] Limiting data collection to only what is necessary for the purpose of the AI system reduces the risk of exposure.[703] Additionally, using anonymization or pseudonymization techniques can maintain data security through increased protection of patient identities when there are concerns about lapses in security, and there is a lack of strong governance systems. Anonymization techniques[704] include removing direct identifiers such as names, addresses, and contact numbers and replacing specific values with broader categories, which is known as generalization. Pseudonymization techniques[705] include replacing direct identifiers with pseudonyms that have no relation to the original data. Anonymization is an irreversible process, while pseudonymization is reversible.

5. **Conduct Regular Risk Assessments and Audits**[701,706]
   Users should perform periodic risk (re)assessments[707] to identify vulnerabilities in AI systems and ensure that data handling processes are appropriate and effective. Conducting regular audit compliance in reference to global and/or national standards ensures that data security mechanisms are updated.

3. Software Change Management Risks

Software change management risks refer to the potential for disruptions or errors when updating or modifying AI systems in healthcare settings.

1. **Ensure Proper Documentation**[708,709]
   Users should document how AI models are used and integrated into the target environment. Information such as the deployment strategy, platform, infrastructure, configuration, testing, monitoring, and maintenance of models should be included. Any challenges, risks, or trade-offs involved in the deployment of the AI system should also be recorded. Deployment documentation can be achieved using tools such as deployment diagrams, deployment scripts, and deployment reports. Effective documentation practices can meet the needs of multiple stakeholders, including auditors and regulatory authorities, enhancing the transparency and accountability of AI models.

2. **Establish Robust Governance Frameworks**[710]
Implement robust governance mechanisms that define roles, responsibilities, and accountability for the deployment and modification of AI systems. Develop policies that ensure compliance with regulatory standards, such as the International Organization for Standardization and International Electrotechnical Commission 42001 (ISO/IEC 42001),[711] which provides guidance for the maintenance and continuous improvement of AI management systems. Strong governance provides a structured approach to mitigate risks, ensuring that algorithms are monitored, evaluated, and updated to minimize incorrect or harmful decisions.

3. **Implement Rigorous Testing and Validation Protocols**[712,713]
Users should conduct regular testing to ensure that AI models are validated in diverse scenarios and utilize real-world testing environments such as black box testing[714] to gradually deploy AI functionalities and minimize associated risks.

4. **Ensure Continuous Monitoring and Maintenance**
Users should establish ongoing monitoring systems to track the performance of AI models and to promptly detect model drift or decay.[715] Model drift or decay refers to the degradation of machine-learning model performance as a result of changes in data or in the relationship between input and output variables.[716] Model drift or decay can jeopardize model performance through faulty decision-making and poor predictions. The figure[717] below provides an overview of suggested components to monitor.

Figure 14: Components of Continuous Monitoring for AI Systems

A Monitoring Metrics

It defines three broad types of metrics: performance, stability and operations based on the use case

- **Performance metrics:** Detection of Performace drift
- **Stability metrics:** Prediction drift, data/feature drift, and concept drift
- **Operations metrics:** Input/Output (IO), Memory, and Central Processing Unit (CPU) usage for predictions, latency when calling Machine Learning Application Programming Interface (ML API) endpoints

B Monitoring Frequency

- Models with self-learning and higher business impact should be monitored more frequently than static models
- More broadly, model risk tiering including materially is critical in determining frequency

C Override Analysis

- Any override or overlay to the model should be documented and duly justified
- Substantial model overrides are signals that a model may require refinement

D Input Monitoring

- Data quality and validity checks
- Additional checks for unstructured data
- **Feature Drift Detection:** assess ranges, valid values, and distributions in both univariate and multivariate level; assess outlier volume/distribution in both univariate and multivariate level

E Output Monitoring

- **Prediction Drift Detection:** assess mean, median, min, max, and distributions for output, as well as stability of the predictions (distributions, volumes)

F Model Monitoring

- Performance Monitoring: diretly measuring perfromance when the target is available; estimating performance when the actual target is compromised.
- Model Stability: analyse stability of the model (concept drift detection, i.e. if the relationship between input and output changes)
  - *Feature Importance Comparison*
  - *Model Benchmarking*

G Trigger Review

- Quanitative Triggers - Test model accuracy and stability on the recent outcome and against a benchmark model (e.g., product sign up rate)
- Qualitative Triggers - Changes in business strategy / regulatory requirements (e.g. product characteristics, product offer conditions)
- Fallback Triggers - Switch to benchmark / legacy model if there is a severe deterioration in model performance (e.g., fallback marketing)
- Processing and capacity triggers - Capture increased model usage or an increase of the data consumption (e.g., increased IC/Memory/CPU demands)

H Action Plan

- Diagnostics and deep dive for additional insights
- Remediation plan for the model retrain/recalibration/review

4. Integration and Interoperability Risks

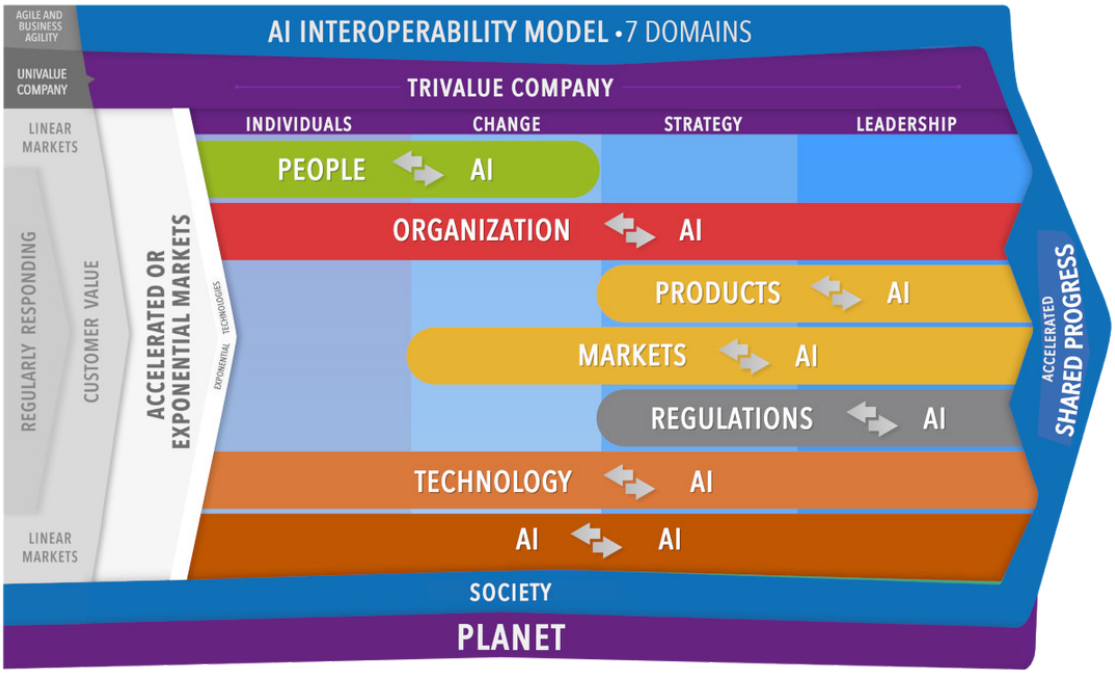
Software change management risks refer to the potential for disruptions or errors when updating or modifying AI systems in healthcare settings.

1. **Integration with Existing Systems and Workflows**[718]
   Users should involve cross-functional teams such as clinicians, IT professionals, and AI experts to ensure an adequate understanding of system processes and AI technologies. A phased implementation approach,719 beginning with pilot projects before gradually scaling up, is a good approach to consider when deploying new AI technology. Users should also assess existing systems and workflows, identify integration points, and establish and follow comprehensive implementation strategies.

2. **Prioritize Data Quality and Standardization**[720]
   Establish robust data governance frameworks to include standardized data collection protocols, advanced data cleaning techniques, and strict access controls and encryption measures. Such measures can significantly enhance interoperability by minimizing data loss or misinterpretation, allowing for reliable insights.

3. **Adopt Interoperability Standards and Frameworks**[721,722]
   Users should adhere to interoperability standards, such as the Health Level Seven International (HL7) and the Fast Healthcare Interoperability Resources (FHIR), to ensure seamless data exchange between AI applications and existing healthcare IT infrastructure. The HL7 is an international standard for exchanging healthcare data, while the FHIR is an open standard that facilitates the exchange of data between new applications.

4. **Facilitate Deployment Using the AI Interoperability Model**[723]
   The AI Interoperability Model is an Enterprise Agility framework that supports the implementation of AI technologies in companies. It provides a structured approach to ensure that AI systems can work seamlessly with each other and with human users. The seven domains of the model ensure that AI is implemented in a responsible and ethical way and that users better understand how systems work together. The figure below provides an overview of the model.



5. **Ensure Consistent Monitoring and Maintenance**[724]
   Users should establish continuous monitoring systems to track the performance and interoperability of AI systems in production. Regularly reviewing and updating AI systems to maintain compatibility with evolving healthcare IT infrastructure and demands are important to facilitate seamless integration between systems.[725]

5. User Skill Gaps

User skill gaps refer to risks ensuing from healthcare deployers lacking the necessary training or expertise to effectively use AI technologies.

1. **Build Multidisciplinary Teams**[726,727,728]
   Involve a diverse team of relevant healthcare professionals, AI experts, and educators to ensure that AI functionalities are aligned with the organization's needs and are user-friendly for deployment. Establishing peer support networks where users can share experiences, challenges, solutions, and best practices for AI system usage can facilitate the successful deployment of AI.

2. **Design Comprehensive Training Programs**[726]
   Design and develop targeted training programs tailored to different user groups (e.g., clinicians, administrative staff, and IT professionals) to allow users to acquire the necessary skills to interact with AI technologies effectively. Continuous education programs are useful to keep users updated on the latest AI modifications and best practices can also help to narrow user skill gaps. Additionally, providing detailed and readily available user manuals, FAQs, and reference guides can complement training programs to boost user skills.

3. **User-Centric AI Design**[729,730]
   Include in-built feedback mechanisms for users to report pain points and suggest improvements for a better user experience to facilitate continuous refinement of AI technologies. Emphasizing a user-centric design in the deployment of AI technologies supports greater stakeholder buy-in and smoother integration with existing workflows.

4. **Create Platforms for Simulation and Testing**[731]
   Creating simulated environments to allow users to practice using AI technologies in a risk-free environment before deploying them in real-life settings can empower them to use AI tools effectively and minimize the risk of error. Implementing pilot projects in controlled settings to evaluate user readiness of AI systems can also help to build user confidence by ensuring adequate acquisition of AI literacy.

5. **Ethical and Legal Education**[732]
   Users should offer education platforms on ethical and legal compliance on the use of Health AI to ensure that users are aware of their responsibilities and the potential impact of their actions when engaging with AI systems.

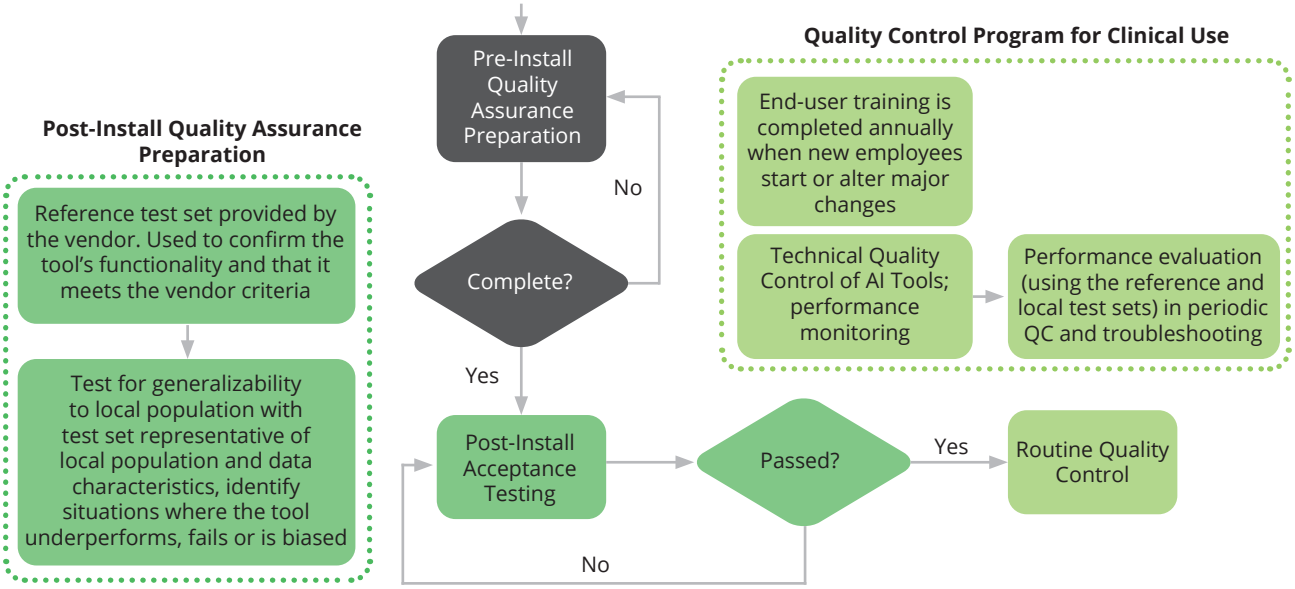
Use-Case Dependent Hazards

1. Lack of Clinical Accuracy and Reliability

Lack of clinical accuracy and reliability occurs when inaccurate or inconsistent AI outputs lead to incorrect medical diagnoses or treatment recommendations[1].

1. **Quality Assurance and Control:**
   Before deployment, users should conduct thorough acceptance testing to ensure that the system is adequate and can perform reliably in the intended environment.[733] This is a crucial step in identifying potential pitfalls early. Conducting explainability tests can help to verify that the AI model's reasoning is aligned with expectations.[734] The flowchart below illustrates the interconnected processes of quality assurance, acceptance testing, and quality control for AI tools in medical settings.[732]

Figure 16: Quality Assurance of AI Tools in Medicine



2. **Implement Fallback Mechanisms**
   Fallback mechanisms can help to mitigate clinical inaccuracies and unreliable AI model outputs. Implementing a human-in-the-loop (HITL) approach allows relevant users to modify or override AI systems' recommendations, ensuring proper oversight.[735] Decision support features include confidence scoring, where AI systems provide a confidence score with each recommendation able to set the threshold for required human review when scores are low.[736]

3. **Monitoring and Feedback Loops**
   Users should implement real-time monitoring systems to consistently track the AI model's performance, allowing for immediate detection of any errors. Maintaining detailed records of AI model deployment is crucial for traceability.[737] Develop mechanisms for users to easily provide feedback on the AI system's performance to allow users to provide feedback to developers for continuous model improvement. Finally, ongoing post-deployment surveillance is conducted to monitor the AI system's performance to ensure that the model consistently performs as intended.[738]

4. **Regulatory Compliance and Legal Considerations[739]**
   Ensure that AI systems comply with relevant regulatory requirements and standards for use in healthcare to maintain the efficacy of systems. External audits, where feasible, can assist in validating the AI system's performance and reliability from an objective standpoint.[740] Establishing legal safeguards, including clearly defined liability and accountability frameworks, as well as protocols for incident reporting and resolutions, are fundamental to addressing potential issues arising from AI system errors or inaccuracies.

2. Bias

Bias refers to disparities in AI predictions or decisions caused by unrepresentative training data or algorithm design, leading to unfair treatment of certain patient groups.

1. **Use Diverse and Representative Data Sets**[741,742]
   Users should ensure that the data sets used are diverse and representative of the target population to reduce bias. Data augmentation, a technique used to artificially increase the size and diversity of the datasets by creating modified copies of existing data to improve model performance and generalization, along with regular audits, can facilitate timely identification and correction of biases.[743]

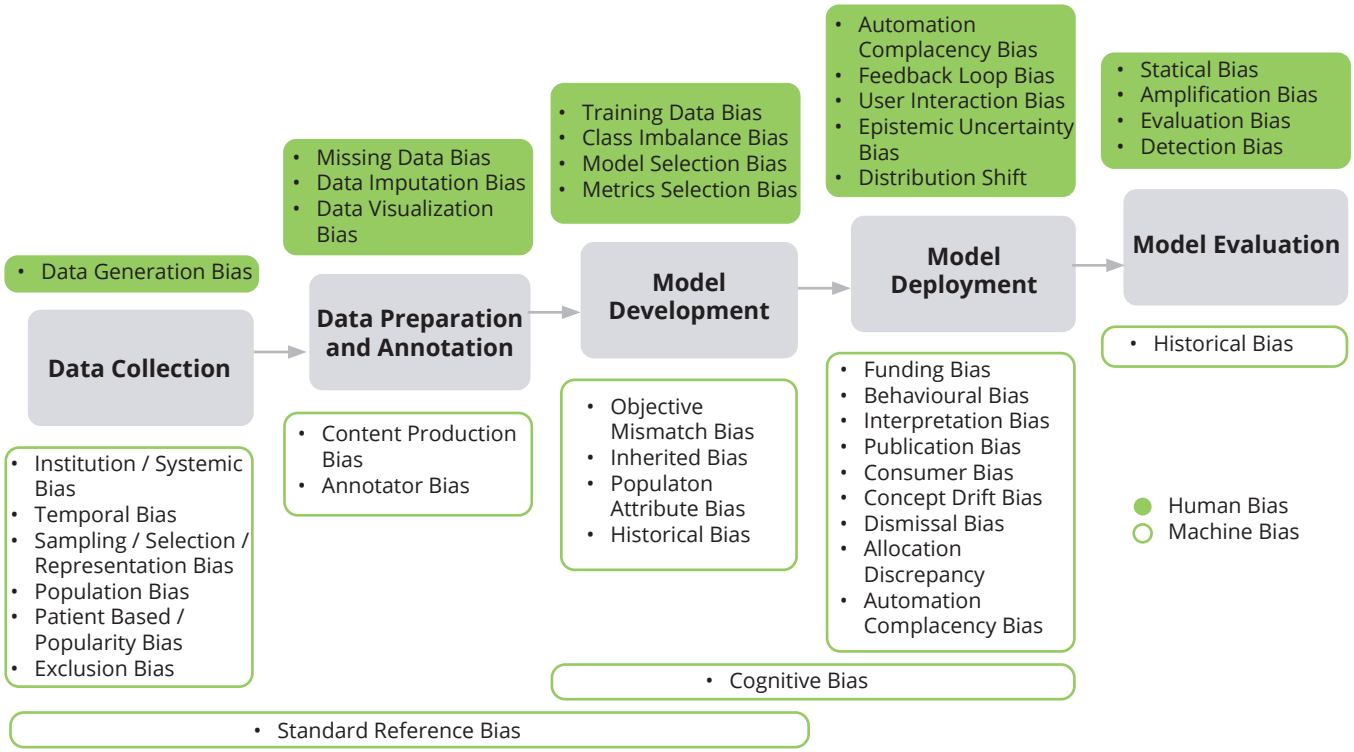
2. **Implement Rigorous Testing and Validation Protocols**[744]
   Conducting rigorous testing and validation prior to deployment ensures that AI systems are safe and effective, especially in healthcare, where there will be a direct impact on patients. Users can also employ fairness metrics. These include statistical parity, equal opportunity, equalized odds, predictive parity, and treatment equality. Fairlearn and AIF360 are fairness metric libraries that provide tools to evaluate fairness in AI models. More information can be found *here*.

3. **Perform Ongoing Monitoring and Evaluation**[745]
   Regular monitoring allows users to promptly identify potential problems or deviations in AI performance arising from biases, allowing for timely interventions. Ongoing monitoring can also help to detect new biases that may emerge as the AI system is applied across diverse populations over time and may not have been apparent during initial deployment.

4. **Assemble Diverse Teams**[746,747]
   Diverse teams are more likely to identify and consider biases from different contexts that will encompass a wider range of specific use cases, contexts, and user groups. As homogenous teams are more likely to generate biased outcomes, diverse teams can better support the risk mitigation associated with bias in AI systems.

The figure below illustrates potential bias throughout the process of AI solution deployment.

Figure 17: Potential Bias in the Various Stages of Data Collection and Model Development (Gichoya JW et al)



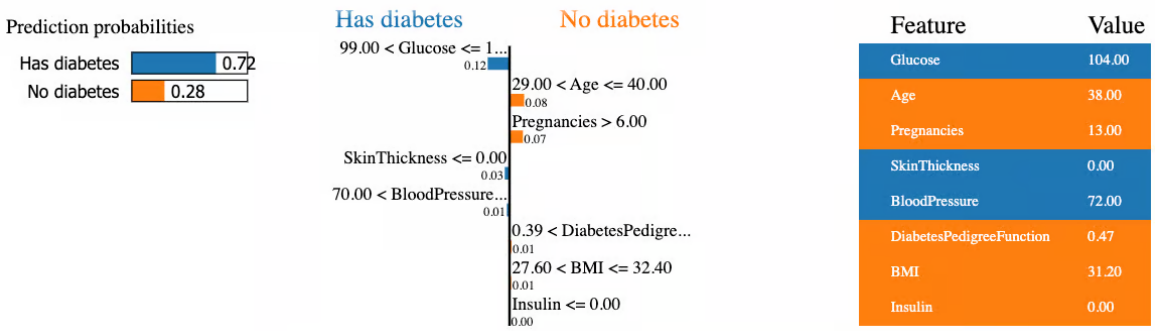
3. Alignment Risks

Alignment risks refer to misalignment between the AI system's objectives and clinical goals, resulting in outputs that do not support desired patient outcomes.

1. **Establish Clear Governance and Oversight**[748]
   Users should establish guidelines and standards for AI algorithms and their use in clinical decision-making. Ensure that the AI system's goals align with healthcare outcomes that focus on patient safety and align with ethical standards. A clear governance framework should be established to ensure that the deployment of AI aligns with clinical objectives.

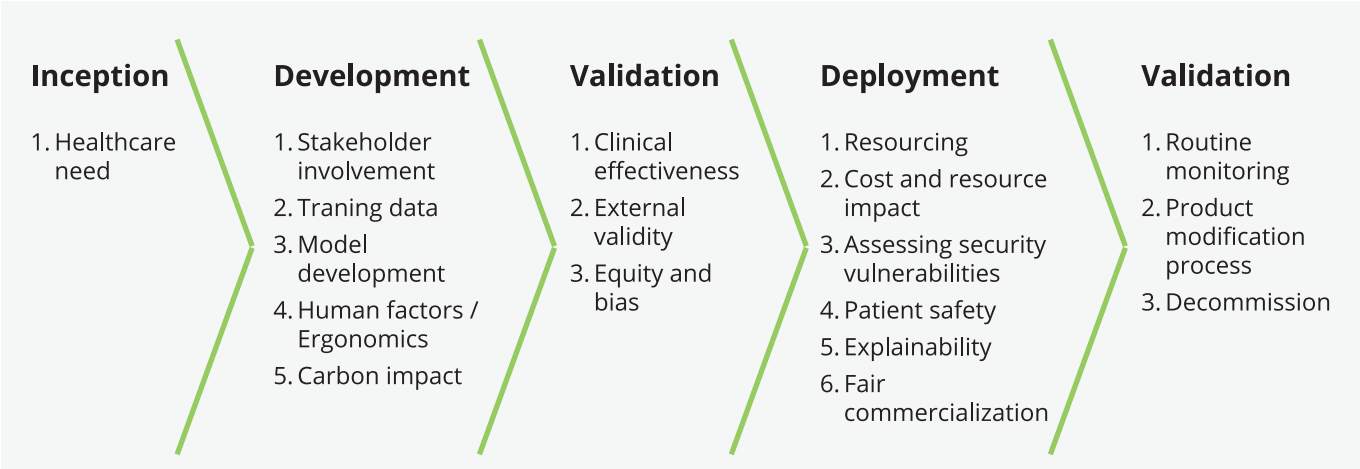
2. **Ensure Human Oversight and Transparency**[749,750,751]
   Ensuring human oversight and transparency in the deployment of AI systems is crucial, as AI algorithms can sometimes produce incorrect results due to data or design limitations. Implementing explainable AI techniques can enable users to understand the rationale behind AI decisions. Examples include incorporating visualizations to explain how algorithms make decisions so that users can better understand their capabilities and limitations. Providing training to users of AI systems can enhance their ability to oversee AI systems effectively and empower users to engage with AI outputs responsibly. In addition to this, it may be useful for users to integrate model-agnostic explainability, such as *Local Interpretable Model-agnostic Explanations (LIME)*, into hospital monitoring processes to increase the explainability of a specific use case for clinicians to support clinician decision-making and inform patients of treatment decisions.

Figure 18: Example of LIME output[752] that could enable clinicians to explain the basis of the AI. This is different from interpretability or knowing how the actual AI model uses these parameters to arrive at its decision.



3. **Conduct Clinical Validation Exercises**[753]
   Clinical validation exercises can help users ensure that AI systems are safe, effective, and reliable before and after deployment. The British standard "BS30440: Validation Framework for the Use of AI in Healthcare" provides guidance on validating AI products in healthcare settings and represents a fully auditable standard for the assessment of healthcare AI products covering the entire product life cycle. The figure below provides an overview of the BS30440.

Figure 19: Overview of BS30440: Validation Framework for the Use of AI in Healthcare



4. **Conduct Regular Audits**
   Users should conduct regular audits to ensure the AI system continues to align with evolving medical standards and clinical practices. The BS30440 framework highlighted above can be used as a reference for auditing AI systems in healthcare.

4. Automation Bias

Automation bias refers to overreliance on AI recommendations by healthcare deployers, potentially overlooking clinical judgment or contrary evidence.

1. **Provide Comprehensive User Training and Education**[754,755,756]
   Users should offer ongoing education and training programs for users to raise awareness about automation bias and its potential consequences. Training and education sessions should reinforce the importance of critical thinking and verifying AI outputs adequately to reduce overreliance on AI systems.

2. **Implement Human-in-the-Loop Approaches**[754,755,756]
   Users should implement workflows that require relevant healthcare professionals to review and validate AI recommendations before acting on them to reduce overreliance on AI systems. This can include involving experts in ongoing evaluations of the AI system's performance and feedback mechanisms for users to report discrepancies or errors in AI outputs.

3. **Establish Clear Protocols for AI Use**[754]
   Establishing clear protocols for AI use can delineate the roles between AI systems and healthcare professionals, ensuring that professionals maintain oversight and possess the final decision-making authority. Such demarcation can help to prevent misunderstandings about the capabilities of AI and reduce the risk of automation bias.

4. **Enforce Ethical Guidelines and Standards**[754]
   Users should ensure adherence to ethical guidelines and standards for the use of Health AI. Such guidelines should address the appropriate use of AI in healthcare without compromising the importance of maintaining human oversight. The World Health Organization (WHO)'s *Guidance on Ethics and Governance of AI for Health* is a good reference.

5. **Incorporate Debiasing Techniques**
   Users can consider incorporating debiasing techniques by introducing interface design features that prompt users to consider alternative recommendations from what AI proposes. Such mechanisms can encourage users to critically evaluate AI outputs and recommendations and reduce overreliance on AI systems.

5. Liability Risks

Liability risks refer to the potential for legal responsibility and financial consequences arising from errors, malfunctions, or adverse outcomes associated with the deployment of AI solutions in healthcare.

1. **Establish Risk Assessment Frameworks**[758]
   Users should implement risk assessment frameworks to obtain an adequate understanding of the potential liability risks associated with AI systems. The Human-Centered Artificial Intelligence (HAI) Policy and Society at Stanford University has proposed a framework for assessing healthcare AI liability risk based on past literature. The framework suggests four major factors to consider when conducting a risk assessment for healthcare AI:
   1) The likelihood and nature of errors (based on the AI model, its training data, its task design, and how it is integrated into clinical workflow).
   2) The likelihood that humans or another system will detect errors before they harm patients (which depends in part on how much time with and visibility into the AI tool humans have).
   3) The potential harm if errors are not caught (especially for tools that perform critical clinical functions or are used in caring for patients with serious health conditions).
   4) The likelihood that injuries would garner compensation in the tort system (which turns on, among other things, the severity of the injury, the ease of proving negligence, and the causal relationship between the AI tool and the injury).

2. **Reinforce Regulatory Compliance**[759]
   Reinforce governance and regulatory frameworks that include clear protocols and guidelines for the extent of use of AI systems. Users should continuously monitor AI systems to ensure that they are serving their intended purpose.

3. **Ensuring High-Quality Data Security Mechanisms**[756]
   To reduce liability risks, users must ensure that data security mechanisms, including encryption, access controls, and anonymization techniques, are robust to safeguard patient data. Regular monitoring and audits of AI systems should be conducted to ensure that they are functioning as intended and to detect any potential issues.

4. **Collaborate with Legal Experts**[760]
   Users should work with legal experts, such as in-house lawyers and developers, where necessary, to understand liability implications and develop contracts to clearly define responsibilities and liabilities. This will help to ensure that company policies and workflows are adequate to address potential legal challenges.

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