

AI IN HEALTHCARE

BUILDING THE FUTURE TOGETHER

JOINT WHITEPAPER - MECOMED & PwC Middle East

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FOREWORD:

Artificial Intelligence is catalysing transformation at pace across every industry, redefining the way both public and private organisations operate and the way their stakeholders (including employees, customers, citizens and patients) engage with them. In healthcare, the advancements of AI technologies are revolutionising the way patients are treated, doctors and nurses work, and how diseases are diagnosed and even understood, creating many opportunities for innovation. With the potential use-cases for AI integration constantly expanding, it is rapidly becoming a core pillar in the future of healthcare delivery, improving patient outcomes and health equity. However, with its application into healthcare, there are also potential ethical and social challenges that are critical for us to be aware of and address. These challenges include addressing biases in AI algorithms and avoiding discrimination, ensuring human autonomy and oversight, addressing data quality and security, providing technical robustness across the digital ecosystem, defining accountability, promoting transparency, determining data ownership and governance structures, engendering trust, ethical adherence, and regulatory compliance.

Mecomed in collaboration with PwC Middle East ran a workshop examining the impact of AI in healthcare. This included representation from SMEs across the whole healthcare ecosystem to address the most critical issues and provide a series of recommendations and actionable insights as we work together to redefine the future of healthcare.



OBJECTIVE

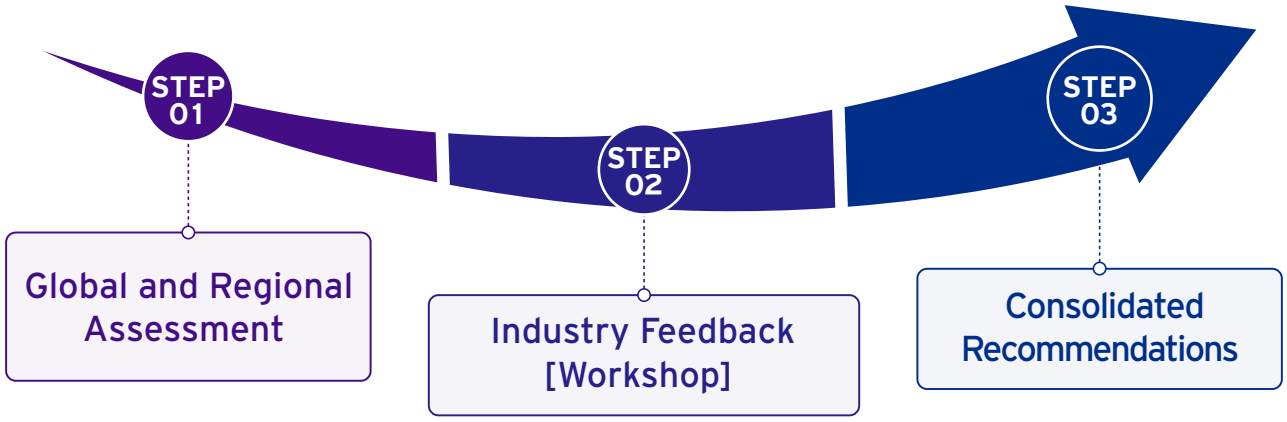


To achieve ethical, reliable, robust, secure, and sustainable AI in healthcare, we need an appropriate and agile policy framework that encourages innovation and research partnerships, builds a data culture that respects personal data privacy and security, supports education and upskilling in the healthcare and regulatory workforce and encourages international cooperation, alignment and harmonization.

The policy framework on AI in healthcare should take into consideration the need for global harmonization of AI regulations, ethical and societal considerations and data quality and management issues. Achieving consistency across regulatory agencies and aligning horizontal approaches with vertical legislation will prove as crucial as the establishment or adoption of specific internationally recognized principles for AI.

Action is required to promote the adoption of responsible and ethical development and use of AI in healthcare, including ensuring the quality and fairness of data used in AI algorithms, protecting intellectual property rights and trade secrets in compliance with Paris Convention for the Protection of Industrial Property and the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights "TRIPS Agreement", and ensuring transparency and explainability of algorithms for regulatory purposes. By addressing these multifaceted issues, policymakers can strike a balance that fosters innovation while upholding necessary regulatory safeguards in the realm of AI in healthcare.

To achieve this objective Mecomed's Digital Health committee collaborated with PwC Middle East to develop an integrated approach to assess the regional/global policy landscape and collated feedback from Industry members by following a three-Step approach:



ASSESSMENT OF CURRENT POLICY LANDSCAPE



Global Overview:

Globally we are seeing a range of policy approaches, with varying legislation, standards, principals and oversight. For example:

United Kingdom

Legislation & regulation: Online Safety Bill (2022, draft); Data Protection and Digital Information Bill (2023, draft)

Standards: Algorithmic Transparency Standard (Central Digital Data Office, 2021)

Principles: A pro-innovation approach to AI regulation (2023)

Canada

Legislation & regulation: Directive on Automated Decision-Making (2019)

Bill C-27; Digital Charter

Implementation Act, including AI and Data Act (AIDA) (2022, draft)

Standards: CAN-ASC-6.2: Accessible

and Equitable AI Systems (2023, draft)

Principles: Canada's Digital Charter (2019)

Oversight: Minister, Proposed AI and Data Commissioner

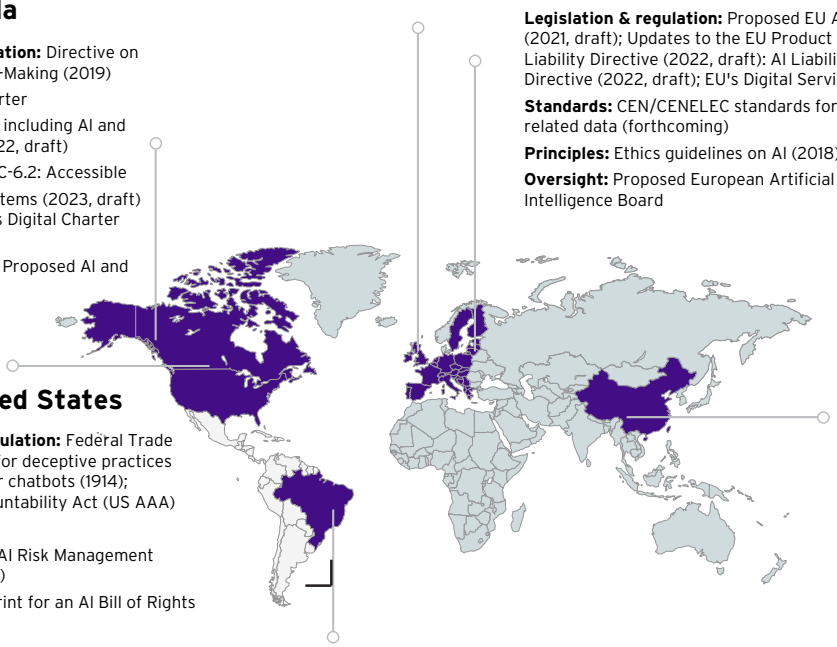
European Union

Legislation & regulation: Proposed EU AI Act (2021, draft); Updates to the EU Product Liability Directive (2022, draft): AI Liability Directive (2022, draft); EU's Digital Services Act

Standards: CEN/CENELEC standards for AI and related data (forthcoming)

Principles: Ethics guidelines on AI (2018)

Oversight: Proposed European Artificial Intelligence Board



China

Legislation & regulation: Chinese Internet Information Service Algorithmic Recommendation Provisions (2021);

Opinion on Strengthening the Ethics and Governance of

Science and Technology (2022)

Standards: National Standards for Autonomous Vehicle Testing (2018)

Principles: New Generation AI Ethics Specifications (2019); New Generation AI Code of Ethics (2021); White Paper on Trustworthy AI (2021); Internet Information Service Algorithmic Recommendation Management Provisions (2021)

United States

Legislation & regulation: Federal Trade Commission Act, for deceptive practices from deepfakes or chatbots (1914); Algorithmic Accountability Act (US AAA)

(2022, draft)

Standards: NIST AI Risk Management Framework (2023)

Principles: Blueprint for an AI Bill of Rights (2023

Brazil

Legislation & regulation: Report and proposed substitute text for draft bills 5051/2019, 21/2020 and 872/2021 (2022, draft); Bill 705 on the compatibility of AI use in the public sector with ESG practices (2022, draft)

Standards: Incorporation of international standards National standards by the Brazilian Association of Technical Norms (ABNT)

Principles: Art. 3 of the proposed substitute text for draft bills 5051/2019, 21/2020 and 872/2021 (2022, draft)

Intergovernmental Organisations

Legislation & regulation: Council of Europe Convention on AI, Human Rights, Democracy and the Rule of Law (2023, draft)

Standards: ISO 31000 Risk management (2009, 2018); ISO/IEC

23053:2022 Framework for AI Systems Using Machine Learning (ML) (2022)

Principles: OECD Recommendation of the Council on AI (2019);

UNESCO Recommendation on the Ethics of AI (2021)

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United States

The U.S. Congress is gathering input on AI policy issues through RFIs, hearings, and briefings intended to educate members and staff as they seek to regulate AI's deployment. The White Housepublished an executive order about AI and agency action will follow, including finalization of an OMB guidance. There are various efforts to build on the NIST AI framework and sector efforts addressing AI safety and security, protecting privacy, supporting workers, promoting innovation and competition, advancing US leadership abroad, and responsible and effective use of government AI.



China

Considered to be advancing as a world leader in AI , China is continuing its approach of cordoning off its market and entrenching a standalone digital ecosystem implementing laws and regulations that will both restrict technologies and data from offshore but also benefit its domestic industries and applications. Various industry groups have noted concerns about the approaches to cross border data flows and the vagueness of its laws.



European Union

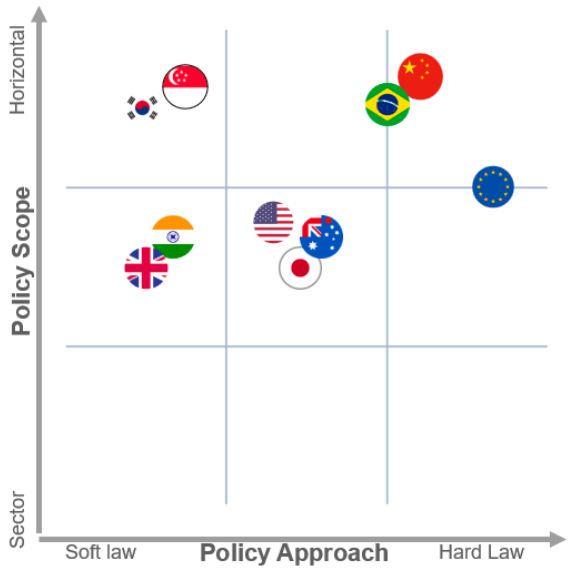
Horizontal regulation with the AI Act introducing requirements for high-risk applications, including AI medical devices, which will require a conformity evaluation: adequate risk assessment and mitigation control plans; high quality of the datasets to minimize bias; activity logging to ensure results traceability; detailed documentation providing information necessary on the system and its purpose to regulators; clear and adequate information to the user; appropriate human oversight measures; high level of robustness, security and accuracy. The implementation started as of second half of 2024 with a transition period of 2-3 years (for example, the transition for MedTech sector is anticipated to be 36 months).[1]



Intergovernmental Organisations

- OECD Framework and revision of AI definition to foster international alignment, enhance clarity and "future proof."
- UNESCO AI Principles in Healthcare.
- Proposed Council of Europe Convention on AI, Human Rights, Democracy and the Rule of Law (2023).
- APEC announcement of creation of a "Resilient and Sustainable Future for All," focused on policy priorities of interconnected, innovative, and inclusive[2].
- G7 development of the Hiroshima AI Process Comprehensive Policy Framework, in cooperation with the Global Partnership for Artificial Intelligence (GPAI) OECD, and to conduct multi-stakeholder outreach and consultation, including with governments, academia, civil society, and the private sector, not only those in the G7 but also in the economies beyond, including developing and emerging economies.

In summary, we are seeing heterogeneous policy approaches regionally/globally:



- Mixed policy approaches
- Focus on innovation: UK, India
- Focus on Regulation: EU, China, Brazil
- Hybrid: US
- Healthcare voice has been limited
- Key issues: bias and discrimination, data privacy and security, human autonomy, accuracy, transparency and accountability, data access, AI skills and literacy

MENA overview:

The increased use of AI is driving significant economic impact, and is expected to add trillions to the global economy by 2030:

$15.7 trillion
Globally

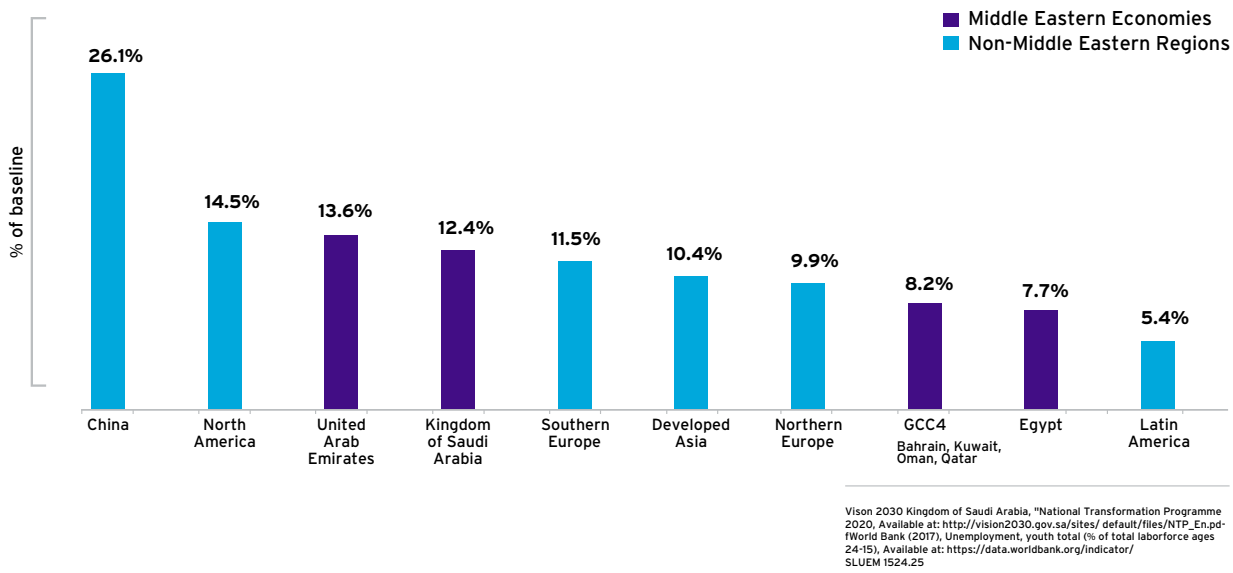
$320 billion
Middle East share (2% of global gains)

Saudi Arabia
(12.4% of GDP)

UAE
(14% of GDP)

At the same time there is an emphasis on the need for AI regulation to support the safe and effective integration of AI technologies in the Middle East. Governments are encouraged to establish frameworks that address the risks associated with AI, including data privacy, cybersecurity, and ethical concerns. Legal institutions must evolve to ensure that AI advancements benefit society while mitigating potential risks, creating an environment conducive to innovation.

Contribution of AI to GDP by region, 2030



Vison 2030 Kingdom of Saudi Arabia, "National Transformation Programme 2020, Available at: http://vision2030.gov.sa/sites/ default/files/NTP_En.pdfWorld Bank (2017), Unemployment, youth total (% of total laborforce ages 24-15), Available at: https://data.worldbank.org/indicator/ SLUEM 1524.25

The AI regulatory landscape in the MENA region is centered on data protection and ethical guidelines to ensure responsible AI deployment.

- **Data Protection Laws:** Countries like Egypt, Kuwait, Bahrain, Qatar, and Oman have implemented data protection laws, forming the foundation for regulating AI systems and ensuring privacy in AI-related activities.
- **AI Ethics and Guidelines:** Pioneers in AI adoption, the UAE and Saudi Arabia have developed ethical guidelines that emphasize transparency, accountability, and fairness. Both countries use a "soft law" approach, issuing guidelines and principles to regulate AI technologies.



United Arab Emirates (UAE):

The Council for Artificial Intelligence and Blockchain are developing an AI-friendly ecosystem[3].

The country introduced AI Ethics and Principles in 2022 and Generative AI Guidelines in 2023[4].

Additionally, Digital Dubai oversees AI-related regulations, and the Dubai International Financial Centre amended its data protection regulations to include AI-specific provisions[5].

Saudi Arabia:

Saudi Arabia's SDAIA (Saudi Data & AI Authority) leads its National Strategy for Data & AI, aiming to make the country a global AI leader by 2030. Saudi Arabia also issued the Personal Data Protection Law (PDPL) in 2021 to govern the processing of personal data, especially with AI technologies[6].

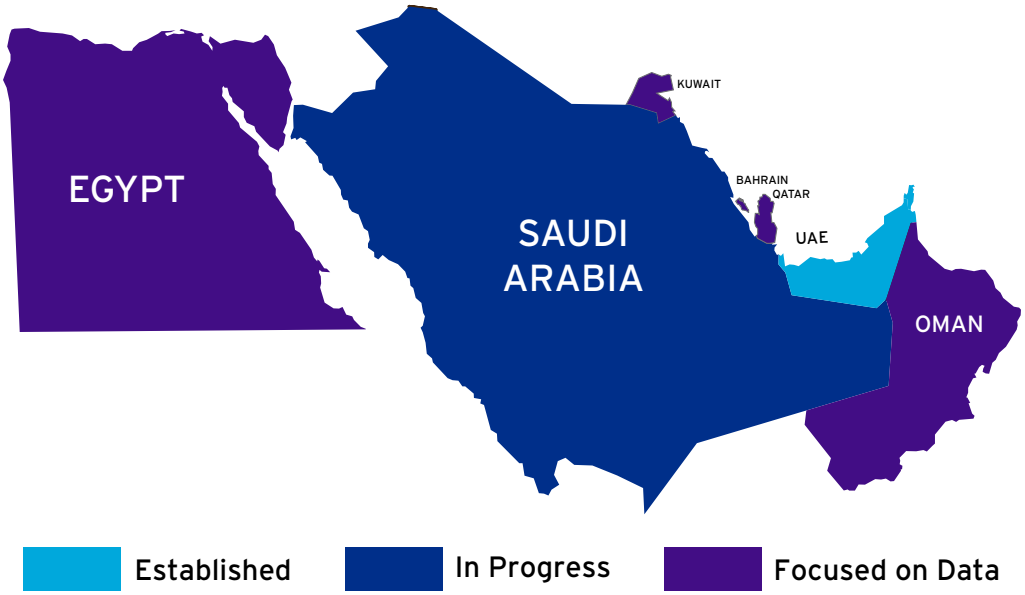
African Union (AU):

The AU has recognized the importance of AI and emerging technologies, with several member states actively developing AI governance frameworks. The AU's Digital Transformation Strategy (2020-2030) aims to integrate AI to accelerate economic development across the continent. It emphasizes ethical AI, data protection, and capacity building.

Regional Trend: Many countries in the MENA region are aligning their AI regulations with global standards, focusing on privacy protection and ethical AI use. This shift is becoming more urgent with the rise of generative AI, raising concerns about privacy and copyright issues.

Smart Africa: As a pan-African initiative, Smart Africa is working on promoting a unified digital economy, including AI policy harmonization across member states. This initiative is focused on fostering AI innovation while ensuring responsible use.

Overall, the MENA region is actively developing its AI regulatory framework, focusing on ethical AI use and safeguarding personal data, with the UAE and Saudi Arabia leading the charge in AI governance.



INDUSTRY COLLABORATION | WORKSHOP

Background

In collaboration with Mecomed, PwC Middle East facilitated the "AI & Healthcare: Building the Future Together" workshop. The event convened over 70 participants from diverse sectors within healthcare and life sciences, both regionally and internationally. The primary objective was to gather industry insights and foster collaboration on integrating AI technologies into healthcare.

This interactive workshop served as a platform for stakeholders across the digital healthcare ecosystem to discuss emerging themes, explore the latest developments in AI policy worldwide, and co-create actionable strategies for the future of healthcare technology.

Participant Profile & Industry Representation

A critical factor in the success of the workshop was the diverse and comprehensive representation of stakeholders from across the digital healthcare landscape. By bringing together key players from various sectors, the workshop fostered rich discussions and facilitated the development of strategies that are both practical and inclusive.



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Participants included:



Policy Makers:

Government officials and regulators responsible for shaping healthcare and AI policies. Their involvement ensured alignment with current regulatory frameworks and future policy directions.



Payers:

Representatives from insurance companies and entities responsible for financing healthcare services. Their insights highlighted economic considerations and potential funding models for AI integration.



Healthcare Providers:

Professionals from hospitals, clinics, and medical practices, including physicians, nurses, and administrators. They offered frontline perspectives on the practical challenges and opportunities of implementing AI in clinical settings.



Big Tech & MedTech Industry Associations

Leaders and innovators from technology and medical device Mecomed member companies, such as Siemens, Stryker, and Johnson & Johnson. They contributed technical expertise and shared advancements in AI technologies relevant to healthcare.



Educational Institutions:

Academics and researchers from universities and research centers like the Dubai Institute of Design and Innovation (DIDI). Their participation ensured discussions were informed by the latest research and educational perspectives.



Patients and Patient Advocates:

Individuals representing patient interests, providing valuable insights into patient needs, concerns, and expectations regarding AI in healthcare.

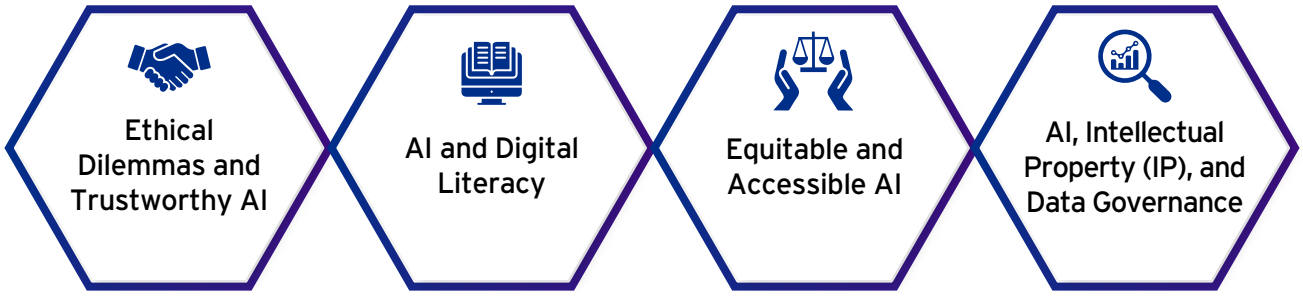


Other Stakeholders:

Organizations involved in digital healthcare advancements, including entities from Dubai Science Park and other innovation hubs.

Workshop Methodology and Focus Areas

The workshop was designed to encourage active participation and collaborative problem-solving. It centered around four critical themes, identified as key to the integration of AI in healthcare:



STRUCTURE AND APPROACH

Team Assignments:
Participants were divided into teams, each focusing on one of the four key themes. This allowed for in-depth exploration of each area.

Interactive Discussions:
Facilitated sessions encouraged open dialogue, with teams identifying challenges and brainstorming strategic solutions.



Facilitation Tools:
Ideas were captured using flipcharts and interactive digital platforms to promote engagement and real-time documentation.

Guiding Questions:
Thought-provoking prompts were provided to stimulate critical thinking and guide discussions toward actionable outcomes.

By integrating the focus areas into the methodology, the workshop ensured that discussions were structured yet dynamic, allowing participants to delve deeply into each theme while benefiting from the collective expertise of the group.

Workshop Methodology and Focus Areas



1. ETHICAL DILEMMAS AND TRUSTWORTHY AI

Objective: Establish robust governance frameworks, ensure transparency, and promote ethical practices in AI applications.

Key Insights:

» **Governance and Oversight:**
The necessity for comprehensive ethical guidelines and approval processes

» **Transparency:**
Building trust through open communication about AI operations

» **Data Privacy:**
Implementing stringent measures to protect patient information

» **Stakeholder Engagement:**
Involving diverse stakeholders early to integrate ethical considerations

» **Bias Mitigation:**
Adopting standards to reduce biases in AI algorithms

» **Global Perspectives:**
Leveraging international insights to enhance ethical frameworks

CONSOLIDATED POLICY RECOMMENDATIONS

This involves addressing the ethical challenges posed by AI in healthcare, such as bias and discrimination. It is crucial to leverage existing bioethics guidelines and risk-based standards for data set and model validation, monitoring, and accountability, and ensure human-in-the-loop mechanisms for AI models, and support upskilling programmes for healthcare professionals and digital literacy among patients. Policymakers should assess the different types of AI systems and categorize them according to risk, establishing compliance obligations accordingly.

- Review existing frameworks applicable to AI
- Identify gaps in policy that need to be addressed
- Adopt and align horizontal principles and sector-specific standards and guidelines for the responsible use of AI to:
- Avoid duplicative legal obligations across different legislations
- Enable a single act to cover multiple legal obligations

GOVERNANCE AND OVERSIGHT:



Importance:

Comprehensive ethical guidelines and approval processes are essential for ensuring that AI systems in healthcare are developed and deployed responsibly. This governance helps mitigate risks and enhances accountability across all levels

Recommendation for Policy Makers:

Establish multidisciplinary ethics boards to evaluate AI projects, incorporating voices from ethics, law, healthcare, and technology. Develop clear approval processes that require comprehensive ethical evaluations before deployment, ensuring compliance with established guidelines and addressing potential risks to patients.

TRANSPARENCY:



Importance:

Building trust among patients and healthcare providers hinges on transparent communication about how AI systems operate, the data they use, and the decisions they make. Transparent practices promote accountability and help demystify AI technologies.

Recommendation for Policy Makers:

Regularly publish reports detailing the performance and decision-making processes of AI systems. Create user-friendly materials that explain how AI tools work, their goals, and their limitations. Encourage open dialogues through presentations, workshops, & community forums where stakeholders can ask questions and provide feedback.

DATA PRIVACY:



Importance:

Protecting patient information is critical to maintaining trust in healthcare systems, especially when integrating AI technologies that rely on large datasets. Stringent data privacy measures safeguard against misuse and breaches.

Recommendation for MedTech Industry Associations:

Implement robust encryption protocols, access controls, and data anonymization techniques to protect patient data. Regularly audit data usage and sharing practices to ensure compliance with relevant privacy regulations. Educate staff about data protection practices and the importance of safeguarding patient information.

STAKEHOLDER ENGAGEMENT:



Importance:

Involving diverse stakeholders early in AI projects ensures that ethical considerations are integrated from the start. This inclusive approach leads to recognizing potential societal impacts and addressing concerns proactively.

Recommendation for MedTech Industry Associations:

Host workshops and focus groups that bring together patients, healthcare providers, ethicists, and technologists to discuss ethical implications and considerations. Utilize surveys and feedback mechanisms to gather insights throughout the development lifecycle, allowing for adjustments based on stakeholder input.

BIAS MITIGATION:



Importance:

Reducing biases in AI algorithms is crucial for ensuring fair and equitable outcomes in healthcare. Bias can lead to disparities in care and outcomes for different patient populations.

Recommendation for Policy Makers:

Adopt best practices for bias detection and mitigation, including diverse data sourcing and continuous model evaluation. Conduct audits of AI algorithms to identify and address biases before deployment. Establish guidelines for fairness and equity that every AI project must comply with throughout its lifecycle.

GLOBAL PERSPECTIVES:



Importance:

Leveraging international insights can enhance ethical frameworks by incorporating diverse cultural, legal, and societal considerations. This global approach fosters the sharing of best practices and lessons learned.

Recommendation for Policy Makers & MedTech IndustryAssociations:

Engage with international organizations and networks focused on AI ethics & healthcare obligations to exchange knowledge & experience. Participate in global discussions, conferences, and working groups that explore ethical challenges and solutions in AI. Tailor insights gained from other regions to inform local ethical guidelines and practices.



2. AI AND DIGITAL LITERACY

Objective: Enhance understanding and skills related to AI among all stakeholders to facilitate adoption and trust.

Key Insights:

» **Multidisciplinary Collaboration:**
Fostering partnerships across different fields

» **Education and Training:**
Developing programs to improve AI literacy among professionals and patients

» **Data Accessibility:**
Balancing access to data with security concerns

» **Patient Involvement:**
Engaging patients in AI development and testing

» **Policy Alignment:**
Ensuring initiatives align with regulatory landscapes

» **Role Clarity:**
Defining the roles of industry, government, and academia

CONSOLIDATED POLICY RECOMMENDATIONS

Focus on addressing the talent gap and promoting training programs to equip Healthcare Professionals with skills needed to thrive in an AI-driven economy is paramount.
Key recommendations include:

- Clearly defining roles and responsibilities of the different actors involved in the development and operation of an AI System
- Supporting education and training
- Policy harmonization and promoting collaboration
- Data sharing frameworks, on an international basis (i.e. cross-border)

ROLE CLARITY:



Importance:

Clearly defined roles help to streamline processes and ensure accountability among the various sectors involved in healthcare AI.

Recommendation for MedTech Industry Associations:

Develop frameworks that outline responsibilities for each stakeholder. For example, industry leaders may focus on technology development, while academic institutions can lead research and training initiatives. Governments can provide oversight and funding for public projects.

MULTIDISCIPLINARY COLLABORATION:



Importance:

AI in healthcare is complex and requires insights from various disciplines such as medicine, computer science, ethics, and sociology.

Recommendation for MedTech Industry Associations:

Establishing collaborative networks can encourage shared research projects, joint workshops, and hackathons. For instance, partnerships between tech companies and healthcare institutions can drive innovation.

EDUCATION AND TRAINING:



Importance:

With the rapid evolution of AI technologies, both healthcare professionals and patients need comprehensive education to utilize AI tools effectively.

Recommendation for Academia and Policy Makers:

Develop certification programs for healthcare professionals that cover AI basics & applications, and create workshops for patients to help them understand how AI interacts with their care. Additionally, online resources and seminars can reach a wider audience.

DATA ACCESSIBILITY:



Importance:

Access to high-quality data is crucial for training effective AI models, yet it poses significant challenges regarding patient privacy and data security.

Recommendation for Policy Makers:

Implement policies that allow for secure data sharing practices and develop anonymization techniques to protect patient identities. Creating a standardized framework for data sharing can help build trust among stakeholders.

PATIENT INVOLVEMENT:



Importance:

Patients are key stakeholders in healthcare, and their involvement can ensure that AI solutions address their needs and concerns.

Recommendation for Policy Makers & MedTech Industry Associations:

Form patient advisory boards to provide input during the development of AI tools. Involving patients in clinical trials can also yield insights on usability and effectiveness, ultimately leading to better outcomes.

POLICY ALIGNMENT:



Importance:

The regulatory landscape for AI in healthcare is continuously evolving. Ensuring alignment with policies like HIPAA (in the U.S.) or GDPR (in Europe) is essential for compliance and ethical use.

Recommendation for Policy Makers:

Policymakers to collaborate with Industry to develop regulations that facilitate innovation while protecting patient rights. Regularly update stakeholders on changes in legislations, policies and/or processes to ensure all initiatives remain compliant.

3. EQUITABLE AND ACCESSIBLE AI



Objective: Ensure AI technologies are accessible to all and address disparities in healthcare.

Key Insights:

- **Standardized Data Sets:**
  Creating representative and accessible datasets
- **Cross-Sector Partnerships:**
  Building collaborations among government, industry, and academia
- **Information Sharing:**
  Promoting continuous dialogue among stakeholders
- **Collaborative Research:**
  Initiating joint projects to pilot AI applications
- **Awareness and Integration:**
  Utilizing various channels to promote AI adoption
- **Funding and Commercialization:**
  Addressing challenges and supporting academic research
- **Awareness and Integration:**
  Utilizing various channels to promote AI adoption
- **Funding and Commercialization:**
  Addressing challenges and supporting academic research

CONSOLIDATED POLICY RECOMMENDATIONS

To ensure smooth adoption and coverage of new technologies in various healthcare systems across markets, we must first ensure the quality and representativeness of data for AI models. Accurate, reliable, and representative data are essential for an acceptable use of AI algorithms. Secondly, sufficient transparency and interpretability of AI algorithms are necessary for scrutiny.

Key recommendations are to expand coverage for AI-based solution, create public and private sandboxes for developers and deployers to test their solutions in a controlled environment, such as on health, outcomes data accuracy and representativeness in AI models.

STANDARDIZED DATA SETS:



Importance:

Standardized datasets are crucial for training AI models that can generalize well across different populations and healthcare settings. Without representativeness, AI applications risk perpetuating biases or failing to provide accurate responses for diverse patient groups.

Recommendation for Policy Makers :

Work towards developing universally accepted data standards that ensure interoperability and accessibility. Collaborate with healthcare organizations to compile and maintain diverse datasets reflective of different demographics, conditions, and treatments. Initiatives like open-data platforms can encourage sharing and transparency.

CROSS-SECTOR PARTNERSHIPS:



Importance:

Collaborations between government, industry, and academia foster innovation, enhance resource sharing, and align efforts to address public health issues effectively.

Recommendation for all Stakeholders:

Establish formal partnership frameworks that outline objectives, roles, and shared resources. Joint initiatives can include public health campaigns, funding for innovative projects, and collaborative development of training programs. Engaging in public-private partnerships can leverage the strengths of each sector to advance healthcare AI.

INFORMATION SHARING:



Importance:

Continuous dialogue among stakeholders is vital for ensuring that insights, challenges, and successes are communicated effectively. This cultivates a culture of trust and collaboration.

Recommendation for MedTech Industry Associations:

Host regular forums, workshops, and webinars to facilitate discussions among researchers, healthcare providers, and policymakers. Use digital platforms to create communities where practitioners can share best practices, lessons learned, and emerging research findings related to AI in healthcare.

COLLABORATIVE RESEARCH:



Importance:

Joint research projects can accelerate the development and validation of AI applications, allowing for shared expertise and resources that enhance innovation.

Recommendation for Policy Makers:

Encourage funding opportunities for multidisciplinary research teams. Establish partnerships between academic institutions and industry to pilot AI applications in real-world settings. Consortia can focus on pressing healthcare challenges, ensuring findings are broadly applicable.

AWARENESS AND INTEGRATION:



Importance:

Raising awareness about AI's potential in healthcare is needed to promote acceptance and ease integration into clinical practices. Stakeholders must understand its benefits to fully engage with the technology.

Recommendation for MedTech Industry Associations & Academia:

Utilize diverse communication channels, including social media, webinars, & community outreach programs, to disseminate information on AI applications. Collaborate with healthcare organizations to integrate AI training into existing curricula & professional development programs.

FUNDING AND COMMERCIALIZATION:



Importance:

Addressing the challenges surrounding funding is crucial for sustaining academic research and facilitating the transition of innovations from the lab to the market.

Recommendation for Policy Makers:

Advocate for increased public and private investment in healthcare AI research. Create grant programs specifically designed to support early-stage innovations. Encourage mentorship programs that link academic researchers with industry partners to help navigate commercialization pathways and market entry challenges.



4. AI, INTELLECTUAL PROPERTY, AND DATA GOVERNANCE

Objective:
Strengthen regulations and frameworks to protect IP and effectively govern data.

Key Insights:

» **Regulatory Frameworks:**
Implementing robust IP laws and data protection regulations

» **Data Sharing Protocols:**
Establishing frameworks for secure data sharing

» **Institutional Adoption:**
Promoting AI integration in healthcare institutions

» **Technical Compliance:**
Developing guidelines aligned with legal requirements

» **Local Adaptation:**
Tailoring practices to national contexts

» **Policy Development:**
Involving end-users in shaping supportive policies

CONSOLIDATED POLICY RECOMMENDATIONS

To foster innovation and clarity in IP protection for AI, it's essential to harmonize domestic laws with IP laws in major jurisdictions, creating a common framework for IP protection and enforcement. Inconsistent application of IP laws across jurisdictions poses obstacles to AI development and adoption.

Key recommendations include:

- Establishing clear and harmonized IP legal frameworks
- Protecting confidential information within transparency mechanisms
- Balancing the rights of human creators with advancements in AI to clarify IP ownership of AI model outputs and training data

REGULATORY FRAMEWORKS:



Importance:

Robust intellectual property (IP) laws and data protection regulations are vital for fostering innovation while ensuring the protection of patient rights and data privacy. A clear regulatory landscape helps build trust among stakeholders.

Recommendation for Policy Makers:

Collaborate with regulatory bodies to establish comprehensive IP frameworks that incentivize innovation in AI technologies while protecting the rights of developers. Ensure that data protection laws, such as GDPR or HIPAA, are robust, clear, and adaptable to technological advancements, helping organizations navigate compliance requirements.

DATA SHARING PROTOCOLS:



Importance:

Establishing secure and efficient data sharing protocols is essential for promoting collaboration among healthcare providers, researchers, and AI developers, fostering innovation through data utilization.

Recommendation for Policy Makers:

Develop standardized data sharing agreements that outline roles, responsibilities, and security measures for all parties involved. Implement encryption and anonymization technologies to protect sensitive data during transmission. Create a centralized platform for data sharing that adheres to established protocols to ensure compliance and security.

INSTITUTIONAL ADOPTION:



Importance:

Promoting AI integration within healthcare institutions is crucial for improving efficiencies, patient outcomes, and overall quality of care. Without institutional buy-in, even the best technologies can fail to deliver their potential.

Recommendation for all Stakeholders:

Conduct outreach programs that highlight successful AI implementations and their impact on operational efficiencies and patient care. Provide training and resources to healthcare professionals to ease the transition. Pilot programs within institutions can showcase effectiveness and build a case for wider adoption.

TECHNICAL COMPLIANCE:



Importance:

Establishing guidelines aligned with legal & regulatory requirements is necessary for ensuring that AI systems are developed, deployed, and utilized lawfully and ethically, reducing risks for institutions.

Recommendation for Policy Makers:

Collaborate with legal experts & healthcare professionals to develop a comprehensive set of technical compliance guidelines that address both data security and patient privacy. Regularly revise these guidelines to account for evolving regulations and technological advancements, providing clear pathways for organizations to follow.

LOCAL ADAPTATION:



Importance:

Tailoring practices to align with national contexts ensures that AI applications in healthcare address specific cultural, legal, and operational realities, enhancing their effectiveness and acceptance.

Recommendation for MedTech Industry Associations:

Engage local stakeholders in assessing their unique needs and requirements. Conduct research to understand cultural attitudes toward technology and healthcare practices specific to each region. Adapt AI technologies and practices to meet local regulations, languages, and healthcare structures to ensure relevance and usability.

POLICY DEVELOPMENT & HARMONIZATION:



Importance:

Involving end-users—including healthcare providers, patients, and policymakers—in the development of supportive policies ensures that regulations reflect the realities of the healthcare landscape and effectively support innovation.

Recommendation for Policy Makers:

Facilitate stakeholder workshops & focus groups to gather insights & recommendations from end-users during the policy development process. Implement iterative feedback loops where draft policies are shared for review and input before finalization. This participatory approach can lead to more practical, effective, and widely accepted policies because currently there seems to be lack of harmonization and conflicting processes between various departments and functions.

Conclusion

With AI catalysing transformation in the healthcare sector, all stakeholders across the healthcare ecosystem have a part to play in ensuring a future where healthcare is both at the forefront of innovation on the one hand, and equitable, ethical and trusted on the other.

While AI regulations are evolving the world-over, these often struggle to keep pace with the speed at which technologies and use-cases are developing, and the resulting national and international regulations vary. Policy makers, healthcare providers, educational institutions, payers, MedTech, innovators and patients urgently need to come together to address the biggest opportunities and threats posed by AI.

By following the actionable insights outlined in this paper, we can ensure a future where healthcare is human-led and tech-powered, driving optimal patient outcomes and building robust healthcare ecosystems that are fit for the future.



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References:

1 : https://artificialintelligenceact.eu/

2 : (https://www.apec.org/press/news-releases/2024/apec-senior-officials-reaffirm-commitment-to-resilient--inclusive-economic-growth)

3 : https://www.wam.ae/en/article/hszrgyim-uae-government-launches-generative-ai-guide

4 : https://ai.gov.ae/wp-content/uploads/2023/03/MOCAI-AI-Ethics-EN-1.pdf

5 : https://www.difc.ae/business/registrars-and-commissioners/commissioner-of-data-protection/regulation-10

6 : https://sdaia.gov.sa/en/SDAIA/about/Documents/Personal%20Data%20English%20V2-23April2023-%20Reviewed-.pdf

7 : https://www.PwC .com/m1/en/publications/potential-impact-artificial-intelligence-middle-east.html

8 : https://ai.gov.ae/wp-content/uploads/2023/03/MOCAI-AI-Ethics-EN-1.pdf

9 : https://dataprotection.africa/ai-and-data-protection-regulation/

10 : https://www.mckinsey.com/industries/public-sector/our-insights/the-potential-value-of-ai-and-how-governments-could-look-to-capture-it

11 : https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/what-every-ceo-should-know-about-generative-ai



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LIST OF ABBREVIATIONS

AI	Artificial Intelligence
DIDI	Dubai Institute of Design and Innovation
GPAI	Global Partnership for Artificial Intelligence
NIST	National Institute of Standards and Technology
PDPL	Personal Data Protection Law
OMB	Office of Management and Budget
RFI	Request For Information
SME	Subject Matter Expert



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