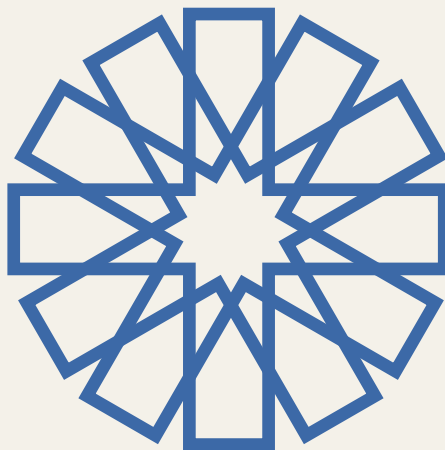


## FOUNDATIONAL PUBLICATION

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# Vision and Strategic Roadmap (2025-2030)

*A structured path to regulated, safe, ethical, and accountable AI integration in healthcare*



# ISMAI

International Society  
of Medical AI

*Machinam Medicorum*

## Executive Summary

The International Society of Medical AI (ISMAI) is a clinician-led organisation established to ensure that the integration of artificial intelligence (AI) in healthcare remains safe, ethical, and governed by those who understand its impact on patients firsthand. As AI systems become more embedded in clinical workflows (ranging from diagnostics to administrative triage) regulatory fragmentation, algorithmic opacity, and the absence of practical oversight mechanisms become increasing concerns. ISMAI exists to address these challenges through this coherent, globally oriented roadmap for 2025-2030, shaped by clinical realities and guided by public interest.

ISMAI envisions a future in which AI serves as a transparent, trustworthy partner in healthcare-improving decision-making, safeguarding patient autonomy, and complementing professional judgement, rather than replacing it. Our mission is grounded in four foundational values: clinical safety, practitioner autonomy, systemic transparency, and multi-sectoral collaboration. We believe that the voices of healthcare professionals must be central to the design, validation, and deployment of AI systems, if these tools are to fulfil their potential without compromising ethical principles or patient wellbeing.

To operationalise this vision, ISMAI has defined seven strategic pillars:

1. **Policy Advocacy** – Amplifying the clinician’s voice in legislative processes, with an emphasis on equitable, evidence-based AI governance across diverse regulatory environments.
2. **Clinical Guideline Development** – Crafting living, specialty-specific frameworks to guide the responsible and practical use of AI in clinical settings.
3. **AI Tool Certification** – Launching a voluntary certification programme that prioritises post-market surveillance, bias mitigation, and clinical transparency.
4. **Hospital Accreditation for AI Readiness (AIRA)** – Introducing a global three-tiered accreditation pathway for assessing healthcare institutions’ preparedness for AI integration.
5. **Training and Education** – Delivering tiered, internationally accessible education (certificate, diploma, MSc) to prepare clinicians for safe and informed use of AI technologies.
6. **International Partnerships** – Collaborating with global bodies (e.g., WHO, EU, OECD) to harmonise AI frameworks and support capacity-building in under-resourced settings.
7. **Standard Setting** – Producing consensus-based standards that align with clinical realities, while advancing algorithmic explainability, fairness, and operational relevance.

These pillars are reinforced by a series of flagship initiatives, including an international symposium series, a peer-reviewed academic journal, a foundational reference book, and a pipeline to AI readiness certification for hospitals. ISMAI’s structured training programmes are tailored to meet the evolving demands of the medical workforce, ensuring that every clinician, from generalist to subspecialist, can engage meaningfully with AI tools in their domain.

Rather than competing with existing regulators or professional societies, ISMAI offers a complementary platform that translates high-level policy into practice. Our work is intentionally adaptive: each programme is reviewed annually to ensure relevance in the face of rapid technological and regulatory change.

## Why ISMAI? Why Now?

The integration of artificial intelligence into healthcare has accelerated dramatically, propelled by advancements in data processing, machine learning, and predictive analytics. Globally, regulatory bodies and policy frameworks are scrambling to keep pace, often adapting rules designed for static medical devices rather than for AI systems that are continually evolving. This asymmetry has highlighted the existence of large gaps and inconsistencies. Some jurisdictions, such as the European Union, are introducing sweeping regulations that classify medical AI as “high-risk,” while others rely on older, less-precise regulations meant for medical devices. Many nations remain in an early or fragmented stage, lacking clear provisions to address algorithmic bias, ongoing performance monitoring, or liability structures. Consequently, a patchwork of rules has emerged, with notable disparities across continents.

Amid this environment, both clinicians and patients often have critical reservations about the reliability of AI tools in day-to-day practice. Studies indicate that many clinicians, although aware of AI’s potential benefits, hesitate to adopt these systems due to concerns for data privacy, algorithmic transparency, and uncertain legal responsibility. Likewise, public trust in AI remains tenuous, with surveys showing that a significant number of patients worry their health data might be misused, or that algorithmic errors could go unchecked.

This climate calls for a unifying voice; one that can align with national and regional authorities, complement existing guidelines, and ensure that AI is used effectively, safely and ethically. Despite advisory documents from global organizations such as the World Health Organization issue advisory documents and

legal mandates from the European Union, there remains a glaring need for a neutral, clinically grounded platform to place these directives in practical contexts. The International Society of Medical AI (ISMAI) has emerged precisely to fulfill this need. Founded and led by clinicians, ISMAI is committed to combining policy objectives, technical standards, and frontline realities to foster patient-centred AI adoption.

ISMAI’s clinician-led model underscores the principle that the individuals who use AI at the bedside or in the clinic should shape its evolution. By grounding our work in professional medical ethics and clinical workflows, we ensure that AI integration occurs, not in a vacuum, but as informed by the intricacies of patient care. Our approach neither dismisses technological innovation nor stifles it; rather, we recognize the urgent necessity to strengthen existing governance and policy guidelines so that AI-driven healthcare is trustworthy, transparent, and equitable.

In creating a global platform that unites practitioners, policymakers, researchers, and developers, ISMAI draws on both longstanding best practices (like those found in medical device certification) and emerging frameworks tailored specifically to machine learning. With this structure, we aim to reduce the unevenness of regulatory approaches, protect patients from potential harms, and support healthcare professionals by providing coherent, validated, and context-aware guidance. It is precisely at this pivotal moment (when AI’s promise is undeniable, yet its oversight remains incomplete) that ISMAI enters, determined to serve as a trusted ally and authoritative resource for the safe and ethical deployment of AI in healthcare worldwide.

## Our Vision and Mission

ISMAI envisions a future in which artificial intelligence is a trusted ally in clinical care—advancing diagnostic accuracy, treatment personalisation, and patient empowerment without sacrificing the core ethical and professional standards of medicine. At the heart of this vision lies a commitment to safeguard clinical autonomy, uphold patient safety, and enable transparent oversight of AI tools by the very professionals who use them. In a global landscape where regulatory frameworks vary widely and new AI technologies evolve rapidly, ISMAI aims to serve as a unifying force, promoting harmonized standards and best practices that prioritise public health and equitable access.

Grounded in four core values (clinical safety, autonomy, transparency, and collaboration) ISMAI's mission is to bridge the gap between technical innovation and frontline clinical practice. We believe clinicians should play a central role in guiding AI's development, validation, and deployment, ensuring that any algorithmic solution is fit for real-world contexts and genuinely serves patients' interests. Our unique proposition is thus a clinician-led governance approach, one that synthesizes emerging regulatory insights (such as the EU's "high-risk" classification, FDA's Total Product Lifecycle policies, and global Good Machine Learning Practice principles) with the lived experiences of healthcare professionals. By working closely with international bodies, local health systems, academic partners, and industry stakeholders, we strive to promote AI policies and certifications that are both scientifically rigorous and operationally feasible.

Ultimately, ISMAI's vision is a health sector in which AI augments, rather than replaces, clinical judgment, bolsters patient trust

through transparent and ethical frameworks, and continually evolves in response to real-world data and outcomes. We endeavour to shape a global consensus around safe, responsible, and innovative AI implementation, affirming that meaningful clinical engagement remains the cornerstone of any transformative technology in healthcare.

## Strategic Pillars of Action (2025-2030)

ISMAI's strategic plan centres on seven interconnected pillars. Collectively, these pillars recognise both the complexity of artificial intelligence (AI) in healthcare and the urgent need for clinician-led guidance. Each pillar addresses a facet of AI governance (from regulatory harmonisation to hands-on training) aimed at ensuring that all AI tools meet stringent standards of safety, equity, and clinical feasibility. Our approach is informed by global developments in medical device regulation, Good Machine Learning Practice (GMLP) principles, and existing professional guidelines, yet remains adaptable to the evolving nature of AI technology.

### I. Policy Advocacy

#### Rationale

Current international governance of health AI is marked by uneven regulatory landscapes. Regions such as the European Union (EU) have introduced robust legislation (e.g., the EU Artificial Intelligence Act, classifying most clinical AI as "high-risk"), while others either adapt general medical device rules or operate in a regulatory vacuum. Rapid innovations in "continuously learning" algorithms pose additional challenges for existing frameworks, which largely assume static software. These conditions create uncertainty for clinicians

seeking clarity on how to deploy AI ethically and safely.

ISMAI, with its foundation in clinical practice, recognises that credible policy must integrate regulatory science with the daily realities of patient care. We aim to amplify the informed voice of frontline practitioners (nurses, doctors, allied health professionals) so that their experiences shape policy discussions at the national, regional, and global levels.

### Goals and Expected Deliverables by 2030

1. **Comprehensive Policy Briefs:** Publish detailed policy briefs each year that dissect new legislative or regulatory measures (e.g., updates to the EU AI Act, the U.S. FDA's 'Total Product Lifecycle' approach) and clarify their implications for clinicians worldwide.
2. **Targeted Roundtables:** Convene at least three high-level dialogues annually with key regulatory bodies (such as the WHO, FDA, Health Canada, and Singapore's Health Sciences Authority) allowing clinicians to provide direct, evidence-based feedback on emerging AI regulations.
3. **Equitable Governance Advocacy:** Work in partnership with NGOs and international organisations to champion the needs of low- and middle-income countries, ensuring that new AI policies do not inadvertently widen global health disparities.

## II. Clinical Guideline Development

### Rationale

Despite the proliferation of AI systems, ranging from radiological diagnostic aids to predictive analytics in intensive care, there is no universally accepted repository of clinical guidelines that address the unique nature of AI-driven tools. Existing documents often focus on

technical validation or risk classification, leaving clinicians uncertain about best practices for integrating AI into day-to-day patient interactions, safeguarding against bias, or explaining AI-generated findings to patients.

ISMAI's clinician-led model enables the drafting of practical, specialty-specific guidelines. Drawing on lessons from international standards and on-the-ground pilot projects, these guidelines aim to ensure that AI tools respect patient autonomy and evidence-based medicine.

### Goals and Expected Deliverables by 2030

1. **Specialty-Specific Frameworks:** Develop, in collaboration with relevant professional societies, step-by-step protocols for AI use in fields such as cardiology, oncology, pathology, and general practice. These protocols will address data input standards, result verification, and clinician responsibilities in case of AI error.
2. **Living Guidelines:** Commit to updating each guideline biennially, reflecting the dynamic nature of machine learning. Changes will be driven by clinical outcomes data, regulatory shifts, and ongoing feedback from practitioners.
3. **Education-Focused Dissemination:** Provide open-access resources (toolkits, quick-reference checklists) to help institutions swiftly incorporate guidelines into clinical workflows. Seek endorsement from leading academic medical centres to bolster adoption.

## III. AI Tool Certification

### Rationale

Regulatory authorisations, such as the FDA's 510(k) process for medical devices or the CE marking process in the EU, have started to



incorporate AI-specific considerations. Yet these pathways often emphasise initial safety and efficacy at the time of approval, lacking robust frameworks for ongoing scrutiny as AI algorithms evolve in real-world settings. This gap leads to concerns about bias creeping into continuously learning systems, as well as about the alignment of AI performance across diverse patient populations.

ISMAI envisions a certification approach that supplements official regulations with ongoing post-market evaluation, clinician feedback mechanisms, and transparent reporting of AI updates. This model mirrors best practices in other safety-critical industries (e.g., aviation), where periodic re-certification ensures technologies remain reliable throughout their operational life.

#### Goals and Expected Deliverables by 2030

1. ***Supplementary Certification Programme:*** Establish a structured voluntary certification that includes real-world performance data, bias mitigation strategies, and patient safety metrics, complementing existing regulatory approvals.
2. ***Capacity-Building and Training:*** Partner with a network of academic hospitals on multiple continents to test a standardised certification methodology, ensuring that evaluations account for varied infrastructure and patient demographics.
3. ***Re-Certification and Reporting:*** Implement a 24-month re-certification cycle, requiring developers to demonstrate how their AI systems have managed data drift, algorithm updates, and compliance with evolving ethical standards.

## IV. Hospital Accreditation for AI Readiness

### Rationale

Many hospitals and clinics are currently unprepared to handle the complexities of AI integration, including data governance, staff training, interoperability challenges, and accountability structures. Emerging accreditation models, such as those introduced by URAC in the United States, demonstrate the value of a formal process that recognises institutions meeting rigorous criteria for AI safety and ethics.

ISMAI's Hospital Accreditation for AI Readiness (AIRA) aims to close this gap. Inspired by existing healthcare quality accreditation schemes (e.g., those by the Joint Commission International), our approach will emphasise continuous improvement and peer-based evaluation.

#### Goals and Expected Deliverables by 2030

1. ***AIRA Implementation:*** Roll out a three-tiered accreditation scheme for healthcare facilities, assessing governance structures, IT security, clinical oversight protocols, and patient engagement measures related to AI.
2. ***Global Pilot Sites:*** Develop detailed resource packs (e.g., how-to guides, staff training modules) to assist facilities preparing for accreditation. Provide on-site or remote consultancy to address identified weaknesses.
3. ***International Recognition:*** Seek endorsements from major regulatory authorities or professional societies so that AIRA accreditation is universally regarded as a marker of AI maturity and patient safety.

and professional associations to recognise these modules as part of mandatory CPD.

## V. Training and Education

### Rationale

Evidence indicates that clinical adoption of AI lags behind technological capability, partly due to insufficient training and uncertainty among healthcare professionals. Surveys consistently highlight clinicians' reservations about algorithmic opacity and the potential for liability issues. Addressing these concerns necessitates structured education at multiple levels of expertise, from basic AI literacy to advanced leadership roles in AI oversight.

ISMAI's position at the intersection of regulation, research, and clinical practice uniquely qualifies it to deliver relevant, up-to-date training. Through tiered programmes, participants can gradually develop competencies in data ethics, bias detection, risk assessment, and human-machine collaboration.

### Goals and Expected Deliverables by 2030

1. **Multi-Tiered Educational Pathways:** Launch certificate (basic), diploma (intermediate), and master's-level (advanced) programmes, each aligned with international standards (e.g., GMLP) and offering practical projects in real clinical settings.
2. **Global Accessibility:** Ensure all core modules are available online, supplemented by local workshops in regions where digital infrastructure may be less advanced. Collaborate with academic institutions in the Global South to facilitate cost-effective, regionally adapted curricula.
3. **Continuing Professional Development (CPD):** Integrate modules into established CPD frameworks, enabling clinicians to earn credits while updating their AI competencies. Encourage medical boards

## VI. International Partnerships

### Rationale

Challenges posed by AI, such as cross-border data sharing, liability variations, and differing cultural norms, cannot be addressed solely within national contexts. Meanwhile, global organisations like the WHO have begun issuing ethical guidelines for AI in health, but the operationalisation of these principles often remains unclear at the local level. ISMAI aims to bridge this gap by fostering multi-stakeholder engagements, ensuring that clinician insights inform global decision-making processes.

### Goals and Expected Deliverables by 2030

1. **Joint Projects with Major Actors:** Establish formal collaboration agreements with bodies such as the WHO, OECD, the European Commission, and national regulators in Asia and the Americas. Focus on shared research and policy initiatives around AI safety and equity.
2. **Global Multi-Stakeholder Summits:** Host annual or biennial summits that unite regulators, clinicians, patients, and industry representatives to review progress, debate new challenges, and coordinate responses to emerging AI technologies.
3. **Support for Low-Resource Settings:** In line with proposals from institutions like the Tony Blair Institute, champion capacity-building for low- and middle-income countries. This may include adapting AI readiness frameworks, training clinical champions, and providing technical assistance to local regulators.

## VII. Standard Setting

### Rationale

While organisations such as the International Medical Device Regulators Forum (IMDRF) and the ISO focus on macro-level standards, there remains a need for more granular and clinically oriented guidelines that are regularly updated as technology evolves. Standards around algorithm transparency, explainability, and bias mitigation are particularly relevant, given the evidence that AI tools often demonstrate variability in performance across different demographic groups.

By leveraging clinical expertise alongside technical knowledge, ISMAI can produce standards that transcend purely theoretical models, ensuring practical applicability within diverse healthcare environments.

### Goals and Expected Deliverables by 2030

1. **Consensus-Based Documents:** Publish consensus statements and checklists that complement formal ISO or IEEE guidelines, tailored to clinical scenarios such as emergency triage, chronic disease management, and diagnostic imaging.
2. **Dynamic Revision Cycle:** Establish a Standards' Committee composed of clinicians, ethicists, data scientists, and patient representatives. This body will meet annually to review and update existing standards, integrating new research and stakeholder feedback.
3. **Reference Implementation:** Develop open-source reference models or toolkits (e.g., templates for AI system documentation or sample data sets for validation) to facilitate consistent interpretation of standards across institutions and regions.

Through these seven strategic pillars, ISMAI outlines a comprehensive vision for embedding AI safely and effectively into healthcare systems worldwide. By uniting policy advocacy, clinical guideline development, certification procedures, accreditation programmes, structured education, international partnerships, and rigorous standard setting, we aim to ensure that AI-driven innovations are grounded in ethical principles and real-world feasibility. This multi-faceted approach reflects ISMAI's core belief that clinicians, working hand-in-hand with policymakers and technologists, are pivotal to shaping a future in which AI consistently serves the best interests of patients.

## Key Initiatives and Activities

This section details the flagship programmes through which ISMAI will implement its strategic goals. Each initiative integrates evidence-based policy insights with frontline clinical realities, ensuring that the Society's outputs remain both scientifically rigorous and responsive to the evolving demands of healthcare systems worldwide. The programmes are structured to reinforce one another, thereby creating a comprehensive ecosystem for ethical, patient-centred AI adoption.

### I. Annual Symposium Series

ISMAI's Annual Symposium Series is designed to bring together a diverse range of stakeholders (clinicians, policymakers, industry representatives, data scientists, and patients) to examine the latest developments and persistent challenges in medical AI. Held once each year and alternating among different regions, each symposium will address region-specific concerns while also reflecting broader international regulatory trends, emerging



ethical debates, and innovative clinical practices. The aim is to foster a shared vocabulary between frontline health professionals and technology experts, aligning clinical needs with feasible AI solutions.

Through keynote presentations, interactive workshops, and focused discussions, participants will delve into matters such as ongoing liability uncertainties, pathways for bias mitigation, and new methods for integrating AI seamlessly into routine care. Every session will be grounded in current evidence and reference evolving frameworks—including those issued by the WHO, the EU, and national regulatory authorities. Proceedings will be published openly, allowing stakeholders who are unable to attend in person to benefit from consensus findings, policy recommendations, and transferable lessons gleaned from real-world case studies.

## II. Academic Journal

ISMAI will launch a dedicated peer-reviewed Academic Journal that concentrates on applied research and policy analysis concerning AI in healthcare. Recognising a gap in existing academic publications (some of which favour purely technical discussions without reflecting clinical realities) this journal will emphasise empirical investigations of AI's impact on patient outcomes, care delivery, and health equity. It will also serve as a forum for scholarly debate over regulatory responses to adaptive algorithms, data privacy, and liability allocation.

Each issue will feature original research papers, systematic reviews, and case studies, alongside commentary from leading clinicians, ethicists, and policy analysts. Submissions will be evaluated by an editorial board comprising experts from diverse backgrounds: physicians, computer scientists, legal scholars, public health professionals, and patient

representatives. In keeping with ISMAI's mission to ensure equitable access to knowledge, the journal will be open access, thereby encouraging the widest possible dissemination of innovative ideas and best practices. Over time, it aspires to guide standard-setting bodies and inform the development of global AI guidelines that are both robust and contextually adaptable.

## III. Foundational Book

A comprehensive Foundational Book will draw together the most pressing knowledge and practical guidance on responsible AI implementation in healthcare. Building on lessons from international regulatory examples, such as the EU Artificial Intelligence Act and the FDA's Total Product Lifecycle approach, this volume will provide clinicians, hospital administrators, and policymakers with a consolidated perspective on how to navigate AI's technical, ethical, and legal dimensions.

The book will examine the lifecycle of AI tools, exploring design, validation, and post-market surveillance. It will also devote significant attention to adaptive systems, given the unique questions that arise when algorithms continuously learn from clinical data. Case studies of both successful and problematic deployments of AI will be included, illustrating the on-the-ground realities that often outpace formal guidance. By weaving together regulatory updates, medical ethics, and real-world insights, the Foundational Book will serve as an authoritative reference for health systems at varied stages of AI adoption.

## IV. Training Courses

ISMAI will introduce tiered Training Courses to address the diverse educational

needs of the clinical workforce. The Certificate programme will focus on foundational concepts, such as data quality, bias awareness, and basic AI literacy. This content is intended for clinicians of all levels who require a grounding in how AI tools function and where they might pose risks or add value. Building on that basis, a Diploma option will delve deeper into the operational and regulatory aspects of AI, including risk management and structured implementation strategies for hospital departments.

For those aiming to assume leadership roles in AI governance, a Master's-level track will offer the most advanced curriculum, covering human-machine collaboration, healthcare data engineering, and institutional oversight of adaptive algorithms. These in-depth modules will reference globally recognised guidelines (such as GMLP and the latest WHO recommendations) while also exploring practical problems encountered in real settings. By providing a structured pathway from introductory to advanced expertise, ISMAI's training will help cultivate a generation of clinicians who can critically evaluate AI claims, guide adoption in their workplaces, and advocate for ethical, patient-centred policies in their jurisdictions.

## V. Hospital Certification Pipeline

In addition to individual learning programmes, ISMAI will establish a Hospital Certification Pipeline to enable healthcare institutions to attain a formal accreditation for AI readiness. The initial phase involves a self-assessment of policies and infrastructures related to AI governance, staff training, cybersecurity, clinical oversight, and patient engagement. Afterwards, facilities will receive evidence-based recommendations and resources aligned with best practices—these

will help address gaps in capability, be they technical or organisational.

Following implementation measures, an on-site or remote evaluation by ISMAI experts will determine whether the institution meets the threshold for accreditation. Should it succeed, the hospital will be awarded an “AIRA-Certified” status, signifying conformity to international standards for safety, transparency, and clinical accountability. This pipeline fosters continuous improvement by encouraging periodic re-evaluation, recognising that as AI evolves, so must the institution's practices. For lower-resource settings, the pipeline will provide tailored support mechanisms, helping new adopters of AI leapfrog more standard but less adaptive approaches. Over time, the Hospital Certification Pipeline promises to deepen public trust by assuring local communities that AI tools are being deployed responsibly and effectively.

## VI. Membership Expansion

All of the above initiatives rely on a robust and engaged membership that brings diverse perspectives and experiences to the table. By growing its membership base globally, ISMAI can more effectively identify emerging challenges, disseminate updates, and mobilise collective expertise. Expansion efforts will focus on attracting frontline clinicians, data scientists, bioethicists, legal scholars, hospital administrators, and patient advocates.

New members will be given access to exclusive events, mentorship programmes, and collaborative research opportunities, along with a voice in ISMAI working groups that shape policy guidance, educational materials, and accreditation standards. In particular, special emphasis will be placed on recruiting members from underrepresented regions (where AI regulations may still be nascent) so

that the Society's outputs remain responsive to inequalities in access to digital technologies and regulatory support. By strengthening its membership in this balanced way, ISMAI ensures that decisions about AI governance are informed by the full range of global contexts, thus enhancing relevance and credibility in the broader discourse on ethical, clinically sound AI.

## Global Collaboration & Recognition

ISMAI recognises that the effective governance of AI in healthcare depends on close coordination with existing international bodies, regulatory agencies, and professional networks. Rather than seeking to supplant or compete with longstanding institutions such as the World Health Organization (WHO) or the European Commission, the Society intends to operate in a complementary manner, aligning its clinician-centred vision with ongoing global initiatives that share overlapping aims. ISMAI's mission to promote safe, ethical, and data-driven AI in health naturally converges with WHO's efforts to articulate high-level frameworks, such as its recent guidance on large AI models, and to build capacity in low-resource contexts through programmes like the Global Initiative on AI in Health. By partnering with WHO and similar agencies, ISMAI can ensure that its clinician-led insights inform wider policy dialogues and that its standards harmonise with international principles, such as those advocated by the International Medical Device Regulators Forum (IMDRF).

In parallel, ISMAI seeks constructive relationships with regional regulators, including the U.S. Food and Drug Administration (FDA) and those operating under the European Union's evolving AI legislative framework, notably the EU AI Act. Because these authorities shape legal requirements for AI's design, deployment, and

oversight, a two-way exchange of expertise is vital. ISMAI can help translate the legislative language of "risk management" and "human oversight" into practical clinical protocols, while regulators, in turn, can guide ISMAI's development of accreditation pathways and educational programmes so that they align with emerging rules and standards. This shared endeavour (merging policy objectives with day-to-day clinical realities) helps reduce the "grey zones" identified in multiple jurisdictions, where AI's unique risks sometimes fall outside conventional medical device classifications.

Extending beyond formal regulatory circles, ISMAI aims to engage with non-governmental organisations and transnational consortia that address equity, capacity-building, and best practices in digital health. Groups such as the Tony Blair Institute, the OECD, and the Global Partnership on AI have published widely on the governance gaps that inhibit safe AI adoption in lower-resource settings. By collaborating with these bodies, ISMAI will direct its efforts toward inclusive strategies, ensuring that smaller-scale facilities, emerging markets, and healthcare systems with limited regulatory infrastructure can benefit from evidence-based AI guidelines. A reciprocal exchange of expertise—where ISMAI's clinician-led approaches inform NGO policy recommendations, and NGO networks amplify ISMAI's frameworks—can fortify the global push for equitable AI distribution and mitigate the risk of widening disparities.

Throughout these alliances, ISMAI maintains a neutral, non-commercial stance, seeking neither to replace local professional societies nor to eclipse governmental mandates. Instead, the Society aspires to serve as a unifying channel that reconciles top-down policy goals with bottom-up clinical realities. In doing so, it embraces shared values with existing actors: transparency, patient autonomy, evidence-based practice, and

context-sensitive implementation. Over time, this approach positions ISMAI as both a reference point for frontline health professionals (offering tangible tools, training, and certification) and as a trusted interlocutor in policy dialogues about ethical and reliable AI usage. By fostering complementarity rather than competition, ISMAI underscores its belief that sustainable progress in AI governance necessitates active, collaborative engagement among clinicians, regulators, global health institutions, and technology innovators alike.

## Adaptation in a Rapidly Evolving Field

ISMAI's strategic roadmap acknowledges that artificial intelligence is not a static technology but an ever-evolving ecosystem shaped by continuous algorithmic updates, changing clinical evidence, and emerging governance frameworks. The regulatory landscape, too, remains in flux: new legislation, such as the EU's AI Act, is expected to refine its definitions and compliance requirements over the coming years, while bodies like the U.S. Food and Drug Administration continue to develop guidance in areas where no explicit laws yet exist. Moreover, diverse regional contexts, spanning advanced economies, rapidly developing markets in Asia, and resource-limited settings in the Global South, amplify the need for flexible approaches that can accommodate differing levels of infrastructural capacity and regulatory maturity.

In light of these uncertainties, ISMAI will operate with an explicitly adaptive mindset. The Society's initiatives (ranging from hospital accreditation to tiered training programmes) will be reviewed annually, drawing on feedback from clinicians, regulatory updates, and new research on patient outcomes. This iterative mechanism allows ISMAI to refine its standards

and recommendations incrementally, ensuring that each revision is informed by the most recent insights into data quality, algorithmic bias, liability precedents, and real-world performance assessments. Regulatory sandboxes, pilot studies, and early adopter experiences will be closely monitored, helping ISMAI to revise its frameworks proactively rather than merely reacting to post-market failures or late-breaking policy mandates.

This commitment to ongoing adaptation also extends to the Society's broader thought leadership. ISMAI will periodically convene working groups, composed of practising clinicians, ethicists, and data scientists, to evaluate new technological trends—for instance, generative AI models in diagnostic imaging or predictive analytics in population health. By maintaining a focused dialogue on these frontiers, the Society can issue timely guidance that harmonises the quest for innovation with the foundational principles of patient safety and clinical autonomy.

Ultimately, ISMAI's approach reflects an ethos of continuous learning, seeking to embed AI into healthcare in a manner that is rigorously evidence-based, equitable, and ethically sound, even as the technological and regulatory landscapes evolve.

## An Open Invitation

ISMAI extends an open invitation to all stakeholders—clinicians, policymakers, researchers, hospital administrators, and patient advocates—to collaborate in forging a future where AI is consistently harnessed for patient benefit, ethical integrity, and system-wide resilience. Grounded in the conviction that technology must serve clinical judgement rather than supersede it, the Society welcomes new members who seek to contribute their expertise in data science, clinical care, legal



analysis, or health administration. Institutions—whether large academic centres or resource-limited hospitals—are encouraged to partner with ISMAI through accreditation programmes or policy initiatives, thus fostering a globally consistent approach to AI readiness and quality assurance.

This invitation also encompasses joint ventures in research, training, and policy advocacy. ISMAI is keen to work with like-minded partners to design innovative educational modules, pilot AI validation protocols, and shape evidence-based governance frameworks that transcend regional boundaries. In addition, the Society's committees and working groups actively welcome fresh perspectives on matters such as algorithmic bias mitigation, liability considerations, or the development of new clinical guidelines. By participating in these avenues, members can shape the Society's evolving body of standards and, in turn, guide the safe and equitable deployment of AI worldwide.

Whether an institution aiming to formalise its AI oversight, a professional body seeking deeper expertise, or an individual clinician driven to ensure ethical usage of cutting-edge diagnostics, every participant enriches ISMAI's collective impact. The Society's aim is to generate a persistent global community that values pragmatism, clinical nuance, and shared responsibility, helping to bridge the gap between policy objectives and real-world patient care. In joining ISMAI, individuals and organisations reaffirm their commitment to ethical innovation, embracing collaborative leadership in an era where data-driven medicine holds immense promise for better patient outcomes and a more responsive healthcare ecosystem.