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PRAXIS
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AI in MedTech:
Revolutionizing Healthcare Through Artificial Intelligence

Knowledge paper

August 2026

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Foreword

Artificial Intelligence is rapidly transforming healthcare worldwide, redefining the way diseases are detected, diagnosed, treated and monitored. For a country like India- with its scale, diversity and growing healthcare needs- AI offers a unique opportunity to strengthen healthcare delivery by improving access, enhancing quality and enabling more efficient utilization of resources.

India has already laid strong foundations for this transformation through initiatives such as the Ayushman Bharat Digital Mission (ABDM), the IndiaAI Mission, the Strategy for AI in Healthcare in India (SAHI) and the Benchmarking Open Data Platform for Health AI (BODH), complemented by the National Medical Devices Policy, 2023, which provides a strategic roadmap for strengthening India's MedTech ecosystem. Together, these initiatives reflect the Government's commitment to fostering innovation, enabling responsible adoption of Artificial Intelligence, strengthening domestic manufacturing and creating a trusted digital health ecosystem. Medical devices represent one of the most promising applications of Artificial Intelligence. By embedding intelligence into diagnostics, imaging systems, monitoring technologies and other medical devices, AI has the potential to augment clinical decision-making, improve productivity of the healthcare workforce and extend quality healthcare to underserved regions. As India aspires to become a global MedTech hub, AI-enabled medical devices can serve as a key driver of innovation, affordable healthcare and export competitiveness.

Realizing this opportunity, however, requires a coordinated ecosystem approach. Robust digital infrastructure, high-quality clinical evidence, predictable regulatory pathways, skilled human resources and collaboration among government, industry, academia and healthcare providers will be essential to translating innovation into large-scale adoption. Building trusted, secure and interoperable data ecosystems will further accelerate the development of AI solutions that are relevant to India's healthcare priorities while ensuring patient privacy and ethical governance. This knowledge paper, "AI in MedTech: Revolutionizing Healthcare Through Artificial Intelligence", provides a timely perspective on the opportunities, challenges and policy considerations surrounding AI-enabled medical technologies. By bringing together global experiences, emerging trends and actionable recommendations, it contributes meaningfully to the ongoing dialogue on strengthening India's MedTech ecosystem.

I commend the efforts of FICCI Medical Devices Committee and Praxis Global Alliance in bringing together this important publication. I am confident that it will serve as a valuable reference for policymakers, industry leaders, innovators, healthcare professionals and other stakeholders working collectively towards building an innovation-driven, globally competitive and patient-centric MedTech ecosystem.

I wish this initiative every success.

Manoj Joshi

Secretary
Department of Pharmaceuticals
Government of India

Foreword
Praxis Global Alliance

Over the past decade, India has strengthened its digital health infrastructure, expanded domestic MedTech manufacturing capabilities and fostered a vibrant innovation ecosystem. As healthcare demand continues to grow, the next phase of progress will depend not only on expanding capacity, but also on deploying technologies that improve productivity, strengthen clinical decision-making and extend access to quality care.

At Praxis Global Alliance, we have been working at the forefront of healthcare and MedTech strategy, partnering with leading healthcare providers, MedTech companies, investors and policymakers on issues spanning market access, commercialization, manufacturing, digital health and AI adoption. Through our proprietary research, industry engagement and advisory work, we have seen first-hand how AI is reshaping every stage of the MedTech value chain- from product design and manufacturing to clinical deployment and post-market performance. This knowledge paper builds on those perspectives, combining Praxis' research with insights from across the healthcare ecosystem.

Developed in partnership with FICCI, the paper brings together perspectives from policymakers, regulators, healthcare providers, MedTech companies, technology innovators and industry experts. Rather than focusing only on technological advances, it examines what will ultimately determine whether AI succeeds at scale: the policy, regulatory, reimbursement and evidence ecosystem required to move AI-enabled MedTech from successful pilots to routine clinical practice.

Our analysis suggests that India possesses what it takes to become a global leader in AI-enabled MedTech. The country combines deep software capabilities, expanding digital public infrastructure, growing manufacturing capacity and one of the world's most diverse clinical environments. The opportunity now is to bring these strengths together through coordinated action across government, industry and healthcare providers to create an ecosystem that enables responsible, scalable and globally competitive AI adoption.

We are grateful to the many policymakers, regulators, healthcare leaders, MedTech companies and technology innovators who generously shared their perspectives during the development of this paper. Their insights have significantly strengthened the analysis and recommendations presented here.

We hope this knowledge paper serves as a valuable resource for policymakers, industry and the broader healthcare community, while contributing to informed dialogue and coordinated action as India shapes the next chapter of AI-enabled healthcare. As this landscape continues to evolve, Praxis Global Alliance remains committed to advancing thought leadership and working alongside stakeholders to help build a globally competitive AI-enabled MedTech ecosystem.

Madhur Singhal

Managing Partner & CEO
Praxis Global Alliance

Foreword
FICCI

Tushar Sharma
Chair, FICCI Medical Device Committee
MD & GM (India & South Asia)
Abbott Healthcare

Bharath Sesha
Co-Chair, FICCI Medical Devices Committee
Managing Director, Philips Indian Subcontinent

Himanshu Baid
Co-Chair, FICCI Medical Devices Committee
Managing Director, Poly Medicure

Bhargav Kotadia
Co-Chair, FICCI Medical Device Committee
MD & CEO, Sahajanand Medical Technologies (SMT)

Healthcare has entered a defining era where Artificial Intelligence (AI) has the potential to fundamentally reshape how care is delivered, experienced, and accessed. As India's medical devices sector stands at a pivotal juncture, the convergence of advanced technologies, manufacturing capabilities, and supportive policy reforms is creating unprecedented opportunities for innovation. AI is emerging as a powerful enabler that can redefine the medical device value chain-from research and product design to manufacturing, quality assurance, regulatory compliance, clinical decision-making, and post-market surveillance.

The increasing demand for intelligent, connected, and patient-centric healthcare solutions calls for a new generation of medical technologies that is accessible, and globally competitive. AI-enabled medical technologies are helping clinicians make informed decisions, supporting earlier diagnosis, enabling personalized treatment, strengthening predictive capabilities, and improving operational efficiency across healthcare settings. Beyond clinical care, AI is also accelerating smart manufacturing, strengthening quality management systems, improving supply chain and enabling data-driven regulatory decisions.

For India, this transformation presents an opportunity to emerge as a global leader in the design, development, manufacturing, and adoption of AI-enabled medical technologies. By leveraging its engineering talent, digital ecosystem, growing startup landscape, and world-class manufacturing capabilities, India can position itself as a trusted partner in delivering affordable, scalable healthcare innovations that address domestic and global healthcare challenges.

The Federation of Indian Chambers of Commerce and Industry (FICCI) has consistently championed policy dialogue and industry collaboration to strengthen India's medical devices ecosystem. This knowledge paper, "AI in MedTech: Revolutionizing Healthcare Through Artificial Intelligence", brings together perspectives from industry leaders, policymakers, healthcare experts, and technology innovators to examine AI's transformative role across the MedTech landscape. It highlights opportunities, regulatory considerations, global best practices, and strategic recommendations to support the responsible integration of AI into India's healthcare ecosystem.

We hope this paper, released during the 9th Edition of India Medical Device 2026, serves as a catalyst for meaningful dialogue, collaborative action, and policy development that will accelerate India's journey towards becoming a global leader in AI-driven medical technology. By embracing AI responsibly and strategically, India can build a medical devices ecosystem that is innovative, globally competitive, patient-centric, and aligned with the vision of Atmanirbhar Bharat and Viksit Bharat 2047.

As we embark on this transformative journey, let us reaffirm our collective commitment to harnessing AI to build smarter medical technologies, strengthen healthcare delivery, foster innovation, and create a resilient MedTech ecosystem that improves lives both in India and across the world.

Glossary of terms

Acronym	Description
ABDM	Ayushman Bharat Digital Mission
ABHA	Ayushman Bharat Health Account
AI	Artificial Intelligence
ANM	Auxiliary Nurse Midwife
API	Application Programming Interface
ASHA	Accredited Social Health Activist
CARPL	Computer Assisted Radiology Platform (CARPL.ai)
CDSCO	Central Drugs Standard Control Organization
CDSS	Clinical Decision Support System
CHC	Community Health Centre
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DoP	Department of Pharmaceuticals
DPDP Act	Digital Personal Data Protection Act
ECG	Electrocardiogram
EHR	Electronic Health Record
EMR	Electronic Medical Record
FDA	Food and Drug Administration (United States)
FHIR	Fast Healthcare Interoperability Resources
FICCI	Federation of Indian Chambers of Commerce and Industry
GMLP	Good Machine Learning Practice
GoI	Government of India
HSA	Health Sciences Authority (Singapore)
ICU	Intensive Care Unit
IHIP	Integrated Health Information Platform
IMDRF	International Medical Device Regulators Forum
INR	Indian Rupee
IRDAI	Insurance Regulatory and Development Authority of India
ISO	International Organization for Standardization
IT	Information Technology
LLM	Large Language Model

Glossary of terms

Acronym	Description
MDR	Medical Device Rules
MedTech	Medical Technology
MHRA	Medicines and Healthcare products Regulatory Agency (United Kingdom)
MoHFW	Ministry of Health and Family Welfare
MRI	Magnetic Resonance Imaging
NHA	National Health Authority
NTEP	National Tuberculosis Elimination Programme
PACS	Picture Archiving and Communication System
PCCP	Predetermined Change Control Plan
PHC	Primary Health Centre
PM-JAY	Pradhan Mantri Jan Arogya Yojana
POC	Point of Care
QMS	Quality Management System
R&D	Research and Development
RWE	Real-World Evidence
SaMD	Software as a Medical Device
TB	Tuberculosis
UHC	Universal Health Coverage
WHO	World Health Organization

Executive summary

Rapid advances in AI, expanding digital public infrastructure, growing clinician acceptance and a vibrant innovation ecosystem, have created a unique opportunity to address some of the country's most pressing healthcare challenges. At the same time, rising disease burden, shortages of healthcare professionals and persistent inequities in access continue to place significant pressure on the health system. AI is therefore emerging not simply as a technology trend, but as a strategic enabler for expanding healthcare capacity and access.

Among the many applications of AI in healthcare, MedTech represents the most immediate and scalable opportunity for India. Medical devices operate at the point of care, continuously generating clinical data that can be enhanced through AI to improve diagnosis, clinical decision-making and workflow efficiency. For India, this is particularly significant because the country's greatest challenge is not simply a shortage of medical devices, but a shortage of specialist expertise. By embedding intelligence directly into devices, AI can enable high-quality screening and clinical decision-making closer to where patients are, improving access without proportionately expanding healthcare infrastructure.

AI-enabled diagnostics is the natural entry point for large-scale adoption, given their reliance on structured data, standardised workflows and measurable clinical outcomes. As these technologies mature, they will evolve from standalone diagnostic tools to connected intelligence platforms supporting integrated, data-driven healthcare delivery.

Despite technological progress and growing stakeholder acceptance, India continues to face an adoption paradox. While AI-enabled MedTech solutions have demonstrated significant promise, few have progressed from successful pilots to clinical deployment. The challenge is no longer proving that AI works- it is creating the ecosystem required for scaled adoption. The paper identifies three interconnected barriers that must be addressed:

- **Data and evidence:** Fragmented health data, limited interoperability and insufficient real-world evidence constrain clinical validation, regulatory approval and post-market monitoring
- **Regulation:** Adaptive AI systems require predictable lifecycle-based regulatory frameworks capable of governing software updates and continuous performance monitoring
- **Reimbursement and procurement:** Current payment and procurement mechanisms rarely recognise the value created by AI-enabled technologies, limiting incentives for provider adoption and continued innovation

Global experience demonstrates that countries which have successfully scaled AI-enabled MedTech have strengthened these ecosystem enablers in parallel. Rather than relying on technological innovation alone, they have combined interoperable digital infrastructure, robust evidence generation, predictable regulation and supportive reimbursement mechanisms.

India has already established many of the foundations required for this transition through initiatives such as the Ayushman Bharat Digital Mission (ABDM), IndiaAI Mission, Strategy for AI in Healthcare in India (SAHI), Benchmarking Open Data Platform for Health AI (BODH) and the evolving Medical Device Software Guidance. Building on these foundations, the paper proposes a coordinated stakeholder action framework focused on strengthening lifecycle regulation, enabling reimbursement, generating India-specific evidence, integrating AI into clinical workflows and fostering collaboration through industry bodies such as FICCI.

India possesses a unique combination of healthcare need, digital public infrastructure, and an increasingly mature innovation ecosystem. If regulation, evidence generation, reimbursement, and procurement evolve together, AI-enabled MedTech can move to become a foundational layer of healthcare delivery: improving healthcare access and strengthening the productivity of India's healthcare system. The opportunity is not simply to adopt AI, but to establish India as a global leader in the responsible development and deployment of AI-enabled MedTech.

India has laid a strong foundation for digital health through the Ayushman Bharat Digital Mission (ABDM). The next logical step would be to build a robust, anonymised and consent-based national health data repository that can be made available for research and innovation. Access to high-quality, diverse and authentic datasets is critical for developing, validating and continuously improving AI models. Such an approach would not only accelerate indigenous AI innovation in MedTech but also enhance the accuracy, reliability and global competitiveness of AI-enabled healthcare solutions developed in India.

-Aman Sharma, Joint Secretary (Medical Devices)
Department of Pharmaceuticals, Government of India

01

The moment and the mandate: AI in India

India's healthcare system is undergoing a period of rapid transformation, driven by expanding digital infrastructure, and accelerating technological innovation. At the same time, a growing disease burden, shortages of healthcare professionals and persistent access inequities continue to place significant pressure on the health system. Advances in AI, combined with digital public infrastructure and increasing clinician acceptance, create an opportunity to rethink how healthcare is delivered. AI is therefore no longer simply a technology trend; it is emerging as a necessary enabler for expanding healthcare capacity and improving access at scale.

1.1 Supply-demand gap

Scale of unmet healthcare demand in India

India's healthcare demand is expected to rise significantly over the coming decade, driven by demographic change, epidemiological transition and increasing healthcare utilisation. A population of over 1.4 billion, rising life expectancy and a rapidly ageing population are increasing the need for healthcare services across the care continuum. At the same time, non-communicable diseases (NCDs) such as cardiovascular diseases, diabetes and cancer now account for over 65% of deaths in India, shifting healthcare demand from episodic treatment towards continuous screening, diagnosis, monitoring and long-term disease management.

These trends are increasing both the volume and complexity of healthcare demand. Patients are living longer with chronic conditions, requiring repeated interactions with the healthcare system, while growing awareness, improved diagnostics and expanding insurance coverage are further increasing healthcare utilisation. These structural shifts are expected to place sustained pressure on India's healthcare system across primary, secondary and tertiary care settings.

The future of healthcare will be shaped by how seamlessly AI is integrated with data, technology and clinical expertise across the patient journey. As these capabilities continue to evolve, it will help create a healthcare ecosystem that is more connected, proactive, and resilient. Our collective focus should be on ensuring these innovations translate into measurable value for patients and health systems alike.

-Bharath Sesha, Philips

Exhibit A: India's rising healthcare needs

~1.47B
India's projected population in 2026, increasing overall healthcare demand across all settings

315M
People living with hypertension (2021), driving sustained demand for chronic disease management

230M+
Projected population aged 60+ by 2036, increasing demand for chronic and geriatric care

101M
People living with diabetes (2021), increasing demand for monitoring, and complication management

~72 years
Average life expectancy, increasing healthcare utilization and long-term disease management

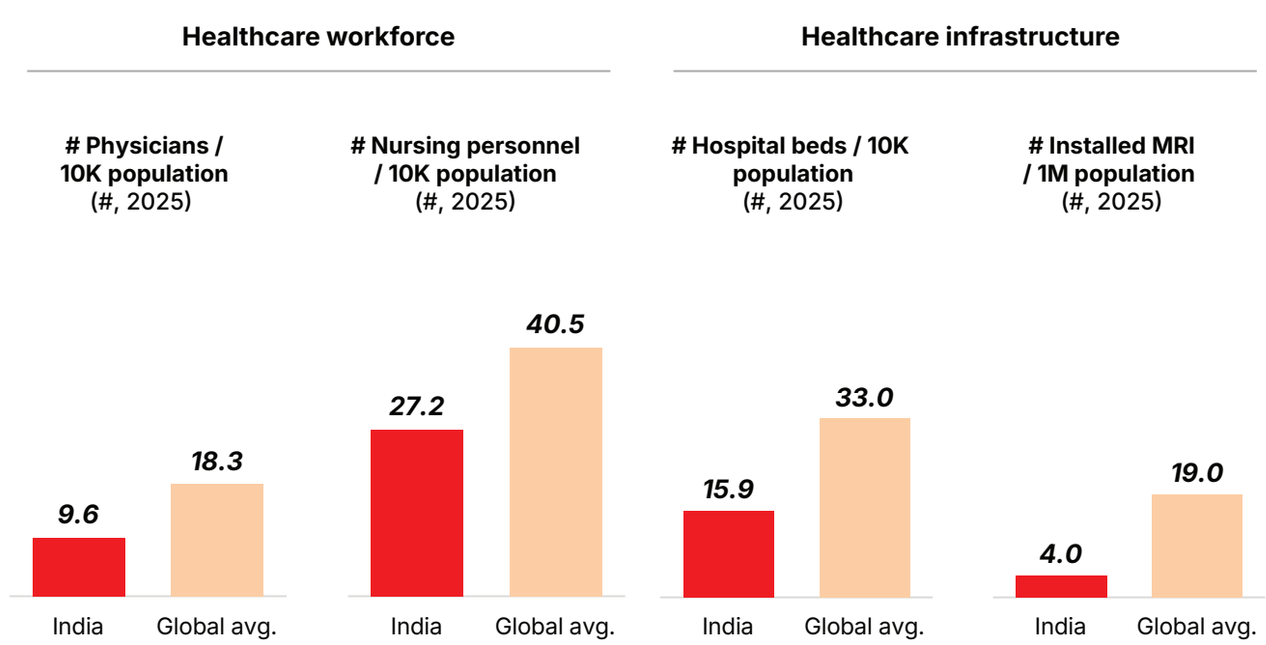
>65%
Share of deaths due to NCDs (2021), reflecting India's growing chronic disease burden

Source(s): UNFPA, ICMR-INDIAB study, WHO, Praxis analysis

Healthcare supply gap

India's healthcare capacity continues to lag the growing demand for care. While the country has expanded medical education and healthcare infrastructure over the past decade, shortages persist across the healthcare delivery ecosystem-including doctors, nurses, hospital beds, and critical medical equipment. According to the World Health Organization (WHO), health workforce shortages remain a major constraint to delivering essential health services. India's hospital bed density also remains below that of many developing economies. As demand continues to rise, expansion in healthcare capacity is struggling to keep pace. Closing this supply gap will require new models of healthcare delivery that increase the effective capacity of the existing system, enabling scarce resources to serve a larger patient population.

Exhibit B: India's healthcare supply constraints



Note(s): Nursing personnel includes nurses and midwives
Source(s): WHO, PRS India, Global economy, Medical buyer, Praxis Health Cloud™, Praxis analysis

India's biggest opportunity is not replacing clinicians but multiplying specialist capacity at population scale.

-Tushar Sharma, Abbott

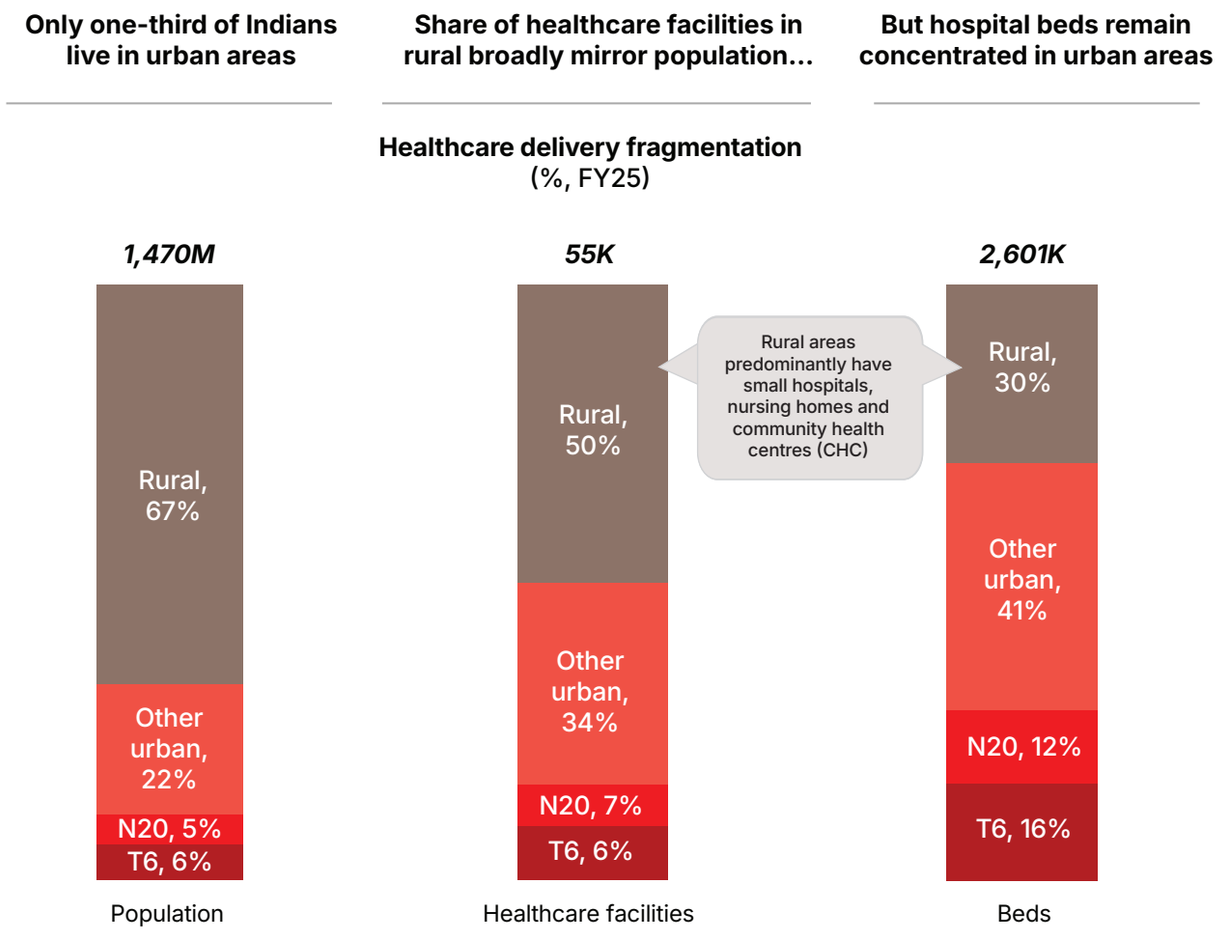
Access disparity in healthcare

Healthcare access in India remains highly unequal across regions and income segments. While over 65% of India's population resides outside Metro / Tier 1 cities, specialist infrastructure, diagnostic capacity and healthcare professionals continue to be concentrated in metropolitan centres. As Exhibit C illustrates, although healthcare facilities are distributed and broadly mirror population distribution, hospital bed capacity remains disproportionately concentrated in urban areas, reflecting the predominance of smaller primary and secondary facilities in rural India

Patients frequently travel long distances to access specialized care, increasing out-of-pocket costs and delaying treatment. The result is a healthcare system where need is greatest precisely where access remains weakest. There's also a significant proportion of the population that remains outside comprehensive healthcare's financial protection - too affluent to qualify for public schemes yet underserved by private healthcare- this "missing middle" also creates a persistent gap in access to timely diagnosis and treatment.

These structural disparities highlight the need for scalable solutions that can extend specialist expertise, strengthen diagnostic capacity and improve the productivity of the existing healthcare workforce.

Exhibit C: Skewed distribution of healthcare infrastructure in India



Note(s): T6 – Top 6 metro cities, N20 – Next 20 cities by population; NH – Nursing homes, MPH – Medium private hospitals, SDH – Sub-district hospital, DH – District hospital, LPH – Large private hospitals, MI - Medical institutions, Healthcare facilities do not include PHCs
Source(s): Praxis Health Cloud™, Praxis analysis

1.2 AI technology activity in India

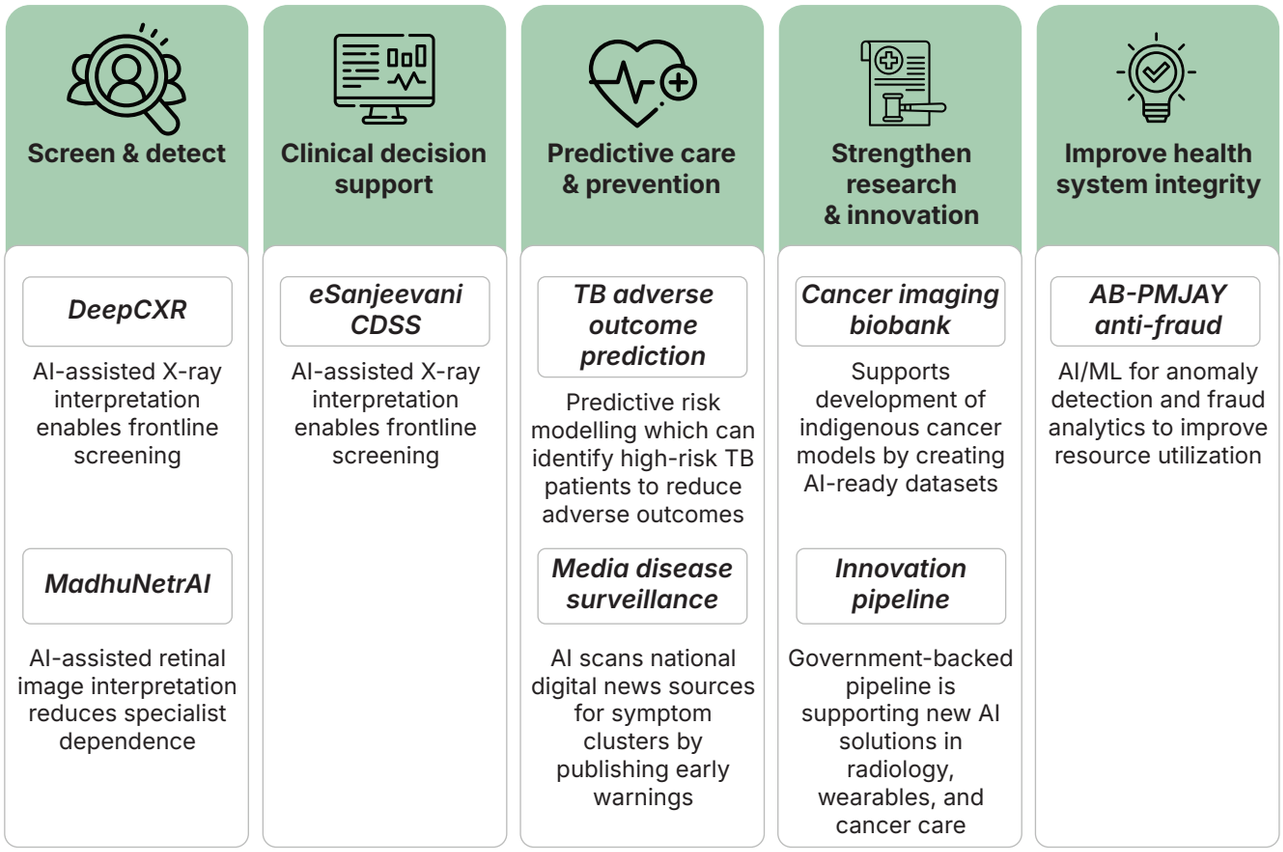
AI evolving from a point solution to a healthcare operating layer

Among the solutions emerging to address these healthcare challenges, artificial intelligence has evolved from a niche innovation to an increasingly integral component of healthcare delivery. In India, AI is no longer confined to isolated pilots in diagnostics or hospital automation; it is increasingly being embedded into routine healthcare workflows, including teleconsultation, clinical decision support, research and administrative processes. Government-led initiatives illustrate how AI is being deployed across the public health continuum rather than as standalone applications (Exhibit D).

This evolution is also supported by India's expanding digital health infrastructure, particularly the Ayushman Bharat Digital Mission (ABDM), which enables digital health identities (ABHA), consent-based health information exchange and interoperable health records. However, digital public infrastructure should not be equated with AI capability. ABDM does not directly enable large-scale AI model development. Instead, it provides the interoperability layer required for AI applications that depend on structured, consented and longitudinal patient data. Today, the most practical use cases of ABDM include AI-assisted clinical decision support and care coordination. As interoperability matures and more longitudinal health records become available, the same infrastructure could support broader system-level applications, including privacy-preserving validation of AI models using federated learning approaches.

Thus, India is building the digital foundations necessary to move AI from standalone applications towards becoming an integrated layer within healthcare delivery.

Exhibit D: Government-led AI deployment across the healthcare continuum



Source(s): PIB, MoHFW, Praxis analysis

What is India building vs. adopting in AI healthcare?

India's healthcare AI ecosystem is evolving along two complementary trajectories. On one hand, Indian innovators are developing AI solutions tailored to the country's unique disease burden, healthcare delivery challenges and resource constraints. On the other, healthcare providers are rapidly adopting globally developed AI technologies to enhance diagnostics, clinical workflows and patient care. This combination of indigenous innovation and selective technology adoption is positioning India as both an important source of healthcare AI innovation and one of the world's largest deployment markets.

India has emerged as a leading developer of AI solutions for high-volume, resource-constrained healthcare settings which are designed not only for the Indian market but also for export and deployment in other health systems. Homegrown companies such as Qure.ai and DeepTek have developed AI algorithms that assist radiologists in detecting conditions such as tuberculosis, stroke and lung abnormalities from medical images, while Niramai applies thermal imaging and machine learning for non-invasive breast cancer screening. Beyond diagnostics, Indian health-tech companies are increasingly applying AI to clinical documentation, hospital operations (e.g. Eka Care), disease surveillance, virtual care and population health management, reflecting a shift towards AI-enabled healthcare delivery rather than standalone diagnostic tools.

India is also beginning to build the digital infrastructure needed to deploy AI at scale. While clinically validated AI algorithms are becoming increasingly available, healthcare providers continue to face challenges integrating, validating and governing multiple AI applications across clinical workflows. Emerging AI deployment platforms such as CARPL.ai illustrate the importance of an interoperability layer that enables hospitals to evaluate, deploy and monitor AI applications from multiple vendors through a common infrastructure. By simplifying integration, reducing implementation complexity and supporting lifecycle governance, such platforms are helping translate AI innovation into routine clinical practice.

At the same time, India's healthcare providers are increasingly adopting AI-enabled technologies developed by global MedTech and digital health companies. Large hospital networks are also deploying AI across operational workflows, including patient triage, capacity planning, clinical documentation and revenue cycle management, demonstrating that AI adoption extends well beyond diagnostic devices.

These trends highlight an important characteristic of India's healthcare AI ecosystem. Rather than following a linear path from technology import to domestic innovation, India is simultaneously building globally competitive AI solutions in areas aligned with its public health priorities while adopting international technologies where they complement existing clinical capabilities.

Healthcare innovation creates value only when it reaches the last mile. The real measure of AI is not how sophisticated the algorithm is, but how many more patients receive timely, high-quality care because of it.

-Madhur Singhal, Praxis Global Alliance

1.3 Acceptance of AI in India

The healthcare ecosystem is increasingly embracing AI

AI adoption in Indian healthcare is moving beyond proof-of-concept towards operational deployment. Healthcare providers, MedTech companies and life sciences organisations are increasingly investing in AI, identifying enterprise use cases and integrating AI into selected clinical and operational workflows. This shift is important because it signals that AI is increasingly being treated as an operational capability rather than a purely experimental technology.

At the same time, the evidence suggests that organisational commitment remains uneven in depth. While leading organisations are scaling AI deployments, overall AI maturity remains relatively low due to limited budget allocation, fragmented data infrastructure and evolving governance frameworks. Enterprise-wide adoption is still constrained by inconsistent leadership commitment, varying organisational readiness and challenges in translating pilot projects into scaled implementation. Accordingly, the relevant interpretation is not that India has fully operationalised AI in healthcare, but that the sector has crossed an important threshold from curiosity to institutional intent.

This unevenness is analytically important because it suggests that "acceptance" should not be understood as a uniform market characteristic. Rather, different parts of the ecosystem are progressing according to their own data maturity, workflow structure, regulatory exposure and capital intensity. The practical implication is that AI in Indian healthcare is likely to diffuse asymmetrically: first in domains with clearer business cases, richer data environments and more structured workflows, and later in settings where infrastructure and operating models are more fragmented.

Exhibit E: AI adoption across the healthcare ecosystem

Pharma & Life Sciences

- **Drug discovery & target identification:** Using ML to analyze biological data / drug ingredient library
- **Clinical trials & patient recruitment:** AI can identify optimal patient populations and simulate trial outcomes
- **Manufacturing optimisation:** AI to enhance yield, quality and efficiency
- **Pharmacovigilance:** NLP / ML to identify trends, potential risks, and optimize treatment protocols

MedTech

- **Product design & virtual prototyping:** AI-driven simulations to test new designs in-silico
- **AI-enabled diagnostics, imaging & robotics:** AI improves diagnostic accuracy and interpretation
- **Remote monitoring & smart devices:** Enables continuous care
- **Post-market surveillance:** NLP / ML based analytics to identify risks
- **Predictive maintenance:** Intelligent systems reduce downtime

Healthcare providers

- **Administrative automation:** AI-powered HMIS / LIS can improve workflow
- **Clinical decision support:** AI can provide real-time support based on patient data and clinical guidelines
- **Follow-up automation:** AI virtual assistants can provide follow-up care instructions and answer queries
- **Readmission-risk prediction:** AI can identify patients at risk of readmission and suggest preventive measures

AI-enabled outcomes

- *Faster innovation*
- *Better clinical accuracy*
- *Higher workforce productivity*
- *Continuous monitoring and safer care*

Source(s): Praxis analysis

Growing clinician and patient trust is supporting AI adoption

However, large-scale adoption will ultimately depend on whether clinicians and patients trust AI as part of routine care. According to the Philips Future Health Index 2025, 76% of Indian healthcare professionals believe AI can improve patient outcomes, 80% believe AI can automate repetitive administrative tasks and 75% believe AI-supported training can strengthen the capabilities of less experienced healthcare workers. While concerns regarding reliability and workflow integration remain, the trajectory suggests clinicians increasingly view AI as an augmentation tool improving productivity, extending specialist expertise and expanding healthcare capacity.

Patient acceptance is similarly evolving. India is among the most AI-ready healthcare markets in Asia-Pacific, with 78% of consumers reporting comfort using AI for at least one healthcare activity, according to industry publications. Patients are increasingly willing to engage with AI for symptom assessment, information access, screening and navigation, provided clinicians remain central to diagnosis and treatment decisions. Across studies, patients consistently express greater willingness to adopt AI when it complements physicians, highlighting the importance of explainability, privacy and clinician oversight in future AI deployments

Policy signals confirming structural trend

Growing adoption of AI is being reinforced by an evolving policy and governance framework. Over the past five years, the Government of India has progressively built the digital infrastructure, innovation ecosystem and regulatory foundations needed to support responsible AI deployment at scale (Exhibit F). Rather than treating AI as a series of standalone pilots, recent initiatives indicate a shift towards institutionalising AI across the healthcare ecosystem.

The IndiaAI Mission provides national support for AI innovation through investments in compute infrastructure, datasets, application development and responsible AI. Within healthcare, the ICMR Ethical Guidelines for Application of AI in Biomedical Research and Healthcare (2023) establish principles for trustworthy AI, while MeitY's AI Governance Guidelines provide broader direction on responsible AI deployment.

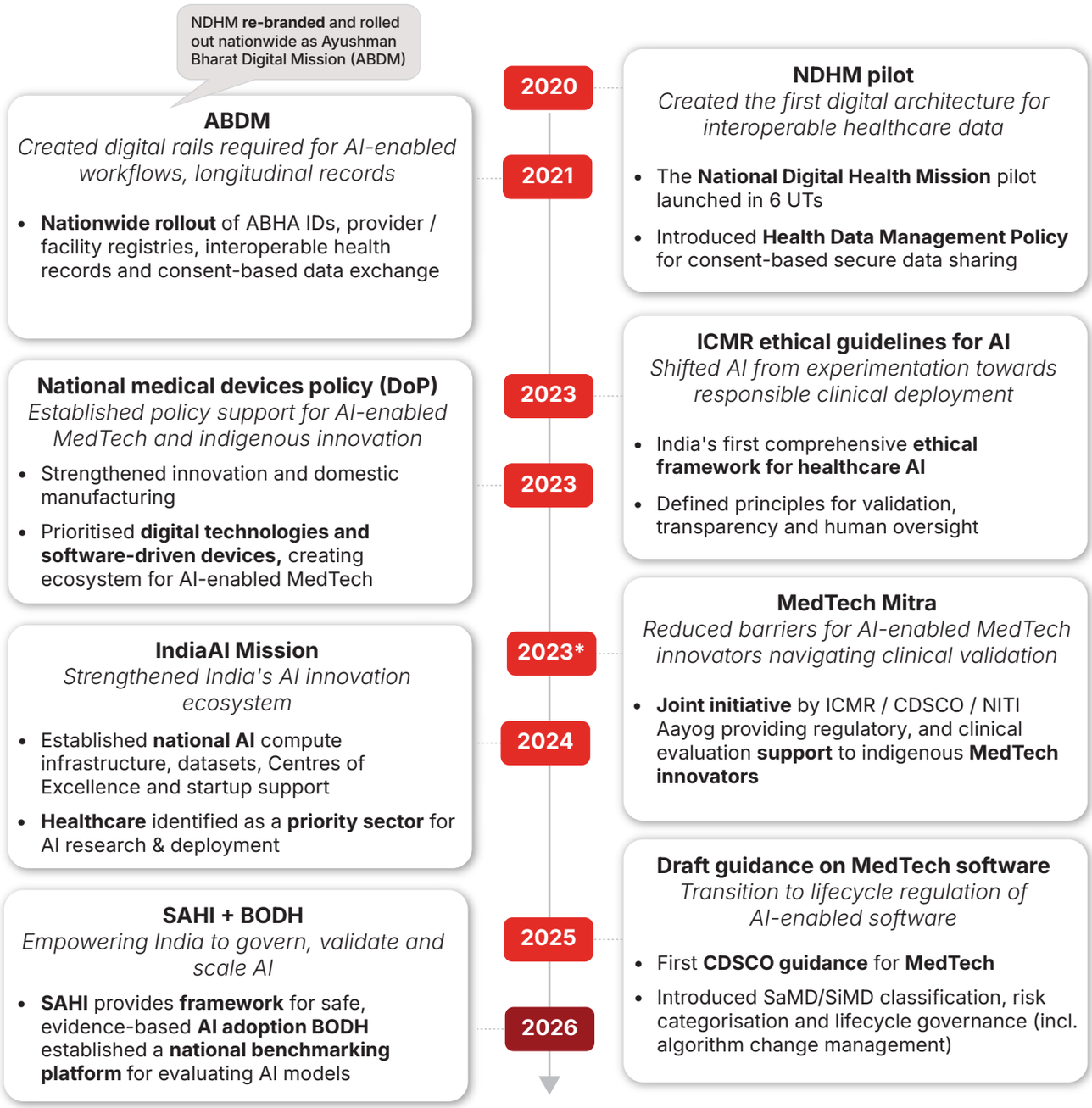
More recently, the Ministry of Health and Family Welfare launched the Strategy for AI in Healthcare in India (SAHI) and the Benchmarking Open Data Platform for Health AI (BODH) to strengthen evidence generation, benchmarking and validation of healthcare AI solutions. These initiatives are significant because they begin to address a central constraint in health AI adoption: the absence of trusted mechanisms for evaluating performance, safety and generalisability before widespread clinical use. They also complement existing data-governance and consent frameworks under ABDM and broader ethical safeguards referenced by the government, including privacy, anonymisation, human oversight and accountability.

These developments signal a long-term policy commitment to integrating AI into India's healthcare system through coordinated investments in governance, evidence generation and regulatory oversight rather than isolated technology pilots.

AI is also helping reduce administrative burden and optimise workflows, enabling clinicians to dedicate more time to direct patient care.

-Bharath Sesha, Philips

Exhibit F: Key policy milestones enabling AI adoption in Indian healthcare (2020-26)



Note(s): ABHA: Ayushman Bharat Health Account; SAHI: Strategy for AI in Healthcare in India; BODH: Benchmarking Open Data Platform for Health AI; MedTech Mitra was launched on Dec 25, 2023
Source(s): PIB, Government websites- ICMR, DoP, NHA, ABDM, Praxis analysis

Level of readiness

Taken together, India's healthcare ecosystem exhibits the three prerequisites for AI adoption: structural healthcare need, technological readiness and growing stakeholder acceptance. The next phase of India's AI journey will depend less on advancing AI capabilities and more on identifying where AI can create the greatest healthcare impact before implementing nationally. This raises the next critical question: where is the right implementation layer for AI to deliver meaningful improvements in healthcare access, productivity and quality?

02

MedTech
as the emerging frontier

Artificial intelligence has applications across the healthcare value chain: from drug discovery and hospital operations to population health management. However, MedTech represents the most immediate and scalable opportunity for AI in India. Because, unlike pharmaceuticals, which deliver therapeutic value after diagnosis, or health IT systems that primarily manage information, MedTech continuously generates structured, multimodal clinical data while remaining embedded within routine care delivery. By embedding intelligence directly into medical devices, AI can extend specialist expertise beyond tertiary hospitals, improve productivity of scarce clinical resources and enable high-quality care closer to patients.

2.1 Why MedTech is the right lens

MedTech - healthcare's most AI-ready layer

Medical devices sit directly at the point where clinical decisions are made. Physiological signals like medical images, ECGs, laboratory results are first captured through a medical device before being interpreted by a clinician. This makes MedTech the primary interface between clinical data and medical decision-making.

Across the MedTech value chain - from diagnostics and patient monitoring to therapeutic devices, surgical robotics, implants and critical care equipment- AI is transforming devices from standalone hardware into intelligent systems capable of sensing, predicting and supporting clinical decision-making. These characteristics make it uniquely suited for AI, allowing algorithms to analyse data in real time, augment clinical interpretation and support decision-making at the point of care.

AI's impact, however, extends well beyond clinical deployment. Across the MedTech product lifecycle, manufacturers are already using AI to accelerate engineering design, product development, simulation, testing, regulatory documentation and manufacturing automation. These applications face fewer regulatory and clinical adoption barriers than AI embedded in patient-facing devices, allowing companies to realise productivity gains and shorten innovation cycles even before AI-enabled products reach routine clinical practice.

For India, this opportunity is particularly significant. The country's healthcare challenge is not simply a shortage of devices, but a shortage of specialist interpretation. Embedding intelligence within devices enables existing infrastructure to deliver greater clinical value without proportionately increasing specialist capacity.

> *AI's impact extends well beyond clinical decision support. It is fundamentally changing how medical devices are **designed, engineered, validated and manufactured**, with the potential to dramatically shorten innovation cycles.*
>
> ***-Bhargav Kotadia, SMT***

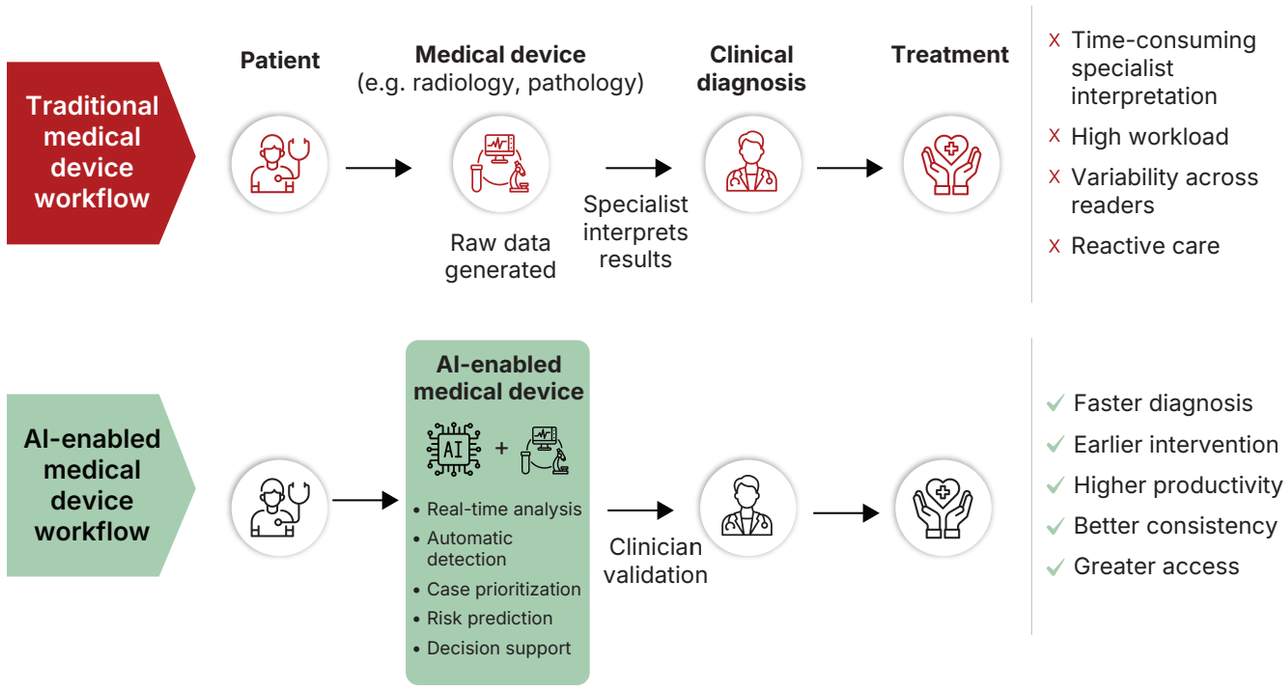
AI transforms MedTech from passive hardware into adaptive platforms

AI fundamentally changes the role of medical devices by shifting them from data acquisition tools to real-time clinical decision-support systems. Traditionally, devices captured measurements that required specialist interpretation. AI now enables devices to automatically detect abnormalities, prioritise critical cases, guide operators during examinations and recommend clinical actions, embedding expert knowledge directly into the device.

This transformation is visible across the MedTech ecosystem. AI-assisted imaging systems can automatically identify suspected lung nodules or intracranial haemorrhage; AI-enabled ECG platforms detect arrhythmias in real time; pathology algorithms prioritise suspicious slides; smart ultrasound systems provide scan guidance that enables less experienced operators to acquire diagnostic-quality images; and continuous patient monitoring systems predict clinical deterioration before conventional thresholds are crossed. Increasingly, medical devices are evolving from standalone hardware into intelligent platforms that sense, interpret and support clinical care.

> *AI can help a relatively younger cardiologist derive the same kind of insights that a much more experienced clinician would have, making high-quality diagnostics more democratised.*
>
> ***-Bhargav Kotadia, SMT***

Exhibit G: AI's value creation potential in MedTech



Source(s): Praxis analysis

AI-enabled diagnostics as MedTech's first large-scale application

Among all MedTech segments, diagnostics has emerged as the earliest and most scalable application of AI. Diagnostic workflows combine four characteristics that make them particularly well suited for AI deployment: they generate large volumes of structured digital data, follow standardised workflows, produce measurable clinical outcomes and address persistent shortages of specialist expertise. Globally, AI is already being embedded across radiology and pathology to improve detection accuracy, prioritise cases and reduce turnaround times.

India is witnessing a similar transition, but scaling AI-enabled diagnostics requires solutions designed for local healthcare realities rather than adaptations of products developed for high-income markets. Devices must function in low-connectivity environments, support general physicians and nurses alongside specialists, remain usable despite infrastructure constraints and be affordable by design. These characteristics are likely to differentiate successful AI-enabled diagnostic products in India from those designed primarily for developed healthcare systems.

Diagnostics has also emerged as the natural first application because AI primarily augments clinician interpretation rather than directly delivering therapy. Compared with therapeutic interventions, diagnostic applications present lower implementation complexity and lower direct clinical risk, allowing regulators and providers to build confidence in AI-assisted decision-making. More advanced therapeutic applications, particularly AI-enabled robotic interventions, will depend not only on algorithmic advances but also on significant progress in robotic hardware, procedural workflows and cost economics.

For these reasons, diagnostics represents the natural entry point for AI-enabled MedTech - not only because the technology is mature, but because its clinical impact is measurable, scalable and closely aligned with India's healthcare priorities.

The future of healthcare relies on collaboration between human expertise and artificial intelligence to transform possibilities into reality. We are entering a new era of AI, one that goes beyond generating information to enabling intelligent action and real-world outcomes. For healthcare in India, this presents a transformational opportunity where AI can help make care more accessible, affordable, and personalized - for India and for the world. Every breakthrough in AI for healthcare will come with a promise of quality care, at scale.

-Chaitanya Sarawate, GE HealthCare

2.2 The distributed care opportunity

AI-embedded MedTech decentralizes care

If diagnostics is the first scalable AI application, its greatest impact lies in extending specialist expertise beyond tertiary hospitals. India's greatest healthcare challenge is not the absence of medical technology but the concentration of expertise. Radiologists, pathologists, cardiologists and other specialists remain clustered in urban tertiary hospitals, while much of the population receives care through primary health centres, community health centres and district hospitals. Expanding tertiary-level specialist capacity to every healthcare facility would require substantial investments in advanced equipment, specialist workforce and supporting infrastructure- an approach that is neither economically feasible nor operationally sustainable.

Rather than replacing this referral architecture, AI-enabled MedTech strengthens it. By embedding intelligence within diagnostic devices, AI enables frontline facilities to perform higher-quality screening, preliminary interpretation and risk stratification, allowing patients requiring specialist care to be identified earlier and referred more appropriately. Clinical decision-making remains under physician oversight, but AI reduces dependence on immediate specialist availability for routine screening and triage. This model has the potential to improve access across multiple underserved populations, e.g., the missing middle that remain underserved despite existing public and private healthcare models, where delayed diagnosis is often driven by limited affordability / access rather than lack of demand.

Beyond point-of-care diagnosis, AI is also enabling new models of connected care. Tele-ICU networks and centralised command centres allow specialists to remotely supervise patients across multiple facilities, extending scarce expertise beyond tertiary hospitals. By enabling continuous remote oversight, connected care models can reduce unnecessary referrals, enable earlier clinical intervention and improve utilisation of specialist expertise across geographies.

Government's AI deployments today, which are concentrated in public health programmes, illustrate this model in practice. As of December 2025, the MadhuNetrAI programme had screened over 7,100 patients across 38 healthcare facilities, enabling AI-assisted diabetic retinopathy screening without requiring an ophthalmologist at every site. Similar AI-enabled approaches are being deployed for tuberculosis screening and community-based diagnostics, demonstrating how AI can expand specialist reach while improving equity in healthcare access.

> *The greatest value will come from AI-powered screening and diagnosis that brings specialist-level support closer to the patient, particularly in primary and secondary care settings.*
>
> ***-Tushar Sharma, Abbott***

Point-of-care intelligence changes the economics of healthcare delivery

Traditional diagnostic pathways rely on centralised infrastructure: patients visit peripheral facilities, samples or images are transmitted to urban centres, specialists interpret results and reports are subsequently returned to the point of care. While clinically effective, this model introduces delays, increases costs and often results in patient attrition before treatment initiation.

Point-of-care intelligence unlocks faster local diagnosis, triage and treatment initiation in settings where distance, specialist scarcity and laboratory access delay care. AI-enabled point-of-care devices compress this pathway by generating actionable clinical insights directly where patients receive care. Instead of simply capturing data, AI-enabled devices interpret findings, stratify patient risk and recommend referral decisions within minutes. This reduces turnaround times, improves utilisation of scarce specialist capacity and enables earlier intervention, particularly in resource-constrained settings. Thus, the centralized diagnostic models which would have 24–72-hour turnarounds are replaced by AI-at-the-device which compresses this turnaround time to minutes; and enables non-specialist operators (ANMs, ASHA workers, pharmacists) to perform screening.

Importantly, AI is likely to deliver the greatest value in India's large public hospitals and district referral centres, where high patient volumes, digital infrastructure and specialist oversight already exist. These facilities can function as hubs within a connected healthcare network, supporting AI-assisted screening at peripheral facilities through telemedicine, teleradiology and interoperable health records. This hub-and-spoke model aligns with WHO recommendations for expanding access to diagnostics through near point-of-care technologies, digital referral systems and remote specialist support rather than replicating advanced diagnostic infrastructure across every facility.

As AI-enabled MedTech becomes integrated with India's digital health infrastructure, including ABDM, diagnostic outputs can be securely linked to longitudinal electronic health records, creating a continuous data loop that supports follow-up care, disease surveillance and future AI model improvement. The result is a shift from episodic diagnosis toward connected, data-driven healthcare delivery.

If AI-enabled devices are designed only for well-connected tertiary hospitals, they will fail to scale; India needs products built for edge inference, offline use, and non-specialist workflows.

-Himanshu Baid, Poly Medicure

03

Crossing the valley of death: **The AI adoption paradox**

AI-enabled MedTech represents one of the most scalable opportunities to improve healthcare access and productivity in India. Yet despite strong clinical promise, widespread adoption remains elusive. India has many of the ingredients required to become a global leader in AI-enabled healthcare. However, relatively few AI-enabled MedTech solutions have progressed from successful pilots to routine healthcare delivery. This is because AI-enabled MedTech requires two complementary ecosystems: one that enables the development of AI through access to representative, consented data and research infrastructure, and another that enables deployment through regulation, reimbursement, procurement and provider adoption. Progress in one without the other will not translate into large-scale clinical impact.

The challenge is no longer proving that AI works. It is building the data, regulatory, and reimbursement infrastructure required for AI to scale from innovation to standard of care.

3.1 The gap between intent and reality

India has solved innovation, but not adoption

Adoption remains fragmented because technological innovation has outpaced readiness in regulation, reimbursement, and interoperable deployment, so many AI MedTech tools can pilot successfully without clearing the path to scaled purchase and routine use.

Also, deployment remains concentrated within large private hospitals, organised diagnostic chains and a few public-sector pilots. The healthcare facilities where AI could create the greatest impact- district hospitals and public health systems, continue to face constraints in procurement, digital maturity, specialist availability and funding. Consequently, India has successfully built AI solutions but has yet to establish the enabling ecosystem required for nationwide deployment.

Why AI-enabled MedTech pilots fail to scale

The pattern of adoption is remarkably consistent across AI-enabled MedTech. AI solutions frequently demonstrate strong diagnostic performance and workflow improvements during pilots, yet relatively few progress to routine deployment. The challenge is not technical validation alone, but the absence of an ecosystem that supports commercial adoption.

Three interdependent gaps explain why many AI-enabled MedTech solutions fail to cross the "valley of death":

- Insufficient real-world evidence, driven by fragmented, non-interoperable datasets and limited post-market performance monitoring
- Regulatory uncertainty around AI-specific governance, lifecycle management and software updates
- Limited adoption pathways, including reimbursement mechanisms and procurement frameworks that enable hospitals to routinely deploy AI-enabled devices

Government initiatives such as MedTech Mitra have begun addressing the early stages of this journey. Launched in December 2023, the programme has supported innovators by facilitating access to regulatory guidance, clinical validation partners and testing infrastructure. However, its current focus is primarily on helping innovators navigate product development and regulatory processes. Broader ecosystem challenges - including procurement frameworks, reimbursement pathways, large-scale clinical evidence generation and post-market adoption, remain largely outside its scope. Scaling AI-enabled MedTech ultimately requires broader reforms across regulation, commercialization and real-world evidence generation that extend beyond support for individual innovators.

The real opportunity lies in bringing India's strengths together while balancing what I would describe as the healthcare triangle - innovation, advanced manufacturing and patient-centered health outcomes.

-Mr. Bharath Sesha, Philips

3.2 Data & evidence gap

AI-enabled MedTech requires AI-ready data ecosystems

Unlike conventional medical devices, AI-enabled MedTech depends on high-quality clinical data throughout its lifecycle- from development and clinical validation to deployment, post-market monitoring and continuous improvement. Developers require large, representative datasets to train algorithms, validate clinical performance and demonstrate safety before regulatory approval. Following deployment, these devices continue to rely on real-world evidence to monitor performance, detect model drift, validate software updates and ensure safety as patient populations and clinical practice evolve.

Consequently, the challenge is not simply access to healthcare data, but the ability to continuously generate high-quality, longitudinal and representative evidence throughout the product lifecycle. Recognising this, leading regulators such as the International Medical Device Regulators Forum (IMDRF), the US Food and Drug Administration (FDA), and the UK Medicines and Healthcare products Regulatory Agency (MHRA) increasingly position real-world evidence and continuous performance monitoring as core components of AI-enabled medical device governance.

India has made significant progress in building the digital foundations required for this transition. The Ayushman Bharat Digital Mission (ABDM) has established a common framework for interoperable health records and consent-based data exchange, while the National Federated Learning Platform- being developed by the National Health Authority (NHA) and IIT Kanpur- aims to enable privacy-preserving AI model development using distributed clinical datasets without requiring patient data to leave hospital systems.

However, digital infrastructure alone does not create AI-ready evidence. Clinical validation and regulatory approval depend on access to multicentre, longitudinal and clinically representative datasets that reflect India's diverse demographics, disease profiles, healthcare settings and device-generated data. This is particularly important because AI models developed predominantly on Western datasets may not generalise reliably to Indian populations or clinical workflows. But building high-quality India-based evidence requires interoperable data ecosystems where imaging systems, laboratory platforms, medical devices and electronic medical records can exchange standardized data across institutions rather than operating in isolated silos.

Today, imaging data often resides within isolated PACS (Picture Archiving and Communication System), laboratory information systems lack common standards across providers, and electronic medical record adoption remains uneven outside large hospitals. As a result, AI developers struggle to generate robust real-world evidence required by regulators, providers and payers before large-scale procurement.

Deep provider integration and routine availability of sufficiently standardised datasets for AI training, validation and workflow-grade deployment across the system are the next steps to ensure meaningful AI integration especially for next generation of medical devices.

From a product development perspective, the priority is enabling access to large, consented datasets that represent India's diverse population. That is essential for building impactful AI models... And we don't need to reinvent the wheel. We can adapt globally developed AI models, but they must be evaluated and continuously improved using Indian data.

-Chaitanya Sarawate, GE HealthCare

Exhibit H: Data requirements across the AI-enabled MedTech lifecycle

Needs

- **Representative datasets:** Models to be trained on diverse Indian populations to improve generalizability
- **High-quality annotations:** Clinician-validated labelling improve model accuracy and reduce bias
- **Interoperability:** Standardized data formats (HL7 FHIR, DICOM, SNOMED CT and LOINC) enable aggregation of data across institutions
- **Indian clinical validation:** Demonstrate safety and effectiveness on Indian populations across geographies, and care settings to minimize bias
- **Clinical governance:** Independent clinical oversight should verify intended use & safety
- **Transparency & explainability:** Mandatory labelling of intended use, performance, limitations, and bias
- **Multi-system integration:** Integrate seamlessly across EMRs, LIS, RIS and other medical devices
- **Workflow integration:** Embed AI within EMRs/PACS instead of standalone applications
- **Cybersecurity:** Adopt software development and IEC 81001-5-1 practices to protect connected devices and patient data
- **RWE:** Continuously assess clinical outcomes after deployment
- **Model drift monitoring:** Detect performance degradation as patient populations or clinical practices evolve
- **Controlled updates:** Implement validated software updates through predefined change-manage ment protocols
- **Federated learning:** Improve AI models across institutions without sharing identifiable patient data
- **Algorithm change management:** Govern model updates through predefined regulatory and validation pathways
- **Privacy-first governance:** Ensure DPDP compliance, consent management and secure data access throughout the AI lifecycle

India today

- Fragmented hospital data
- Variable data quality
- No AI-specific validation framework
- Proprietary systems
- Limited interoperability
- Limited lifecycle regulation and monitoring
- Regulatory uncertainty
- Limited implementation guidance

Note(s): HL7 FHIR – Health Level Seven Fast Healthcare Interoperability Resources: standard for exchanging electronic health records; DICOM – Digital Imaging and Communications in Medicine: standard for storing and exchanging medical images; SNOMED CT – Systematized Nomenclature of Medicine – Clinical Terms: standardized clinical terminology; LOINC – Logical Observation Identifiers Names and Codes: standard for laboratory tests and clinical observations; IEC 81001-5-1 – International standard for cybersecurity of health software and connected health IT systems; ISO 13485 – Quality management systems for medical devices; IEC 62304 – Medical device software lifecycle processes; IEC 82304-1 – Safety and quality requirements for standalone health software; ISO 14971 – Risk management for medical devices
Source(s): Input from BPL team, Praxis analysis

3.3 Regulatory gap

India's regulatory framework is evolving from device regulation to AI governance

India already regulates AI-enabled medical devices through the Medical Devices Rules, 2017. However, the pace of AI innovation also creates a regulatory challenge that differs fundamentally from conventional medical devices. While hardware platforms may remain unchanged for years, AI-enabled software evolves through frequent updates, performance improvements and retraining. Lengthy or unpredictable approval processes can therefore delay access to newer algorithm versions, creating a mismatch between the pace of technological innovation and regulatory decision-making. This reinforces the need for lifecycle regulatory approaches that enable timely evaluation of validated software updates rather than one-time product approval.

CDSCO's Draft Guidance on Medical Device Software (2025) is an important step, introducing formal distinctions between Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD), risk-based classification and algorithm change protocols. However, much of this framework remains under development. Key gaps remain in operationalising AI-specific regulation, including:

- Predictable software classification and approval pathways for AI-enabled products
- Governance of adaptive AI, including software updates and algorithm modifications after deployment
- Lifecycle performance monitoring, including management of model drift and periodic revalidation
- Post-market surveillance frameworks supported by real-world clinical evidence
- Clear implementation timelines, regulatory guidance and medico-legal accountability frameworks to provide certainty for manufacturers, providers and investors

India's next priority is therefore not creating new regulation but operationalising predictable AI-specific regulatory pathways with defined approval timelines, lifecycle monitoring and update mechanisms.

3.4 Procurement & reimbursement gap

Clinical value alone does not drive adoption, payment does

For most healthcare providers, AI represents an additional cost rather than a reimbursable clinical service. Although AI may improve diagnostic accuracy and workflow efficiency, hospitals have limited financial incentive to invest when reimbursement mechanisms do not recognise the technology. Existing mechanisms reimburse procedures rather than intelligence. Consequently, providers receive the same reimbursement whether diagnosis is supported by conventional devices or AI-enabled systems, limiting financial incentives for adoption despite demonstrated improvements in productivity and clinical performance.

Even India's public insurance programmes, including Ayushman Bharat PM-JAY and the Central Government Health Scheme (CGHS), do not provide dedicated reimbursement pathways for AI-enabled diagnostics. As a result, providers often absorb the incremental costs of AI deployment because the additional value created by AI is not reflected in payer reimbursement.

For many AI-enabled medical devices, particularly capital equipment, procurement can be an even greater barrier to adoption than reimbursement. Pricing and procurement mechanisms for regulated medical devices continue to focus on predefined device categories, technical specifications and acquisition cost rather than technology-enabled clinical value. While there is periodic revision of ceiling prices for devices such as coronary stents and knee implants to improve affordability, procurement decisions, particularly in public hospitals, are typically driven by tender specifications, technical compliance and upfront price, with limited consideration of improvements in clinical outcomes, workflow efficiency or long-term health-system value.

As software increasingly drives improvements in image quality, workflow automation, diagnostic confidence and productivity, procurement frameworks also need to evolve in what they evaluate. Tender specifications should progressively recognise the value created by

A conventional medical device, once approved, does not change. An AI-based medical device can evolve continuously through software updates, algorithm retraining, and expanded use cases.

-K. Guruswamy, BPL

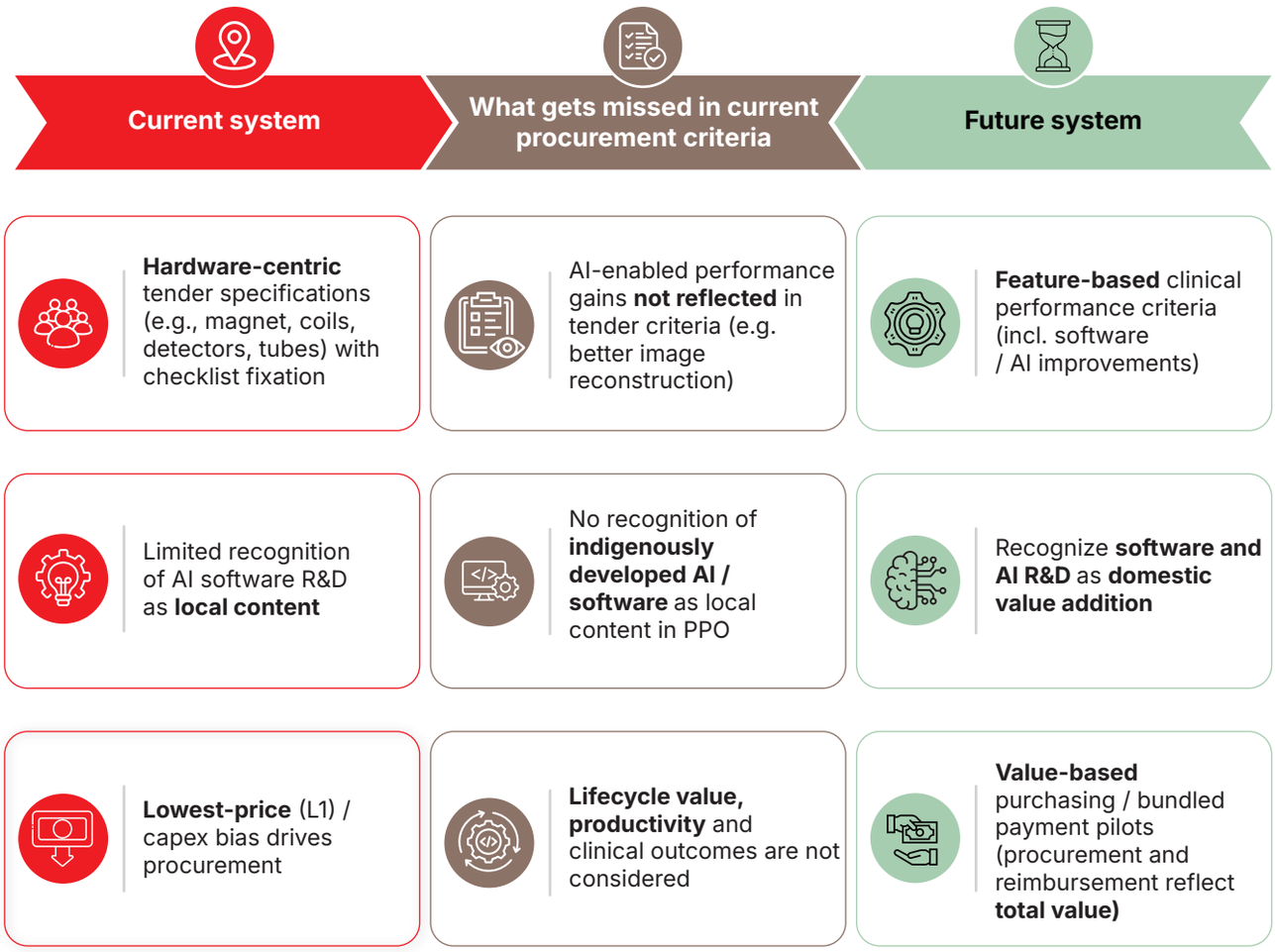
AI-enabled software alongside traditional hardware characteristics, ensuring that purchasing decisions reflect overall clinical and operational performance rather than hardware specifications alone.

The absence of value-based procurement not only discourages provider adoption but also weakens commercial incentives for manufacturers to introduce and continuously upgrade AI-enabled technologies in the Indian market. The innovation ecosystem depends on the recognition of incremental technological value to justify continued investment and ensure that patients have timely access to cutting-edge medical technologies. While reimbursement determines whether providers are paid for using AI-enabled technologies, procurement determines whether those technologies are purchased in the first place. Procurement should therefore progressively shift from evaluating acquisition cost alone towards assessing long-term clinical outcomes, operational efficiency and health-system value.

The software is often treated as something that simply comes with the device, rather than as a source of value in itself. That mindset needs to change for regulators.

-Bhargav Kotadia, SMT

Exhibit I: Procurement 2.0: from hardware specs to AI-enabled clinical value



Note(s): PPO: Public Procurement Order
Source(s): Input from Philips team, Praxis analysis

04

The path forward: Coordinated action

India has already established many of the foundations required for AI-enabled MedTech: a growing innovation ecosystem, expanding digital public infrastructure, increasing clinician acceptance and an emerging regulatory framework. The next phase of growth will depend less on technological breakthroughs and more on coordinated action across policymakers, regulators, healthcare providers, payers and industry.

Global experience also demonstrates that AI adoption does not occur through isolated innovation. It is the result of coordinated ecosystem development in which regulation, evidence generation, reimbursement, procurement and provider adoption evolve together. India now has the opportunity to build this enabling architecture while leveraging its unique strengths in digital public infrastructure and healthcare innovation.

4.1 Global playbooks

Countries that scaled AI-enabled MedTech built ecosystems

The experience of leading healthcare systems demonstrates that AI adoption is driven not by technology alone, but by coordinated ecosystem development. Countries that have successfully deployed AI-enabled MedTech have invested in three mutually reinforcing enablers:

- Data and evidence ecosystems, comprising interoperable digital infrastructure, representative clinical datasets, and mechanisms to generate real-world evidence across the product lifecycle
- Regulatory frameworks that provide clear, risk-based pathways for AI-enabled devices, including guidance for software updates and lifecycle oversight
- Procurement and reimbursement mechanisms that create incentives for providers to adopt validated AI technologies in routine clinical care

Rather than developing these capabilities in isolation, leading markets have advanced them in parallel. Digital infrastructure enables evidence generation, evidence supports regulatory approval and reimbursement decisions, and wider clinical adoption generates additional real-world evidence to continuously improve AI performance. While countries such as the United States, United Kingdom, Germany, Singapore, and South Korea have adopted different approaches, each has built a coordinated ecosystem that aligns these three enablers.

India has already established strong foundations through the Ayushman Bharat Digital Mission (ABDM). The next phase is to build on this foundation by strengthening regulatory pathways, expanding real-world evidence generation, and developing reimbursement mechanisms that support the adoption of validated AI-enabled MedTech. International experience suggests that no single policy intervention is sufficient; scaled adoption depends on coordinated progress across all three ecosystem enablers.

Global leaders ensure data infrastructure exists for AI deployment

AI leaders have increasingly shifted their focus to developing trusted health data infrastructure that enables AI development, validation and deployment at scale. Common characteristics include interoperable electronic health records, standardized data formats, privacy-preserving data sharing mechanisms and secure research environments that allow AI models to be developed using real-world clinical data while maintaining patient confidentiality.

The United Kingdom's NHS Federated Data Platform exemplifies this approach by connecting data across hospitals while allowing each organisation to retain control over its own data. Rather than creating a centralized repository, the platform enables near real-time operational analytics, supports AI-enabled clinical workflows and provides the digital foundation for future AI applications across the NHS.

In South Korea, the government is explicitly expanding healthcare data infrastructure to accelerate AI-enabled essential care: it is integrating national university hospital clinical data into a healthcare big-data platform, expanding national integrated bio-big-data, and creating mechanisms to link data across institutions while protecting privacy.

The true value of connected devices lies not in individual data streams but in their ability to integrate with EMRs, clinical decision-support systems, AI platforms, and national digital health infrastructure

-K. Guruswamy, BPL

Similarly, mature digital health ecosystems increasingly rely on privacy-enhancing technologies such as federated learning and secure data environments, enabling AI models to learn from distributed datasets without transferring identifiable patient records. These approaches improve model generalizability while addressing privacy, security and data sovereignty concerns.

Global leaders regulate AI throughout its lifecycle

Faster-moving markets have typically paired core device regulation with clearer software-specific guidance, iterative validation norms and more mature manufacturer expectations. Thus, leading regulatory agencies have moved beyond conventional device approval toward lifecycle regulation of AI-enabled medical devices. The US FDA, UK MHRA and Singapore's Health Sciences Authority (HSA) all recognise that AI-enabled software requires oversight across development, deployment, monitoring and post-market maintenance rather than only at the point of initial approval.

While their regulatory approaches differ, they are built on common principles including safety, effectiveness, transparency, human oversight and risk management. Frameworks such as the IMDRF's Good Machine Learning Practice (GMLP) principles provide a shared foundation for the safe development and deployment of AI-enabled medical devices, while Singapore's *Artificial Intelligence in Healthcare Guidelines (AIHGle) 2.0 further clarifies the responsibilities* of developers, deployers and users.

A key shift is the move towards regulating algorithm change rather than only the first version of a device. The FDA's Predetermined Change Control Plan (PCCP) framework is designed to let manufacturers pre-specify certain AI updates so the device can improve safely over time without starting from zero every time the model changes. FDA has authorised more than 1,500 AI-enabled medical devices, supported by guidance covering PCCPs, transparency and post-market monitoring. The UK MHRA and Singapore HSA also acknowledge that AI and ML systems adapt over time, and both tie their guidance to post-market vigilance and controlled change pathways.

India has largely aligned with global regulatory principles but remains in the early stages of operationalising AI-specific governance. The opportunity is therefore not to reinvent regulation, but to accelerate implementation through internationally harmonised standards.

"India can lead the next wave of AI-enabled healthcare- not just by building world-class innovation, but by creating a regulatory framework that is globally benchmarked, risk-proportionate, and agile enough to bring safe technologies into clinical practice faster.

-Madhur Singhal, Praxis Global Alliance

Exhibit J: Benchmarking global AI-enabled MedTech regulatory frameworks

Regulatory capability	US FDA	UK MHRA	Singapore HSA	India CDSCO + DoP
Risk-based AI MedTech classification	• **Global leader** • Most comprehensive lifecycle framework with clear expectations for adaptive AI	• **Advanced and innovation-focused** • Strong focus on regulatory experimentation and future-ready regulation	• **Pragmatic, fast adopter** • Agile regulator combining international alignment with innovation support	• **Emerging framework** • Strong innovation ecosystem, but regulatory framework is still evolving
Lifecycle / post-market AI oversight	• Dedicated AI lifecycle guidance integrated into existing FDA pathways	• Developing a dedicated AI-as-a-Medical Device framework with regulatory pilots	• Risk-based AI regulation aligned to international standards	• AI-specific categorization is still evolving
Lifecycle / post-market AI oversight	• Total Product Lifecycle (TPLC) approach covering development through post-market monitoring	• Lifecycle-based oversight with emphasis on continuous monitoring		• Comprehensive lifecycle AI regulation is not yet established
Predetermined algorithm updates (PCCP / equivalent)	• Formal guidance for approval of predefined AI model updates	• Developing Software and AI as a Medical Device Change Programme	• Launched a pilot Change Management Program	• No formal PCCP-equivalent pathway yet
Good Machine Learning Practice alignment	• Co-developers of GMLP		• IMDRF-aligned guidance	• Limited incorporation of GMLP into regulatory requirements
Regulatory innovation pathway / sandbox	• Strong pre-submission pathway but no sandbox	• AI Airlock is a dedicated regulatory sandbox for AI as a medical device	• HSA has an innovation office and AI-SaMD Sandbox	• MedTech Mitra supports innovation, but it is not a formal sandbox

Low maturity — High maturity

Note(s): PCCP - Predetermined Change Control Plans; FDA: Food and Drug Administration; MHRA: Medicines and Healthcare products Regulatory Agency; HSA: Health Sciences Authority; CDSCO: Central Drugs Standard Control Organization; DoP: Department of Pharmaceuticals
Source(s): FDA, MHRA, HSA, CDSCO, Praxis analysis

Global procurement & reimbursement models converted innovation into routine care

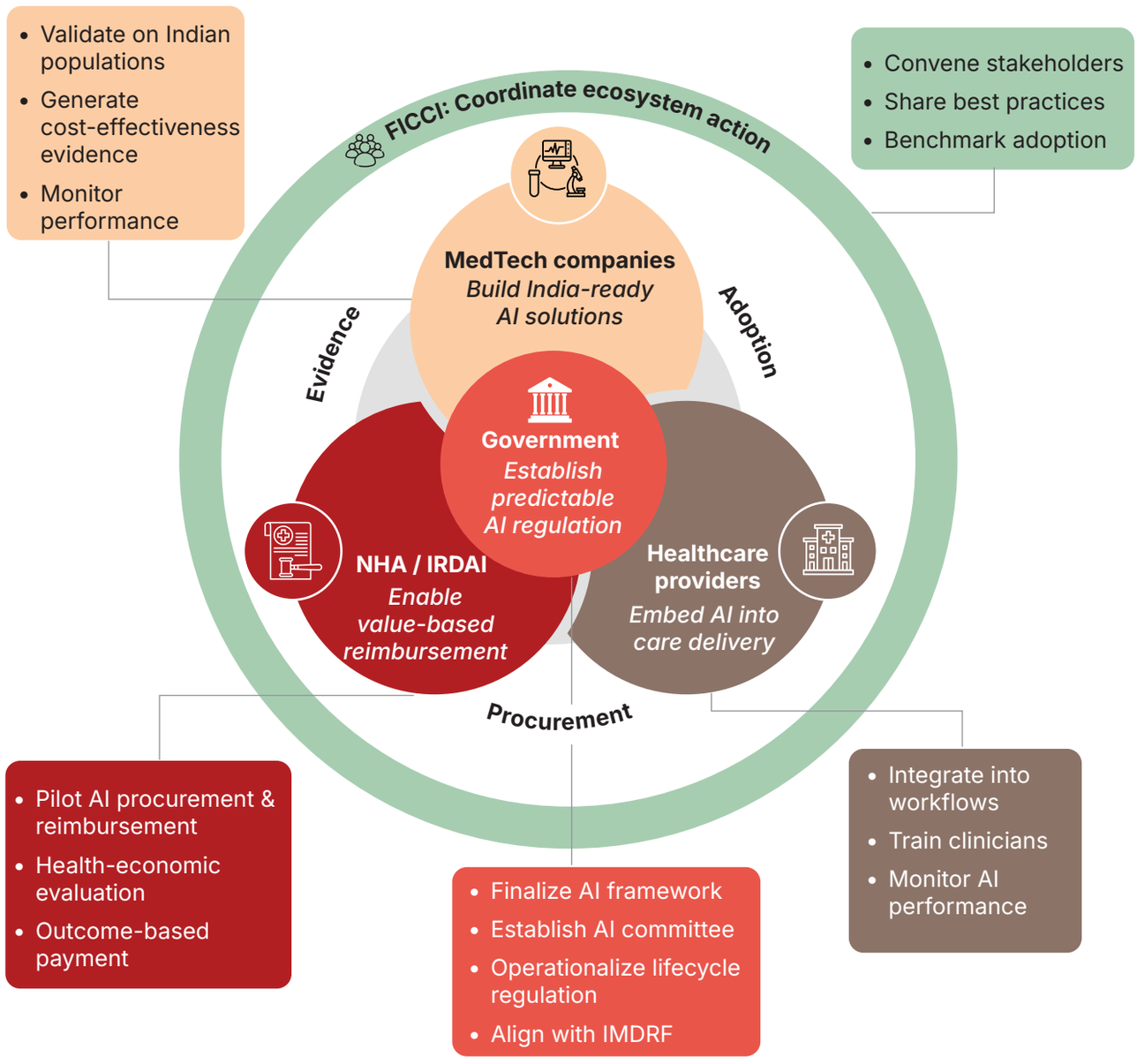
Markets that created payment pathways for digital and AI-enabled diagnostics allowed providers to move from experimentation to scaled service delivery, because reimbursement converts innovation from a discretionary purchase into an investable care pathway with clearer return on deployment.

International experience demonstrates that reimbursement is often the single most important catalyst for AI adoption. The United Kingdom's MedTech Funding Mandate (MTFM) requires NHS commissioners to fund selected approved technologies (e.g., HeartFlow FFRCT has been listed since 2021, with continued support in 2024-25). South Korea introduced national insurance reimbursement for AI-assisted neuroimaging through VUNO Med-DeepBrain (AI-based 3D brain MRI for neurodegenerative disease) in 2022, allowing radiologists to bill an additional fee for AI-assisted reads. In the United States, AI-enabled diagnostics increasingly receive reimbursement through dedicated Centers for Medicare & Medicaid Services (CMS) payment mechanisms and procedural coding.

These examples illustrate a common principle: reimbursement transforms AI from an innovation project into a sustainable clinical service. Without defined payment pathways, adoption remains dependent on discretionary budgets and isolated pilots.

4.2 Stakeholder action map

Exhibit K: Stakeholder ecosystem enabling AI in MedTech



Source(s): Input from FICCI team, Praxis analysis

Government bodies (MoHFW, CDSCO, DoP & Niti Aayog): Establish a predictable regulatory pathway

The government's foremost priority is to provide regulatory certainty that gives innovators confidence to invest while ensuring patient safety. India should build on the Medical Devices Rules, 2017, along with the SAHI and BODH initiatives, by establishing a comprehensive lifecycle regulatory framework for AI-enabled medical devices. Such a framework should define software risk classification, clinical validation requirements, algorithm change protocols, cybersecurity expectations and post-market performance monitoring, while progressively aligning with IMDRF principles to support global harmonisation.

However, regulation alone is unlikely to accelerate adoption unless accompanied by robust implementation mechanisms. CDSCO should establish a dedicated AI in MedTech Technical Expert Committee to provide consistent interpretation of emerging technologies, guide implementation of Software as a Medical Device (SaMD) guidance and reduce regulatory uncertainty for developers. As AI adoption increases, regulators themselves should also leverage AI-enabled review tools to automate dossier screening, identify documentation gaps and accelerate review timelines without compromising safety.

Finally, India should strengthen the evidence ecosystem underpinning regulatory decisions. This includes developing representative Indian validation datasets and standardised evaluation pathways that allow both domestic and globally developed AI models to demonstrate safety and performance on Indian populations without duplicative clinical development. A publicly accessible national registry of authorised AI-enabled medical devices- including approved indications, supporting evidence and regulatory status- would further improve transparency, clinician confidence and market adoption.

NHA & IRDAI: Build procurement & reimbursement pathways for public health priorities

Without procurement & reimbursement pathways, AI remains an innovation project rather than a routinely adopted healthcare service. NHA and IRDAI, in collaboration with MoHFW, ICMR, Niti Aayog and public procurement agencies, have a critical role in creating demand by establishing mechanisms that recognise the clinical and economic value of AI-enabled MedTech.
A phased approach is likely to be most effective.

In the near term, NHA, NHM (MoHFW) and public procurement agencies should establish structured framework for pilot programmes to demonstrate clinical impact, workflow improvements and health-system value under real-world Indian conditions. These pilots should generate the implementation and health-economic evidence needed to support broader procurement decisions.

To accelerate evidence generation, MoHFW and ICMR should develop an agile, express Health Technology Assessment (HTA) pathway for AI-enabled MedTech. The framework should enable innovators to rapidly submit validated AI solutions for assessment, generating standardized clinical and health-economic evidence that supports procurement and purchasing decisions.

Alongside evidence generation, procurement frameworks should also evolve. Current procurement models primarily reward acquisition cost and hardware specifications rather than long-term clinical value. NHA and MoHFW should establish a multi-stakeholder working group to develop value-based procurement methodologies that move beyond L1 evaluation towards clinical outcomes, workflow improvements, health-economic evidence and total health system value. Public procurement policies should also progressively recognise investments in domestic software development and AI R&D as part of local value addition, reflecting the growing contribution of software to AI-enabled medical devices.

Where reimbursement is applicable, AI-enabled diagnostics addressing high-burden diseases could be incorporated into existing PM-JAY packages through pilot reimbursement programmes linked to clinical outcomes and health-economic evaluation. As evidence accumulates, technologies demonstrating measurable improvements in outcomes, efficiency and cost-effectiveness could transition into routine reimbursement, following approaches similar to the UK's MedTech Funding Mandate.

Government procurement should increasingly reward better outcomes, greater efficiency, reduced complications, improved patient experience, and long-term health system value.

-Tushar Sharma, Abbott

MedTech & AI companies: Build evidence for India's healthcare realities

India's next generation of AI-enabled MedTech should be designed for the realities of its healthcare system rather than adapted from high-income markets. This means developing solutions that are affordable, resilient to variable connectivity, capable of operating in resource-constrained settings, support multilingual users and integrate seamlessly with ABDM-enabled workflows.

Design alone, however, is not sufficient. As reimbursement and procurement increasingly become evidence-driven, developers must demonstrate not only algorithm performance but also measurable improvements in clinical outcomes, operational efficiency and health-system value. Multicentre validation studies on representative Indian populations, supported by health-economic analyses and real-world implementation data, will become essential for regulatory approval, procurement and reimbursement decisions.

Finally, companies should work collaboratively rather than independently to accelerate ecosystem development. Partnerships with hospitals, academia, start-ups and regulators can support clinical validation, regulatory readiness and technology refinement. Industry-led incubators and innovation platforms can further reduce barriers for emerging companies by providing access to validation partners, regulatory guidance and implementation support.

Healthcare providers: Integrate AI into clinical workflows

Healthcare providers ultimately determine whether AI progresses beyond successful pilots into routine clinical practice. Achieving this requires AI to be embedded within existing clinical workflows rather than introduced as a standalone technology. Integration with PACS, electronic medical records and ABDM-enabled systems, coupled with clear clinical ownership and workflow redesign, will be essential for sustainable adoption.

Equally important is building institutional capability. Hospitals should establish multidisciplinary AI governance committees responsible for technology selection, deployment oversight, clinical safety and post-market monitoring. At the same time, AI literacy should be integrated across undergraduate medical education, postgraduate training and Continuing Medical Education (CME), ensuring clinicians are equipped to evaluate, use and oversee AI-enabled technologies responsibly.

Healthcare providers also have a critical role in generating the evidence needed for wider adoption. Public hospitals can serve as early adopters of validated AI-enabled MedTech, contributing real-world clinical and health-economic evidence while sharing implementation learnings across the broader healthcare ecosystem.

Industry Bodies (FICCI MedTech): Convene the ecosystem

Scaling AI-enabled MedTech requires sustained coordination across government, regulators, healthcare providers, academia and industry. As a neutral convenor, industry bodies such as FICCI MedTech are uniquely positioned to bridge these stakeholders, facilitate consensus and accelerate implementation beyond policy announcements.

Rather than focusing solely on advocacy, FICCI MedTech can play three complementary roles. First, it can convene multi-stakeholder working groups on AI regulation, reimbursement, interoperability and clinical validation to resolve implementation bottlenecks. Second, it can curate industry evidence, international best practices and adoption benchmarks to inform policy development and regulatory evolution. Finally, it can strengthen ecosystem capability through workshops, implementation playbooks, regulatory guidance and recurring knowledge-sharing platforms that enable organisations to learn from early deployments.

By aligning stakeholders around shared priorities and facilitating continuous dialogue, industry bodies can help translate policy intent into sustained adoption of safe, effective and clinically validated AI-enabled MedTech.

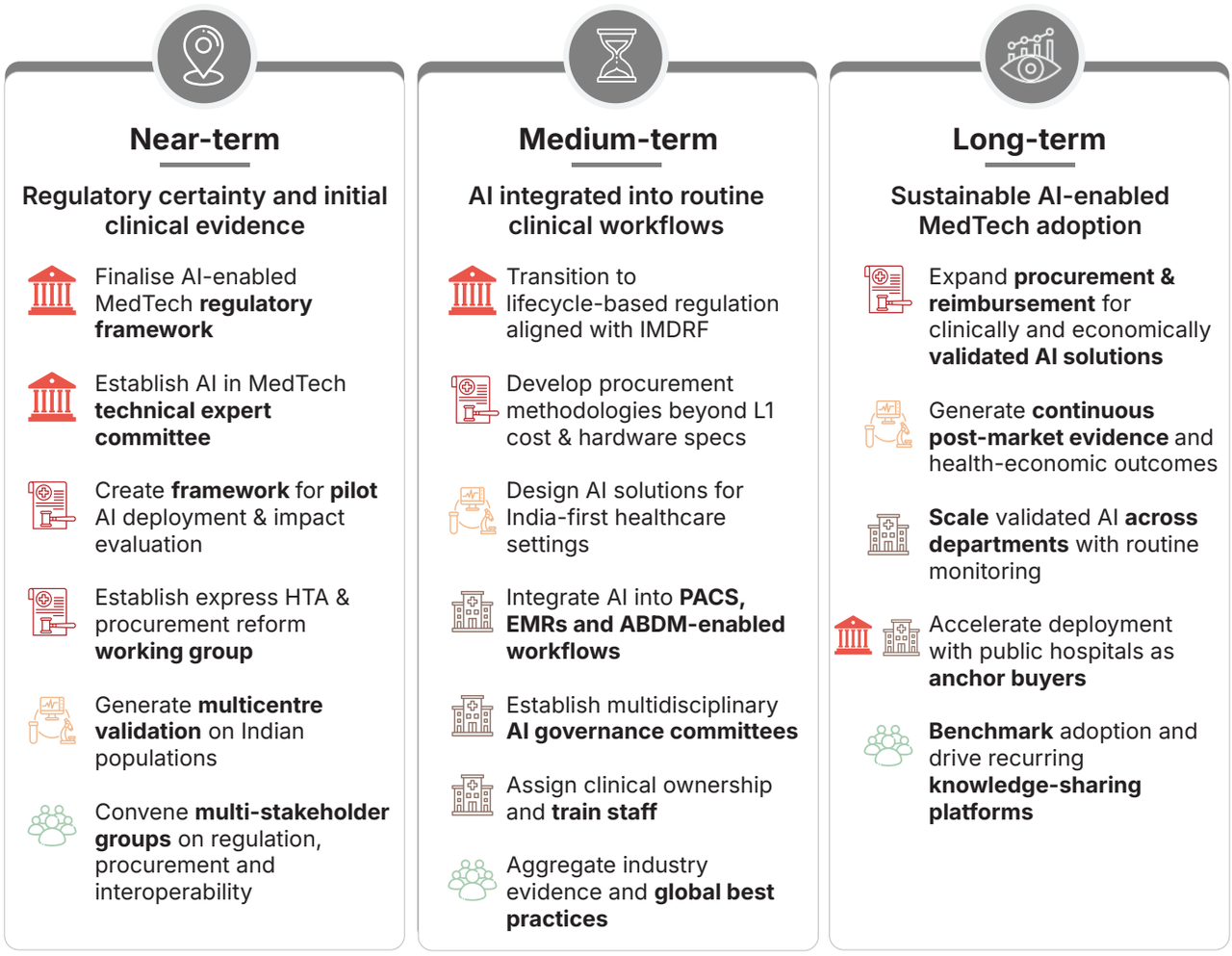
AI needs to become part of medical education. That's where the adoption cycle starts- if clinicians are trained to use these tools early, they'll use them in clinical practice.

-Chaitanya Sarawate, GE HealthCare

With strong public-private collaboration and enabling regulatory and policy frameworks, AI can help expand access to quality care, improve clinical outcomes, and accelerate progress towards Viksit Bharat 2047.

-Bharath Sesha, Philips

Exhibit L: Stakeholder action map for scaling AI-enabled MedTech



Source(s): Input from FICCI team, Praxis analysis

4.3 Closing thesis

India's opportunity in AI-enabled MedTech is not defined by technology alone. It is defined by timing. Few countries simultaneously possess India's combination of healthcare need, digital public infrastructure, engineering capability and rapidly expanding innovation ecosystem. The challenge is no longer identifying AI use cases; it is creating the institutional mechanisms that allow validated innovations to scale across the healthcare system.

If India succeeds in aligning regulation, reimbursement, evidence generation, procurement and provider adoption, AI-enabled MedTech can evolve from isolated pilots into a foundational layer of healthcare delivery. In doing so, AI will not simply improve medical devices, it will expand the reach of specialist expertise, strengthen primary care, improve equity in healthcare access and enhance the productivity of an increasingly constrained healthcare workforce.

The opportunity, therefore, is larger than technology adoption. It is the opportunity to build one of the world's first healthcare systems in which AI-enabled MedTech is designed not for the most advanced hospitals, but for the largest and most diverse patient population.

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About FICCI

Established in 1927, Federation of Indian Chambers of Commerce and Industry (FICCI) is the largest and oldest apex business organisation in India. Mahatma Gandhi addressed FICCI's 4th AGM in 1931. Our 98th AGM was held in November 2025. With our rich legacy, FICCI would play an even greater role as India emerges as the 3rd largest economy.

FICCI works with its key stakeholders to foster active engagement and dialogue with decision makers, to support steps that are good for commerce and industry. As a member-led and member-driven organisation, FICCI represents over 2,50,000 companies across all segments of economy including public, private and multinationals.

The diverse membership base of FICCI across all Indian states includes both direct and indirect members through its 300 affiliated regional and state level industry associations. FICCI has a large international presence via partner agreements with 250 national business associations in over 100 countries.

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