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WORLD ECONOMIC FORUM

Earning Trust for AI in Health: A Collaborative Path Forward

WHITE PAPER

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Contents

Foreword

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Artificial intelligence (AI) holds great promise to transform healthcare – enhancing diagnostics, optimizing workflows and improving health outcomes for all. However, realizing AI's benefits responsibly demands a fundamental evolution of how health systems, with their diverse set of stakeholders, develop and build trust in innovation.

Existing evaluation frameworks – built for products that remain typically unchanged after approval, such as pharmaceuticals and medical devices – are not fully equipped to manage the dynamic, evolving nature of AI technologies. The probabilistic behaviour of certain AI systems introduces new dimensions of uncertainty that traditional, deterministic approaches cannot fully address.

To manage these challenges effectively, regulatory models must evolve. Dynamic governance mechanisms such as regulatory sandboxes, life-cycle evaluation and post-market monitoring will be essential to ensure that AI systems remain safe, effective and equitable throughout their lifespan. Complementary to legislation, guidelines can help maintain innovation while setting clear societal guardrails and industry standards.

Equally important is strengthening technical capacity among regulators, innovators and healthcare leaders to develop a shared understanding of AI's capabilities and risks. Public–private partnerships should be positioned at the core of this transformation – co-developing standards, supporting regulatory innovation and building shared infrastructures for evaluation and monitoring. Strong international collaboration will be critical to harmonize approaches, foster interoperability and enable scaling of AI technologies across health systems.

If we act now, we can embed trust in the foundations of digital health transformation. By aligning innovation with ethical principles and focusing on continuous evaluation, AI can fulfil its promise: improving health outcomes, enhancing system resilience and expanding access to high-quality care throughout populations.

Executive summary

AI will reshape healthcare, but realizing its full potential requires responsible governance, trust and global collaboration.

Healthcare systems globally face growing pressures: rising costs, workforce shortages and persistent inefficiencies. In this context, AI offers transformative opportunities to enhance patient outcomes and optimize system performance. However, realizing AI's benefits in healthcare demands responsible development, rigorous evaluation and a deliberate focus on building trust among stakeholders.

Today's medicine regulatory frameworks – largely designed for pharmaceuticals and medical devices – are not fully suited to manage the probabilistic, dynamic nature of AI technologies. Traditional evaluation methods, which emphasize pre-market validation, struggle to accommodate AI systems that evolve post-deployment. As AI adoption accelerates, regulatory models must evolve accordingly.

This paper, developed through a collaboration between the World Economic Forum's Centre for Health and Healthcare and Boston Consulting Group (BCG), identifies three urgent priorities to earn trust for AI in health:

1. **Address fragmentation and build technical capacity**
   - Current AI ecosystems are fragmented, and many health leaders lack a deep understanding of AI technologies.
   - Health systems must build technical literacy among decision-makers to critically assess and responsibly integrate AI solutions.
2. **Adapt evaluation and regulatory frameworks**
   - New approaches, such as regulatory sandboxes, post-market surveillance and life-cycle monitoring, are essential.
   - Guidelines must complement legislation to enable innovation while maintaining high standards of safety, effectiveness and equity.
   - Independent quality assurance resources and real-world testing environments, such as those being developed under initiatives like the Testing and Experimentation Facility for Health AI and Robotics (TEF-Health), can support more dynamic development.
3. **Promote public–private collaboration**
   - Public–private partnerships (PPPs) should move beyond consultation to active co-development of evaluation standards and monitoring frameworks.
   - Such collaboration is vital to ensure that regulatory practices keep pace with AI innovation while safeguarding patient trust and public health objectives.

This paper also emphasizes the importance of global coordination. Divergences in AI regulatory approaches across regions – especially between the Global North and Global South – risk creating barriers to the scalable deployment of AI in healthcare. Capacity-building efforts, especially in under-resourced health systems, are crucial to ensure equitable benefits from AI advances.

Ultimately, the future of AI in healthcare must be grounded in adaptability, transparency and shared responsibility. By strengthening evaluation processes, building technical capacity and fostering structured public–private collaboration, health systems can unlock the transformative potential of AI while upholding patient safety and trust and ensuring broader access to innovation.

The path forward demands continuous innovation not only in technology but also in regulation and system design. The time to act is now, to ensure that AI fulfils its promise of delivering better health outcomes for all.

Introduction

Building a trustworthy health AI ecosystem demands new regulatory models, continuous evaluation and close collaboration across the public and private sectors.

Healthcare expenditure has been rising faster than GDP over the past 20 years, with at least 20% deemed to be wasteful.[1] At the same time, healthcare is facing a serious workforce crisis. The World Health Organization (WHO) estimates a deficit of 10 million health workers by 2030, particularly in low- and middle-income countries (LMICs).[2] Healthcare workers are exhausted: approximately 50% of healthcare professionals suffer from burnout.[3]

In this context, artificial intelligence (AI) technologies bring significant opportunities to address health system crises. AI technologies are poised to fundamentally change how society organizes medical care, shifting critical tasks and augmenting health workers' performance leading to improved patient outcomes[4] and operational efficiency.[5]

Industry must be a responsible leader and visionary in the process of carving out spaces for AI technologies in the health sector. Industry leaders need to balance AI risks related to impact on patient safety and privacy (direct and often indirect, such as delayed diagnosis and treatment) with the need to advance innovation. In doing so, the private sector can contribute to the development of a positive public perception of AI technologies in order to earn the trust of the health sector. However, this process is likely to take place in a very challenging environment in which practices and policies struggle to keep up with the rapid pace and disruptive nature of AI innovations in healthcare:

- AI is an emerging industry, with most players less than 10 years old, whereas healthcare is a mature industry dominated by established organizations. This mismatch risks slowing innovation – for example, as entrenched processes and structures may limit the adoption of new technologies.

- The number of AI products is growing rapidly, with the global AI market estimated at almost $200 billion in 2023, a threefold increase from $62 billion in 2020.[6] In contrast, the pharmaceutical market is characterized by a small number of products that require long and costly development. For instance, the United States Federal Drug Administration (FDA) approves an average of 47 drugs per year (2021–2023),[7] with the average development cost and timeline per drug being $2.8 billion and 15 years, respectively.[8] In 2020, the number of new AI technologies entering the health sector eclipsed that of new pharmaceuticals.[9]

- Deterministic and rule-based AI and machine learning (ML) models can be used to perform an array of tasks (e.g. image segmentation, classification and risk prediction) and are generally considered reproducible (even if not fully explainable), whereas probabilistic AI technologies, such as generative AI (GenAI), are:[10]

  - Intended to create new data in a non-deterministic and dynamic way rather than identify patterns

  - Developed on (unstructured) datasets so large that developers cannot know everything about the data

  - Not created for an individual product, as foundational models are adapted for various applications

Current evaluation processes predominantly focus on the safety, effectiveness and economic dimensions of healthcare innovations, covering products such as pharmaceuticals, medical technologies and deterministic software. The probabilistic nature of AI technologies results in some incompatibilities with existing processes. There is a need to adapt and modify the current frameworks to accommodate the unique characteristics of probabilistic AI technologies.[11]

The World Economic Forum's Digital Healthcare Transformation (DHT) Initiative, in partnership with BCG, aims to bring a fresh perspective on how to build high-quality AI technologies that help build trust within the health sector. The initiative engaged with more than 50 experts in this field,[12] who highlighted three areas that present urgent challenges:

- Current health AI ecosystems are fragmented, with insufficient understanding of AI technologies in health from health leaders.

- Stakeholders in the healthcare ecosystem must ensure that evaluation processes offer sufficient adaptability and flexibility to keep pace with the swift advance of AI technologies, while retaining high standards of evidence.

- There is no global consensus on when public–private interactions are most vital to facilitate the development and deployment of high-quality AI technologies that earn the trust of the health sector.

Throughout this journey, it is imperative to remain focused on the goal, which is to improve health outcomes for all. The path forward requires policy, systems and technological innovation stemming from public–private collaboration as well as a steadfast commitment to using technology for the improvement of healthcare and health systems.

1 Empowering trustworthy AI in health: The urgent need for collaboration

Both the public and the private sectors have an important role to play in developing effective regulation of AI in healthcare.

1.1 Global divergences challenge the scaling of AI in health

Regulatory frameworks for AI are crystallizing around the world, with countries proposing the first generation of AI-specific legal frameworks, especially in the Global North:

- **The United States now prioritizes national competitiveness and economic strength, favouring policies to foster innovation**. This is based on the hypothesis that limiting federal oversight will promote innovation and the development of a skilled workforce in the private sector. However, technical assessors will likely remain important for assessing AI as a medical device.
- **In contrast, the European Union has enacted the Artificial Intelligence Act (EU AI Act), which was adopted by the EU Parliament in March 2024**. This comprehensive legislation categorizes AI systems according to risk levels and applies proportional control on high-risk applications. Within the healthcare sector, AI technologies are also subject to other regulations, such as the Medical Device Regulation, In Vitro Diagnostic Regulation, General Data Protection Regulation and European Health Data Space Regulation.[13] The resulting framework provides comprehensive legislative coverage for AI technologies in the health sector, though the fragmented nature of this regulatory framework may result in legal inconsistencies.
- **Other jurisdictions in Organisation of Economic Co-operation and Development (OECD) countries – such as Canada, Japan, South Korea, the United Kingdom and Australia – are advancing their own AI regulations**, many of which align closely with the EU's norms and values on safety, privacy and accountability.
- **In contrast, regulation in the Global South is fragmented and often under-resourced**, resulting in significant governance gaps. However, some nations are proactively developing AI regulations that are adapted to their unique socioeconomic, cultural and technological circumstances.

These divergences are creating friction in the deployment of AI-based health technologies across countries and regions, especially for multinational companies that must navigate multiple legislative environments. Greater international harmonization of regulatory approaches could help reduce such barriers.[14]

1.2 The private sector is key to driving progress and standardization

The private sector should play a pivotal role, building high-quality AI systems capable of operating effectively under diverse global regulations and addressing the unique risks associated with AI in healthcare in order to maintain trust in the health sector.

Healthcare industry players and institutions developing and using AI systems face greater scrutiny and hesitancy to change compared to other industries deciding to accept AI systems[15] (both deterministic and non-deterministic), requiring information on consistency, reproducibility, biases in data (such as demographic disparities), unintended AI responses (i.e. "hallucinations"), data privacy,[16] opacity and potential for technology misuse. These requirements all help to ensure that AI technologies can be safely, securely and equitably deployed within the health sector.

To help the development of high-quality AI technologies conducive to building trust, the OECD categorized three types of tool for trustworthy AI: procedural, technical and educational.[17] Based on this classification, the authors of this paper studied the tools companies can develop depending on their own context and jurisdictions:

- **Procedural tools:** This includes the development of rigorous evaluation and evidence generation processes or robust risk detection mechanisms that are built on outcomes that matter to patients, healthcare professionals and health systems.
- **Technical tools:** Technical tools deal with issues related to use of AI such as transparency, detecting bias and how explainable AI systems are. It notably includes life-cycle or data-management tools, with meticulous management of data sources, systematic classification and tracking of data lineage and ensuring metadata completeness.

– **Educational tools:** Training programmes, workshops and continuous learning modules are essential to equip staff at all levels with the necessary knowledge and skills to engage with AI systems effectively.

1.3 AI regulations must be crafted to keep pace with innovation

Most of the experts convened for this study emphasized the need for capacity-building among public stakeholders to develop regulatory frameworks appropriate for AI technologies. Regulations for health innovations have historically been built to assess static products. However, AI technologies are capable of evolving post-deployment, meaning the need for post-deployment monitoring is more critical than before. On the positive side, AI tools can become safer and better after release as the size of their dataset increases; however, current post-market monitoring processes also risk falling short of being able to intervene in a timely manner should an unforeseen or undesirable evolution occur in the AI technology. That said, some regulatory innovation has taken place to accommodate the evolving capabilities of AI technologies, such as through the introduction of predetermined change control plans in the United States that allows certain predicted changes to be approved theoretically, thus lessening the regulatory burden on AI developers.

There is a strong case for a global capacity-building effort that **should use local capabilities** (through PPPs, for instance, as discussed in Section 3) **as well as financing** (through international aid and domestic sources). Interviews and workshops conducted for this paper highlight a broad consensus on the lack of literacy and on the need for enhanced capacity-building to enable regulatory collaboration and develop appropriate regulatory frameworks and guidance documents. This could also include regulatory reliance mechanisms such as mutual recognition, where trusted assessments by one authority can be used by others.

In response to these challenges, the Global Agency for Responsible AI in Health (HealthAI), a non-profit organization, was created to expand countries' capacity to regulate AI in health, particularly in the Global South. It is actively supporting the establishment of government-led regulatory mechanisms within countries to accelerate the standards-based validation of AI technologies. HealthAI is also developing a global regulatory network, a public registry of approved AI solutions and an associated global early-warning system for AI products; it also offers advisory services on AI policies. Its report, *Mapping AI Governance in Health: From Global Regulatory Alignments to LMICs' Policy Developments*, published in September 2024, represents a first step in the implementation of national and regional regulatory mechanisms to form a global regulatory network.[18] It examines global AI governance policies developed by key international institutions from an interoperability perspective and presents country-specific analyses of four countries representing different regions to offer diverse perspectives on the challenges and progress in the governance of AI in health.

2 The need for a pragmatic approach: Guidelines, sandboxes and post-market surveillance

The most effective way forward for AI innovation in healthcare combines regulation with post-market performance monitoring.

2.1 Legislation can build a strong baseline for governing AI in health

Globally, governments are actively prioritizing the development and updating of legislation related to data protection and AI. This regulatory momentum reflects a global recognition of the need to manage the implications of AI technologies: "policymakers have progressed from the 'understand' stage … to the 'shape' stage".[19] However, AI regulation remains nascent across regions with variable balance between allowing innovation and enforcing regulation and security.

Legislative developments are often slow and are not easy to adapt in the face of the rapidly changing AI environment. AI is still an emerging technology, for which opportunities for new applications are regularly discovered. Legislative developments pertaining to AI technologies will need to ensure that any novel developments are not stifled. For instance, the EU AI Act only outright forbids the use of AI for certain purposes and practices that are inconsistent with the norms and values of the EU.[20] Beyond that, it indicates certain areas (e.g. medical devices) where additional scrutiny is warranted yet imposes no limitations on how AI can be deployed within those areas, thus safeguarding the innovation potential.

National legislative initiatives may lead to a fragmented international landscape on topics such as AI standards, sharing of best practices or mutual recognition of regulations. Navigating changing legislative environments can result in short-term uncertainty that may temporarily hamper innovation, as companies may be hesitant about investing in new ideas until the regulatory context becomes clearer. Fragmentation also makes it challenging for AI technologies to be scaled within regions, as the market access requirements in different countries within a single region may not align. On a global level, a degree of fragmentation is to be expected as different norms and values informing market access processes underpin health systems worldwide.[21] Nonetheless, multilateral cooperation could drive increasing regulatory convergence over time.

There is a strong case for a guidelines-based approach to complement legislative frameworks and establish more nuanced and detailed provisions. Regulators can continue to build on existing practices[22] such as those used to permit certain medical products before full market authorization[23] (see Box 1). These practices are governed by regulatory frameworks and operationalized through guidelines, thus making use of the flexibilities that guidelines provide while ensuring that any innovation aligns with societally acceptable boundaries.

BOX 1 **Exceptions to market access practices in healthcare**

Health regulators already adapt their regulatory practices in emergency situations. For instance, many regulators grant access to drugs before market authorization for patients suffering from a serious illness who have no viable treatment options available to them:

- Expanded Access Program (EAP) in the United States
- Temporary Authorization for Use in France
- Early Access Medicine Scheme in the United Kingdom
- Exceptional Use Authorization (EUA) for medical devices in the United Kingdom

These schemes operate under regulatory oversight and are often time-limited and evidence-dependent. Similarly, dedicated frameworks support provisional access to digital health technologies while evidence is still being generated:

- PECAN (France): pilot allowing provisional access for digital tools with ongoing data collection
- DiGA (Germany): provisional fast-track reimbursement for digital health apps
- Early Value Assessment (United Kingdom): rapid assessment of technologies addressing unmet needs

2.2 Sandboxes provide a safe space in which the private sector can innovate

Dedicated testing environments such as regulatory sandboxes can help promote the development of high-quality AI technologies in health (see Box 2 for definition). Sandboxes must be adapted to the context and environment in which they operate. In countries with comprehensive regulatory frameworks, sandboxes can focus on tailoring or modifying regulatory provisions and processes, while they should provide a foundational framework to support innovation in countries (Lebanon and Pakistan, for example) that are still developing a clear regulatory framework.[24] Furthermore, it is important that regulatory sandboxes are focused on a specific industry (e.g. healthcare) so that any sector-specific requirements can be embedded in the design of the sandbox (such as in Portugal).[25] Carefully designed regulatory sandboxes can help innovators collect insights on the real-world performance of AI technologies in health while ensuring that patient safety and privacy are protected within a clearly defined environment.

BOX 2 **Regulatory sandboxes in health**

A sandbox is a framework created by health authorities or regulatory agencies to allow healthcare innovators to test new digital health technologies with tailored regulatory constraints. A sandbox often provides resources, such as datasets or advisory support, to assist innovators and can even extend to creating digital public goods – open access software or data intended to contribute to sustainable digital development, for example.

Sandboxes for AI can:

- Enhance the understanding of AI solutions before they enter the market
- Support the development of effective enforcement policies and technical guidance to mitigate risks
- Foster AI innovation by providing a controlled testing environment for emerging AI technologies[26]

For example, the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) launched AI Airlock in spring 2024, its first regulatory sandbox for AI as a Medical Device (AIaMD). The goal of the project is to understand and accelerate "solutions to novel regulatory challenges for AIaMD" due to a marked increase in innovative devices entering the UK market. The MHRA is seeking to "balance appropriate oversight to protect patient safety with the agility needed to respond to the particular challenges presented by these products to ensure that regulation does not present undue barriers to innovation".[27]

2.3 Post-market surveillance can help cope with the evolving nature of AI

Evaluation efforts are a pivotal practice for establishing trust in AI technologies. This encompasses rigorous methodologies for both pre-market validation and ongoing post-market surveillance, assessing the safety, effectiveness and fairness of AI technologies in health.

There is a strong consensus among health stakeholders that post-market surveillance (see Box 3) **enables the early detection of new risks and iterative adaptation**, which is particularly suited for AI technologies. It involves life-cycle monitoring of AI technologies using real-world data to ensure continued safety and efficacy, as the accuracy of AI technologies can change between development and post-deployment.

BOX 3 Post-market surveillance of medical devices

"Post-market surveillance is a set of activities conducted by manufacturers, to collect and evaluate experience gained from medical devices that have been placed on the market, and to identify the need to take any action. Post-market surveillance is a crucial tool to ensure that medical devices continue to be safe and well performing, and to ensure actions are undertaken if the risk of continued use of the medical device outweighs the benefit."

World Health Organization (WHO). (2020). *Guidelines for Post-Market Surveillance and Market Surveillance of Medical Devices, Including In Vitro Diagnostics.* https://www.who.int/publications/i/item/9789240015319

Post-market surveillance includes approaches such as pharmacovigilance methods that aim to detect and prevent adverse effects in AI-enabled medical devices. For example, the FDA has developed dedicated tools[28] designed to spot changes to inputs of medical devices enabled with AI, monitor their outputs and recognize why their performance varies.

3 The importance of public–private partnerships for AI in health

Public–private partnerships are critical to leveraging the private sector's unique capabilities to build high-quality AI technologies that meet the needs of the health sector.

3.1 The role of public–private partnerships in regulating medical devices, including software

The private sector has a unique role to play in promoting the deployment of high-quality AI technologies that can earn the trust of the health sector in the current fragmented landscape. PPPs allow for pooling skills, funding and risks in order to accelerate innovation.

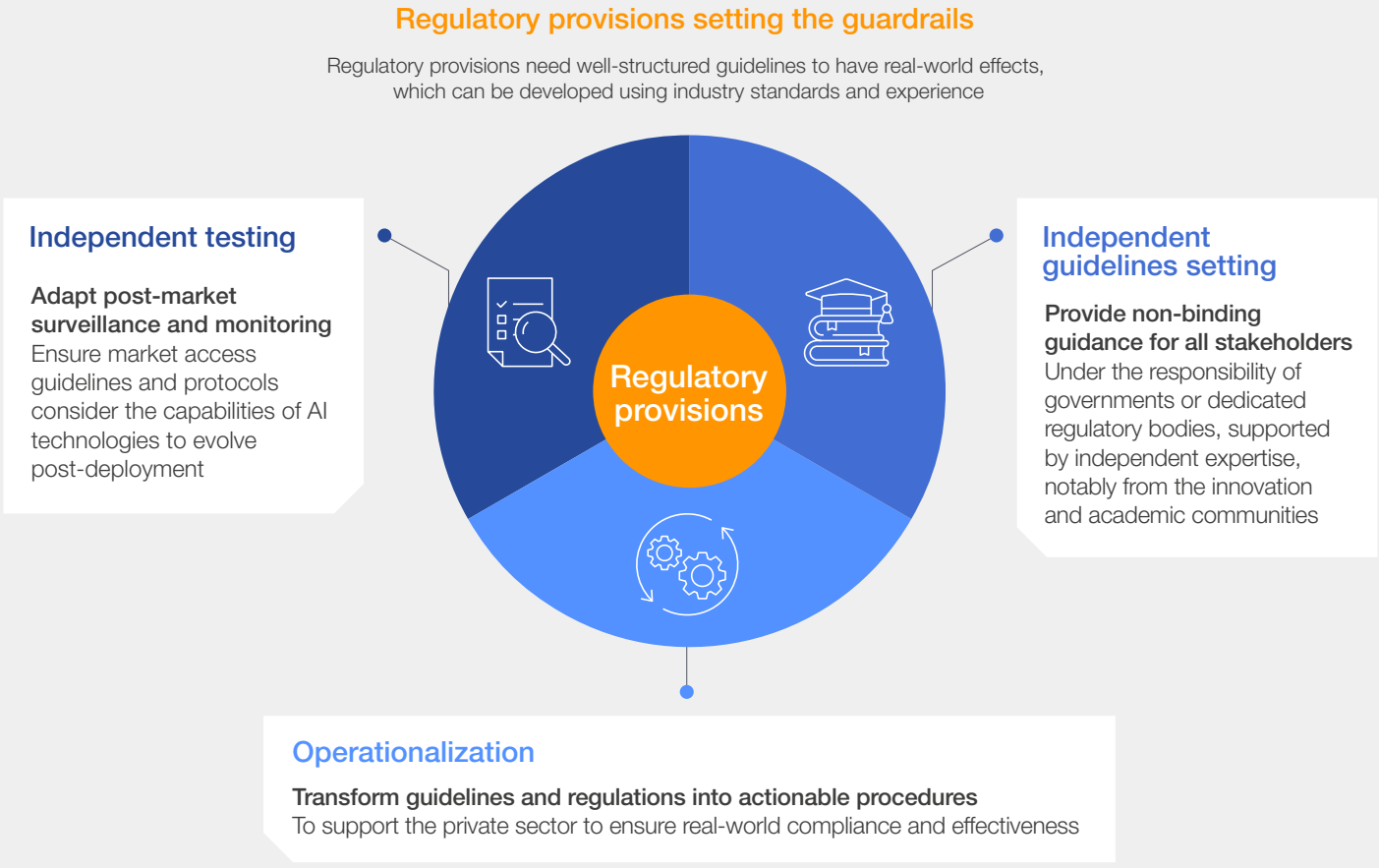
Prior to the widespread emergence of AI technologies, several PPPs were established to help harmonize the regulatory landscape for medical devices, such as the International Medical Devices Regulators Forum (IMDRF) and the Global Harmonization Working Party (GHWP). In recent years, a number of PPPs have emerged specifically for AI technologies in health that coexist with, and build on top of, the work of the IMDRF, GHWP and other medical devices-focused PPPs, for example:

- The Coalition for Health AI (CHAI) was created to harmonize standards and AI health reporting. It is a community made up of health systems, public and private organizations, academic bodies, patient advocacy groups as well as AI and data-science practitioners.[29]
- The Trustworthy and Responsible AI Network (TRAIN), spearheaded by Microsoft and various health organizations, was launched in 2024 to promote ethical AI use, focusing on safe and equitable AI deployment.

3.2 Private sector capabilities can help test and operationalize the regulatory process

Private-sector involvement in the policy development process (see Figure 1) **is important to co-create high-quality guidelines for AI technologies in health.** Most AI technologies for health are developed by private innovators.[30] These innovators can provide critical insights into how their evidence-generation capabilities compare to local guidelines detailing the desired evidence requirements in order to help identify a balanced evidence framework that is feasible for innovators and yields high-quality insights for regulators.

FIGURE 1 | **Proposed framework for regulating AI in health**



Source: World Economic Forum and Boston Consulting Group analysis

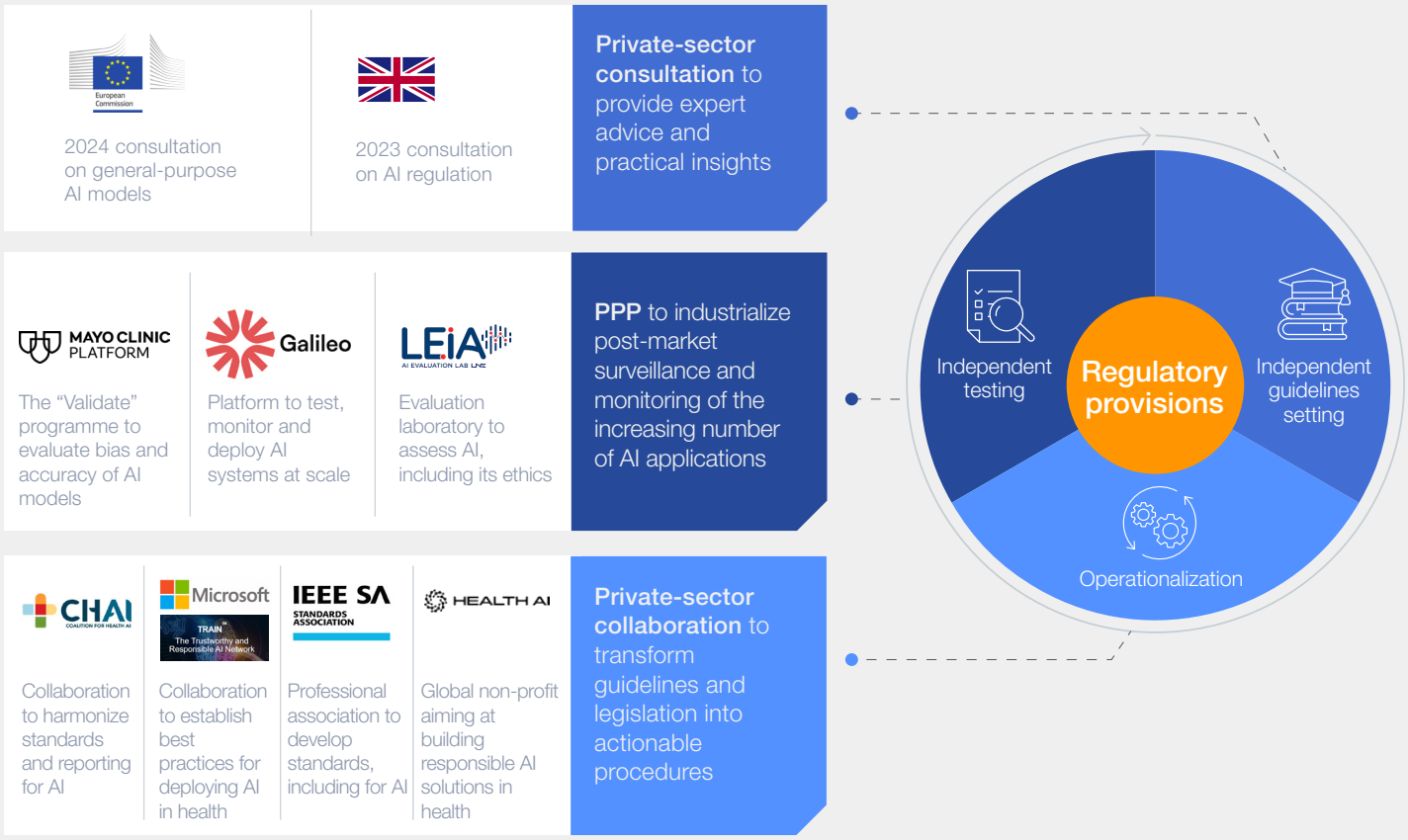
Private-sector involvement should be carefully designed to preserve regulatory integrity and independence, while taking advantage of the sector's unique skills and capabilities. Thus, it is essential to mobilize the private sector at the right steps of the regulatory process (see Figure 1):

- **First, the private sector should be consulted in the upstream phases of the regulatory and guidelines development processes.** The private sector can support the ecosystem to provide non-binding guidance that over time will inform legislation on AI in health.
- **Second, private-sector involvement should extend to the translational aspects of legislation.** A legislative framework sets out a high-level vision for the roles of AI technologies in society, paired with appropriate boundaries and guardrails. The development and implementation of guidelines that aim to realize this high-level vision can benefit greatly from industry input, offering insights into how that vision can be realized through purposeful and public value-driven innovation. For instance, the world's first international standard dedicated to AI management systems (ISO/IEC 42001:2023) was developed through international collaboration involving diverse stakeholders.[31]
- **Third, the private sector is ideally placed to develop and scale pre- and post-market testing and monitoring approaches to detect deviations in the performance of AI technologies and correct them.** The private sector is best positioned to provide the technical expertise needed to build real-time monitoring capabilities. For example, US company Galileo has developed a platform that embeds accurate evaluations directly into AI development workflows.[32]

Regulators already create frameworks for private-sector engagement. However, most of the companies interviewed for this paper reported challenges in making consistent and meaningful contributions. Appropriately involving private-sector actors in the policy process and implementing feedback loops can help ensure that guidelines for AI in health keep pace with technological advances.

FIGURE 2 | **Examples of private-sector involvement in the regulatory process**

Renewed private-sector engagement:
Regulatory provisions need well-structured guidelines to have real-world effects, which can be developed using industry standards and experience



Source: EU consultation: https://digital-strategy.ec.europa.eu/en/consultations/ai-act-have-your-say-trustworthy-general-purpose-ai; UK consultation: https://www.gov.uk/government/consultations/ai-regulation-a-pro-innovation-approach-policy-proposals; FDA consultation: https://www.fda.gov/media/122535/download; Mayo Clinic Platform: https://www.chiefhealthcareexecutive.com/view/ai-success-in-healthcare-requires-transparency-public-private-partnership

3.3 Quality assurance resources: An approach to PPPs for independent testing and training

Quality assurance resources are being established to evaluate and validate AI models independently, using consensus-driven standards and best practices. These resources are structured environments, often in form of labs hosted at a network of quality assurance resource providers (QARPs). They can use a set of community-approved best practices for developing trustworthy health AI, such as those proposed by the Coalition for Health AI (CHAI) or the US National Academy of Medicine's AI Code of Conduct.

Beyond model evaluation, such assurance resources in a network of QARPs can serve as a key infrastructure investment across an AI model's entire life cycle (development, deployment, post-deployment governance and monitoring), supporting a range of critical stakeholders in the health AI ecosystem. For example, they can accelerate model training given their access to robust, heterogeneous data, speeding up development and improving model performance across communities, or they can support longitudinal governance for deployed AI models. The role of QARPs and assurance resources continues to evolve and expand as the concept is tested and scaled.

At the end of 2024, CHAI introduced a framework to certify quality assurance resources primarily led by the private sector. Similarly, in the EU, a network of testing and experimentation facilities (TEFs) is being established[33] – hospital platforms, living labs and laboratory testing facilities, for example. These facilities will give innovators the capacity to carry out tests and experiments on their AI technologies in large-scale and sustainable real or realistic environments.

Conclusion

Health-system leaders, regulatory bodies and the private sector must collaborate to unlock AI's full potential while mitigating its associated risks.

Healthcare tech companies are working to accelerate the development of high-quality AI technologies that meet the needs of the health sector across the world. Clear regulatory frameworks and supporting guidelines will be critical to foster the purposeful innovation of health AI technologies. Unlocking this new approach will require three strategic shifts:

1. **Build technical expertise among health leaders and clinical decision-makers**

   Health leaders and clinicians should seek to upskill and engage with technical experts with healthy scepticism, actively challenging technical propositions to ensure that they align with the overarching vision. In the future, understanding the capabilities, limitations and risks of AI technologies will no longer be the sole responsibility of chief technology officers (CTOs) but will become a fundamental skill for health leaders and clinicians to adapt evaluation practices to the presence of AI technologies.[34]

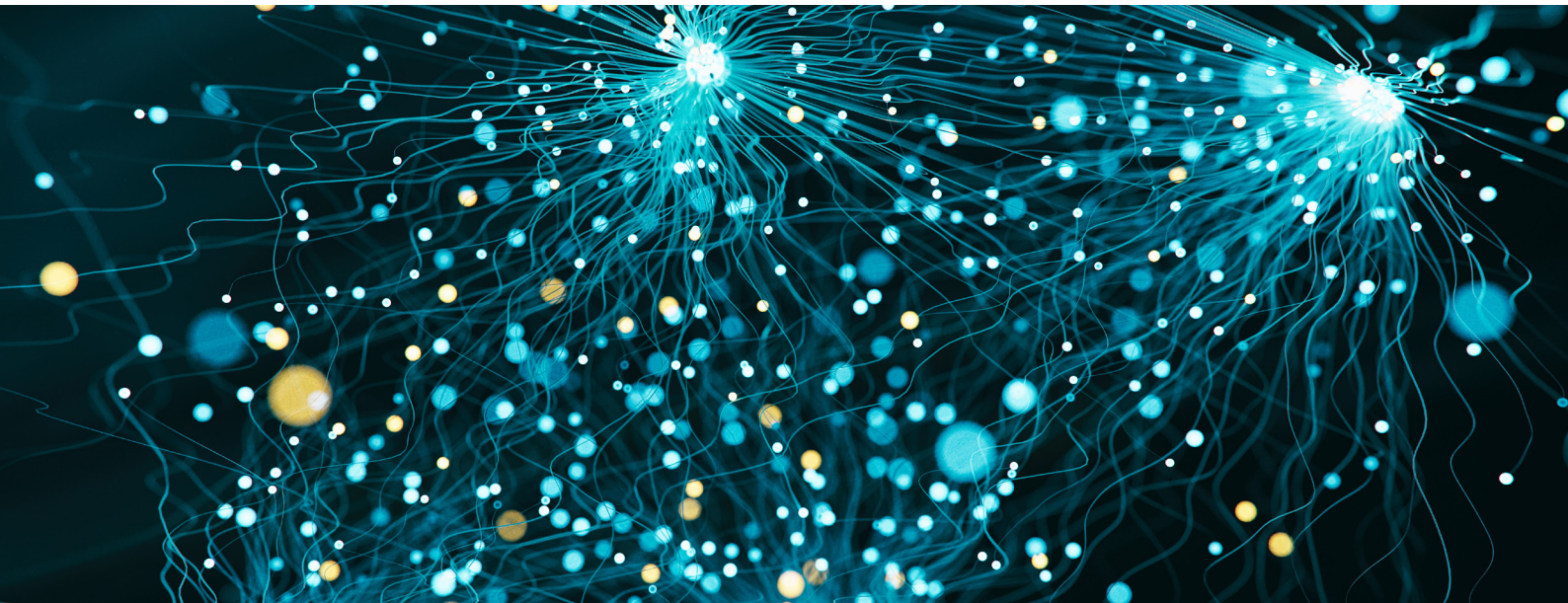
2. **Support the translation of legislative goals into actionable guidelines that create incentives for purposeful innovation**

   The emergence of the first generation of AI-focused legislation establishes a paradigm within which the use of AI technologies is considered acceptable. The next step of developing complementary guidance documents and infrastructure can benefit significantly from public–private engagement, such as the organization of regulatory sandboxes, rigorous evaluation methods including pre- and post-market surveillance and AI assurance resources to detect early signals of AI-related risks as soon as possible and with full transparency. Trust can be earned even before legislation comes into effect by adhering to existing guidelines and standards.

3. **Mobilize public–private partnerships to actively engage the private sector in lifecycle management**

   Private-sector involvement in AI systems' evaluation efforts is important due to the rapidly evolving AI innovation landscape. PPPs are necessary to engage with the private sector in order to cope with the increasing number of AI technologies that need to be tested and must be compliant with a growing set of requirements. In addition, these partnerships can play a crucial role in supporting the acceleration of model training and development as well as post-deployment monitoring.

Promoting cooperative engagement such as public–private partnerships and prioritizing upskilling and evaluation practices can create an innovation environment that is agile and transparent. Collaborative action can build a system that not only harnesses AI to revolutionize healthcare but does so in a way that prioritizes patient safety and trust. The future of AI in health has immense promise, and with collective effort, society can ensure that it delivers on that promise responsibly.



Appendix: A selection of regulatory sandbox initiatives

Approach	Country / Responsible entity	Sector	Objectives
Energy regulation sandbox[35]	United Kingdom – Ofgem	Energy	Allow for innovation in products, services and business models that are restricted by current regulations. Ofgem can provide: – Guidance, comfort and time-limited derogations from specific rules – Confirmation that an activity is permissible – Rule removal through a derogation
FinTech regulatory sandbox[36]	Singapore – Monetary Authority of Singapore (MAS)	Financial services	Temporarily relax regulatory requirements to allow for experiments with innovative business ideas in a live environment. The MAS can support an experiment by loosening selected legal and regulatory requirements during the sandbox. The Sandbox Plus programme also includes grants for first movers.
RBI's regulatory sandbox[37]	India – Reserve Bank of India (RBI)	Financial services	Governed by oversight and safeguards, market participants can test products, business models and services in a live environment. The test product should include new/emerging technology (such as application program interface, data analytics and mobile technology) or innovative use of existing technology. Products to be tested should address a particular problem and deliver clear benefits for consumers.
Licensing Experimentation and Adaptation Programme (LEAP)[38]	Singapore – Ministry of Health of Singapore	Health	Enable safe experimentation in healthcare services in Singapore. Under the programme, which was introduced to support the emergence of telemedicine, regulators work with providers to understand the operating models and risks connected to it and develop regulations. The programme may include subsidies.
ARCEP's regulatory sandbox[39]	France – Telecommunications Regulation Authority for Electronic and Postal Communications (ARCEP)	Telecommunications	Allow temporarily relaxed regulation for up to two years to enable players to experiment with innovations supported by 5G technology. The sandbox includes a frequency band (26 GHz) allocated to innovators by ARCEP.
Sandbox notification	Thailand – National Broadcasting and Telecommunication Commission (NBTC)	Telecommunications	Facilitate testing of the technology for adopting 5G in Thailand. This is an area-based regulatory sandbox, under which experiments in NBTC-designated locations are not subject to existing regulations.
Unmanned Aircraft System Integration Pilot Program[40]	United States – Federal Aviation Administration (FAA)	Transport	Test the safe use of unmanned aerial vehicles (UAVs), also often referred to as drones, for a period of 30 months. Under the scheme, private-sector applicants could partner with state, local or tribal governments to apply for a waiver from United States airspace regulation to test UAVs.
Japan Regulatory Sandbox[41]	Japan – Cabinet Secretariat	Cross-sectoral	Enable innovators to demonstrate cutting-edge technologies and business models in any sector. The sandbox framework includes the System to Remove Grey Zone Areas and the System of Special Arrangements for New Business Activities (allowing for a participant to ask for exemption from regulatory requirements).

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Editor, Astra Content

Endnotes

1. Organisation for Economic Co-operation and Development (OECD). (2017, January 10). *Tackling wasteful spending on health*. https://www.oecd.org/en/publications/tackling-wasteful-spending-on-health_9789264266414-en.html
2. World Health Organization (WHO). (n.d.). *Health workforce*. Retrieved May 12, 2025, from https://www.who.int/health-topics/health-workforce#tab=tab_1
3. World Economic Forum. (2023, September 13). *Why addressing burnout among healthcare workers is crucial to advance health-related SDGs*. https://www.weforum.org/stories/2023/09/addressing-healthcare-worker-burnout-and-the-urgent-path-to-sdg3-health/#:~:text=Building%20bridges%20for%20comprehensive%20community,food%20insecurity%20and%20the%20environment.
4. Han, R., et al. (2024, May). Randomised controlled trials evaluating artificial intelligence in clinical practice: A scoping review. *The Lancet Digital Health 6*(5), E367–E373. https://www.thelancet.com/journals/landig/article/PIIS2589-7500(24)00047-5/fulltext
5. Fisches, Z. V., et al. (2024). Strategies for integrating artificial intelligence into mammography screening programmes: A retrospective simulation analysis. *The Lancet Digital Health 6*, E803–814. https://www.thelancet.com/pdfs/journals/landig/PIIS2589-7500(24)00173-0.pdf
6. Grand View Research. (2024). *Artificial intelligence market size & trends*. https://www.grandviewresearch.com/industry-analysis/artificial-intelligence-ai-market#:~:text=The%20global%20artificial%20intelligence%20market%20size%20was%20estimated%20at%20USD,USD%201%2C811.75%20billion%20by%202030
7. US Food and Drug Administration. (n.d.). *Novel drug approvals for 2023*. Retrieved May 12, 2025, from https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2023
8. Singh, N., et al. (2023, May 24). Drug discovery and development: Introduction to the general public and patient groups. *Frontiers in Drug Discovery 3*. https://www.frontiersin.org/journals/drug-discovery/articles/10.3389/fddsv.2023.1201419/full
9. Kastrup, N., et al. (2024). Landscape and challenges in economic evaluations of artificial intelligence in healthcare: A systematic review of methodology. *BMC Digital Health 2*. https://bmcdigitalhealth.biomedcentral.com/articles/10.1186/s44247-024-00088-7
10. Widder, D. G., et al. (2024, November 27). Why “open” AI systems are actually closed, and why this matters. *Nature 8040*, 827–833. https://www.nature.com/articles/s41586-024-08141-1
11. Hendrix, N., et al. (2022). Assessing the economic value of clinical artificial intelligence: Challenges and opportunities. *Value in Health (25)*3, 331–339. https://www.sciencedirect.com/science/article/pii/S1098301521017435
12. The team conducted interviews with experts from the regulation space, the private sector, civil society organizations and multilateral organizations. Five workshops were also organized, two of which were specifically tailored for regulators.
13. Schmidt, J., et al. (2024, August 27). Mapping the regulatory landscape for artificial intelligence in health within the European Union. *npj digital medicine 7*, 229. https://www.nature.com/articles/s41746-024-01221-6
14. World Health Organization (WHO). (2023, October 19). *Regulatory considerations on artificial intelligence for health*. https://www.who.int/publications/i/item/9789240078871
15. The team acknowledge that the scrutiny and hesitancy are not an AI-specific phenomenon and are equally relevant to other areas of innovation in health, such as pharmaceuticals and medical technologies.
16. For example, DeepMind partnered with the Royal Free London NHS Foundation Trust in 2016 only to discover later that DeepMind had accessed identifiable patient records without proper tracking mechanisms.
17. Organisation for Economic Co-operation and Development (OECD). (2021, June 28). *Tools for trustworthy AI: A framework to compare implementation tools for trustworthy AI systems*. https://www.oecd.org/en/publications/tools-for-trustworthy-ai_008232ec-en.html
18. HealthAI. (2024). *Mapping AI governance in health: From global regulatory alignments to LMICs’ policy developments*, 32. https://clias.iecs.org.ar/wp-content/uploads/2024/10/HealthAI_GlobalLandscapeReport_Oct.2024.pdf
19. Ibid., 22.
20. Busch, F., et al. (2024, August 12). Navigating the European Union Artificial Intelligence Act for Healthcare. *npj digital medicine 7*, 210. https://www.nature.com/articles/s41746-024-01213-6
21. van Kessel, R., et al. (2025). *A scoping review and expert consensus on digital determinants of health*. Bulletin of the World Health Organization. https://cdn.who.int/media/docs/default-source/bulletin/online-first/blt.24.292057.pdf?sfvrsn=125e259_3
22. The United Nations emphasizes that “effective governance should leverage existing institutions that will have to review their current functions in light of the impact of AI”. See HealthAI. (2024). *Mapping AI governance in health: From global regulatory alignments to LMICs’ policy developments*, 32. https://clias.iecs.org.ar/wp-content/uploads/2024/10/HealthAI_GlobalLandscapeReport_Oct.2024.pdf

23. For GenAI tools, regulators could also build upon existing regulations for health professions. Regulators could mandate that GenAI tools undergo specific training, examinations, periodic assessments and retraining. For more insights, see Blumenthal, D., & Patel, B. (2024, September 4). *How to regulate generative AI in health care*. Harvard Business Review. https://hbr.org/2024/09/how-to-regulate-generative-ai-in-healthcare

24. "Lebanon currently lacks specific strategy, laws, statutes, or regulations that govern AI or its use in health." "Pakistan hasn't released any laws yet for AI or AI in health … As a federated republic with healthcare managed at the provincial level, regulating AI in health may face additional challenges due to decentralization." HealthAI. (2024). *Mapping AI governance in health: From global regulatory alignments to LMICs' policy developments*, 56, 60. https://clias.iecs.org.ar/wp-content/uploads/2024/10/HealthAI_GlobalLandscapeReport_Oct.2024.pdf

25. Schmidt, J., et al. (2024, August 27). Mapping the regulatory landscape for artificial intelligence in health within the European Union. *npj digital medicine 7*, 229. https://www.nature.com/articles/s41746-024-01221-6

26. World Economic Forum. (2024, January 9). *Transforming healthcare: Navigating digital health with a value-driven approach.* https://www.weforum.org/publications/transforming-healthcare-navigating-digital-health-with-a-value-driven-approach/; OECD. (2020, June 12). *The role of sandboxes in promoting flexibility and innovation in the digital age*. https://www.oecd.org/en/publications/the-role-of-sandboxes-in-promoting-flexibility-and-innovation-in-the-digital-age_cdf5ed45-en.html; World Health Organization (WHO). (2023). Regulatory considerations on artificial intelligence in health. https://iris.who.int/bitstream/handle/10665/373421/9789240078871-eng.pdf

27. UK Government. (2024, May 9). *AI Airlock: The regulatory sandbox for AIaMD*. https://www.gov.uk/government/collections/ai-airlock-the-regulatory-sandbox-for-aiamd

28. US Food and Drug Administration. (n.d.). *Methods and tools for effective postmarket monitoring of artificial intelligence (AI)-enabled medical devices*. Retrieved May 12, 2025, from https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/methods-and-tools-effective-postmarket-monitoring-artificial-intelligence-ai-enabled-medical-devices

29. Coalition for HealthAI. (n.d.). *Responsible use of AI in health*. Retrieved May 12, 2025, from https://chai.org/

30. Muehlematter, U. J., et al. (2021, March). Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): A comparative analysis. *The Lancet Digital Health 3*(3), e195–e203. https://pubmed.ncbi.nlm.nih.gov/33478929/

31. American National Standards Institute. (2023, December 27). *Using AI responsibly: US leads efforts to develop ISO/IEC 42001, Artificial Intelligence Management System Standard*. https://www.ansi.org/standards-news/all-news/2023/12/12-27-23-using-ai-responsibly-us-leads-efforts-to-develop-iso-iec-42001

32. Galileo. (n.d.). *Unlock evaluation intelligence for AI teams*. Retrieved May 12, 2025, from https://galileo.ai/

33. European Commission. (n.d.). *Sectorial AI testing and experimentation facilities under the Digital Europe Programme*. Retrieved May 12, 2025, from https://digital-strategy.ec.europa.eu/en/policies/testing-and-experimentation-facilities

34. 34 Car, J., et al. (2025, January 31). *The Digital Health Competencies in Medical Education Framework: An international consensus statement based on a Delphi study*. JAMA Network Open. https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2829788

35. Ofgem. (n.d.). *Energy regulation sandbox*. Retrieved May 12, 2025, from https://www.ofgem.gov.uk/energy-regulation-sandbox

36. See Monetary Authority of Singapore. (n.d.). *Overview of regulatory sandbox*. Retrieved May 12, 2025, from https://www.mas.gov.sg/development/fintech/regulatory-sandbox

37. See Reserve Bank of India. (n.d.). *Enabling framework for regulatory sandbox*. Retrieved May 12, 2025, from https://www.rbi.org.in/Scripts/PublicationReportDetails.aspx?UrlPage=&ID=938

38. See Ministry of Health Singapore. (2024, October 28). *Regulatory sandbox*. https://www.moh.gov.sg/others/health-regulation/regulatory-sandbox/

39. See ARCEP. (2019, January 31). *The French government and Arcep issue a call for the creation of 5G trial platforms in the 26 GHz band* [Press release]. https://en.arcep.fr/news/press-releases/view/n/5g-16.html

40. See US Federal Aviation Administration. (n.d.). *UAS integration pilot program*. Retrieved May 12, 2025, from https://www.faa.gov/uas/programs_partnerships/completed/integration_pilot_program

41. See Cabinet Secretariat. *On the regulatory sandbox system* (Japanese language) https://www.cas.go.jp/jp/seisaku/s-portal/pdf/underlyinglaw/Japans_Regulatory_Sandbox.pdf and IFLR (2019, July 20). *Japan: Sandbox reform*. https://www.iflr.com/article/2a63afeimueh7mpx1lb0g/japan-sandbox-reform

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