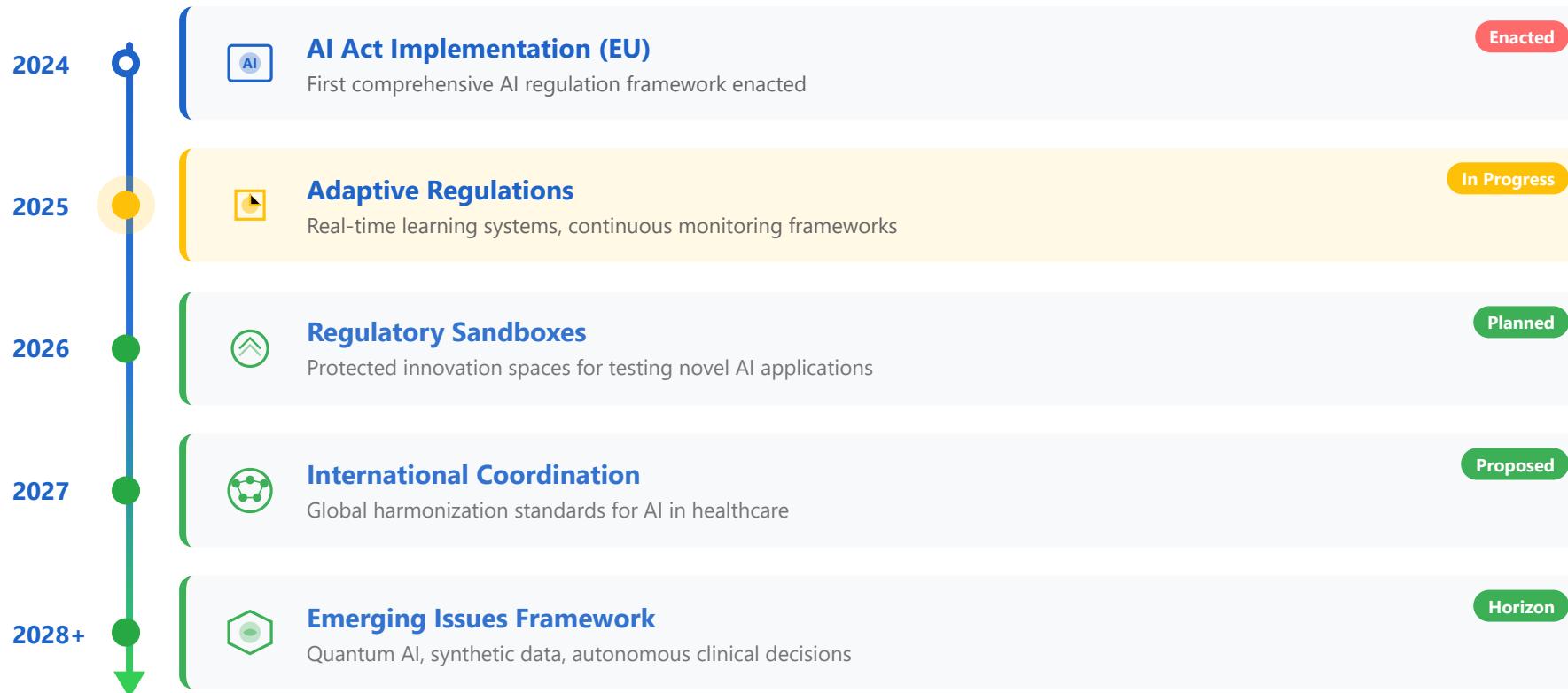


Future Regulations in AI Healthcare



2024

AI Act Implementation (EU)

First Comprehensive AI Regulation Framework



► Key Components

- Risk-based classification system (minimal, limited, high, unacceptable)
- Mandatory conformity assessments for high-risk AI systems
- Transparency requirements for AI-generated content
- Prohibition of certain AI practices (social scoring, manipulation)
- Specific provisions for general-purpose AI models

► Healthcare Impact

Medical AI systems used for diagnosis, treatment decisions, or patient monitoring are classified as high-risk applications. These require rigorous documentation, quality management systems, human oversight mechanisms, and post-market surveillance. Healthcare providers must ensure AI systems meet safety and performance standards before clinical deployment.

Implementation Timeline

2025 Adaptive Regulations

Real-Time Learning Systems & Continuous Monitoring

The AI Act entered into force in August 2024, with a phased implementation: prohibited practices (6 months), general-purpose AI rules (12 months), and full compliance for high-risk systems including healthcare AI (24-36 months).

► Dynamic Regulatory Approach

- Continuous performance monitoring of deployed AI systems
- Real-time risk assessment and adaptation mechanisms
- Automated compliance checking and reporting tools
- Machine learning for regulatory pattern detection
- Feedback loops between regulators and developers

► Healthcare Applications

Adaptive regulations enable healthcare AI systems to evolve safely in response to new medical evidence and patient



2026 Regulatory Sandboxes

Protected Innovation Spaces for Novel AI Applications

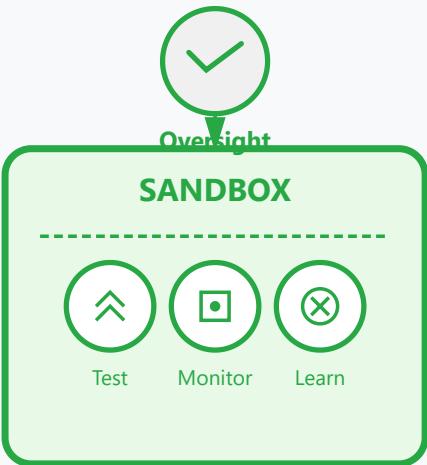
populations. Regulators can track model drift, performance degradation, and emerging safety signals without waiting for periodic reviews. This approach balances innovation with patient safety through intelligent oversight.

Key Innovation

Unlike traditional static regulations, adaptive frameworks use AI to monitor AI, creating responsive governance that keeps pace with technological change while maintaining rigorous safety standards.

► Sandbox Framework

- Controlled testing environment with regulatory exemptions



- Close collaboration between innovators and regulators
- Defined scope, duration, and success criteria
- Graduated pathway from sandbox to full approval
- Shared learning across participants and regulators

► Healthcare Innovation Benefits

Regulatory sandboxes allow breakthrough AI technologies to be tested in real clinical settings with appropriate safeguards before full regulatory approval. This accelerates innovation for AI-powered diagnostics, personalized treatment algorithms, and predictive health monitoring while gathering evidence of safety and efficacy under regulatory supervision.

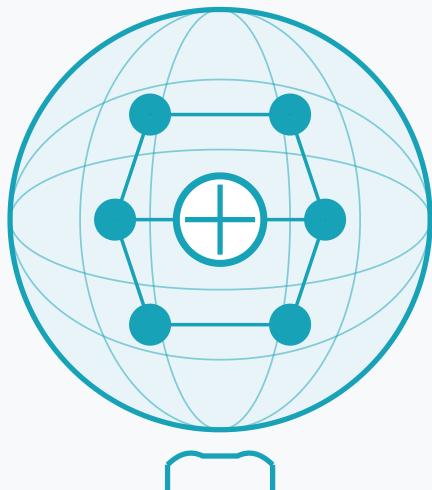
Example Applications

Novel AI systems for rare disease diagnosis, experimental treatment optimization algorithms, AI-assisted surgical planning tools, and next-generation clinical decision support systems can be validated through sandbox programs before widespread deployment.

2027

International Coordination

Global Harmonization Standards for AI in Healthcare



► Harmonization Goals

- Common standards for AI safety and efficacy assessment
- Mutual recognition of regulatory approvals across jurisdictions
- Shared databases for adverse events and safety signals
- Coordinated approach to emerging AI technologies
- International guidelines for clinical AI deployment

► Global Healthcare Impact

International coordination eliminates redundant regulatory processes, accelerates global access to beneficial AI technologies, and ensures consistent safety standards worldwide. Healthcare providers can confidently adopt AI systems approved in one region knowing they meet internationally recognized standards. This particularly benefits low- and middle-income countries by leveraging global expertise.

2028+

Emerging Issues Framework

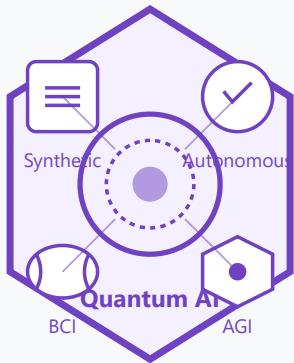
Quantum AI, Synthetic Data & Autonomous Clinical Decisions

Key Organizations

WHO, FDA, EMA, and regional regulatory bodies collaborate through frameworks like the International Medical Device Regulators Forum (IMDRF) to establish common AI standards, share best practices, and coordinate regulatory science initiatives.

► Emerging Technologies

- Quantum computing-enhanced AI for molecular simulation and drug discovery
- Synthetic patient data for privacy-preserving AI training
- Fully autonomous diagnostic and treatment decision systems
- Brain-computer interfaces integrated with AI assistants
- Artificial general intelligence in clinical settings



HORIZON TECHNOLOGIES

► Regulatory Challenges

These frontier technologies pose unprecedented regulatory questions: How do we validate synthetic training data? What level of autonomy is acceptable in life-critical decisions? How do we assess quantum AI systems that operate beyond human verification? The emerging issues framework must be flexible, anticipatory, and grounded in ethical principles while fostering responsible innovation.

Proactive Governance

Rather than reactive regulation, this framework emphasizes horizon scanning, early stakeholder engagement, and adaptive policies that can evolve with technology. It includes ethics boards, public deliberation, and continuous reassessment of fundamental assumptions about AI in healthcare.