

Future Policy Directions

Future regulatory policies are evolving in line with AI technology development



AI Act (EU)

Comprehensive regulatory framework for high-risk AI systems



Adaptive Regulation

Flexible regulatory model for continuously learning AI

Expected Policy Changes

- **Real-World Evidence Expansion:** Increase in RWE-based approvals
- **Digital Health Integration:** Integrated regulation of SaMD, wearables, and telemedicine
- **Enhanced Algorithm Transparency:** Growing requirements for Explainable AI
- **Fairness Assessment:** Mandatory bias testing and fairness metrics
- **Strengthened Cybersecurity:** Expanded software security requirements
- **Accelerated International Harmonization:** Global standardization centered on IMDRF



Performance Standards

Standardized benchmarks and metrics



Audit Automation

AI-based regulatory compliance tools



Digital Twin

Simulation-based validation



Key Point: Regulations are evolving to ensure patient safety without hindering innovation, and companies must proactively prepare for these trends