

## 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