Global Regulatory Landscape

Medical AI systems are **directly linked to patient safety** and are subject to **strict regulatory frameworks**

FDA
United States

EMA
European Union

MHRA
United Kingdom

Health Canada
Canada

PMDA
Japan

MFDS
South Korea

Risk-Based Classification
Application of differentiated regulatory levels based on device risk

Clinical Evidence Requirements
Submission of data to demonstrate safety and effectiveness

Post-Market Surveillance
Continuous performance monitoring and reporting obligations

International Harmonization
Efforts to unify regulatory standards through IMDRF