

# AI in Healthcare Needs Global Policy Minds

The most advanced AI won't matter without the right governance.

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## THE DATA

# 1,500

### AI medical devices authorized by FDA

The FDA has cleared 1,500 AI-driven medical devices since 2017, but evidence for most remains limited.

This surge in approvals reveals a critical gap: regulatory speed is outpacing clinical validation. While AI tools are being deployed in hospitals and clinics, the real-world performance data to support their safety and efficacy often lags behind.



# 01

## Regulation Is the First AI Layer

AI in healthcare isn't just about algorithms—it's about governance. The moment a device is authorized, it enters clinical workflows without a full evidence base. This creates a feedback loop where deployment drives adoption before proof, making policy the first line of defense against harm.

# 02

## Evidence Must Catch Up to Deployment

The 1,500 FDA-approved AI devices represent a massive real-world experiment—yet only a fraction have undergone peer-reviewed validation. Without coordinated global policy frameworks, the risk of algorithmic bias, diagnostic drift, and unintended clinical outcomes increases exponentially, especially in under-resourced health systems.

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