The Lux Policy Compass for Medical Devices and Diagnostics

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Agenda

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2 | Major Impacts Across MDD Sectors

3 | Key Takeaways

The Lux Policy Compass

The Lux Policy Compass

Business impact

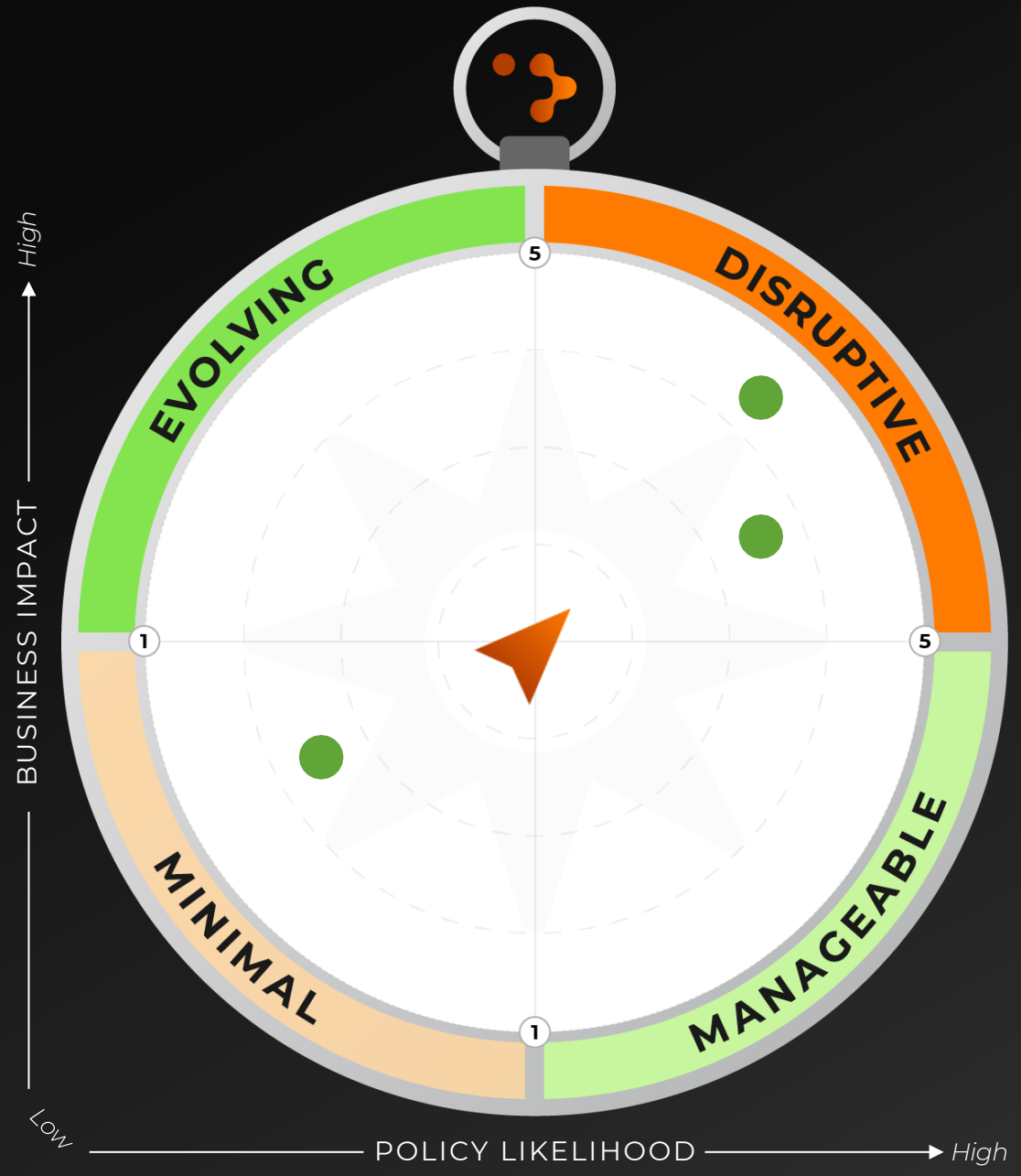
The business impact score represents how a policy affects the six major aspects of the industrial sector and its value chains, including:

- Input
- Process
- Product
- Partners
- Demand
- Incentives

Policy likelihood

The likelihood of a policy or regulation to materialize, from ideation to implementation. Key considerations include:

- Policy's current status
- Governmental approval
- Political volatility



The Lux Policy Compass

Minimal

Policy likelihood: *Low* | Business impact: *Low*

Evolving

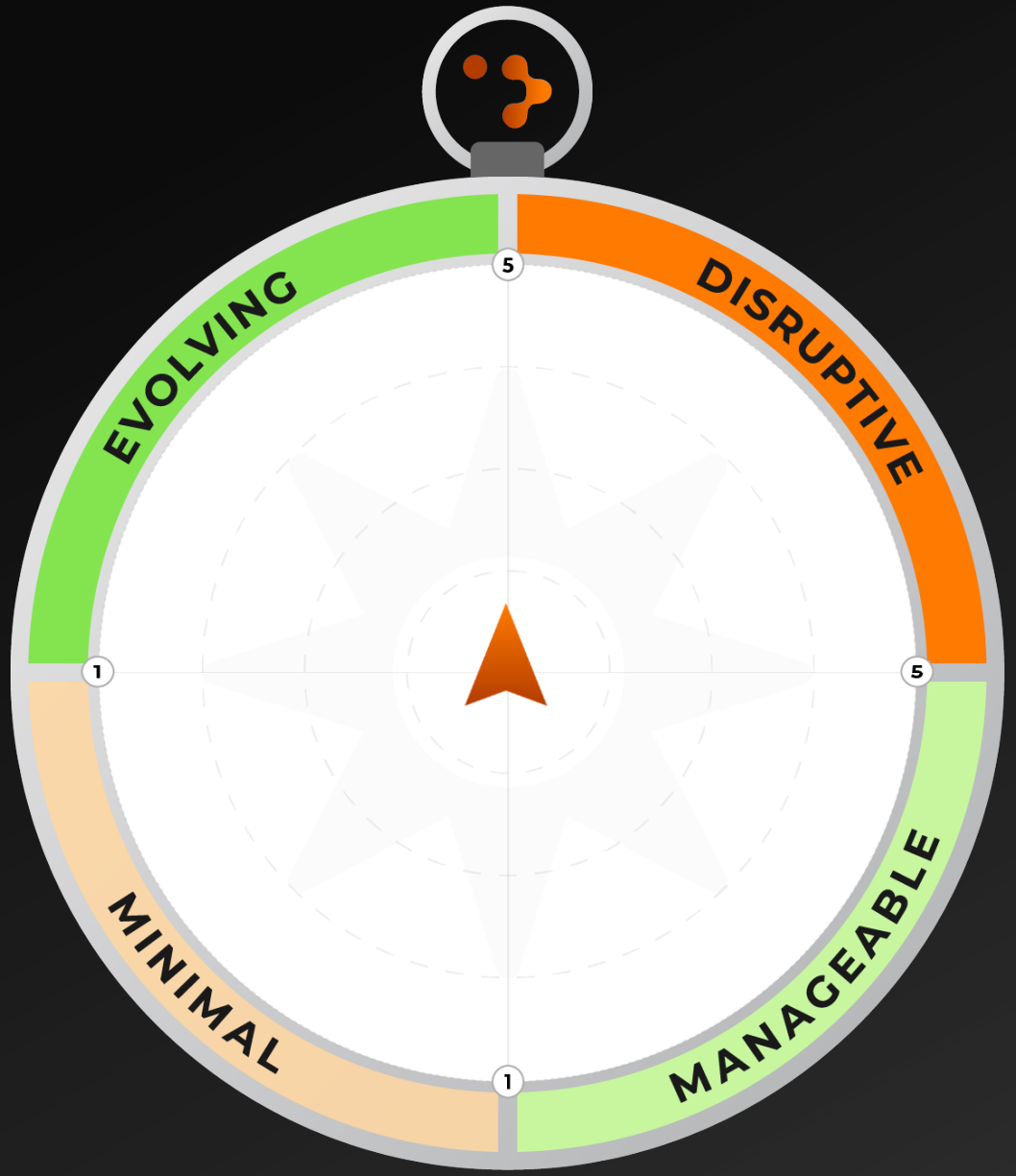
Policy likelihood: *Low* | Business impact: *High*

Manageable

Policy likelihood: *High* | Business impact: *Low*

Disruptive

Policy likelihood: *High* | Business impact: *High*



The Lux Policy Compass is a guide

1

How can I avoid risks from policy/regulation in my technology innovation strategy?

2

How can I make the most of policy-generated opportunities for innovation?

3

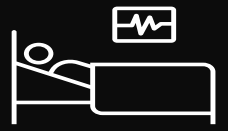
In what cases does policy/regulation affect how, where, when, and with whom I should pursue innovation?

Major Impacts Across MD&D Sectors

Lux for Innovation Leaders

Build Precision Treatment and Care

Optimize targeted care while aligning on priorities and cost to drive impact at scale. Leverage precision to cut recovery time, minimize errors, and improve outcomes across urgent and routine conditions.



Innovate Point-of-Care Solutions

Evaluate reliable, connected point-of-care and at-home monitoring solutions to accelerate treatment decisions, reduce hospital stays and readmissions, expand access, and enhance user experience.

Healthcare Operational Excellence

Transform repetitive tasks across care settings to relieve workforce shortages and evolving care pressures, enabling clinicians to focus on complex decision-making.

Streamline Laboratory Workflows

Overcome lab bottlenecks by addressing costs, workforce shortages, and high volumes by leveraging advanced technologies and workflow orchestration systems.

POLICY COMPASS

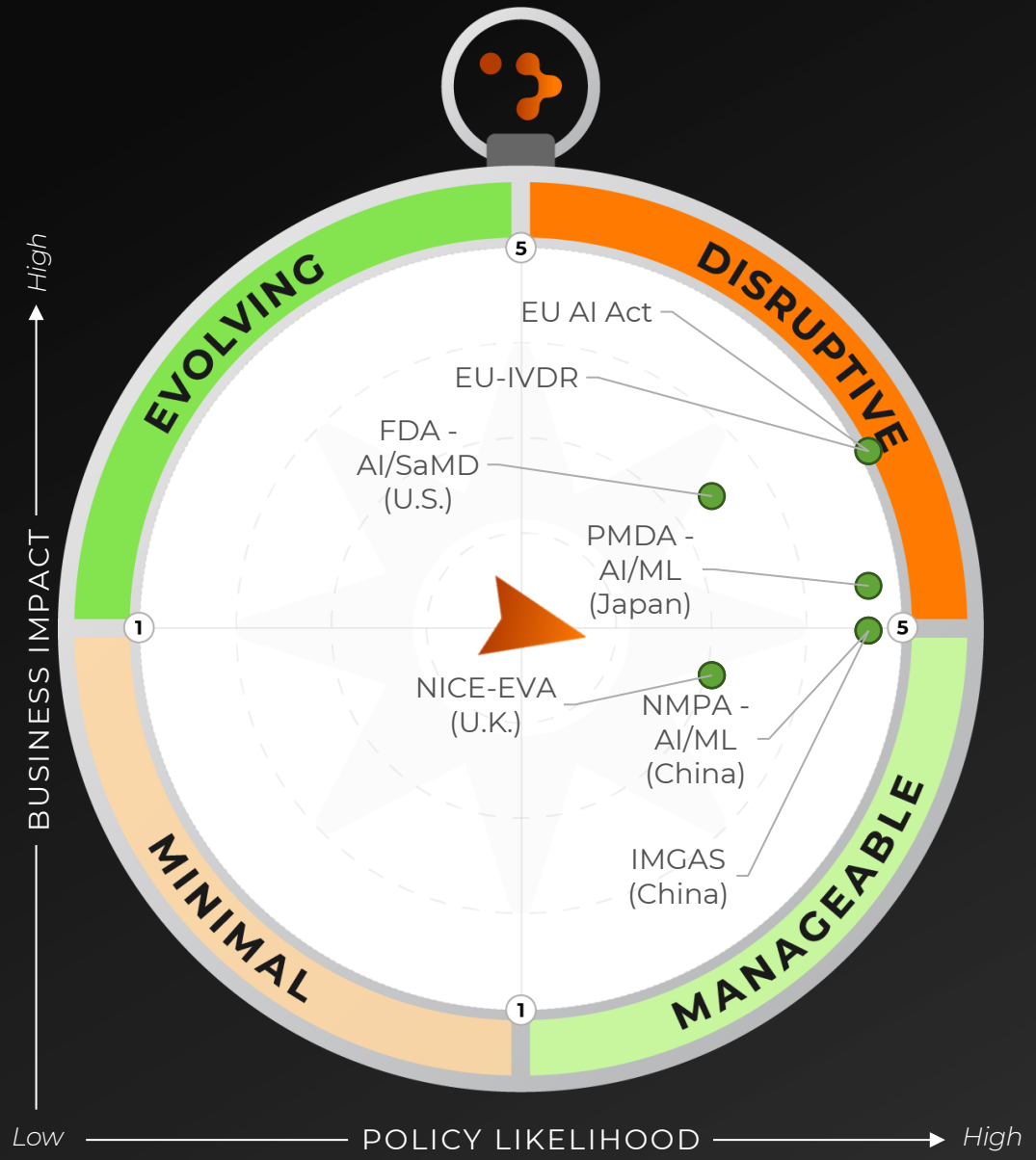
Build Precision Treatment and Care

Build for precision care as a regulated, scalable operating model

- Precision care is now becoming a regulated operating model.
- Regulators and payers converge on life cycle accountability.
- Asia is no longer an observer but is moving in tandem with the U.S./EU.

POLICY TITLE LEGEND

EU AI Act	**IMGAS (China):** Interim Measures for Generative AI Services
FDA – AI/SaMD (U.S.): FDA Framework for AI and Software as a Medical Device	**EU-IVDR:** EU In Vitro Diagnostic Regulation transition changes (Reg. 2017/746 + 2023/607)
NMPA – AI/ML (China): National Medicinal Products Administration Guiding Principles for AI/ML-Enabled Medical Devices	**NICE-EVA (U.K.):** National Institute for Health and Care Excellence Early Value Assessment
PMDA – AI/ML: Japan's Pharmaceutical and Medical Devices Agency – AI/ML guidelines	



POLICY HIGHLIGHT

NICE-EVA Act

Improving credibility, but not an adoption shortcut

- The U.K.'s NICE-EVA aims to accelerate access to promising medtech and digital health innovations.
- While it boosts early credibility, there is no guarantee of National Health Services (NHS) adoption.

LUX TAKE

NICE-EVA can validate your story, but it won't build your market for you. Adoption is still dependent on local NHS purchasing decisions.

NICE National Institute for Health and Care Excellence

Image source: NHS

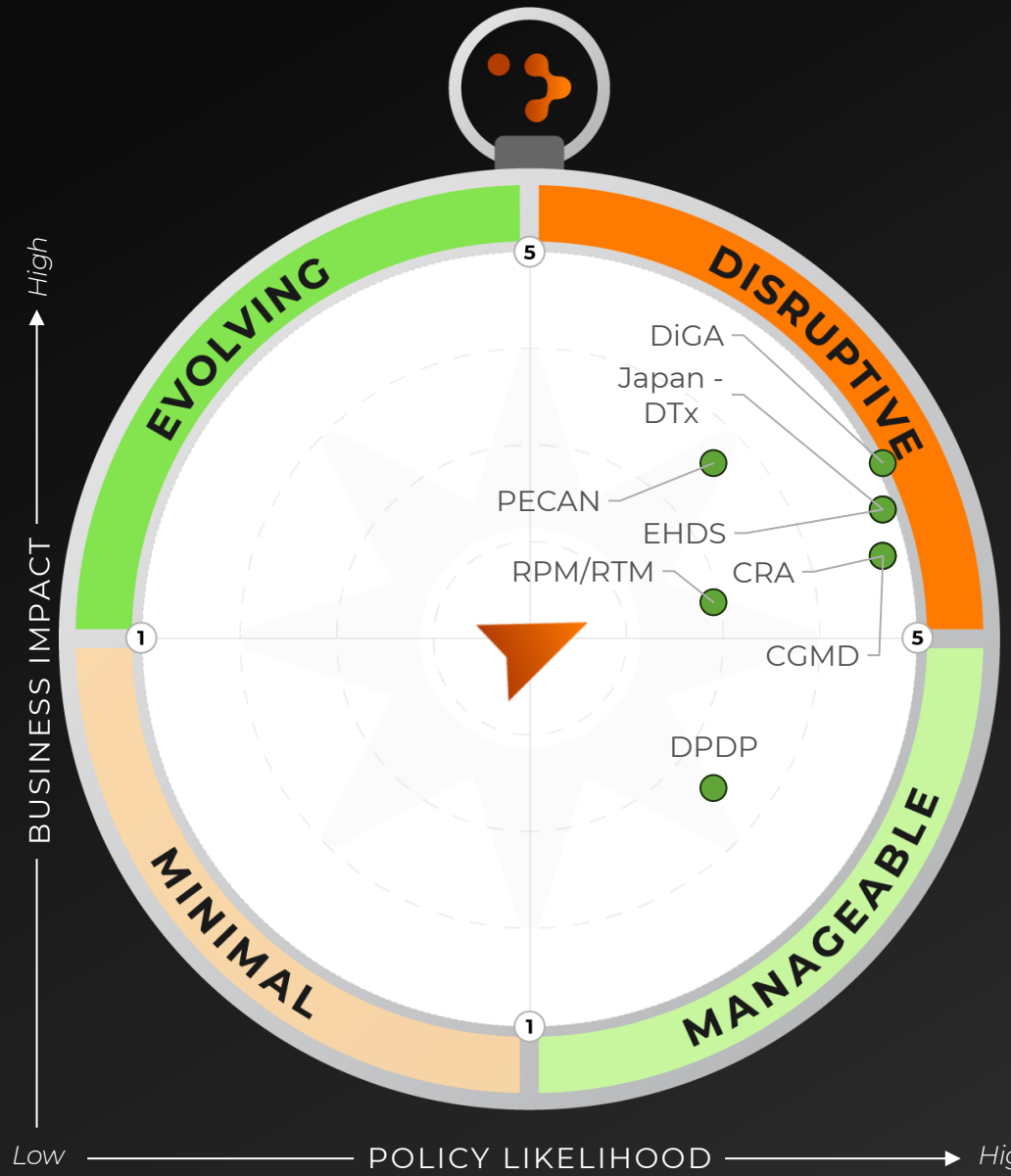
POLICY COMPASS

Innovating Point-of-Care (POC) Solutions

Winning in POC will depend on operational execution

- Policy is making POC care more scalable and reimbursable.
- Regulation is raising the bar.
- Companies must align evidence, secure connectivity, and compliance to scale.

POLICY TITLE LEGEND	
EHDS (EU): European Health Data Space Regulation 2025/327	**RPM/RTM (U.S.):** Medicare Remote Physiologic Monitoring/Remote Therapeutic Monitoring coverage
CRA (EU): Cyber Resilience Act	**DiGA (Germany):** Digitale Gesundheitsanwendungen
CGMD (U.S.): FDA Cybersecurity Guidance in Medical Devices (June 2025)	**PECAN (France):** (Prise en Charge Anticipée Numérique) & Digital Medical Devices (DMD)
DPDP (India): Digital Personal Data Protection Act	**Japan-DTx:** Japan Digital Therapeutics framework



POLICY HIGHLIGHT

Japan-DTx guidelines

National policy creates a clear market pathway for digital therapies

- Japan shows that DTx can move from pilot to routine care when regulatory clearance and reimbursement are coordinated through a national pathway.
- Japan's National Health Insurance model gives software-based treatments a real commercialization route, especially for POC-adjacent care built around monitoring, adherence, and early intervention.

LUX TAKE

Japan serves as a policy-aligned entry market for high-impact offerings that combine strong evidence with operational readiness for frontline deployment.

PMDA
独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Image source: CureApp

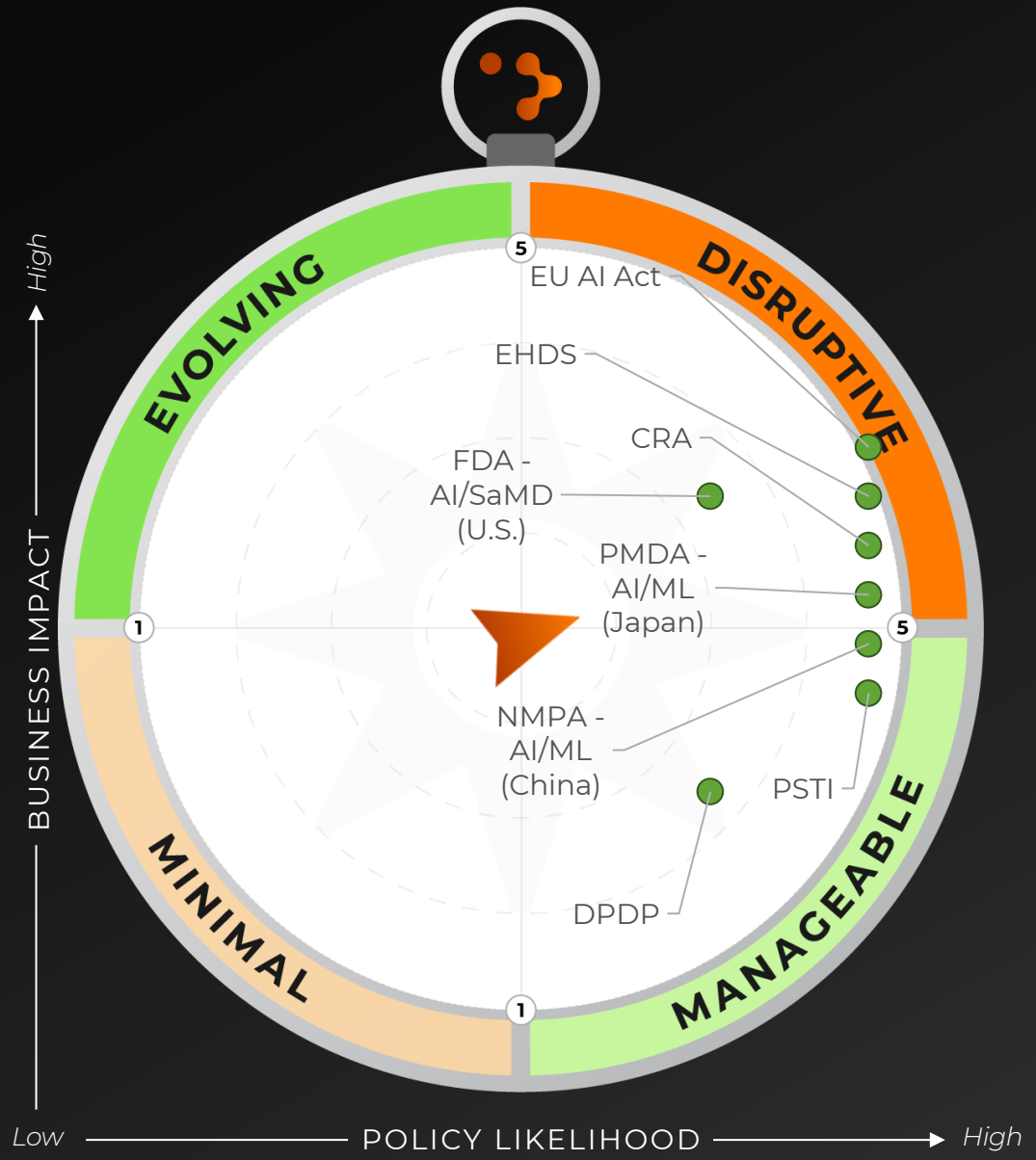
POLICY COMPASS

Healthcare Operational Excellence

Operational excellence now needs an audit trail, not just a playbook

- Operational excellence is becoming a regulated capability.
- Healthcare operators must now manage physical and digital resilience together.
- Winners will be companies building for life cycle execution.

POLICY TITLE LEGEND	
EU AI Act	**EHDS (EU):** European Health Data Space Regulation 2025/327
FDA – AI/SaMD: US FDA Framework for AI and Software as a Medical Device	**DPDP (India):** Digital Personal Data Protection Act
NMPA – AI/ML (China): National Medicinal Products Administration Guiding Principles for AI/ML-Enabled Medical Devices	**CRA (EU):** Cyber Resilience Act
PMDA – AI/ML (Japan): Pharmaceutical and Medical Devices Agency – AI/ML guidelines	**PSTI (U.K.):** Product Security and Telecommunications Infrastructure Act

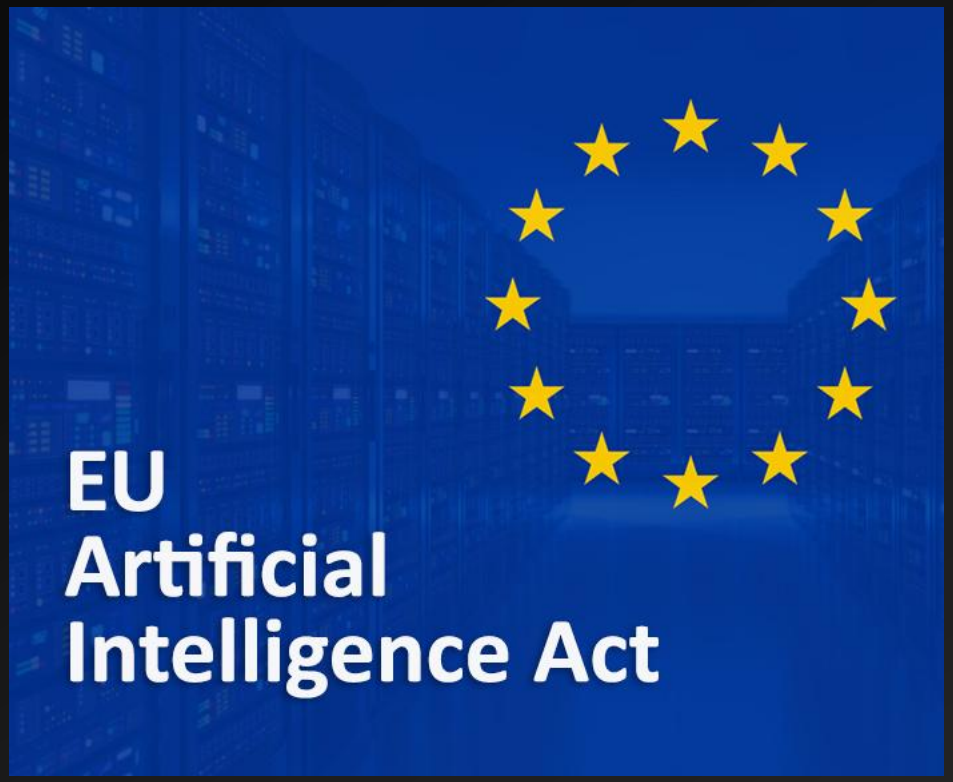


POLICY HIGHLIGHT

EU AI ACT

Regulation puts clinical AI on ops mode

- The EU AI Act turns AI workflows into regulated operations, raising standards not just for products but also for how hospitals deploy and manage AI in routine care.
- Governance is becoming a procurement requirement, with buyers favoring vendors that can prove auditable oversight, controlled updates, and real-world performance monitoring.



LUX TAKE

The EU AI Act is already highly consequential because it is forcing AI-enabled devices and workflows into a more formal, life-cycle-managed operating model under staged implementation through 2027–2028.

European Union

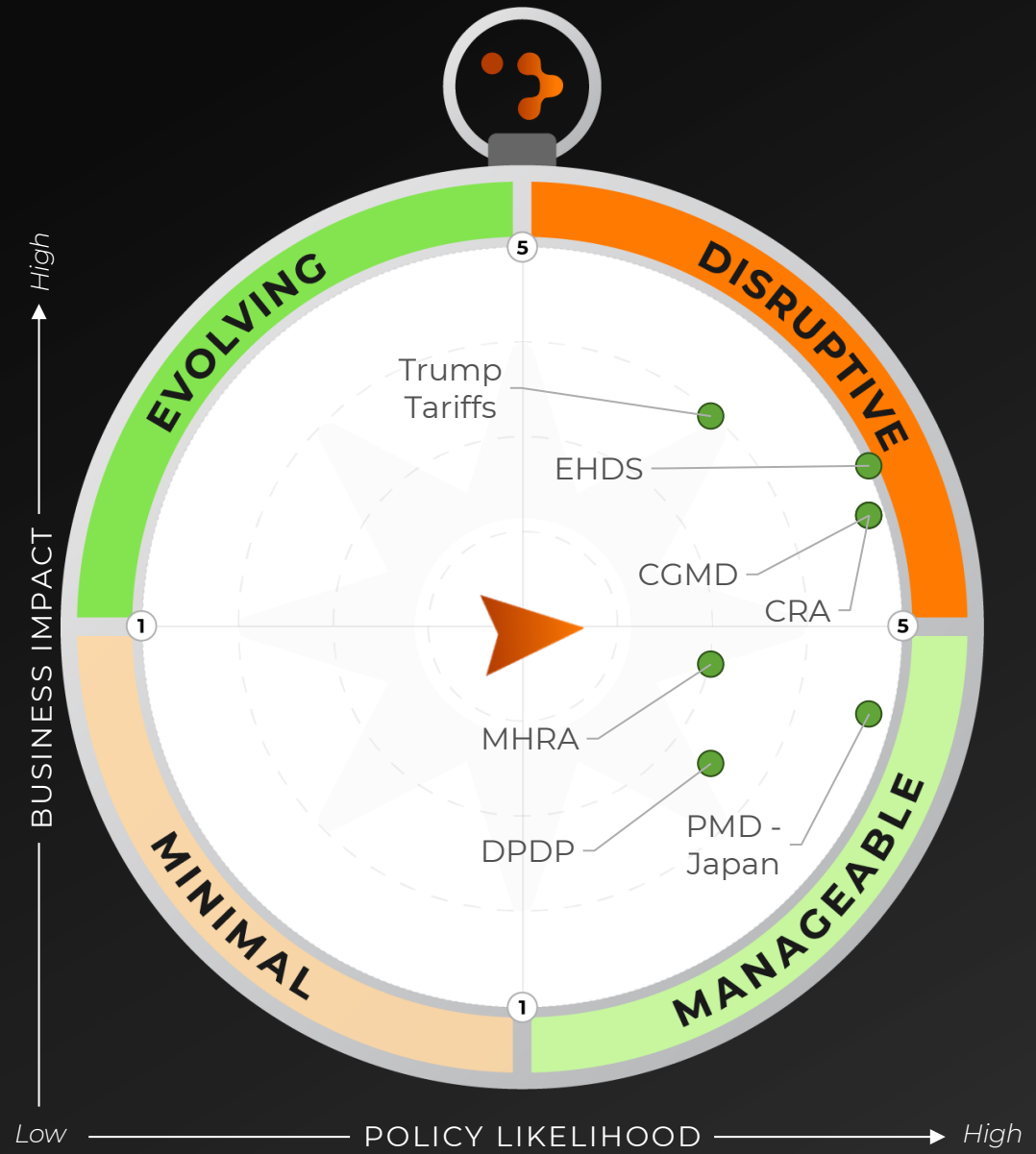
Image source: EU

POLICY COMPASS

Streamlining Laboratory Workflows

Lab workflows are shifting from an efficiency initiative to an operational requirement

- Lab modernization is becoming policy driven.
- Automation now serves as risk mitigation, not just efficiency.
- Winning labs will operate as closed-loop systems.



POLICY TITLE LEGEND	
Trump Tariffs	**CGMD (U.S.):** FDA Cybersecurity Guidance in Medical Devices
MHRA (U.K.): Medicines and Healthcare Products Regulatory Agency	**DPDP (India):** Digital Personal Data Protection Act
EHDS (EU): European Health Data Space Regulation 2025/327	**CRA (EU):** Cyber Resilience Act
PMD - Japan: 2025 PMD Act amendment (Act No. 37 of 2025)	

POLICY HIGHLIGHT

FDA's Cybersecurity Guidance in Medical Devices

CGMD makes secure connectivity a lab operations requirement

- Cyber weaknesses now threaten throughput and continuity, as vulnerabilities in analyzers, middleware, or reporting platforms can disrupt the full diagnostic workflow.
- Procurement will increasingly favor vendors with life cycle security built in, including secure updates, SBOMs, patching, and vulnerability response.

LUX TAKE

Companies that lag will increasingly face delayed implementations, constrained remote servicing, and procurement resistance as cyber readiness becomes inseparable from streamlined laboratory performance.

FDA U.S. FOOD & DRUG ADMINISTRATION

Image source: FDA

Key takeaways

1

The competitive divide in MD&D is shifting toward policy readiness.

Clinically strong products that lack robust AI governance, data control, cybersecurity, or post-market discipline will struggle to move past introduction.

2

Governance and evidence-creation capabilities will be differentiators.

Buyers are prioritizing solutions that arrive with operational infrastructure, not just technical promise.

3

Rising regulatory scrutiny extends timelines for product launch plans.

Companies will need to make difficult capital allocation decisions and accelerate divestment of products that can’t justify ongoing life cycle investment.

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About Lux

Lux Research fuels innovators to not only imagine what's possible in the future but also operationalize innovation success in the near term. We deliver research and advisory services to inspire, illuminate, and ignite innovative thinking that reshapes and grows businesses. Using quality data derived from primary research, fact-based analysis, and opinions that challenge traditional thinking, our experts focus on finding truly disruptive innovations that are also realistic and make good business sense.

The "Lux Take" is trusted by innovation leaders around the world, many of whom seek our advice directly before placing a bet on a startup or partner — our clients rely on Lux insights to make decisions that generate fantastic business outcomes. We pride ourselves on taking a rigorous, scientific approach to avoid the hype and generate unique perspectives and insights that innovation leaders can't live without.

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