

From Static Law to Adaptive Governance

Regulating Medical AI at the Speed of Innovation

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Example

Imagine an AI system for diagnosing heart disease has been approved.

Six months later, the algorithm has updated itself based on new data.

Doctors trust it, patients rely on it – but the approval and the law still apply only to version 1.0.

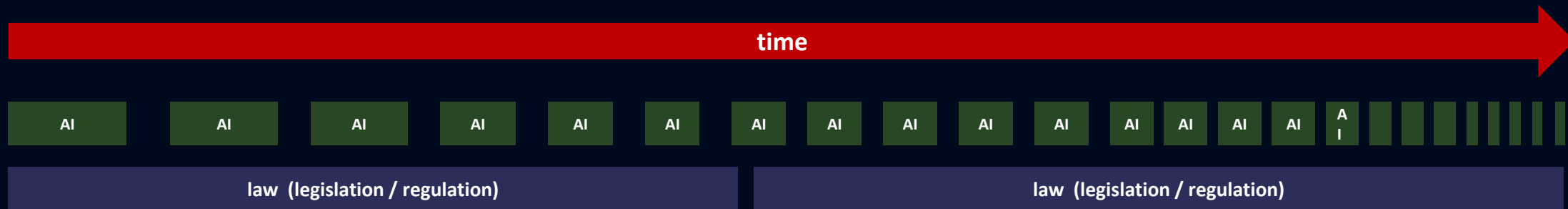
Can we still use version 1.2?

Who is responsible if version 1.2 makes a mistake?

→ **The law is still frozen in time, while the AI has already moved on.**

I. Static Law vs. Innovation

The Innovation – Law Gap



Timeline : AI cycle = months → AI innovation cycles are measured in weeks or months.
 law cycle = years/decades → Legal frameworks take 5 to 10 years to adapt.

The AI technology moves every few months – the law takes years to change.

→ **structural mismatch.**

I. Static Law vs. Innovation

Structural Mismatch

Innovation cycles: fast, iterative.

Legal cycles: slow, static.

Risks: regulatory gaps, risks, legal certainty, delays, health/safety, fundamental rights.

In both, the US and EU, regulators have struggled with AI systems that continuously learn.

The law is built for 'static' products, not for evolving algorithms.

II. Limits of Static Law

How to move from static rules to adaptive governance to ensure legal certainty, risk control, and fundamental rights protection, without restricting innovation?

II. Limits of Static Law

Traditional Legal Instruments

Directives, regulations, case law.

Strengths: stability, clarity, legal certainty.

Weaknesses: rigidity, non-adaptive, delay.



Proof of Concept

Can we provide a solution to the example based on static law?

II. Limits of Static Law

Why This Matters

Patient safety.

Trust in health systems.

Fundamental rights & democratic legitimacy.

Fundamental Rights at Stake

Life & Health.

Privacy & data protection.

Equality & non-discrimination.

Human dignity & autonomy.

III. Adaptive Governance

Adaptive Governance

Law as a dynamic system?

Continuous monitoring &
recalibration of the law?

Core Objectives

Legal certainty.

Risk control.

Protection of fundamental rights.



III. Adaptive Governance

Principles of Adaptive Governance

Anticipatory: look ahead, not back.

Proportionate: fit risk to response.

Transparent: legitimacy & trust.

Democratic Legitimacy & Accountability

Public participation.

Multi-level governance (global, regional (i.e. EU) national).



Comparative Lessons

EU AI Act opportunities & gaps.

US FDA adaptive pathways.

OECD/WHO initiatives.

III. Adaptive Governance

What is adaptive governance?

Laws and regulatory systems that anticipate change, remain flexible, and evolve iteratively – without losing democratic legitimacy.

Need for adaptive governance?

Traditional law assumes products are fixed at approval. AI systems evolve continuously.

→ How to oversee a moving target?

Governance dilemma

Challenge: balancing innovation, legal certainty, and fundamental rights.

→ Too much rigidity kills innovation,
too much flexibility erodes certainty and trust.



III. Adaptive Governance

Do we already have models of adaptive governance?

EU Approach

AI Act and **MDR**: new pathways, but still static approvals.

EHDS: data governance, but no adaptive oversight.

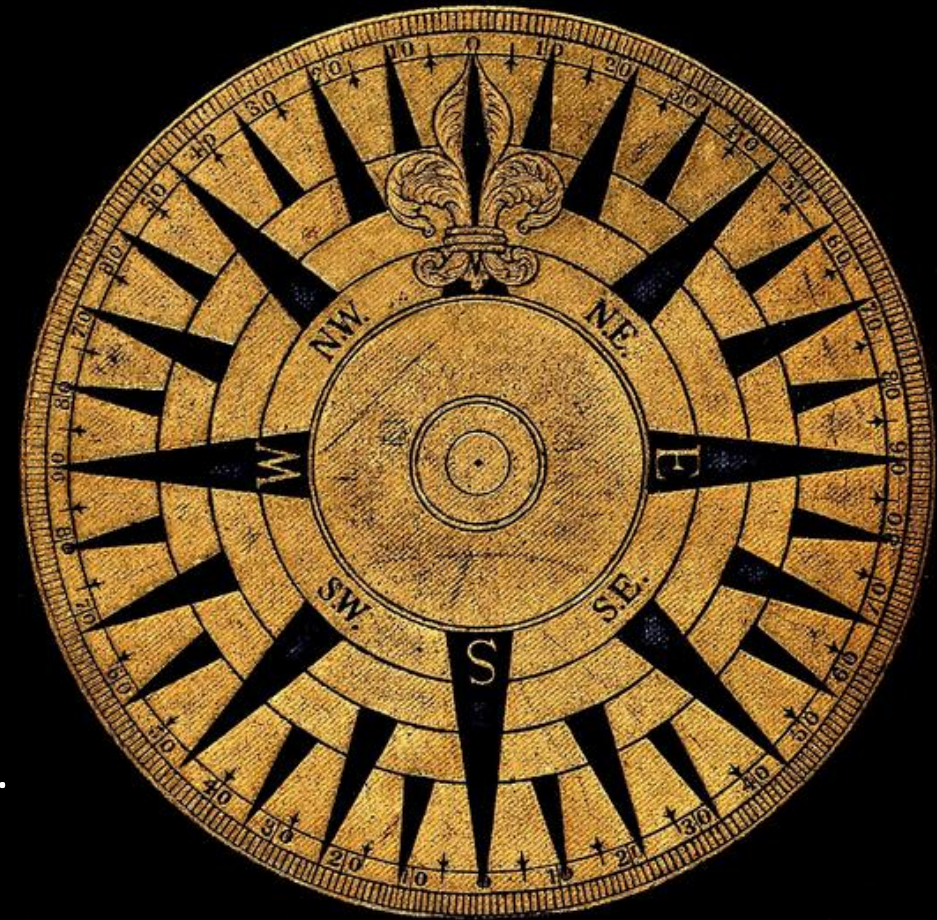
US Approach

Predetermined Change Control Plan (FDA): flexibility for AI updates.

→ Step towards adaptive regulation, but still cautious.

International law

OECD principles, **WHO** guidance, and **global health law initiatives**: more values-driven, global perspective on trustworthy AI.



III. Adaptive Governance

Anticipatory
regulation

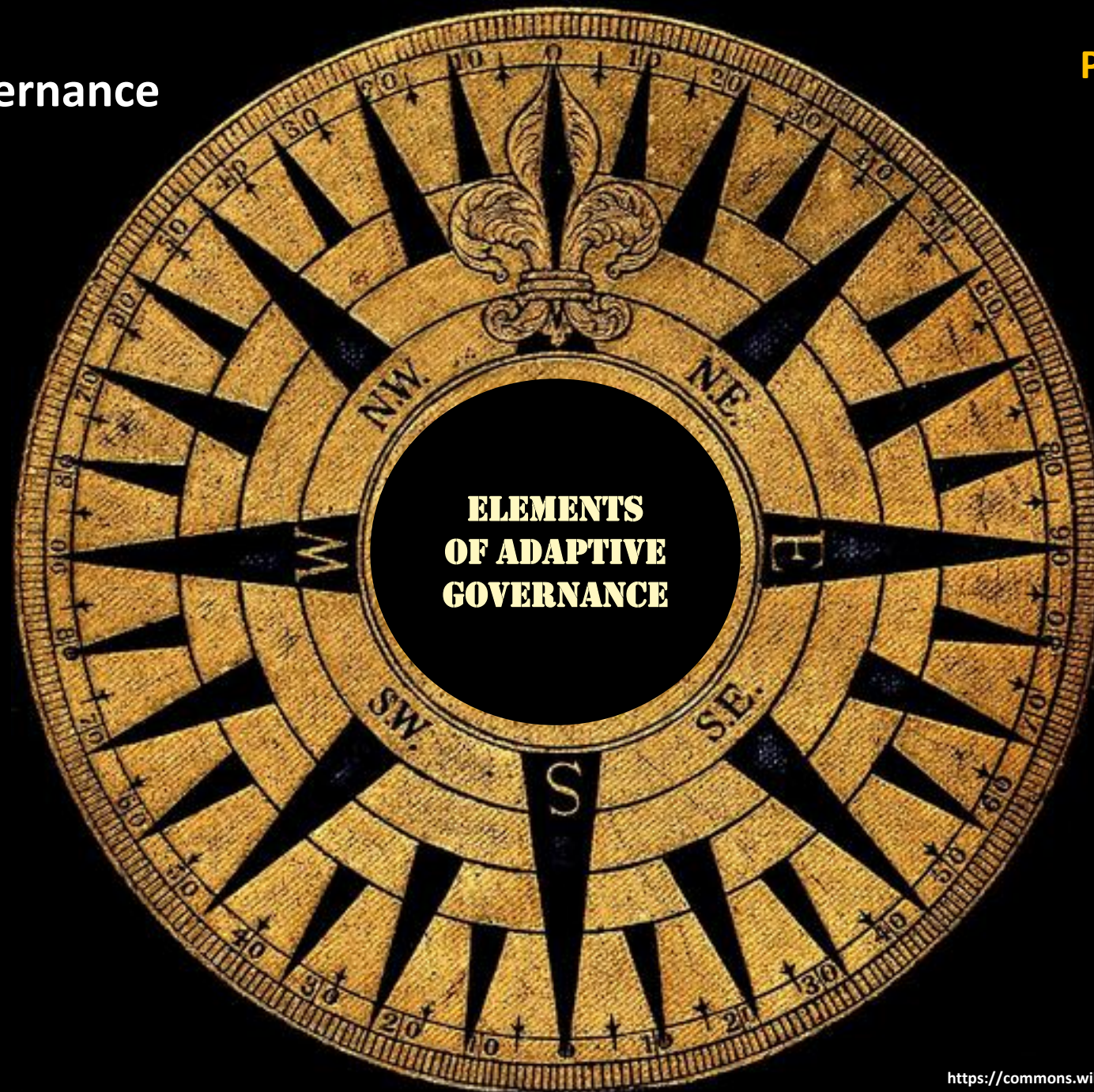
Accountability
&
Enforceability

Democratic
legitimacy

Proportionality
&
risk-based
oversight

Transparency
&
explainability

Iterative
review



IV. Strategies Forward

Anticipatory Regulation

- Foresight & horizon scanning.
- Regulatory sandboxes.

Proportionate Oversight

- Risk-tiering models.
- Differentiating high-risk vs. low-risk AI.

Transparency & Explainability

- Auditability requirements.
- Clinical & patient communication.

Principles

IV. Strategies Forward

Continuous Monitoring & Updating

- Lifecycle monitoring.
- Obligations for ongoing risk assessment.

Instruments

Institutional Architecture

- Role of health data access bodies.
- Coordination between regulators.

Global Dimension

- Harmonisation vs. national sovereignty.
- Role of WHO, WIPO, ITU, UNESCO, OECD, Council of Europe.

V. Closing

Key Takeaways

Static law cannot keep pace with AI.

Adaptive governance could ensure legal certainty and rights protection.

Trust and legitimacy are the foundations of responsible AI in healthcare.



This formula is simple but difficult ...

**Innovation must not undermine rights,
rights must not block innovation,
and regulation must build trust.**

Thank you!

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