HEALTH INSIGHTS 2026, KUOPIO

Personalised Medicine and EU AI Act

Turning Compliance into Clinical Advantage

Katri Harjuveteläinen

REGULYN

What the AI Act Means for Regulated Organisations

Broad Scope

Is it an AI system or safety component?

Are you based in EU or does the system output reach EU?

Is the system in R&D phase or is it developed solely for scientific R&D purposes?

Key Roles and Risk Tiers

Provider

Deployer

Unacceptable
“Must not be used”

High-risk
“Extensive obligations”

Limited risk
“Transparency”

Minimal risk
“No EU AI Act obligations”

Mapping AI Use Cases

Personalised Treatment Path

Personalised Dosing

Hidden risks

- R&D Exemption
- Provider Assumption

What Uncertainty Costs

- Technology -

OpenEvidence Withdraws Clinical AI Platform From UK And Europe Over Regulatory Uncertainty

THE LANCET *Regional Health* Europe

This journal Journals Publish Clinical Global health Multimedia Events About

CORRESPONDENCE · Volume 65, 101718, June 2026 · *Open Access* Download Full Issue

The Need for Regulatory Certainty on Medical AI: Lessons From the OpenEvidence Geoblocking in the EU and UK Over the EU AI Act

The Lancet: Regional Health Europe Vol 65

Distilled Post

Turning Compliance Into Advantage

Clinical Advantages

AI that fits the patients' needs

Human judgement involved

Preparedness for incidents

"Compliance is what makes a clinical tool adoptable"

Timing is the Difference

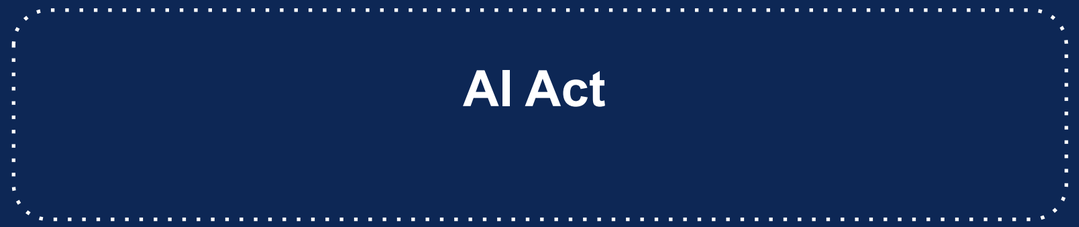
Proportionate compliance effort and cost.

Less delays and duplicated work.

Lasting partnerships and trust.

“The difference between compliance as a blocker and compliance as an advantage is timing. “

Do the Work Once



MDR/IVDR **GDPR** **CTR**

“Scalable compliance means finding synergies with existing frameworks”

Final thoughts

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