

Trilateral KI-Reallabor Pilot — Germany's Simulated AI Regulatory Sandbox for High-Risk Medical AI

AI in the Public Sector · Good practice · Germany

Quality score: 73/100

Evidence strength: Descriptive / self-reported

Summary

Germany's Bundesnetzagentur, Hesse's digitalisation ministry and the federal data-protection commissioner simulated an EU AI Act sandbox with two medical-device start-ups, producing a public roadmap ahead of the deadline for member states to stand up real sandboxes.

Key dimensions

Dimension	Score
Evidence of impact / measured public value	2/3
Transparency, fairness & accountability	3/3
Transferability / demonstrated replication	2/3
Scalability beyond pilot	1/3
Governance, capability & sustainability	3/3

Evaluated by C-NAPSE

Data sources

[C-NAPSE web research](#) — accessed 2026-07-13

[Bundesnetzagentur \(Federal Network Agency\), Hessian Ministry for Digitalisation and Innovation, and the Federal Commissioner for Data Protection and Freedom of Information \(BfDI\)](#) — accessed 2026-07-13

[Bundesnetzagentur — Trilaterales Pilotprojekt zur Simulation eines KI-Reallabors erfolgreich abgeschlossen](#) — accessed 2026-07-13

[BfDI — Trilaterales Pilotprojekt zur Simulation eines KI-Reallabors erfolgreich abgeschlossen](#) — accessed 2026-07-13

[Hessen Digitales — Erfolgreiches Pilotprojekt zur Simulation eines KI-Reallabors](#) — accessed 2026-07-13

[Bundesnetzagentur — Begleitforschung zum Pilotprojekt KI-Reallabor \(Abschlussbericht, PDF\)](#) — accessed 2026-07-13

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