Elsa — the FDA's Agency-Wide Generative-AI Tool for Scientific Reviewers

AI in the Public Sector · Good practice · United States of America

Quality score: 40/100

Evidence strength: Moderate

Summary

The FDA rolled out its generative-AI assistant Elsa agency-wide after a pilot review task reportedly dropped from days to six minutes, but independent reporting found the tool hallucinating citations and studies, with no clear public definition of success or accuracy guardrails.

Key dimensions

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

Evaluated by C-NAPSE

Data sources

C-NAPSE web research — accessed 2026-09-03

U.S. Food and Drug Administration (FDA) — accessed 2026-09-03

FDA — Completion of first AI-assisted scientific review pilot and agency-wide AI rollout timeline — accessed 2026-09-03

Medical Economics — FDA's new AI tool Elsa faces accuracy concerns — accessed 2026-09-03

Applied Clinical Trials Online — FDA's Elsa AI tool raises accuracy and oversight concerns — accessed 2026-09-03

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