Health Canada's Adaptive Machine-Learning Medical Device Sandbox — a $73,733 Pre-Experiment That Ended in Guidance Instead of a Sandbox

AI in the Public Sector · Good practice · Canada

Quality score: 60/100

Evidence strength: Moderate

Summary

Health Canada spent $73,733 (Nov 2022–Mar 2023) designing a sandbox for adaptive ML medical devices. It then concluded that updated guidance was enough: its Feb 2025 ML device guidance lets pre-approved change plans replace re-licensing for each model update.

Key dimensions

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

Evaluated by C-NAPSE

Data sources

C-NAPSE web research — accessed 2026-11-22

Health Canada, with the Treasury Board Secretariat's Centre for Regulatory Innovation (CRI) — accessed 2026-11-22

Centre for Regulatory Innovation — REEF project summary: Adaptive ML-enabled medical devices — accessed 2026-11-22

Health Canada — Advanced therapeutic products: candidates — accessed 2026-11-22

Health Canada — ATP framework for regulating and authorizing — accessed 2026-11-22

Healthy Debate — Health Canada's controversial 'regulatory sandbox' (Nov 2021) — accessed 2026-11-22

BLG — Health Canada's evolving regulatory framework for ML-enabled medical devices (Feb 2025) — accessed 2026-11-22

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