Beyond the Black Box: a NICE- and CDA-Aligned Transparent Generative AI Framework for HEOR Evidence Synthesis and Generation

MSR27

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INTRODUCTION

- Generative artificial intelligence (GenAI) offers transformative potential for evidence synthesis; however, its adoption in health technology assessment (HTA) remains limited because of concerns about the opacity ('black-box' nature) of GenAI workflows **(Figure 1)**
- This study proposes a comprehensive GenAI implementation framework aimed at enhancing its acceptability across global HTA bodies

METHODOLOGY

- The core requirements were synthesized using the AI position statements involving HTA bodies (NICE, CDA-AMC) and methodological standards groups (ISPOR, HTAi, and the Cochrane RAISE framework)
- A structured framework was developed by mapping high-level regulatory expectations regarding transparency, accountability to actionable operational steps, specifically designed to mitigate trust-deficits and increase the acceptability of GenAI for HEOR processes

RESULTS

A comprehensive GenAI implementation framework was developed comprising five core pillars (**Figure 2**):

- **Human-in-the-loop:** Defines AI as an assistive tool, where submitting organizations retains the accountability and implements safeguards to preserve critical appraisal skills of human reviewers
- **Compliance and Security:** Ensures alignment with regional AI laws, auditability of decision pathways, and protection against security threats (prompt injection attacks)
- **Quality and Bias Control:** Mandates formal bias checks and reporting, comparison against human benchmarks, and rigorous fact-checking to mitigate AI hallucinations while ensuring AI outputs are accurate and reliable
- **Reproducibility and Research Integrity:** Enforces locked workflows, version control, and standardized reporting templates (adhering to ELEVATE-GenAI domains) to ensure outputs remain reproducible and contestable
- **Intellectual Property and Legal Integrity**: Assigns liability to the submitting organization, mandating compliance with copyright laws and licensing agreements to ensure all AI-generated evidence is legally defensible

Figure 1. Challenges of Black-Box GenAI Applications in Evidence Generation

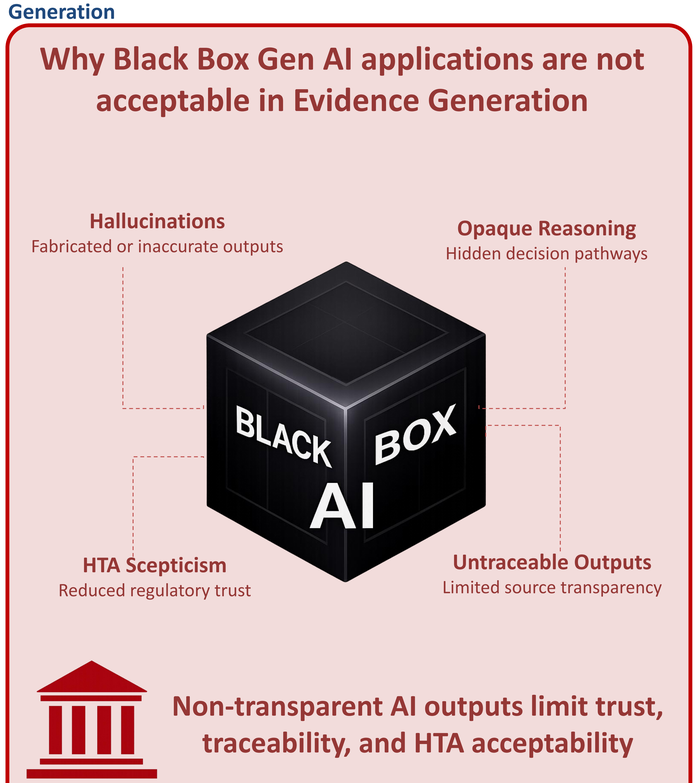


Figure 2. Five-Pillar Governance Framework for Transparent GenAI

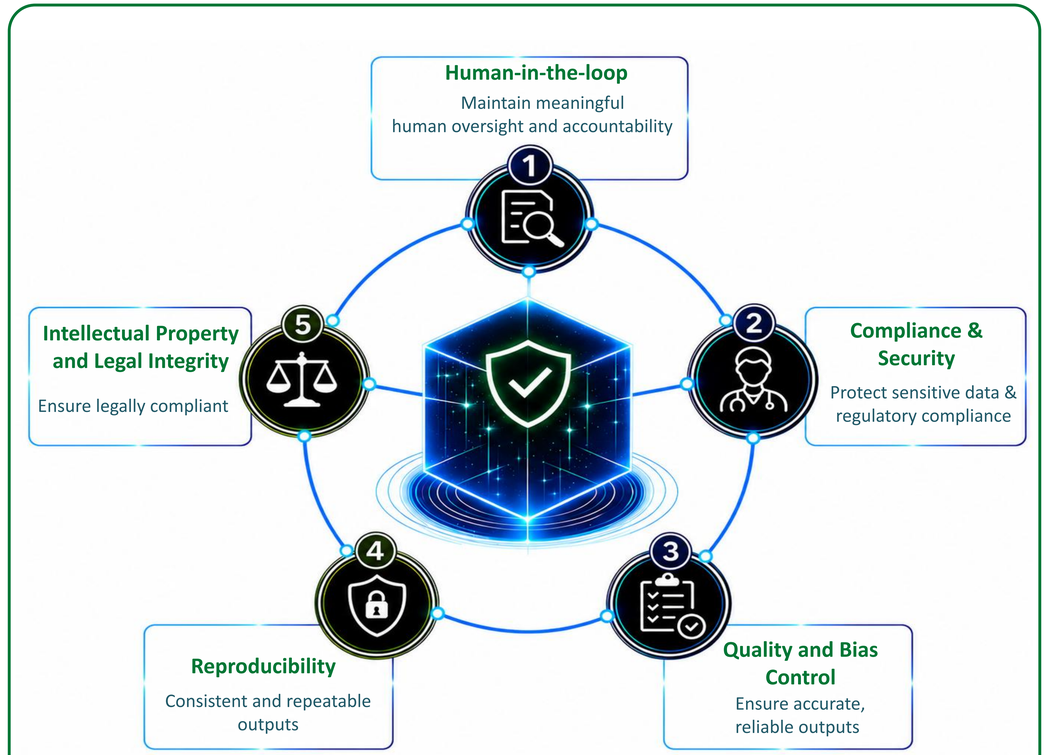
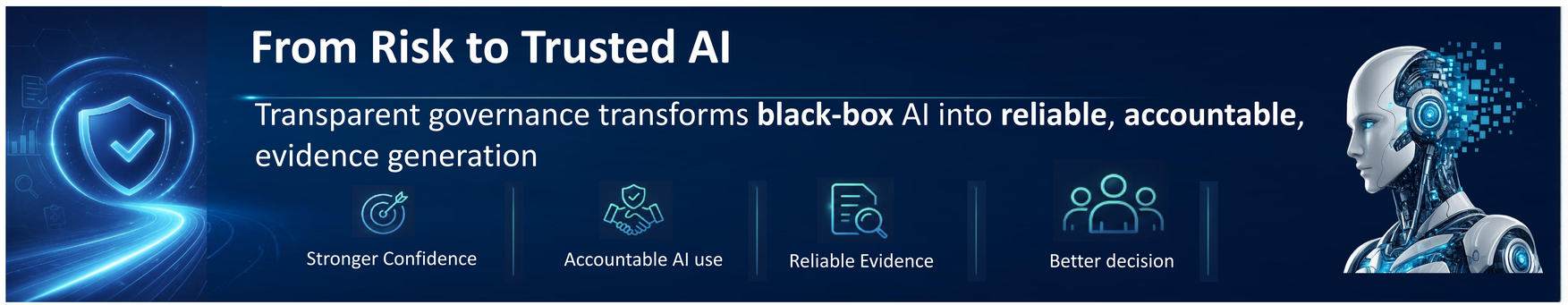


Figure 3. Potential Impact of Transparent Governance for Trusted GenAI in Evidence Generation



CONCLUSIONS

- The application of the proposed framework across standard HEOR use cases-including systematic literature reviews, real-world evidence synthesis, and health-economic modelling, demonstrated the potential of GenAI as a reliable tool for evidence synthesis and generation
- The framework ensured outputs remained traceable, inspectable, and human-verified, helping bridge the 'acceptability gap' while meeting the rigorous transparency standards of global HTA bodies

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