062: From Prompt Engineering to Policy: The Advances of Generative AI in the Last Year

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Introduction and Objectives

- Objective: To provide an overview of **key developments** in Generative AI (GenAI) relevant to HEOR and HTA from 2024 to early 2025.

- Structure: I will cover **policy** milestones, international **initiatives**, **evaluation** frameworks, and foundational **publications**

Usage

Industry-Wide Diffusion of GenAI in 2024

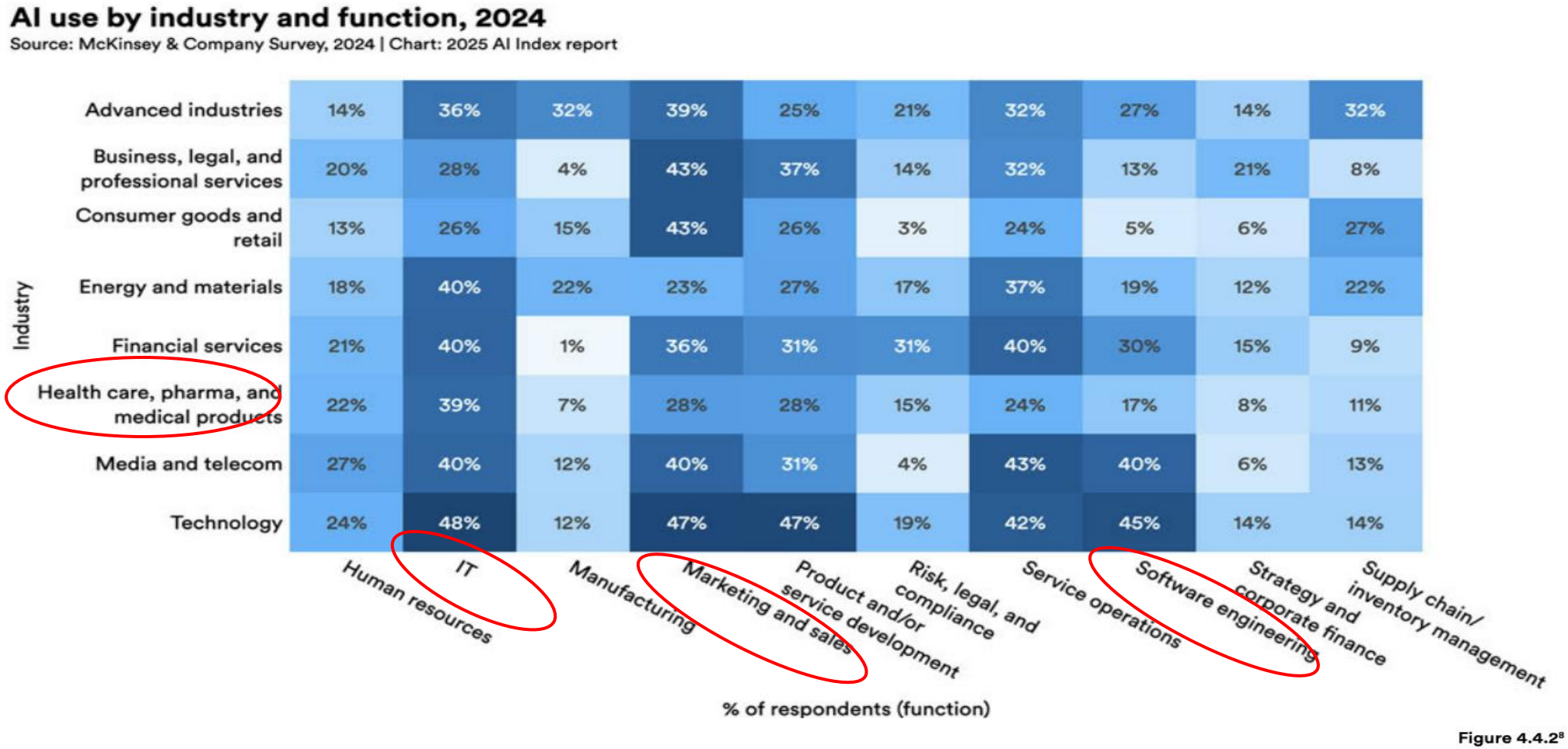


Figure 4.4.2[8]

Source: The AI Index 2025 Annual Report

Policy

Evolving Regulatory and Policy Landscape

- **NICE Position Statement** (Aug 2024): Recognizes potential of GenAI, outlines early guidance for cautious integration into evidence development.
- **NICE Statement of Intent** (Nov 2024): Signals intent to develop formal evaluation criteria for GenAI outputs.
- **FDA Guidance** (Jan 2025): Introduces a risk-based credibility assessment framework for AI-generated evidence, focused on transparency and validation.

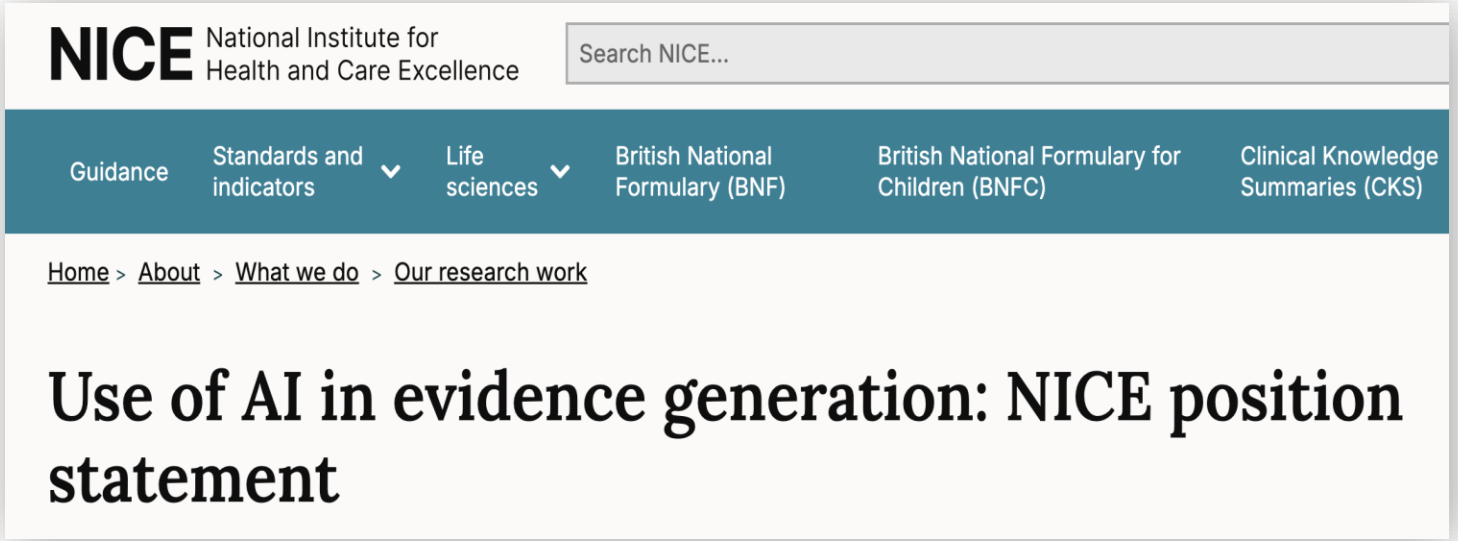
NICE National Institute for Health and Care Excellence

FDA

Policy

NICE Position Statement: Generative AI for SLRs and Evidence Synthesis

- AI can automate **key stages** of systematic reviews and meta-analyses improving **efficiency**, though **validation** is ongoing.
- Ensuring **transparency and explainability** in AI-driven processes is critical to maintain **trust** and **accountability**.
- Methodological rigor must be upheld by applying **established frameworks** (e.g., Cochrane, PALISADE) to **minimize bias** and **validate** AI outputs in evidence synthesis.



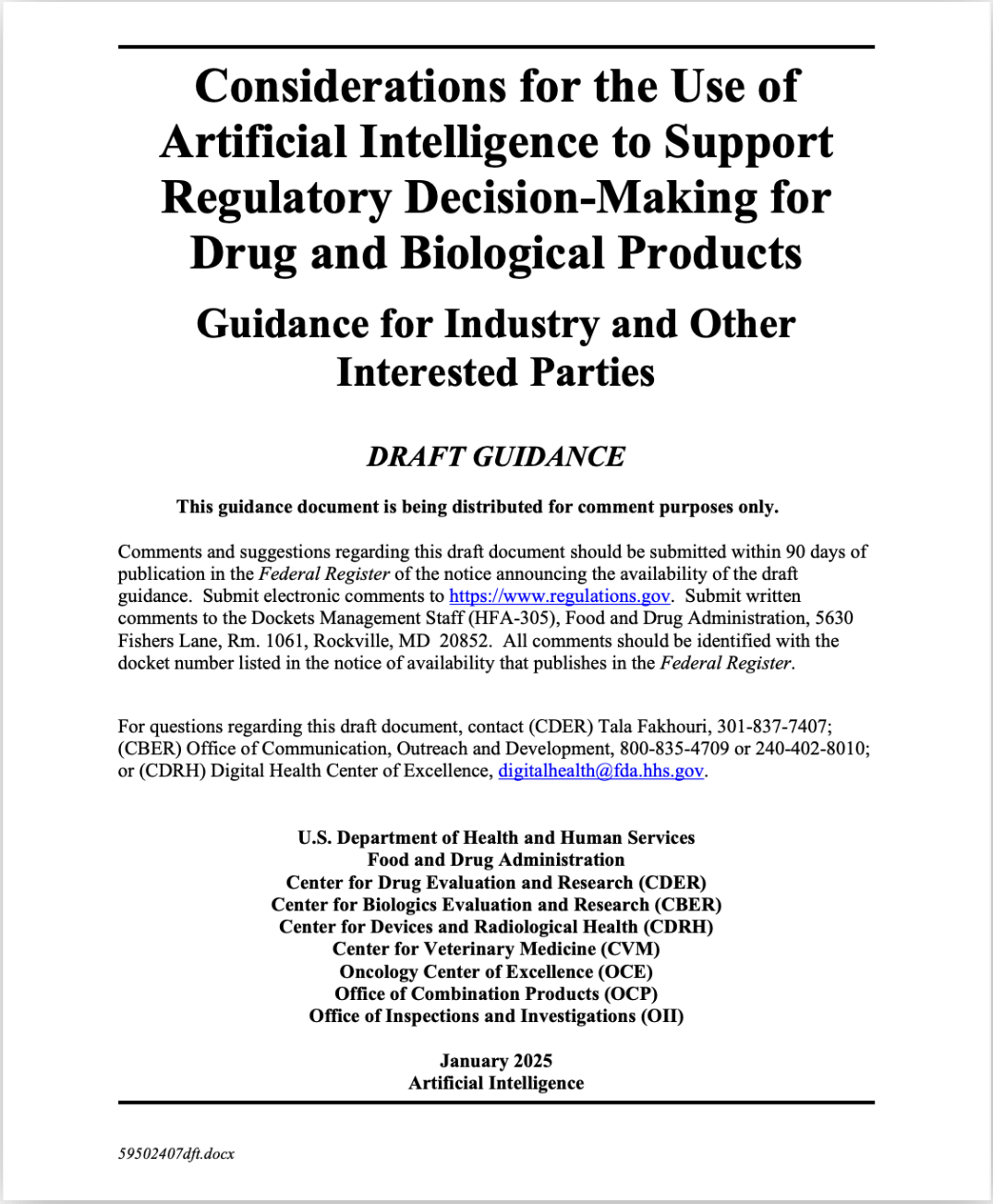
NICE. Use of AI in evidence generation: NICE position statement. 2024. Accessed 20 September, 2024.

Policy

FDA Guidance

January 2025

- Introduces a **risk-based credibility assessment framework** for AI-generated evidence, focused on transparency and validation



Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry and Other Interested Parties

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Tala Fakhouri, 301-837-7407; (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010; or (CDRH) Digital Health Center of Excellence, digitalhealth@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Center for Veterinary Medicine (CVM)
Oncology Center of Excellence (OCE)
Office of Combination Products (OCP)
Office of Inspections and Investigations (OII)

January 2025
Artificial Intelligence

59502407dft.docx

Policy

Global Health Technology Assessment Initiatives

HTAi 2025 White Paper:

- **Proposal:** Leverage AI across the HTA lifecycle to enhance efficiency, equity, and responsiveness, while ensuring ethical, transparent, and collaborative implementation.
- **Next Steps:** Create white papers, taskforces, and use case repositories to guide responsible, standardized AI adoption in HTA.

Potential for GenAI to support JCA:

- Early integration of GenAI into JCA processes: applications in PICO scoping, evidence mapping, and initial literature reviews.

Automated Mass Extraction of Over 680,000 PICOs from Clinical Study Abstracts Using Generative AI: A Proof-of-Concept Study

Reason, T., Langham, J. & Gimblett, A. Automated Mass Extraction of Over 680,000 PICOs from Clinical Study Abstracts Using Generative AI: A Proof-of-Concept Study. *Pharm Med* **38**, 365–372 (2024)

Frameworks for Evaluating Generative AI Outputs

Importance of critical appraisal frameworks for AI-driven analyses.

- **TRIPOD-LLM**
- **ELEVATE-AI-LLMs**

Evaluation

TRIPOD-LLM

Consensus Statement

https://doi.org/10.1038/s41591-024-03425-5

The TRIPOD-LLM reporting guideline for studies using large language models

Received: 24 July 2024

Accepted: 21 November 2024

Published online: 8 January 2025

Check for updates

Jack Gallifant[1,2,3], Majid Afshar[4,29], Saleem Ameen[1,5,6,29], Yindalon Aphinyanaphongs[7,29], Shan Chen[3,8,29], Giovanni Cacciamani[9,10,29], Dina Demner-Fushman[11,29], Dmitriy Dligach[12,29], Roxana Daneshjou[13,14,29], Chrystinne Fernandes[1,29], Lasse Hyldig Hansen[1,15,29], Adam Landman[16,29], Lisa Lehmann[16,29], Liam G. McCoy[17,29], Timothy Miller[18,29], Amy Moreno[19,29], Nikolaj Munch[1,15,29], David Restrepo[1,20,29], Guergana Savova[18,29], Renato Umeton[21,29], Judy Wawira Gichoya[22,29], Gary S. Collins[23,24], Karel G. M. Moons[25,26], Leo A. Celi[1,27,28] & Danielle S. Bitterman[3,8]

Extension of traditional reporting standards to GenAI applications, aimed at enhancing reproducibility and accountability.

Evaluation

ELEVATE-AI-LLMs Framework – ISPOR Working Group on Generative AI

The ELEVATE-AI LLMs Framework: An Evaluation Framework for Use of Large Language Models in HEOR: an ISPOR Working Group Report

Authors: Rachael L. Fleurence, PhD[1], Dalia Dawoud, PhD[2,3], Jiang Bian, PhD[4,5,6], Mitchell K. Higashi, PhD[7], Xiaoyan Wang, PhD[8,9], Hua Xu, PhD[10], Jagpreet Chhatwal, PhD[11,12], Turgay Ayer, PhD[13,14] on behalf of The ISPOR Working Group on Generative AI.

Proposed benchmarking methodology to evaluate quality, reliability, and limitations of LLM-generated evidence.

An Evaluation Framework for use of LLMs in HEOR: ELEVATE-AI LLMs Framework and Checklist

Evaluation

What is being proposed ?

The **ELEVATE-AI LLMs** framework and checklist is a practical, domain-specific tool for systematically assessing LLM performance in HEOR research over 10 domains.

What are the implications for the practice of HEOR?

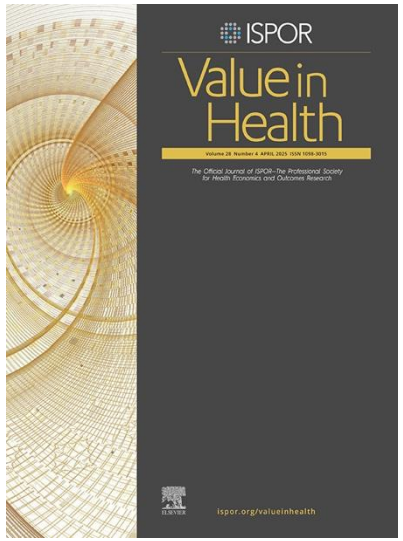
The **ELEVATE-AI LLMs** framework and checklist promote rigorous evaluation and reporting standards, enabling HEOR professionals to integrate LLMs responsibly in healthcare research.

The ELEVATE-AI Framework and Checklist

Reference: Fleurence et al. ISPOR Working Group on Gen AI ArXiv, 2024

Publications

Key Publications and Conceptual Frameworks



ISPOR Report

Generative Artificial Intelligence for Health Technology Assessment: Opportunities, Challenges, and Policy Considerations: An ISPOR Working Group Report

Rachael L. Fleurence, PhD, Jiang Bian, PhD, Xiaoyan Wang, PhD, Hua Xu, PhD, Dalia Dawoud, PhD, Mitchell Higashi, PhD, Jagpreet Chhatwal, PhD, on behalf of the ISPOR Working Group on Generative AI

A Taxonomy of Generative AI in HEOR: Concepts, Emerging Applications, and Advanced Tools – An ISPOR Working Group Report

Rachael L. Fleurence, PhD[1], Xiaoyan Wang, PhD[2,3], Jiang Bian, PhD[4,5,6], Mitchell K. Higashi, PhD[7], Turgay Ayer, PhD[8,9], Hua Xu, PhD[10], Dalia Dawoud, PhD[11,12], Jagpreet Chhatwal, PhD[13,14]

PRACTICAL APPLICATION

Check for updates

Using Generative Artificial Intelligence in Health Economics and Outcomes Research: A Primer on Techniques and Breakthroughs

Tim Reason[1] · Sven Klijn[2] · Will Rawlinson[1] · Emma Benbow[1] · Julia Langham[1] · Siguroli Teitsson[3] · Kasper Johannesen[4] · Bill Malcolm[3]

Key Take Aways

- Rapidly moving space globally and across industries
- GenAI is maturing rapidly, prompting responses from policymakers, regulators, and researchers.
- Key themes: exploration, upskilling, validation, policy developments.

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Poll

Poll #3: In the next 12 months, what will be the most impactful to accelerate GenAI adoption in HEOR, Access and HTA?

a) More HTA and regulatory authorities publishing actionable guidelines on GenAI use
b) Peer-reviewed publications of successful GenAI applications
c) Targeted training and education on GenAI methods and techniques