

BACKGROUND

Systematic literature reviews and literature-surveillance workflows are essential to evidence-based healthcare and HEOR, where timely evidence synthesis informs health technology assessment, reimbursement submissions, economic modeling, real-world evidence generation, value assessment, and clinical or policy decisions. PRISMA 2020¹ reinforces the importance of transparent, reproducible reporting through structured checklists and flow diagrams for systematic reviews.

AI-enabled tools may improve the scalability of evidence synthesis, but require human-centric design, a clear context of use, risk-based validation, documentation, performance assessment, lifecycle oversight, and transparent reporting, consistent with emerging FDA and EMA guidance and principles.²⁻⁴

SafeSearch Pro™ is an **expert-supervised literature-surveillance workflow** designed to standardize evidence identification, screening, classification, and extraction while retaining human validation. This evaluation examines whether **SafeSearch Pro™** can support review performance comparable to dual independent human review while reducing reviewer time and workload.



METHODS

A comparative methods evaluation was conducted using two parallel workflows applied to the same review question, search strategy, eligibility criteria, and reviewer-calibration process:

- ✓ **SafeSearch Pro™ workflow:** AI-enabled citation screening, relevance classification, data extraction, and structured human validation
- ✓ **Manual workflow:** Dual independent human screening and extraction using conventional systematic literature review procedures.

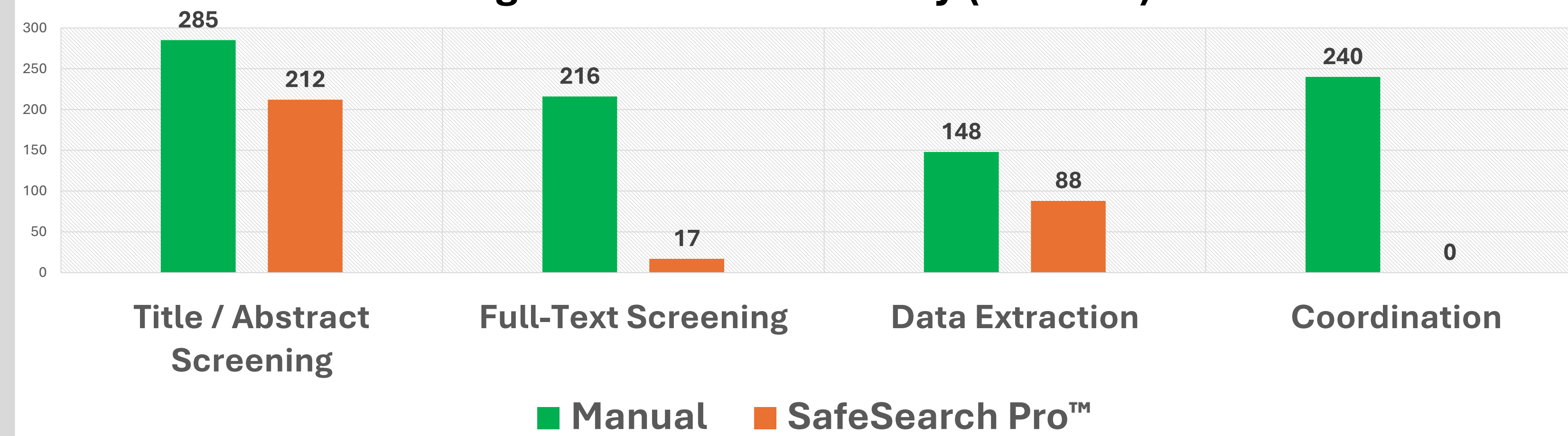
Reviewers completed a calibration exercise before screening to align interpretation of inclusion, exclusion, and extraction criteria. Outcomes were assessed across four domains: evidence yield, efficiency, reviewer workload / burden, and decision consistency.

Evidence-yield outcomes included records screened, full-texts reviewed, and final included studies. Efficiency outcomes included time spent on screening, full-text review, extraction, and coordination. Reviewer workload was assessed using post-task measures of cognitive load, perceived effort, and fatigue. Decision consistency was evaluated using intra-arm disagreement rates and agreement statistics.

Feature	Manual workflow	AI-enabled workflow
Literature sources searched	PubMed + Embase	PubMed + Semantic Scholar
Citation pool screened	753 citations	2,534 citations

RESULTS

Figure 1. Time / Efficiency (minutes)



SafeSearch Pro™ expert-supervised workflow reduced total review time by 64%.

Figure 2. PAAS Mental Effort

(1=very, very low mental effort; 9=very, very high mental effort)

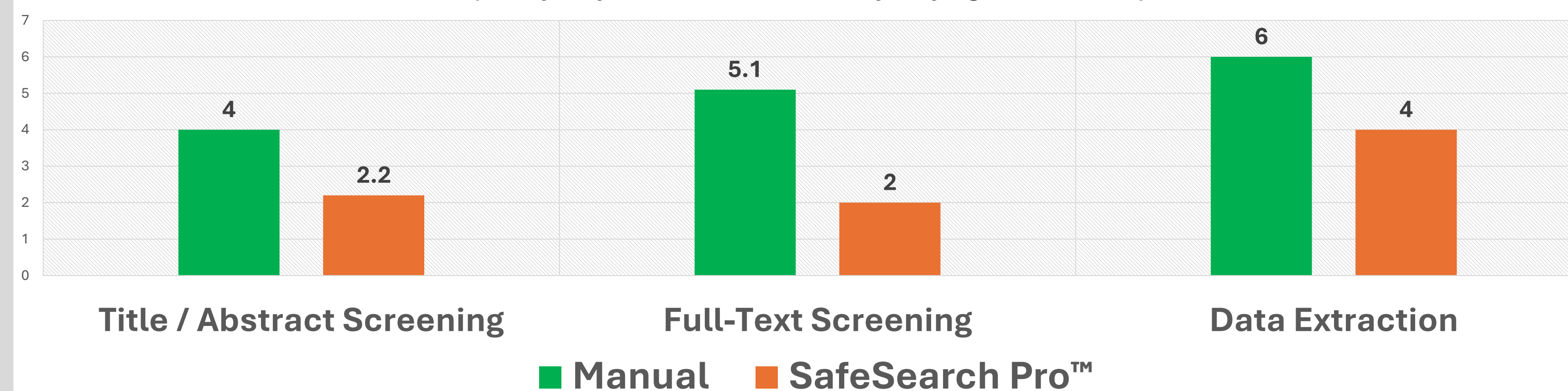
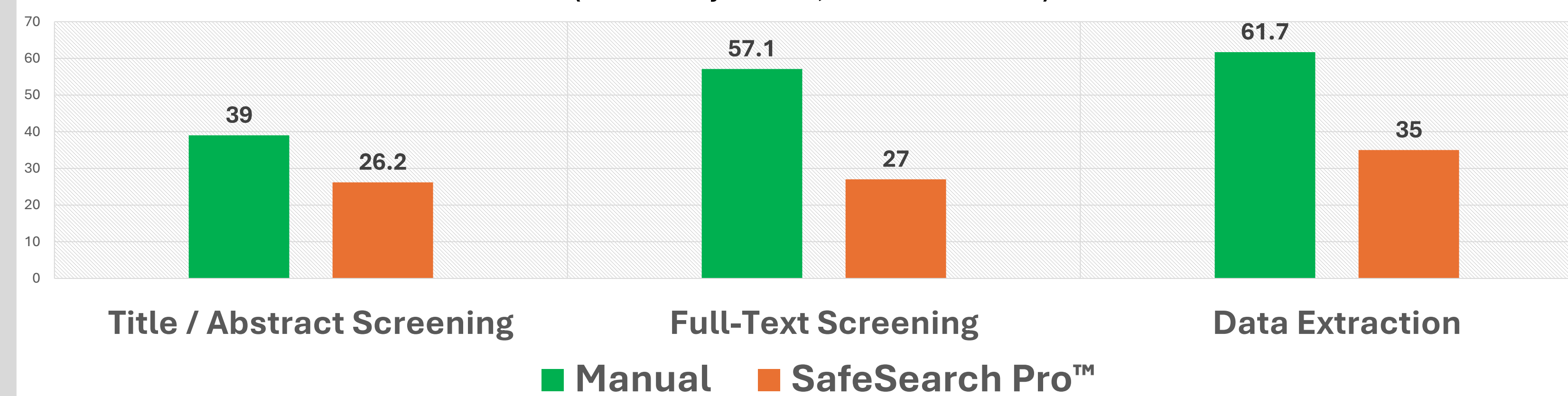


Figure 3. RSME Perceived Effort

(0=absolutely no effort; 150=extreme effort)



SafeSearch Pro™ expert-supervised workflow reduced perceived workload / burden across all review phases, with PAAS and RSME scores consistently lower than manual review.

Table 1. Evidence-yield, efficiency, and reviewer workload outcomes

Outcome / Metric	Manual review	AI-enabled workflow	Interpretation
Records screened	753	2,534	+236% more records screened
Included studies	16	16	Same final included study count
Operational time	10.8 h	5.3 h	51% reduction
Total time incl. coordination	14.8 h	5.3 h	64% reduction
Title / Abstract throughput	159 records / h	717 records / h	4.5x faster
Full-text throughput	15 papers / h	92 papers / h	6.1x faster
Inter-arm discordance	31.5%	1.1%	28x fewer proportional disagreements
Outcome / Metric	Estimate	95% CI	
Sensitivity (PPV adjusted)	92.3%	66.7%–98.6%	Comparable evidence capture
F1 Score (adjusted)	82.8%	-	Based on sensitivity and adjusted PPV

Note: Final adjudication of manual-review decisions is ongoing. Therefore, classification metrics are preliminary because manual decisions have not yet been fully adjudicated to establish a verified gold-standard reference set.

CONCLUSIONS

In this comparative evaluation, an expert-in-the-loop AI workflow screened a larger citation pool than manual review while producing the same final included-study count.

SafeSearch Pro™ reduced operational review time by 51%, reduced total time including coordination by 64%, lowered reviewer-reported burden across review phases, and showed fewer proportional intra-arm disagreements.

SafeSearch Pro™ transformed a labor-intensive HEOR review workflow into a faster, lower-burden, more consistent expert-validation process, screening 3.4× more citations and achieving the same included-study yield in less time.

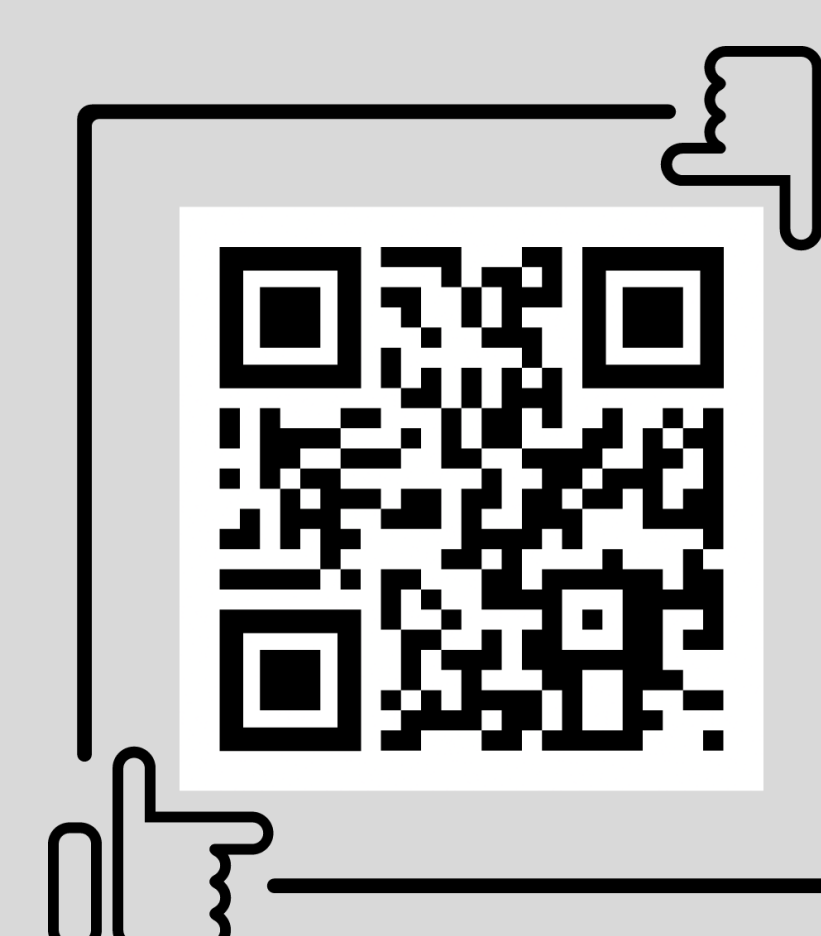
These findings support AI-assisted, expert-supervised literature surveillance as a scalable approach for HEOR evidence generation.

KEY TAKEAWAYS

- AI expanded evidence reach:** The AI workflow screened 2,534 citations versus 753 manually, a 236% larger citation pool.
- Included-study yield was preserved:** Both workflows identified a final sample of 16 included studies.
- Review time fell substantially:** AI reduced operational time by 51% and total time including coordination by 64%.
- Reviewer burden was lower across phases:** PAAS and RSME scores favored the AI workflow during title/abstract screening, full-text screening, and extraction.
- Decision consistency improved:** Intra-arm disagreement was 1.1% with AI versus 31.5% manually.
- Comparable database coverage:** Both workflows demonstrated comparable biomedical database coverage across PubMed/Embase in the manual arm and PubMed/Semantic Scholar in the AI arm.

REFERENCES

- [1] Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. 2021;372:n71.
- [2] European Medicines Agency. Reflection paper on the use of Artificial Intelligence (AI) in the medicinal product lifecycle. EMA/CHMP/CVMP/83833/2023. Final version adopted by CHMP 9 September 2024 and by CVMP 11 September 2024.
- [3] U.S. Food and Drug Administration. Artificial Intelligence-Enabled Medical Devices. FDA Digital Health Center of Excellence. Updated periodically.
- [4] U.S. Food and Drug Administration; European Medicines Agency. Guiding Principles of Good AI Practice in Drug Development. January 2026. Content current as of January 14, 2026.



SCAN ME

SafeSearch Pro™ aligns with emerging Good AI Practice principles by using a clearly defined context of use, expert human oversight, structured validation, traceable documentation, fit-for-purpose performance assessment, and transparent reporting to support responsible evidence generation.

Interested in hearing more? Scan the QR code to email the lead author.