Artificial Intelligence (AI) in Oncology Health Technology Assessment (HTA): Current Applications, Limitations, and Implications for Living-HTA

HTA25

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OBJECTIVES

→ To review current AI applications across the oncology HTA evidence pathway, emerging guidance, and assessed improved efficiency from existing AI implementations for Living-HTA

BACKGROUND

- Oncology HTA increasingly requires complex, interconnected evidence packages spanning systematic literature reviews (SLRs), clinical study reports (CSRs), real-world evidence (RWE), and economic modelling.
- Growing evidence volumes and frequent updates created substantial operational bottlenecks. AI tools have been proposed to improve efficiency; however, concerns remain regarding validity, transparency, regulatory acceptance, and applicability to Living-HTA processes

METHODS

- A scoping review was conducted of peer-reviewed publications January 2023-December 2025, and HTA and regulatory guidance/methodological frameworks on AI-assisted evidence generation. We searched biomedical literature databases using terms on AI, machine learning, large-language models (LLMs), oncology, HTA, SLR, RWE, and economic modelling.
- Institutional websites and reference lists were reviewed.
- Selection focused on applications or guidance relevant to oncology HTA.
- Additional structured extraction was conducted to:
  - → Map AI tool capabilities across SLR workflow steps
  - → Assess coverage, integration, and output formats
  - → Identify validation evidence and alignment with HTA requirements

RESULTS

- Across reviewed guidance, HTA bodies consistently emphasize transparency, validation, bias assessment, and human-in-the-loop governance as prerequisites for acceptability (**Table 1**)
- Detailed review of HTA and regulatory guidance confirms consistent expectations[1-8]
  - → Explicit disclosure of AI use in submissions
  - → Validation against alternative or manual methods
  - → Reproducibility and explainability
  - → Bias identification and mitigation
  - → Ongoing monitoring and governance
- These requirements reinforce that AI-assisted outputs must meet the same evidentiary standards as traditional approaches
- Most implementations remain fragmented, static, and project-based. Few support continuously-updated evidence synthesis or materially shorten end-to-end Living-HTA timelines, as outputs typically require re-execution when scope, comparators, or jurisdictional requirements change[9-19] (**Table 2**)
- AI-assisted SLR tools were mapped across key workflow steps, including protocol design, search strategy, screening and review, data extraction, study-level synthesis, bias assessment, interpretation, and reporting outputs

Findings indicate

- Most tools support isolated steps rather than the full workflow
- Limited integration between screening, extraction, and synthesis
- Lack of standardized trial-level structuring and HTA-aligned outputs
- Outputs are typically static, project-based, and not designed for continuous updating
- Published validation studies across AI-assisted SLR approaches demonstrate screening sensitivity typically >95% under human oversight with the efficiency gains primarily at task level
- A review of recent (2025 – 2026) published validation studies evaluating integrated AI-assisted SLR systems report [20-22]: sensitivity approaching ~99%, specificity ~98%, and very low false-negative rates (<1%)
- These findings suggest that higher performance may be associated with integrated, continuously maintained systems rather than isolated task-level tools
- The structural limitation identified across tools is their reliance on project-based execution models, where SLRs are initiated per project, core steps (search, screening, extraction, synthesis) are repeated, and outputs are static at completion
- In contrast, emerging approaches described in the literature as Living SLR systems maintain[20-21] persistent SLR infrastructure, continuous evidence ingestion, and iterative updates across workflow steps
- This enables SLR transition from batch evidence processing to continuous evidence maintenance (**Figure 1**)
- Within this context, Real-Time AI-augmented Living SLR (REAL-SLR) approaches have been described as systems that:
  - → Maintain core SLR processes continuously rather than per project
  - → Integrate AI-assisted screening and extraction with ongoing updates
  - → Support incremental evidence incorporation
  - → Operate under human-in-the-loop validation frameworks
- These approaches align with HTA expectations, including transparency, reproducibility, and continuous evidence readiness

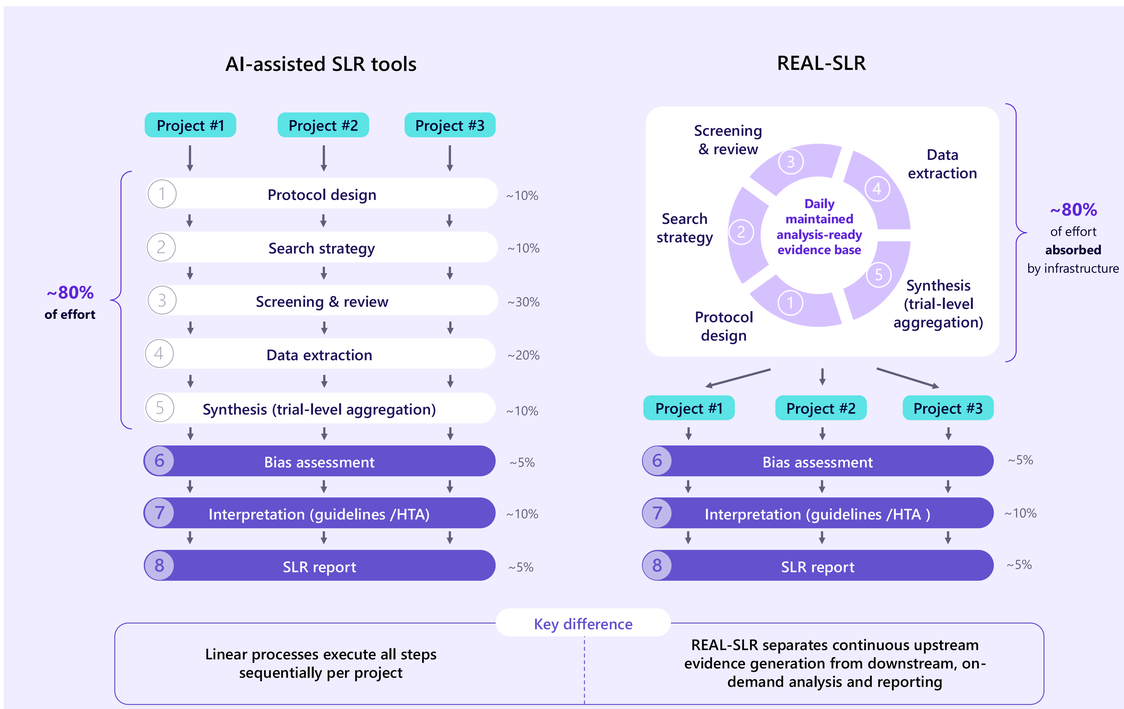
Table 1. Regulatory and methodological guidance on AI in evidence generation

Authority / Organization	Key Guidance Elements	Reference
NICE	• Transparency of AI involvement required in submissions • Validation against alternative methods; human oversight requirements • Assessment of potential bias; reproducibility and explainability	*[1]*
EMA	• Documentation of AI use across the medicinal product lifecycle • Risk management, validation, and compliance with data governance standards • Labeling and disclosure of AI use to HTA bodies	*[2, 3]*
FDA	• Validation expectations for AI/ML systems; documentation of training data • Risk management; transparency in regulatory submissions • Ongoing monitoring post-approval	*[4]*
Cochrane	• Protocol registration of AI use in PROSPERO (systematic reviews) or OSF (scoping reviews) • Validation studies demonstrating performance vs. manual approaches • Bias assessment; reporting aligned with PRISMA extensions	*[5]*
ISPOR	• Methodological guidance on AI-assisted parameter extraction • Validation requirements; comparison of AI-assisted vs. traditional methods • CHEERS 2022 and modeling good practice guidelines for documentation	*[6, 7]*
ISPE	• Guidelines for AI use in pharmacoepidemiology • Data governance and confidentiality requirements • Bias assessment; validation and quality assurance standards	*[8]*

Table 2. AI-assisted SLR tools and the SLR processes that they support

Tool	Protocol design	Search strategy	Screening & review	Data extraction	Synthesis (pub - trial grouping)	Bias assessment	Interpretation (guidelines / HTA context)	SLR report (Excel/Word)
DistillerSR[11]	**!** (protocol configuration possible but not a formal protocol authoring tool)	**!** (support, document, operationalize)	**✓ (AI)** Sensitivity: 14%[9] Specificity: 95%[9] False negative: 21%[9]	**✓ (AI)**	**!** (can group via custom fields but no enforced trial hierarchy)	✓	X	**!** (CSV structured data download)
Covidence[12]	X	X	**✓ (AI)** Uses most relevant sorting	✓	X	**!** (basic RoB templates; limited customization)	X	**!** (CSV structured data download)
EPPI-Reviewer[13]	**!** (protocol configuration possible but not a formal protocol authoring tool)	X	**✓ (AI)** Uses priority screening	✓	X	✓	X	**!** (CSV structured data download)
Nested Knowledge[14]	**!** (protocol configuration possible but not a formal protocol authoring tool)	**!** (support, document, operationalize)	**✓ (AI)** Sensitivity: 99%[14] Specificity: 46%[14] False negative: n/a	**✓ (AI)**	✓	**✓ (AI)**	**!** (supports visualization / dashboards but no direct HTA / guideline linkage)	✓
Rayyan[15]	X	X	**✓ (AI)** Sensitivity: 78%[10] Specificity: 99%[10] False negative: 21%[10]	X	X	X	X	**!** (exports available but limited formatting and reporting features)
Abstrackr[16]	X	X	**✓ (AI)** Sensitivity: 60%[10] Specificity: 99%[10] False negative: 39%[10]	X	X	X	X	X
ExaCT[17]	X	X	X	**✓ (AI)**	X	X	X	**!** (exports extracted data but not full SLR reports)
RobotReviewer[18]	X	X	X	X	X	**✓ (AI)**	X	**!** (outputs bias reports but not full SLR reporting formats)
LaserAI[19]	X	X	**✓ (AI)** No published validation benchmarks	**✓ (AI)**	**!** (supports extraction concepts relationship specification)	✓	X	**! (AI)** (generates summaries but not submission-ready standardized reports)

Figure 1. AI-assisted SLR tools vs. living REAL-SLR framework



CONCLUSIONS

- → While AI-assisted workflows show promise across components of oncology HTA, current implementations have rarely translated into sustained efficiency gains for Living-HTA.
- → Achieving this objective will require approaches that move beyond task-level automation toward integrated, governed systems capable of continuous evidence maintenance.
- → Clear implementation frameworks and governance models are needed before AI can reliably support living-HTA

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