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ISPOR Europe 2026
8-11 November 2026
Vienna, Austria

HTA272

Are current evidence synthesis standards fit for the EU joint clinical assessment era?

Gaps across PRISMA, Cochrane, ISPOR, and HTA guidance

BACKGROUND

The EU Joint Clinical Assessment (JCA) requires timely, population / intervention / comparator / study design (PICOS)-specific, and continuously-updated evidence submissions.

However, traditional systematic literature reviews (SLRs) remain largely static and resource-intensive, while guidance for living systematic reviews (LSRs) and artificial intelligence (AI)-assisted evidence synthesis continues to evolve.

OBJECTIVES

This study evaluated whether existing methodological guidance adequately supports JCA evidence requirements and identified gaps relevant to HTA practice.

METHODS

A structured review of seven major guidance sources was conducted, including PRISMA, Cochrane guidance, Cochrane RAISE guidance, The Professional Society for Health Economics and Outcomes Research (ISPOR) recommendations, National Institute of Clinical Excellence (NICE) guidance, Canada's Drug Agency (CDA) guidelines, and EU JCA methodological documents.

All guidance were qualitatively assessed against requirements relevant to JCA-ready evidence generation, including continuous updating, AI-assisted review processes, transparency, governance, reproducibility, auditability, and support for evolving PICOS frameworks.

KEY TAKEAWAYS

Current guidance treats LSRs and AI as separate methodological developments rather than components of a continuous evidence ecosystem.

A framework integrating living evidence methods, AI, and HTA governance has been proposed to bridge this gap, and better align evidence generation with JCA requirements to support more timely, transparent, and decision-ready submissions.

RESULTS

Three major gaps were identified in existing methodological guidance:

- LSRs are recognized within methodological guidance but remain insufficiently operationalized for routine HTA use.
- AI-assisted evidence synthesis is increasingly acknowledged, yet governance, validation, and auditability requirements remain inconsistently defined.
- No reviewed framework fully supports continuously updated, PICOS-specific evidence generation aligned with JCA timelines.

These identified gaps have informed the development of a Real-time AI-assisted Living Systematic Literature Review (REAL-SLR) framework integrating continuous evidence surveillance, AI-assisted study identification and extraction, expert validation, version-controlled updates, and transparent audit trails.

The framework further enables dynamic evidence stratification across key clinical dimensions including disease stage, biomarker status, line of therapy, comparator class, trial design, guideline status, and HTA relevance.

Figure 1. **AI in evidence generation capabilities mapping to existing guidelines**

No single existing guideline that fully defines a JCA-ready, continuously updated, AI-assisted evidence-generation framework.
Required capabilities are distributed across methodological frameworks

Evidence synthesis & reporting

Needed capability	Strongest methodological precedent
Systematic, comprehensive review methodology	Cochrane / NICE
Transparent reporting	PRISMA
Living / continuous updating	Cochrane
Reproducible searches and evidence processes	Cochrane / NICE / ISPOR / CDA-AMC

Responsible AI & governance

Needed capability	Strongest methodological precedent
Responsible AI use	RAISE
Human accountability and governance	RAISE / NICE / EU JCA
Audit trail of AI use	EU JCA / RAISE

HTA & JCA alignment

Needed capability	Strongest methodological precedent
AI specifically within HTA	NICE
AI specifically within JCA	EU HTACG 2026 AI principles

Adaptability to evolving evidence

Needed capability	Strongest methodological precedent
Multiple/evolving PICOS	EU JCA
Rapid re-analysis under changed research questions	EU JCA + ISPOR, indirectly Cochrane

Figure 2. **Comparison of SLR guidelines on AI-readiness**

Qualitative assessment of key guidelines against JCA-ready evidence generation requirements

Assessment across 7 criteria essential for JCA-ready evidence generation

GUIDELINES / FRAMEWORKS	1. CONTINUOUS UPDATING	2. AI-ASSISTED REVIEW PROCESS	3. TRANSPARENCY	4. GOVERNANCE / HUMAN OVERSIGHT	5. REPRODUCIBILITY	6. AUDITABILITY / TRACEABILITY	7. SUPPORT FOR EVOLVING / MULTIPLE PICOS
1 **PRISMA 2020** PRISMA	**Partial** Supports updated reviews in reporting	**Limited** Does not address AI use	**Strong** Clear reporting standards	**Partial** Implies human role	**Strong** Detailed reporting enables reproducibility	**Partial** Reporting supports audit	**Partial** Allows reporting of amendments
2 **Cochrane Handbook (v6.5)** Cochrane	**Strong** Explicit guidance for living reviews	**Partial** Limited specific AI guidance	**Strong** Transparency core to methodology	**Strong** Human oversight integral	**Strong** Detailed methods ensure reproducibility	**Strong** Clear records and documentation	**Partial** Allows updates and scope changes
3 **Cochrane RAISE Guidance** RAISE	**Partial** Not focused on continuous updating	**Strong** Comprehensive AI framework	**Strong** AI use must be transparently disclosed	**Strong** Human accountability mandatory	**Strong** Tool validation and performance expectations	**Strong** Logging, validation and reporting	**Partial** Supports adaptation within reviews
4 **ISPOR Good Practices (2026 update*)** ISPOR	**Partial** Allows updating existing reviews	**Partial** Emerging GenAI guidance	**Strong** Transparency in methods and deviations	**Partial** Human review expected	**Strong** Reproducible searching and methods	**Strong** Protocol deviations and audit trail	**Partial** Search strategy adapts to amended PICOS
5 **NICE Guidance** NICE	**Partial** Evidence surveillance and guideline updates	**Strong** Formal position on AI use (2024)	**Strong** Transparent and replicable evidence	**Strong** Human oversight and responsibility	**Strong** Explicit, valid and replicable methods	**Strong** Study selection logs and exclusions	**Partial** Scope refinements allowed
6 **CDA-AMC Guidelines** CDA-AMC	**Partial** Not designed as living reviews	**Partial** Limited explicit AI guidance	**Strong** Transparent protocols and public search strategies	**Strong** Independent review and oversight	**Strong** Systematic methods and critical appraisal	**Strong** Documented processes and traceability	**Partial** PICOS refinements permitted
7 **EU JCA Methodological Documents (HTA Reg.)** EU JCA	**Limited** No explicit living review requirement	**Strong** AI use principles adopted (HTACG, Jul 2026)	**Strong** Explicit disclosure of AI and methods	**Strong** Accountability and human oversight required	**Strong** Compliance with HTA methods must be verifiable	**Strong** Tool versions, dates, prompts and logs required	**Strong** Multiple PICOs from Member States supported

*ISPOR GenAI Good Practices Task Force findings (2026)

EU JCA guidance uniquely addresses multi-PICO needs and AI accountability, while Cochrane provides the strongest foundation for living systematic reviews and RAISE offers comprehensive AI governance.

JCA-ready evidence generation requires integration of living evidence, governed AI, dynamic multi-PICO responsiveness, transparency, reproducibility and auditability.

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ABBREVIATIONS

AI, artificial intelligence; **C-DA-AMC**, Canadian Drug Agency–Agence des médicaments du Canada; **EU**, European Union; **HTA,** health technology assessment; **ISPOR,** International Society for Pharmacoeconomics and Outcomes Research; **JCA**, joint clinical assessment; **LSR**, living systematic review; **NICE,** National Institute for Health and Care Excellence; **PICOS,** population, intervention, comparator, outcomes, and study design; **PRISMA,** Preferred Reporting Items for Systematic Reviews and Meta-Analyses; **RAISE,** Responsible AI in Evidence Synthesis; **REAL-SLR,** Real-time AI-assisted Living Systematic Literature Review; **SLR**, systematic literature review.