GenAI for Next-Generation JCA Workflows: Automating Evidence generation While Ensuring Transparent, Traceable EU-HTA Submissions

HTA84

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Science-led HEOR & Tech-driven AI

INTRODUCTION

- The evolving European access landscape, characterized by the EU Joint Clinical Assessment's (JCA) strict submission timelines and the HTA Coordination Group's (HTA CG) scoping recommendations, mandates the rapid integration of heterogeneous clinical evidence, placing unprecedented pressure on HEOR teams and significantly elevating the risk of delays and costly rework[1-3]
- The objective of this study is to outline a pragmatic framework for integrating generative AI (GenAI) into JCA workflows in accordance with the HTA CG guidance on the scoping process, to overcome resource constraints and deliver timely, verifiable evidence packages

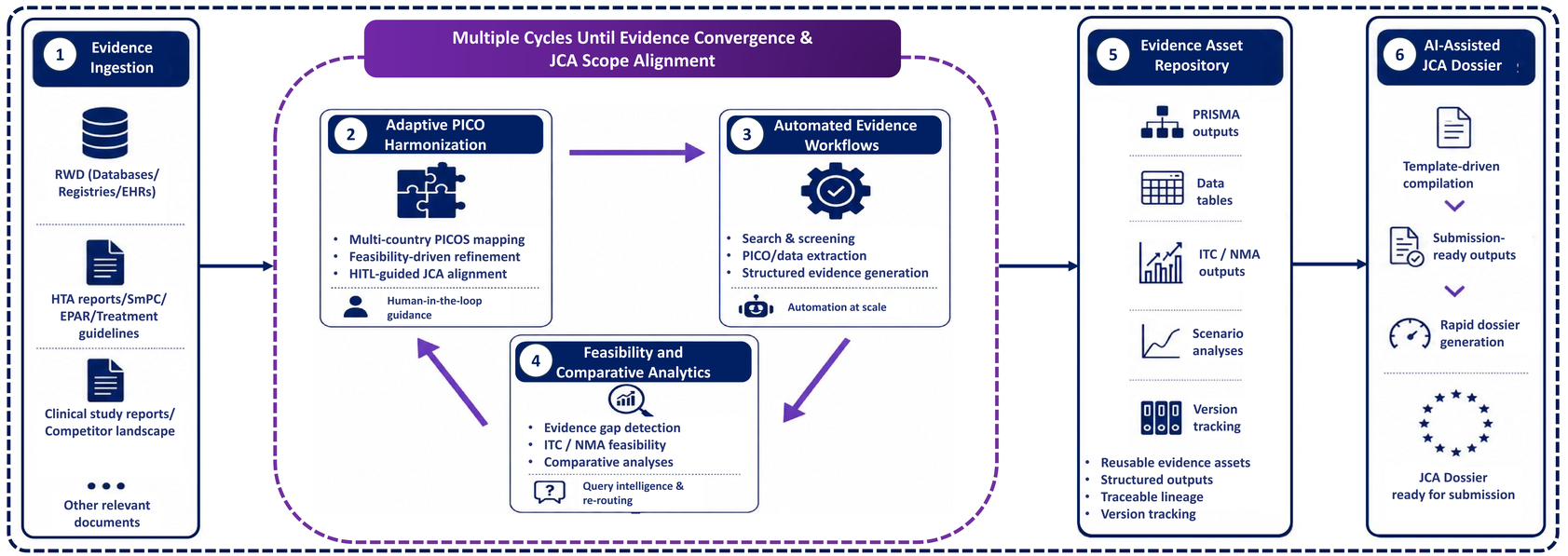
METHODS

- We developed a RAG-enabled GenAI evidence pipeline to support the JCA lifecycle from readiness assessment to submission (**Figure 1-2**)
- The proposed framework integrates structured trial data and unstructured documents and enables automated literature screening and PICO extraction, with configurable logic to adapt PICO elements to country- and assessment-specific requirements
- The resulting structured evidence was used to support feasibility assessment, Indirect treatment comparisons, and dossier preparation
- System components were evaluated by cross-functional experts to assess accuracy, completeness, traceability to source evidence, and alignment with predefined PICO scopes

RESULTS

- The GenAI- and RAG-enabled adaptive JCA framework was evaluated across multiple use cases involving both structured and unstructured evidence sources. These included trial documents, anonymized real-world data from disease registries and electronic health records, competitive intelligence reports, treatment guidelines, and prior HTA assessments
- Following AI-assisted prediction and harmonization of potential PICOS requirements across JCA member states, a consolidated expert-validated PICOS set was established to guide downstream evidence generation activities
- Based on this harmonized scope, the framework enabled rapid literature screening, efficient identification of relevant evidence, and structured data extraction to generate reusable, analysis-ready evidence outputs under full human oversight and in compliance with regulatory requirements
- These evidence outputs supported downstream feasibility assessments, indirect treatment comparisons or network meta-analyses, and JCA dossier preparation, while maintaining full citation provenance and traceability through the RAG-enabled architecture
- Cross-functional expert evaluation confirmed that the proposed framework met predefined quality criteria for accuracy, completeness, traceability, and alignment with target PICO scopes
- In addition, the framework demonstrated meaningful operational efficiencies across the JCA lifecycle, including accelerated evidence generation, reduced manual effort, improved audit readiness, and substantial time-savings across key workflow activities (**Figure 3**)

Figure 1: High-Level Overview of Proposed GenAI and RAG Enabled Adaptive JCA Framework



Note: In accordance with HTA AI guidelines, the adaptive JCA framework utilizes human-in-the-loop oversight to secure quality assurance and accountable, reason-backed decisions. Furthermore, the implementation of RAG establishes full traceability, enabling comprehensive audit trails and verifiable citations.

Abbreviations: AI: Artificial intelligence; CSR: clinical study report; EHR: electronic health record; EPAR: European Public Assessment Report; FA: feasibility assessment; GenAI: generative artificial intelligence; HTA: health technology assessment; HITL: human-in-the-loop; ITC: indirect treatment comparison; JCA: Joint Clinical Assessment; MA: meta-analysis; NMA: network meta-analysis; PICOS: population, intervention, comparator, outcomes, and study design; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RAG: retrieval-augmented generation; RWD: real-world data; SmPC: Summary of Product Characteristics.

Figure 2: High-Level Overview of RAG Pipeline for Data Ingesting, Processing, and Vectorization

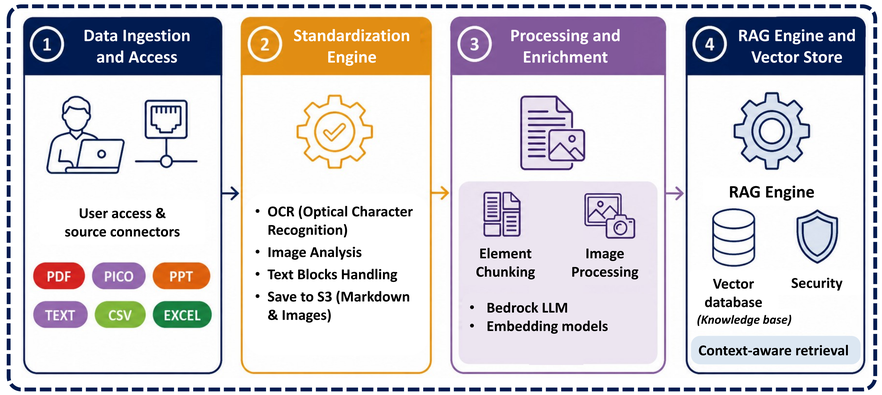
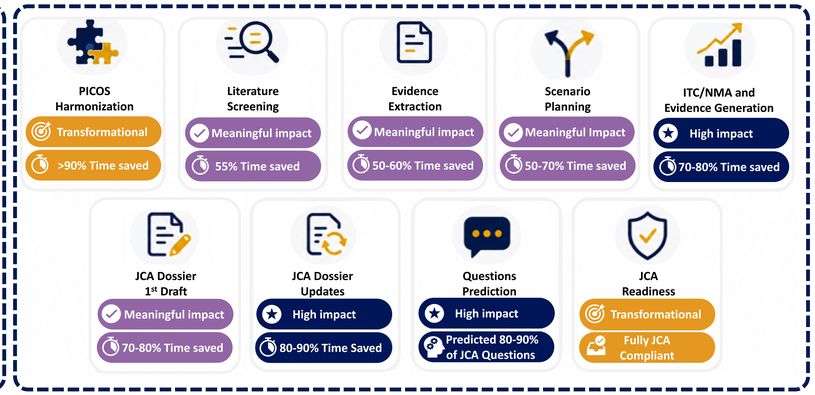


Figure 3: GenAI-Driven Optimization Opportunities Across the JCA Lifecycle



CONCLUSIONS

- Success in the JCA era demands a shift from purely manual drafting to cost and time-efficient intelligent automation
- Prioritizing the development of GenAI-ready evidence structures is critical to facilitating the timely completion of JCA documents
- By adopting the proposed GenAI framework, manufacturers can accelerate evidence readiness, reduce inefficiencies, and improve the likelihood of timely market access across Europe

~80%
Reduction in JCA preparation time

JCA Readiness
All Evidence Scenarios with traceability and adaptability

Accelerated
Patient Access to Innovative Drugs

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Disclosure: ISM, RK, BS, GK, and SP the authors declare that they have no conflict of interest

ISPOR, May 17-20, 2026, Philadelphia, PA, United States