

Sukriti Sharma¹, Sumeet Attri¹, Barinder Singh², Shubhram Pandey¹, Rajdeep Kaur¹, Nicola Waddell², Michael Marentette³
¹PharmacoEvidence, Mohali, India, ²PharmacoEvidence, London, United Kingdom, ³PharmacoEvidence, Montreal, QC, Canada

INTRODUCTION

- BB documents facilitate scientific dialogue, which informs product development strategies, strengthening future HTA submissions and supporting reimbursement potential
- These documents serve as a bridge between manufacturers and HTA bodies, enabling early alignment on evidence requirements and support positive HTA decisions
- BB development is resource-intensive, requiring substantial time and expert input, often involving iterative synthesis of clinical, economic, and real-world evidence across multiple therapeutic areas. The integration of AI into this process presents an opportunity to enhance consistency and efficiency without compromising the scientific rigor essential to regulatory and payer engagement

OBJECTIVE

- This study explores the feasibility and efficiency of applying GenAI, within a RAG framework with structured human oversight, to automate the development of accurate, relevant, and traceable BB content for NICE HTA submissions

METHODS

- A structured workflow was developed to support the generation of NICE BB content using GenAI within a RAG framework, complemented by systematic human oversight. **Figure 1** provides a comprehensive depiction of the entire process

Data Ingestion and Pre-processing

- Relevant source documents, including disease area literature, guidelines, and prior NICE submissions for comparator technologies, were uploaded into the system. Documents were standardized into structured markdown format and segmented into discrete, traceable knowledge units. Metadata tagging and indexing enabled efficient retrieval of source content while preserving provenance for auditability and cross-referencing

RAG-Based Content Generation

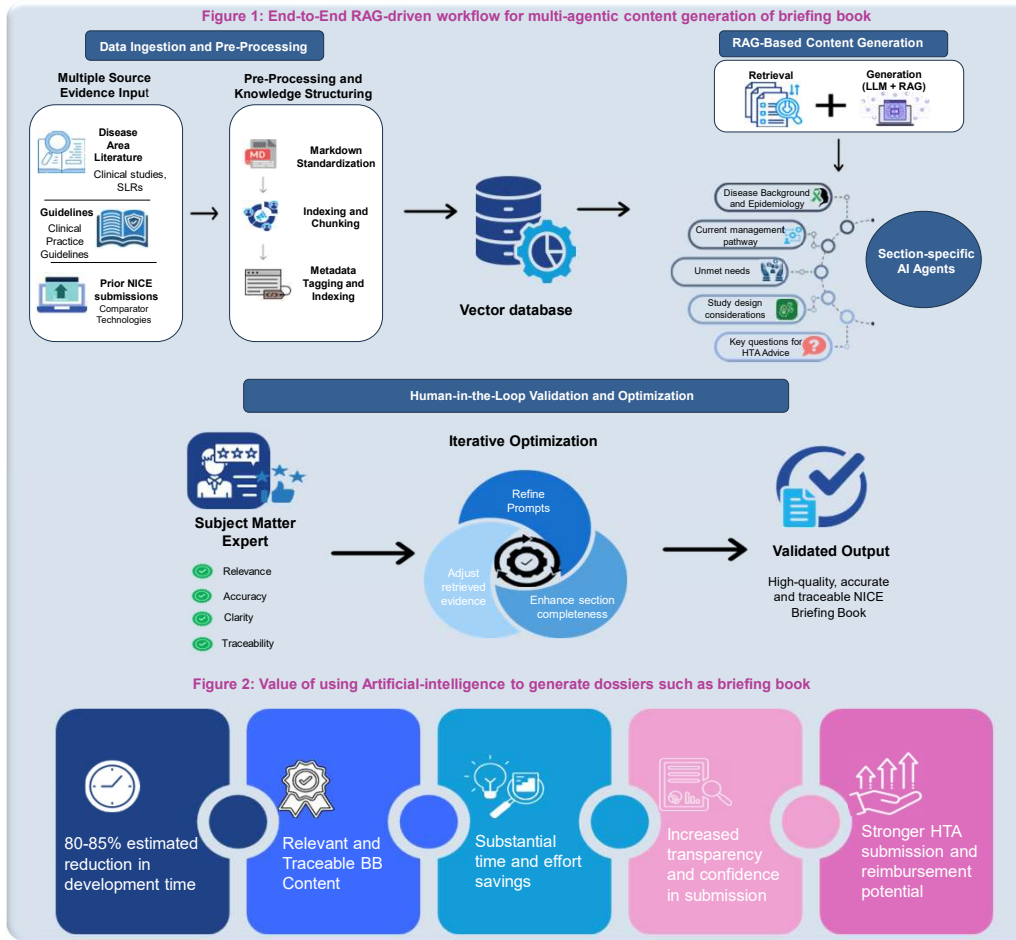
- The RAG pipeline facilitated controlled retrieval of indexed source materials. Section-specific AI agents were configured to generate BB components aligned with the NICE scientific advice template, including: disease background and epidemiology, current management and treatment pathway, unmet medical needs, study design considerations, key questions for HTA advice
- Previous NICE submissions for relevant comparator technologies were used as reference material to contextualize and frame HTA-focused key questions

Human-in-the-Loop Validation and Optimization

- Generated content underwent structured review by an SME to assess relevance, factual accuracy, clarity, and traceability to source documents. SME feedback was incorporated iteratively to refine prompts, adjust retrieved evidence, and enhance section completeness. Particular emphasis was placed on validating unmet needs and refining HTA advice questions, where expert judgment is critical

CONCLUSIONS

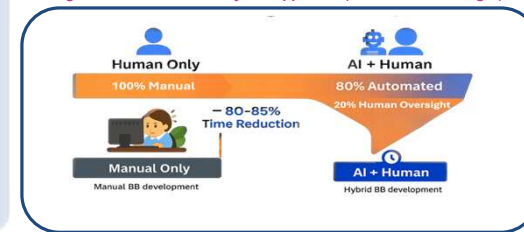
- ❖ This study demonstrates the feasibility of GenAI-generated BB documents for HTA submissions, achieving substantial reductions in time and effort while maintaining relevance, accuracy and traceability
- ❖ As payer landscapes grow increasingly complex and evidence requirements continue to evolve, scalable and transparent AI-driven solutions will be essential to sustaining timely, high-quality HTA engagement
- ❖ These findings position GenAI not as a replacement for subject matter experts, but to support human expertise - freeing them to focus on strategic reasoning, evidence interpretation, and scientific dialogue
- ❖ Further research is warranted to evaluate generalizability across different HTA bodies and broader application areas



RESULTS

- Our AI-enabled workflow was developed in alignment with the NICE (UK) position statement, CDA position paper and Cochrane recommendations for responsible use of AI in evidence generation, including methodological rigor, transparency, and reproducibility¹⁻³
- BB sections were successfully generated using the GenAI-enabled RAG framework, covering key NICE scientific advice components including disease background, current clinical management pathways, unmet medical needs, study design overview, and HTA-focused key questions
- Outputs were generated in tabular and graphical formats (such as pie charts, bar/line graphs) with minimal human intervention
- Final BB outputs were reviewed for internal consistency, alignment with NICE expectations, and appropriate cross-referencing
- SME endorsement was achieved across all critical quality parameters, with content consistently rated high for relevance, accuracy, and source traceability, demonstrating strong alignment with NICE submission standards
- Section-level performance varied in a clinically meaningful way:
 - Disease background and management pathway sections achieved approximately 90-95% acceptance with minimal revision, reflecting the framework's strength in synthesizing structured, evidence-rich content
 - The unmet needs section required targeted SME refinement (10-15%) to enhance contextual interpretation and strategic framing - areas where domain expertise and nuanced clinical judgment remain essential
 - HTA key questions were largely appropriate as generated, with supplementary questions incorporated during expert review to further strengthen the scientific dialogue
- The RAG-enabled pipeline ensured accurate citation, cross-referencing and evidence linkage across BB sections, enhancing transparency, traceability and confidence in the generated outputs
- The hybrid AI-human workflow successfully balanced automation with expert oversight, delivering submission-ready content while preserving the scientific rigor and strategic depth required for HTA engagement
- Notably, the approach achieved an estimated 80-85% reduction in BB development time compared with traditional manual processes - a substantial efficiency gain that enables teams to redirect expert effort toward higher-order tasks such as strategic positioning and evidence gap analysis (**Figure 3**)

Figure 3: Manual versus hybrid approach (AI + human oversight)



References: 1. NICE. Use of AI in Evidence Generation: Position Statement, 2025. 2. CADTH – Position Statement on AI in Evidence Generation, 2025. 3. Cochrane guidance on use of AI

Abbreviations: AI: Artificial intelligence; BB: Briefing book; CDA: Canadian Drug Agency; GenAI: Generative AI; HTA: Health technology assessment; LLM: Large language model; NICE: National Institute for Health and Care Excellence; RAG: Retrieval augmented generation; SLR: Systematic literature review; SME: Subject matter expert

Correspondence: Barinder Singh (Barinder.singh@pharmacoEvidence.com)
Disclosure: SA, SS, SP, RK, NW, MM, and BS, the authors declare that they have no conflict of interest