Automated AMCP Dossier Development using a Retrieval-Augmented Generation (RAG)-Based Multi-Agent Approach

MSR207

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INTRODUCTION

- American Managed Care Pharmacy (AMCP) dossiers are critical components of formulary submissions and payer decision-making in the United States[1]
- The development of AMCP dossiers requires integration of diverse evidence sources, including clinical trial data, real-world evidence, health economics models, and patient-reported outcomes
- Manual dossier creation can be time-consuming and error-prone due to changing market dynamics and competitive settings
- Generative Artificial Intelligence (GenAI) accelerates AMCP dossier development by automating evidence synthesis, content generation, and enhancing speed, consistency, and accuracy, while maintaining traceability, accuracy, and regulatory adherence[2]

OBJECTIVE

- This study explored the utility of GenAI to automate the creation of key sections in an AMCP dossier for a psychiatric disorder to produce reliable, traceable outputs through a human-in-the-loop approach

METHODS

- A Python-based interface was developed using the Claude 3.7 Sonnet GenAI
- The tool, deployed on a secure Amazon Web Services (AWS) cloud infrastructure combined a Retrieval-Augmented Generation (RAG) framework with a multi-agent architecture to ensure that outputs were fully traceable to source documents
- A total of 110 documents including journal articles, conference abstracts, treatment guidelines, and epidemiology data sources were uploaded into the RAG pipeline for processing of text, tables, and figures/plots
- The prompts directed the large language models (LLMs) to retrieve relevant information from publications related to product information, disease description, clinical evidence, value and modeling report, additional data as well as dossier appendices associated with the disease
- The agents were configured to generate different AMCP sections, in accordance with established Format for Formulary Submissions, version 5.0, and the outputs were validated by subject matter experts (SMEs) for relevance, completeness, accuracy, language, and overall quality, using a 5-point Likert scale (**Figure 1**)

Figure 1. Evaluation Parameters of GenAI-Generated AMCP Dossier

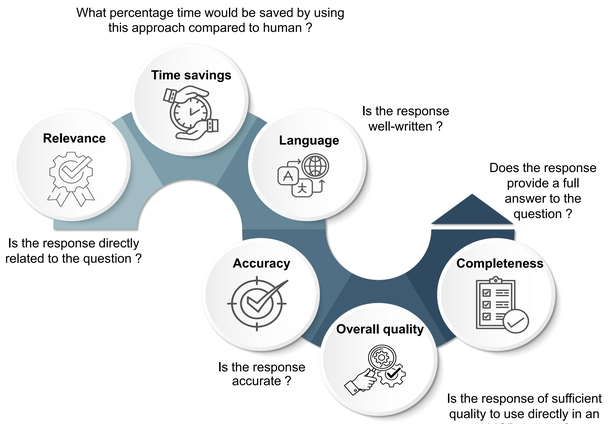
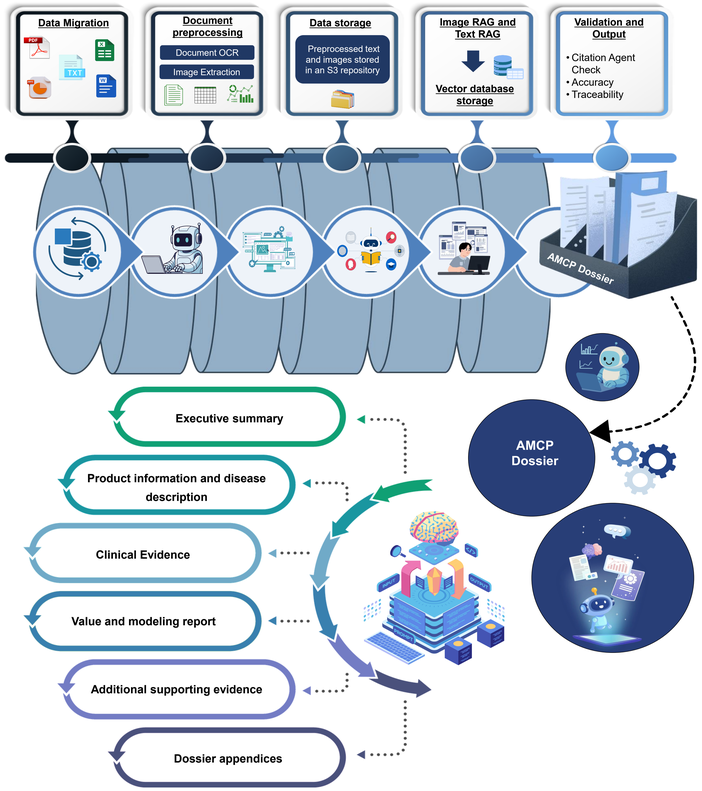


Figure 2. Schematic Diagram of the AI-Assisted AMCP Dossier Process



RESULTS

- A 150 pages AMCP dossier was generated, encompassing sections on executive summary, product and disease description, clinical, value and modeling report, and appendices
- Outputs in tabular and graphical formats (such as bar graphs, pie charts and line graphs) were generated without any human intervention (**Figure 3**)
- While most figures and tables were generated accurately, a small number of bar graphs and tables required manual formatting adjustments; however, all underlying data remained fully traceable to source references
- Based on Likert scale assessment, the SMEs strongly agreed that all generated content was relevant and accurate to the topic under consideration (94% strongly or somewhat agreed; **Figure 4**)
- Further, responses were largely complete (85% somewhat agreed), but could be further improved by prompt editing
- In all sections, there were instances of repetition, however SMEs concurred that the responses were mostly well-written (98% strongly or Somewhat agreed)
- SMEs agreed that the overall quality of the generated outputs was sufficient for incorporation into an AMCP dossier development (95% strongly or somewhat agreed; **Figure 4**), although manual review and editing were required

Figure 3. GenAI-Generated Visual Outputs

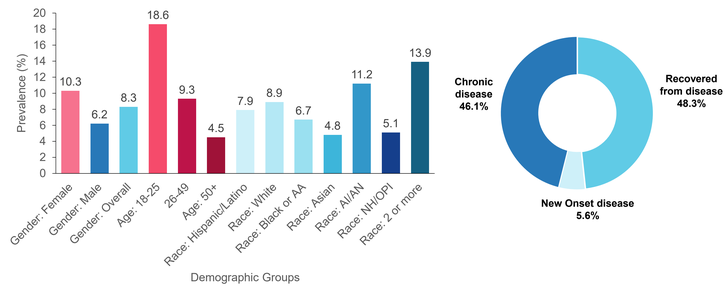
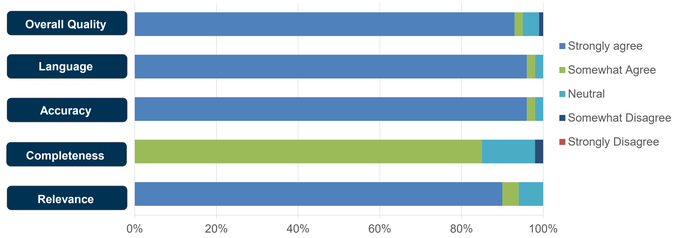
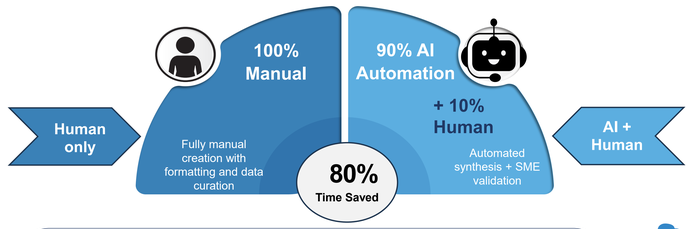


Figure 4. SME Evaluation of LLM Generated AMCP Dossier Content



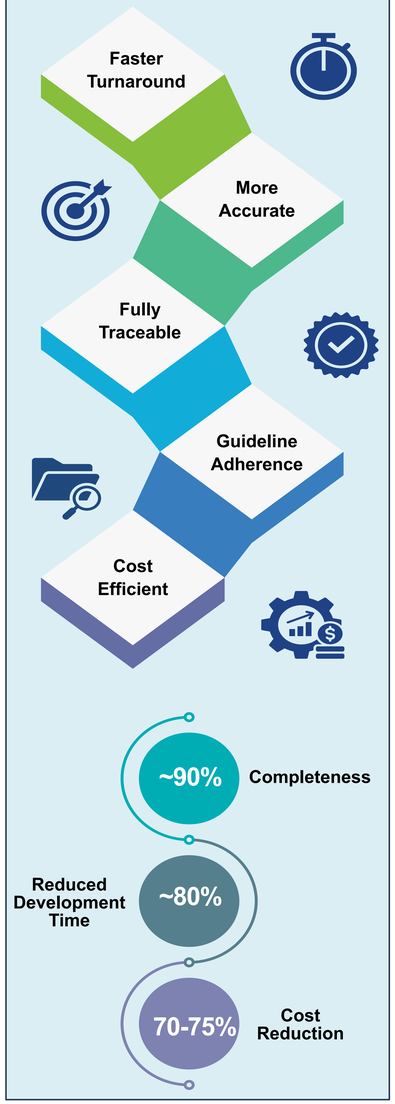
- Overall, the automated approach generated a draft that was ~90% complete, reduced development time by ~80% compared to manual methods, and resulted in 70-75% cost reduction (**Figure 3**)

Figure 5. Manual versus AI-Assisted Workflow with Human Oversight



- ✓ The AI-generated content demonstrated a high level of accuracy and writing quality, capturing most relevant details with minimal hallucinations or copying errors
- ✓ Overall, the outputs aligned well with expectations for a first-draft report; however, human review remains essential to ensure completeness and accuracy

IMPLICATIONS



CONCLUSIONS

Well-structured Dossier
The AI-driven system demonstrated strong capability in producing well-structured AMCP dossier outputs, including narrative text, tables, and plots across multiple sections

Efficiency
GenAI speeds up AMCP dossier development, reducing timelines from weeks or months to days while maintaining accuracy, traceability, and guideline adherence

Human-in-loop approach
Through structured SME validation, the approach enables efficient, compliant content generation, supporting responsible AI integration in health economics and outcomes research

Future Directions
Further testing is needed to refine prompts and evaluate LLMs for other report and dossier type

References

1. AMCP Format for Formulary Submissions 5.0, Guidance on Submission of Pre-approval and Post-approval Clinical and Economic Information and Evidence, *jmcp.org*. 2024; 30(4b) **2.** Yung R et al., Retrieval-augmented generation for generative artificial intelligence in health care. *Njp. Health Systems*. 2025; 2(2)

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

Abbreviations: AI/AN: American Indian / Alaskan Native; AMCP: American Managed Care Pharmacy; AWS: Amazon Web Services; GenAI: Generative Artificial Intelligence; LLM: Large Language Models; NH/OPI: Native Hawaiian / Other Pacific Islander; OCR: Optical Character Recognition; RAG: Retrieval-Augmented Generation; SME: Subject Matter Expert

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