HTA169

Harnessing Generative Artificial Intelligence for Global Value Dossier Development

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Objective

To evaluate the role of generative artificial intelligence (genAI) in global value dossier (GVD) development, considering efficiency, accuracy, value narrative strength and alignment with a predefined product strategy.

Background

- GVDs are comprehensive, evidence-based documents that synthesise large volumes of information.
- Their development is time- and resource-intensive, and requires integrating complex data into a scientifically accurate, compelling value narrative.
- Research to date has focused on using genAI to summarise clinical trial data for clinical value chapters of GVDs, or health technology assessment dossiers which tend to follow more prescriptive and rigid structures.[1–4]
- The use of genAI in highly strategic disease background and unmet need GVD chapters has been less widely explored.

Methods

- The 'Disease Background, Burden and Unmet Needs' section of a GVD for a hypothetical Alzheimer's disease treatment was developed via separate genAI-assisted and manual workstreams in a head-to-head comparison. Each workstream consisted of a unique medical writer, senior reviewer and project manager.
- Both workstreams followed our standard procedures for GVD writing: outline development (stage one) then draft development (stage two; **Figure 1**). Both stages included senior review of initial drafts.
  - Two approaches to genAI-assisted draft development were tested: *de novo* drafting from a set of defined sources using retrieval augmented generation (RAG) (Approach A) and synthesis of human-written study summaries of the same sources into narrative text (Approach B).
- Project manager review was blinded at each stage to ensure objectivity. Key metrics are detailed in **Figure 1**.
- Analyses of technical accuracy and value narrative strength were also informed by qualitative insights.

Results

Stage One: Outline

- Overall, time to a final GVD outline was 5.7 hours faster in the genAI-assisted workstream versus the manual workstream, representing a 62% time saving using genAI (**Figure 2**).
- Within stage one, time savings compared with manual development occurred predominantly in generating the initial outline (83%; **Figure 2**), whereas time spent reviewing and refining the outline was comparable between the two workstreams.
- Although human intervention was required in the genAI-assisted workstream to ensure outline completeness, flow and relevance, revisions were not time-intensive.

Stage Two: Section Drafting

- GenAI drafting using Approach A resulted in low accuracy and lack of a coherent value narrative, and would have required substantial human rewriting to produce an acceptable section draft, and was therefore not taken forward.
- Approach B generated a higher quality output than Approach A.
- In Approach B, the medical writer became more familiar with the evidence base which meant that identification and corrections of hallucinations and misinterpretations of data were easier than with Approach A. Approach B was also perceived by the medical writer as more enjoyable than approach A.
- Time taken for initial draft development using genAI-assisted Approach B was reduced by 50% compared with the fully manual approach (**Figure 2**).
- Senior and project manager review times were comparable for the manual and genAI-assisted (Approach B) workstreams (**Figure 2**). While more substantial edits were required to refine the overall value narrative in the genAI-assisted workstream versus the manual workstream after senior review, both drafts provided a good starting point for further refinement.
- Total time from outline to a final project manager-reviewed draft was reduced by 27% with genAI-assisted Approach B versus the fully manual approach, leading to an overall time saving of 36% across outline and draft development (**Figure 2**).

Limitations

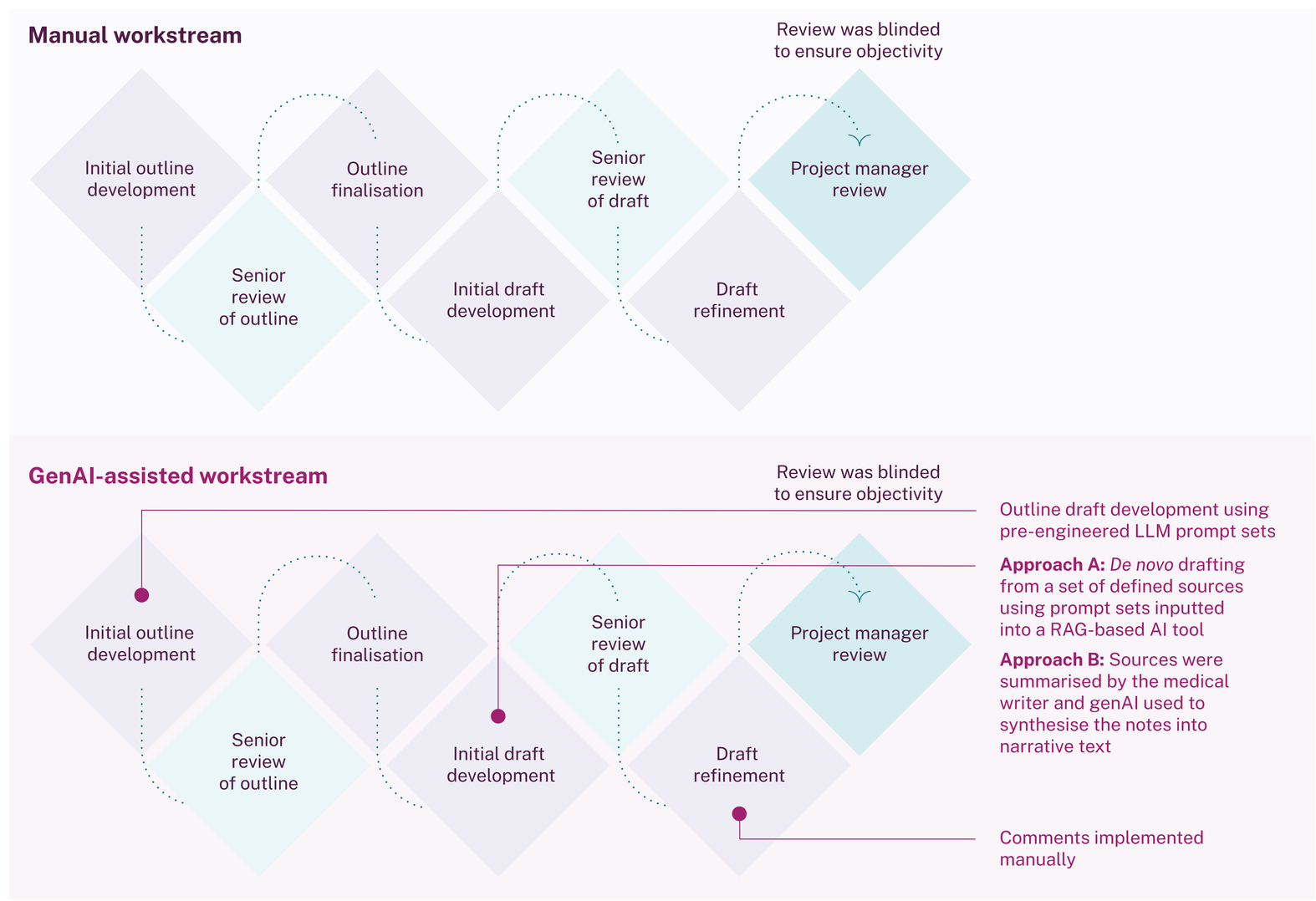
- Differences between workstreams in time taken and feedback provided at each stage could reflect differences in individual senior reviewer/project manager preferences rather than genuine differences.
- Actual time savings for a particular GVD may be affected by the complexity of the disease area and product messaging.

Conclusion

In a head-to-head comparison, use of genAI in combination with human refinement for outline and draft development provided substantial time savings whilst still generating a suitably high quality 'Disease Background, Burden and Unmet Needs' GVD section in terms of accuracy and narrative strength. When used appropriately, genAI can streamline GVD development, but human expertise remains essential to ensure outputs are accurate, comprehensive and compelling.

FIGURE 1

Overview of study design: head-to-head comparison of genAI-assisted and manual GVD development workflows



Key time metrics measured (quantitative)

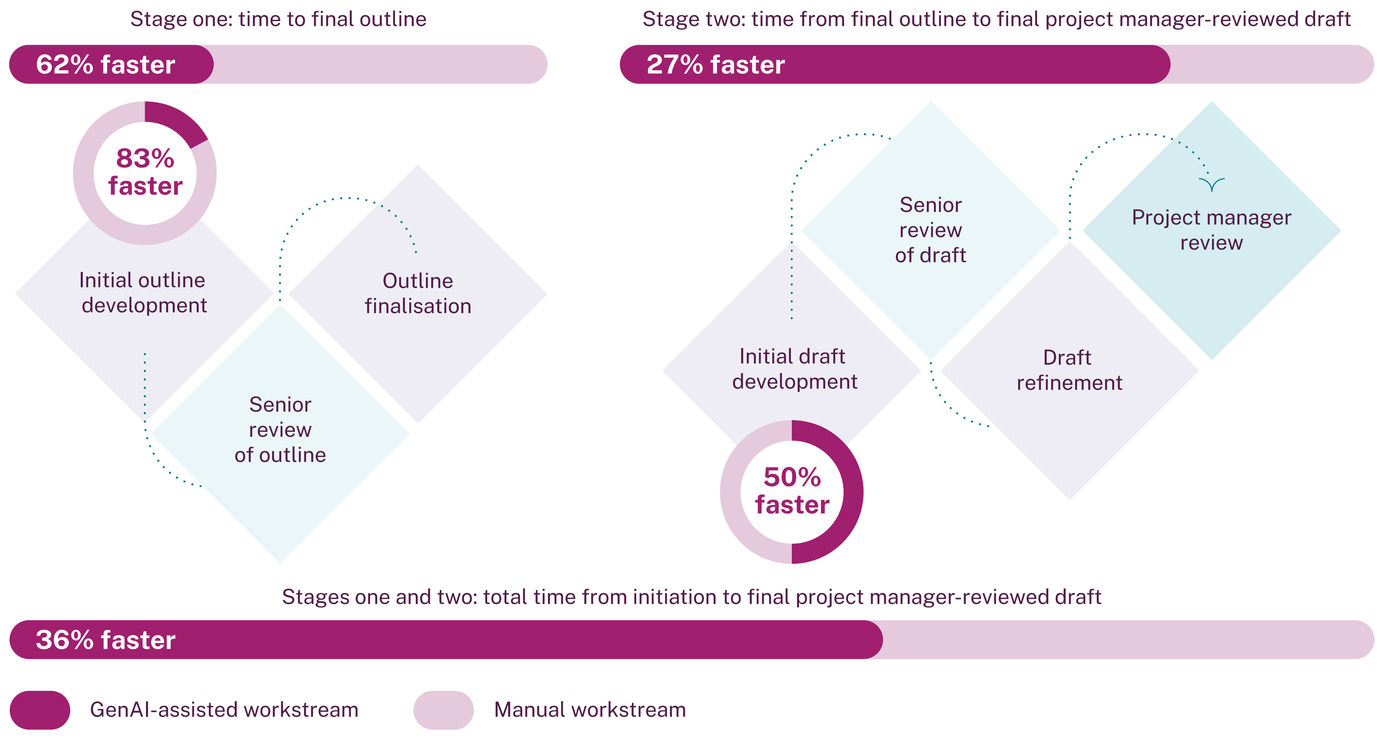
- Time for initial outline development
- Time to final outline
- Time from final outline to initial draft development
- Time from final outline to final project manager-reviewed draft
- Total time from initiation to final project manager-reviewed draft

Key quality metrics measured (qualitative)

- Outline: completeness, flow
- Draft: accuracy, narrative strength

FIGURE 2

Time comparison by stage of GVD development with genAI-assisted vs manual workstreams



Percentage time savings reflect a comparison between the genAI-assisted workstream (Approach B) and the manual workstream.

Abbreviations: genAI: generative artificial intelligence; **GVD:** global value dossier; **LLM:** large language model; **RAG:** retrieval augmented generation.

References: [1]Jost J. et al. HTA113. Presented at ISPOR Europe, 17–20 November 2024. Barcelona, Spain; [2]Beatson LZ. et al. MSR71. Presented at ISPOR Europe, 17–20 November 2024. Barcelona, Spain; [3]Aggarwal S. et al. HTA229. Presented at ISPOR Europe, 17–20 November 2024. Barcelona, Spain; [4]Gofman L. et al. HTA74. Presented at ISPOR, 13–16 May 2025. Montréal, Canada. **Acknowledgements:** The authors thank Jenny Chen, Costello Medical, for graphic design assistance. We also thank Matt Griffiths, Kirsten Dundas, Natalie Hearmon, Helen Chambers and Alex Porteous for their review and editorial assistance in the preparation of this poster.

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