From GVD to HTA - Preparing for Success in the EU JCA era with GenAI Enhanced Efficiency

Larisa Gofman[1], Molebedi Segwagwe[2], Sahil Sharma[3]
[1]ZS Associates, Princeton, NJ, USA; [2]ZS Associates, London, UK; [3]ZS Associates, New Delhi, India.

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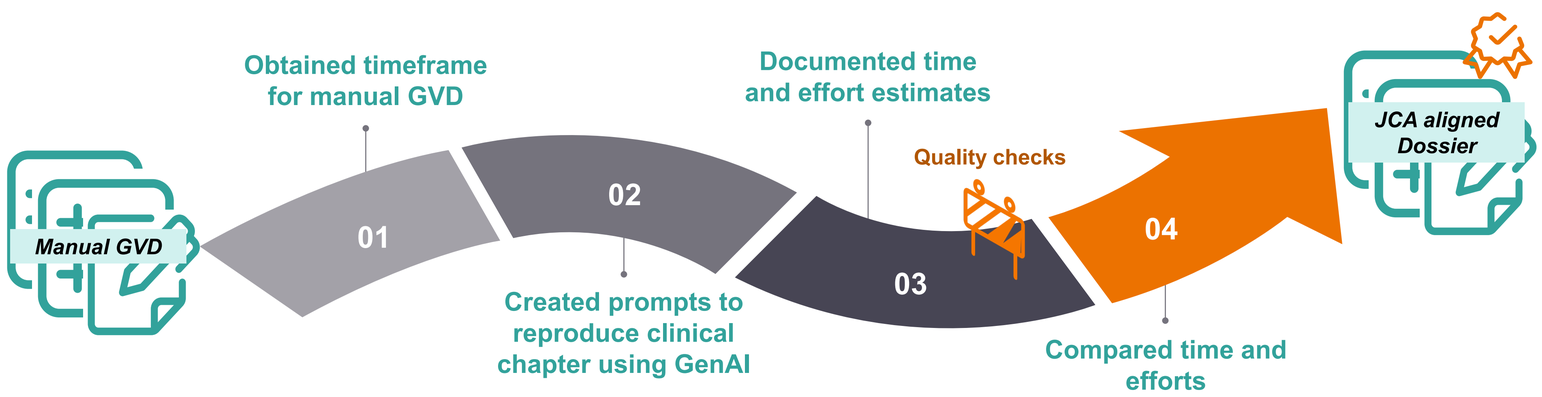
Background & Objectives

- With Joint Clinical Assessment (JCA) being applicable to new oncology and advanced therapeutic medicinal products (ATMPs) in the EU since January 2025, health technology developers (HTDs) face unprecedented pressures to deliver timely, aligned evidence packages
- These findings explore how Generative-AI (Gen-AI) can be leveraged to accelerate and optimize the end-to-end submission process and highlight the urgency to synchronize Global Value Dossier (GVD) and JCA dossier development

Methods

- We obtained historical data development timeframes for a clinical section of a GVD, synthesizing all relevant evidence and comparators for the submission, developed fully by human-in-the-loop absent of any AI technological enablers
- We compared this with a Gen-AI accelerated approach, reproducing the clinical section of the same GVD and estimated the differences in time and effort to produce a document of the comparable quality and accuracy
- Emphasis was placed on using Gen-AI to streamline repetitive, time-intensive drafting processes

Figure 1: Process of comparing a GenAI accelerated GVD that aligns with JCA dossier



Results

- Deployment of Gen-AI to support GVD development led to efficiency in literature review summarization, clinical evidence harmonization, and drafting of value messages for JCA-relevant sections. Clinical evidence outputs generated by the Gen AI tool were determined comparable in quality compared with traditionally developed GVDs, with limited hallucinations and errors in the Gen-AI output
- Given the substantial volume of available evidence and the need to initiate early development of GVDs, it is essential to establish efficient processes for identifying and mapping the most relevant clinical data required for the JCA. Prioritizing and developing key GVD sections early in the process will facilitate the timely and effective completion of the JCA document

Figure 2: Shared evidence requirements between GVD and JCA

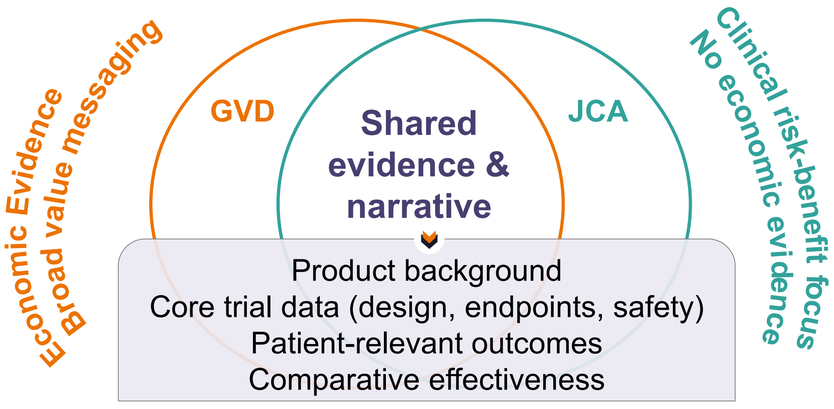
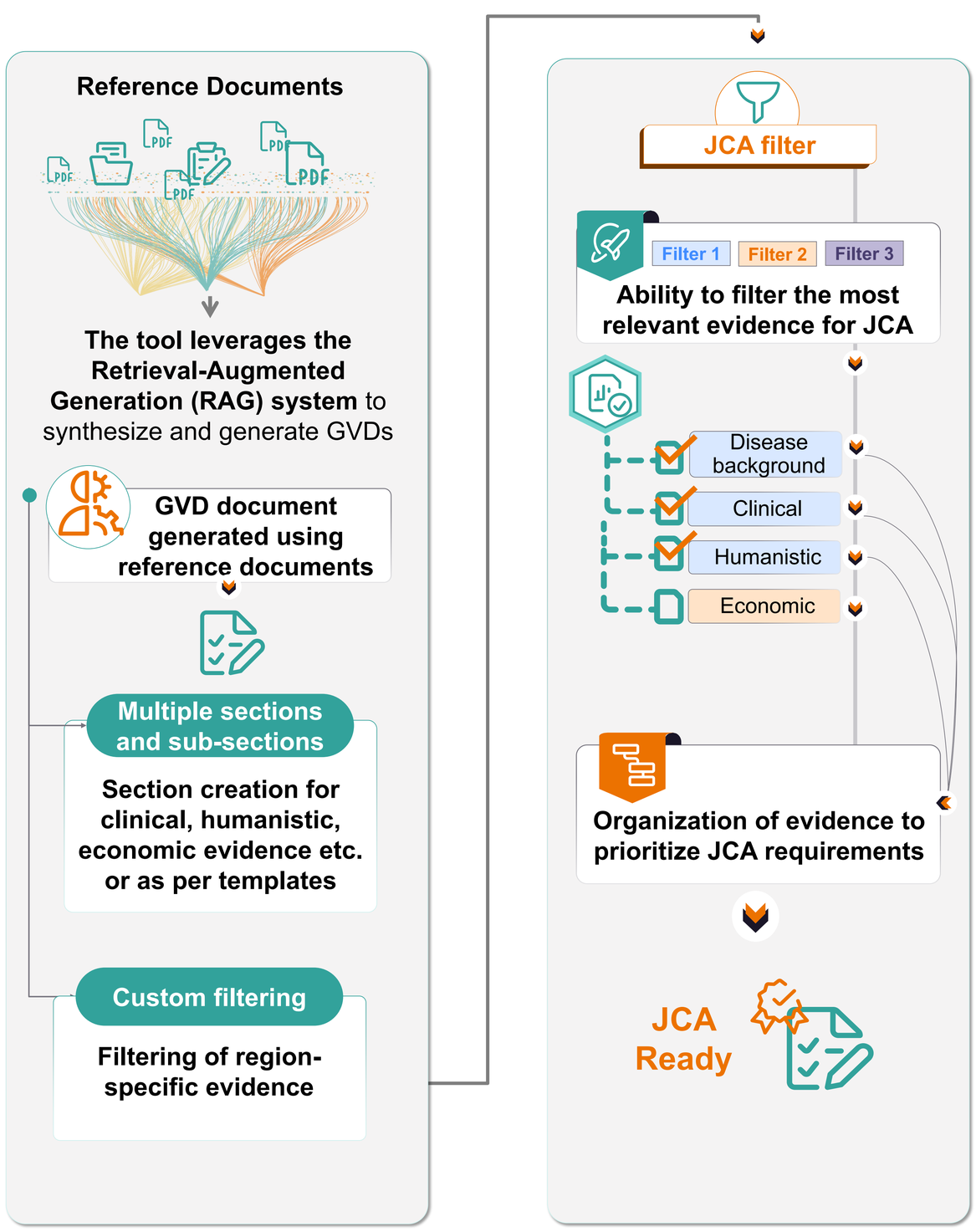


Table 1. Driving efficiency through shared evidence mapping

Section/ Chapter	Global Value Dossier (GVD)	Joint Clinical Assessment (JCA)	Overlap
Product & Disease Background	Epidemiology, burden of disease, treatment landscape, unmet needs	Information on medicinal product, description of medical condition, population, clinical management	Use same product description, unmet need & management narrative
Clinical Evidence	Full details of trials, plus supportive studies, endpoints, results	Clinical trial evidence: design, endpoints, outcomes, safety	Use same Core trial results (HCT control, phlebotomy reduction, safety)
Patient-Relevant Outcomes	PROs, QoL improvements, treatment burden	Outcomes relevant to patients (QoL, functional outcomes)	Use same PRO and QoL evidence as applicable
Comparative Effectiveness	Direct/indirect comparisons vs SoC	Comparative effectiveness vs relevant comparators	Use same effectiveness & safety evidence (PICOs)
Economic Evidence	Cost-effectiveness models, budget impact, resource utilization, payer messaging	Not included in JCA	Applicable in GVD only
Value Proposition / Messaging	Clinical, economic, and humanistic value narrative; lifecycle positioning	Clinical benefit–risk profile, added value vs comparator	GVD messaging broader; JCA focused on clinical risk-benefit

Figure 3: Streamlining evidence through mapping from GVD to JCA



Conclusion

- The convergence of regulatory and HTA timelines increases the cost of rework and delays. Gen-AI-driven tools help overcome resourcing bottlenecks and enable rapid iteration of JCA-compliant content while maintaining consistency across internal and affiliate-facing deliverables
- Strategic Gen-AI use also supports faster adaptation to national HTA nuances post-JCA. Success in the JCA era demands not only early planning and cross-functional coordination but also intelligent automation
- By embedding Gen-AI into the GVD-to-HTA workflow, HTDs can accelerate evidence readiness, reduce inefficiencies, and improve the likelihood of timely market access across Europe

References

1. European Commission. Joint Clinical Assessment for Medicinal Products. https://health.ec.europa.eu/document/download/ced91156-ffe1-472d-85eb-aa6a91dd707e_en?filename=hta_htar_factsheet-jca_en.pdf Accessed September 1, 2025.
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