Using Generative AI to Facilitate Strategic Publication Planning

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Project Insights

AI serves as a tool to augment rather than replace human expertise.

Medical writers and clinical experts remain essential to validate outputs, correct errors, interpret clinical significance, and ensure strategic relevance of findings.

Medical communications project teams are essential to transforming and packaging useful AI outputs into deliverables that meet expectations.

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Conclusions

- GenAI can support expedited production of literature analyses for publication teams by rapidly identifying and extracting outcomes of interest.
- Human oversight remains essential to ensure quality of outputs, and for interpreting strategic relevance of findings.
- This approach enabled rapid identification of variations in clinical outcome definitions and analytical methods used to assess treatment effects in a rare disease, informing literature gaps and publication planning strategies.

Introduction

- Successful gap analyses inform strategic publication and integrated evidence planning activities and guide medical education initiatives.[1]
- Despite their importance, gap analyses can be difficult to perform, often requiring the processing of large amounts of information. There may also be challenges related to identifying and framing initial questions.
- We explored the utility of generative artificial intelligence (GenAI) to identify and retrieve outcomes of interest as part of literature gap analysis and strategic publication planning.

Methods

- Publications (manuscripts and congress abstracts) of phase 3 trials evaluating the clinical impact of approved therapies for rare heart failure were identified in Embase using broad search terms.
- Search results were exported and the title and abstract were manually reviewed for relevance.
- ChatGPT-4o was prompted to reformat each shortlisted record into a simplified, structured output.
- Then, using a closed-system approach, ChatGPT-4o-mini was instructed to analyse the formatted dataset (collated abstracts) to identify key outcome categories and extract detailed outcome definitions and analysis methods.
- A medical writer reviewed the ChatGPT outputs for quality and accuracy.
- The synthesised report was reviewed, and outputs were used to support identification of data generation gaps for publication planning (**Figure 1**).

Results

- Approximately 50 publications of interest were identified.
- ChatGPT processed the publications nearly instantaneously and generated a list of study outcome categories in seconds (**Box 1**).
- ChatGPT extracted clinical outcome definitions and analyses rapidly.
- Outputs were further optimised using structured, iterative prompting.
- ChatGPT reliably reported straightforward information such as the key trial outcomes assessed and specific definitions of outcomes;
  - for example, capturing detailed descriptions of composite endpoints including hierarchical statistical assessment approaches, to enable human users to understand intricacies between different trials and properly assess endpoint and data comparability.
- Advantages and limitations of using GenAI for a strategic gap analysis are summarised in **Table 2**.
- Given ChatGPT was unable to produce useful visual outputs, all informative visuals were created manually to complement the qualitative extraction tables created by ChatGPT (**Figure 2**).

Reference

1. Focus Area Working Group: Medical Strategy and Launch Excellence. *Bridging the gap: Understanding and implementing gap analyses.* https://medicalaffairs.org/wp-content/uploads/2023/06/FINAL-SLIDES-MAPS_Gap-Analysis-Webinar_FINAL_23Jun47.pdf. 2023. Accessed 15 December 2025.

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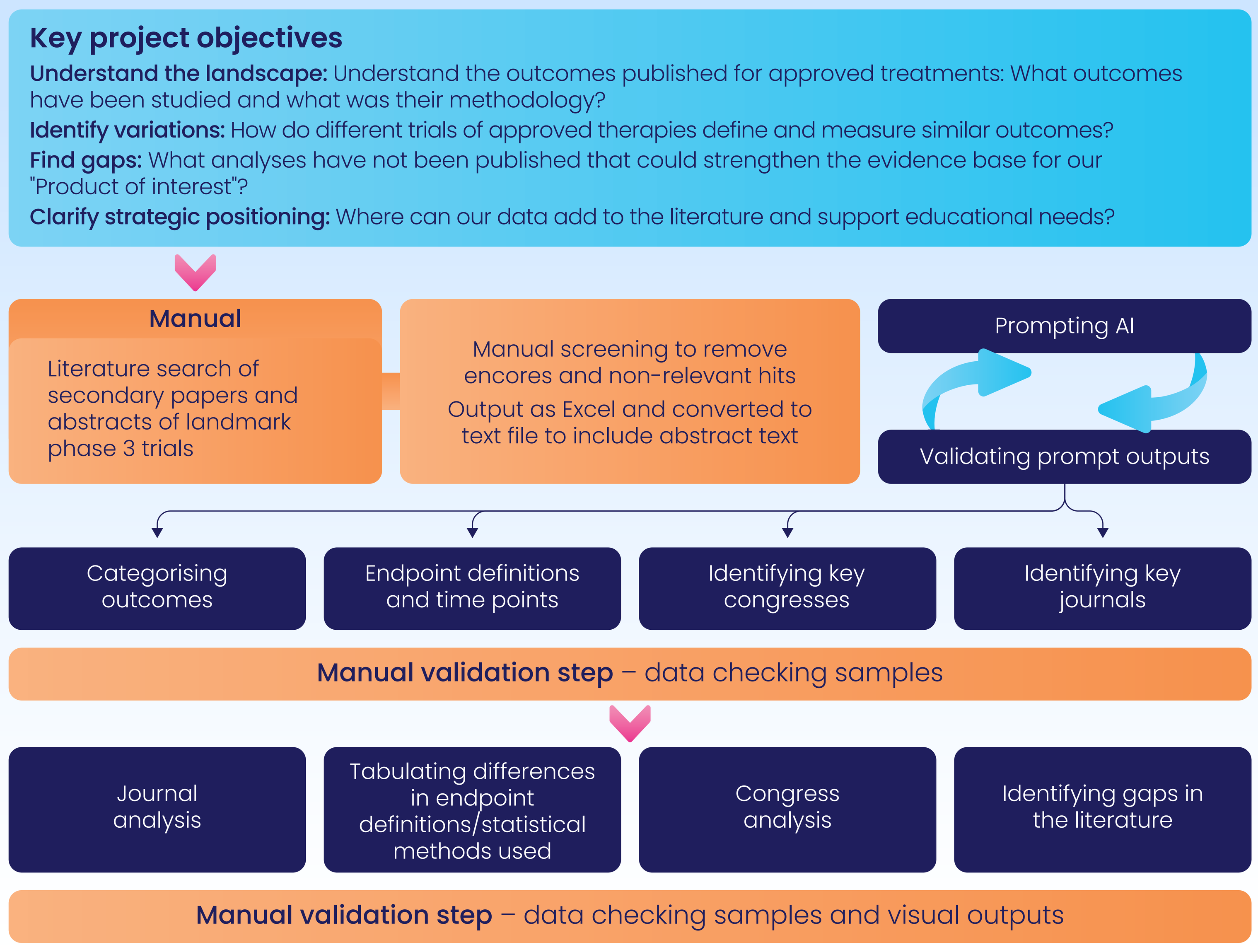
Figure 1. Approach to performing a strategic gap analysis with GenAI



GenAI, generative artificial intelligence.

Box 1. Gap analyses categories[a]

1. Mortality outcomes (all-cause, cardiovascular)	5. Echocardiographic parameters (LVEF, cardiac dimensions)
2. Hospitalisation outcomes (heart failure-related, all-cause)	6. Biomarkers (NT-proBNP, troponin)
3. Functional capacity (6-minute walk test, peak VO_2)	7. Safety outcomes (adverse events, serious adverse events)
4. Quality of life measures (KCCQ, EQ-5D)	8. Composite endpoints

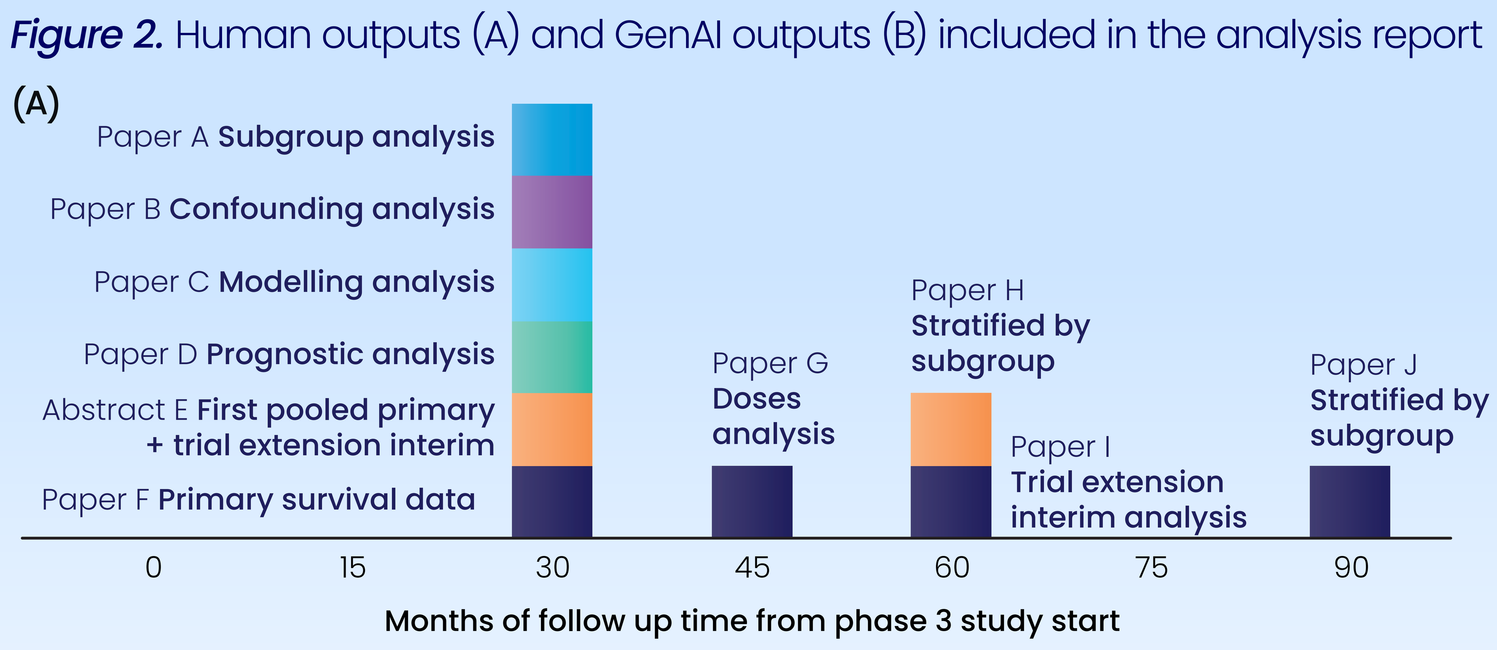
[a]Example categories assessed by ChatGPT
EQ-5D, EuroQol-5 dimensions; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, left ventricular ejection fraction; NT-proBNP, N-terminal pro-B-type natriuretic peptide; VO_2, volume of oxygen.

Table 2. Advantages and limitations of GenAI-supported strategic gap analysis

Advantages	Limitations
Extracted clinical outcome definitions and analyses rapidly and accurately	Analysis limited to published abstracts only, overinterpretation of findings and inaccurate quantification of results
Efficiently and accurately extracted information when given a dataset that was pre-focused by a human	Unable to produce useful visual outputs such as histograms and bar charts
Able to tabulate findings with a logical and coherent structure	Occasional hallucination, misclassification, and loss-of-context errors

Figure 2. Human outputs (A) and GenAI outputs (B) included in the analysis report

(A)



(B)

Publication	Follow-Up Duration	Definition and Analysis
Paper H	Up to 60 months	All-cause death (including heart transplant or mechanical assist) stratified by a prespecified subgroup category; analysed via Cox proportional hazards models
Paper F	30 months	Investigator-reported deaths adjudicated by independent committee; time-to-event (Kaplan–Meier) curves and Cox models
Paper B	30 months	Deaths assessed in a specific subgroup of participants alive at Month 30; adjusted via principal stratification to account for survivor bias; relative risks computed
Paper I	58.5 months	All-cause deaths counted in continuous-investigational drug vs placebo-to-investigational groups; analysed by Cox proportional hazards
Paper D	30 months	All-cause mortality evaluated via Cox proportional hazards, with baseline variable as a prognostic covariate and interaction term for treatment effect
Paper C	30 months	Parametric time-to-event models fitted to survival data; disease-specific covariates assessed as predictors of mortality hazard
Paper G	Median 51 months	Cox proportional hazards model for all-cause death; parametric gamma model used to extrapolate placebo survival beyond trial period
Paper A	30 months	Mortality included as first component of hierarchical win-ratio by a baseline subgroup category; standalone Kaplan–Meier counts also reported
Abstract E	Up to 36 months	All-cause mortality assessed via Cox model in pooled primary trial and long-term extension data set
Paper J	Up to 90 months	All-cause mortality assessed via Cox model in pooled primary trial and long-term extension data set

GenAI, generative artificial intelligence.