Breaking the Bottleneck: A Novel Human+AI Process for Generating Fully Annotated, Foundational-Draft PRO Manuscripts from Source Materials in Under 48 Hours

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OBJECTIVES

The timely dissemination of patient-reported outcomes (PRO) is both an economic and ethical imperative[1,2], yet PRO manuscripts are a critical bottleneck in the publication pipeline. Reliance on third-party vendors often results in lengthy turn-around times; generic AI tools have problems with trust, because of risks of bias, factual inaccuracy, inconsistent quality, and lack of regulatory compliance. To address this, we developed a bespoke Human+AI collaborative process engineered for the rapid generation of scientifically robust, secondary PRO manuscripts.

METHODS

The input to the process are unstructured source materials, including CSP, SAP, and TFL. The process combines a hybrid retrieval-augmented generation (RAG) framework, which grounds all AI-generated output in verified source documents, with a proprietary definitive AI scoring rubric (DAIS™) to ensure data fidelity, elimination of hallucinations, and adherence to industry and regulatory guidelines, including CONSORT-2025, CONSORT-PRO, GPP22, and data privacy laws[3,4,5]. A core component of the process is a mandatory review by a SME to ensure scientific integrity before the draft is delivered.

RESULTS

The process has been applied repeatedly to deliver a fully formed foundational draft, complete with abstract, plain-language summary, source-traced data points, full tables, design explanations for figures, and a transparently constructed and auditable reference list (including an associated RIS file). These high-quality, foundational-draft secondary PRO manuscripts are generated in under 48 hours. Trust is enhanced because the process reproduces results consistently and includes source traceability, immutable audit trails, transparency and explainability, and benchmarking and metrics.

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KEY TAKEAWAY

By reducing time to publication, our novel Human + AI manuscript generation accelerates the delivery of critical patient evidence to decision-makers, ensuring life-improving therapies reach patients sooner.

CONCLUSION

This capability directly addresses the challenge of timely dissemination of PROs to decision-making bodies by accelerating the high-quality generation of these critical, value-evidence publications. To formally quantify its impact on time-to-publish and quality, a rigorous comparative validation against traditional human-only and generic LLM methods is currently underway, with initial results expected in early 2026.

References

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Foundational Draft Generation Process:

- The process begins by sourcing key study documents—the clinical study protocol (CSP), statistical analysis plan (SAP), and tables, figures, and listings (TFL)—from the study team. This content is then ingested.
- Using a large language model, a preliminary draft (V1) is created by applying a specific template for PRO manuscripts, alongside guidelines such as CONSORT 2025 and its PRO extensions.
- Refinements for this draft are generated using a collection of rubrics (DAIS) and the scientific communication plan (SCP), which inform the creation of Draft V2.
- A human subject-matter expert (SME) reviews Draft V2. Furthermore, an AI-generated literature review and source quality control (QC) are applied to validate every assertion in the manuscript.
- The final deliverable is a foundational draft manuscript, complete with notes for the study team.