A Human+AI Process for Generating Fully-Annotated, First-Draft Plain-Language Trial Summaries from Source Materials in Under 24 Hours

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Background

The input to the process is a draft clinical study report (CSR). The process combines a hybrid retrieval-augmented generation (RAG) framework, which grounds all AI-generated output in verified source documents. The output of the process is a draft plain-language trial summary (PLTS) intended for rapid turnaround by a medical writing team. We have piloted the process with a leading pharmaceutical company and have a formal study planned for Q1 2026 to assess its efficacy.

Learning Objectives

Timely dissemination of plain-language trial summaries is both an economic and ethical imperative[1,2]; consequently we have developed a bespoke Human+AI collaborative process engineered for the rapid generation of scientifically robust, regulatory-compliant, patient-accessible PLTS.

Results/Evaluation

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The deployed process combined a RAG framework[3], which grounds all AI-generated output in verified source documents, with a proprietary definitive AI scoring rubric to ensure data fidelity, elimination of hallucinations, and adherence to industry and regulatory guidelines, including (EU) No 536/2014. A core component of the process was a mandatory review by a subject-matter expert (SME) that ensures scientific integrity before the draft is delivered to the study team. The process has been applied repeatedly (N=7) to deliver a fully formed draft PLTS with source-traced data points, full tables, and design explanations for figures. These high-quality drafts were generated in 8 to 24 hours. The medical writing team reported that trust was enhanced because the process reproduces results consistently and includes source traceability, immutable audit trails, transparency and explainability, promotional-language checks, reading-level metrics, and benchmarking against existing processes, which takes weeks rather than days.

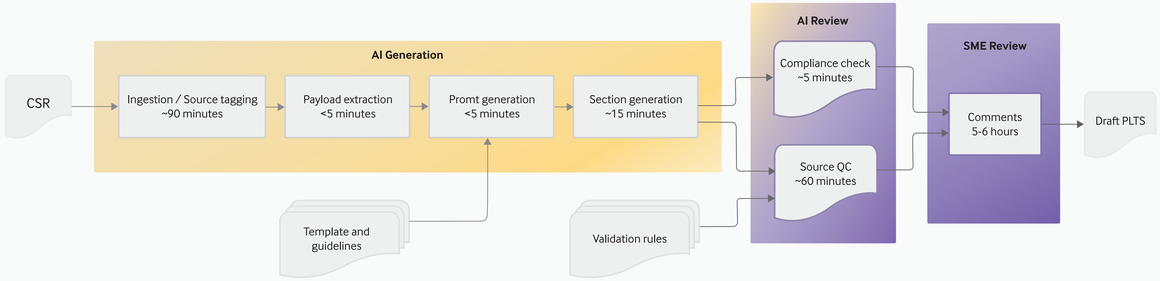

Figure: *The input to the process are unstructured source materials, typically a draft CSR, although the process also can work directly from a clinical study protocol (CSP), statistical analysis plan (SAP), and tables, figures, and listings (TFL). The AI-generation Step includes data ingestion and verification, data extraction and prompt generation, and PLTS generation. This step takes approximately 120 minutes. The automated AI-review Step includes source quality control (QC) and a compliance check on regulatory content, factual accuracy, language, and patient-centricity. This step takes approximately 60 minutes. The SME Review Step takes 5 to 6 hours. Once the draft manuscript is completed, it is subject to review by the author team.*

Conclusions

This capability directly addresses the challenge of timely dissemination of clinical study results to study participants by accelerating the high-quality generation of these critical publications[4,5]. 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.

> **"The end-to-end process is typically 4 months in total. With the hybrid Human+AI process, it is down to 6 weeks.**

References

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Walter Bender: Nothing to disclose
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Keywords

Artificial Intelligence (AI), Plain Language Summaries (PLS), medical/scientific communications

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