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What is the Problem?

- Writing clinical research manuscripts is time-consuming, typically requiring medical writers 20-30 hours to complete a rough draft.
- The process is repetitive and tedious, demanding significant manual effort.
- Medical writers must interpret and work with inconsistent, semi-structured data, leading to increased complexity.
- Technical jargon and complex language add cognitive overhead and slow down the overall writing process.

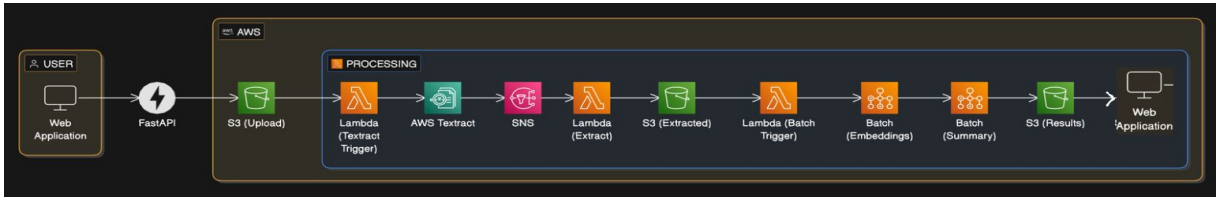
Solution

- Built an AI-powered data pipeline to streamline the process of writing clinical research manuscripts.
- Automatically extracts and standardizes key information from semi-structured clinical trial protocols, reducing the time and effort to create a rough draft.
- Utilizes natural language processing and ensures secure data handling throughout the entire manuscript generation process.
- Makes the overall writing process faster, efficient, and accessible for medical writers at AOIC.

Technical Challenges

- **Complex Input Data**: Each input document is 200+ pages of inconsistent, semi-structured data with no standard format.
- **Hybrid Retrieval**: Used a hybrid search to extract the exact right paragraphs in the document and rerank them for relevance.
- **Querying**: Optimized data extraction by using queries to extract key data from input, reducing noise for our summarization model.
- **Balancing speed, reliability, and cost**: Ensured fast and reliable manuscript generation process while staying within budget.

Architecture Diagram



Example "Design" Section in Protocol

4.1. Overall Design

This will be a Phase 3, randomized, observer-blind, active-controlled, case-driven study to investigate the safety, efficacy, and immunogenicity of mRNA-1010 versus an active comparator in adults ≥50 years of age. Participants will be randomized in a 1:1 ratio to receive a single injection of mRNA-1010 or an active comparator. Randomization will be stratified by age category (≥50 to <65 years or ≥65 years) at Screening and influenza vaccine status in the previous influenza season (received or not received). Approximately 50% of enrolled participants will be ≥65 years of age at Screening, including approximately 10% who are ≥75 years of age at Screening.

- Study duration (including screening) is expected to be approximately 6 to 8 months for each participant but could be longer if the influenza season is longer than expected.
- Participants will have up to 3 in-person visits (Screening, Day 1 [Baseline], and Day 29) and up to 4 telephone contacts (Day 8, Month 3 [Day 91], Month 6 [Day 181], and the End of the Influenza Season Visit). Additionally, in-person unscheduled visits will be arranged for participants who meet criteria for protocol-defined respiratory illness (refer to Table 4).
  - The Screening and Day 1 (Baseline) activities may be performed on the same day or on different days. Additionally, Screening Visit activities may be performed over multiple visits if within the 28-day screening window.
  - Study completion (EOS) will occur at either the Month 6 (Day 181) Visit or at the

Example "Design" Section in Manuscript

TRIAL DESIGN AND OVERSIGHT

This phase 3, double-blind, randomized, active-controlled trial enrolled participants at 301 sites in 11 countries in the Northern Hemisphere. The trial was approved by appropriate institutional review boards and was conducted according to the applicable principles of the International Council for Harmonisation Good Clinical Practice guidelines, the E6(R2) Good Clinical Practice guidelines, the principles of the Declaration of Helsinki, and all local laws or regulations. All the participants provided written informed consent before enrollment. Oversight was provided by an independent data and safety monitoring board.

LobsterAI Result

Trial Design and Oversight

mRNA-1010-P304 was designed as a Phase 3, randomized, observer-blind, active-controlled, case-driven study to investigate the safety, efficacy, and immunogenicity of the mRNA-1010 candidate seasonal influenza vaccine compared with a licensed inactivated seasonal influenza vaccine. The study targeted adults aged 50 years or older to support the licensure of mRNA-1010 for the prevention of influenza disease caused by any influenza A or B strains in this population. The study was conducted in accordance with the Declaration of Helsinki, International Council for Harmonisation Good Clinical Practice guidelines, and applicable local laws and regulations. An independent Data and Safety Monitoring Board (DSMB) periodically reviewed blinded and unblinded data to evaluate the safety of all participants and provide recommendations regarding the continuation of the study.