

## **Artificial Intelligence-Assisted Processing of Clinical Trial Safety Reports: a Pilot Implementation Study**

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### **1. Background**

Clinical trial safety reports require labor-intensive manual processing for data extraction and Principal Investigator review. Baseline assessment demonstrates 1.3 minutes per report processing time, which at institutional volumes of 500-1,000 monthly reports creates significant operational burden. Per Food and Drug Administration (FDA) regulations (21 CFR 312.60) investigators should review all investigational new drug (IND) safety reports received from sponsors as a part of the investigator's responsibility to protect the rights, safety, and welfare of trial participants. Safety report processing also generates substantial institutional revenue through per-report billing (\$50-150/report, \$50,000-150,000 annually), but manual workflows constrain capacity and delay compliance timelines. Artificial intelligence platforms offer potential for automation, but optimal implementation strategies in regulated research environments remain undefined.

### **2. Goals**

To develop and validate a standardized AI-driven methodology for processing clinical trial safety reports that eliminates the need for manual data extraction.

### **3. Solutions and Methods**

This pilot study evaluated AI-assisted processing of Council for International Organizations of Medical Sciences (CIOMS) safety reports using the Northwell AI Hub platform (Gemini primary model version 2.5 Flash and 2.5 Pro). Two researchers, each independently processed safety reports manually versus AI assisted to generate cumulative monthly summaries of external reports, comparing processing times and accuracy. Prompt refinement was conducted iteratively with cross-validation between researchers. Variables assessed included report format variations (with/without summary cover pages), batch upload capacity, and output accuracy.

### **4. Outcomes**

Manual data extraction for site processing required 23-25 minutes for 20 reports at a rate of approximately one report/minute for both Researcher one and Researcher two. Initial AI prompt optimization occurred over a two-month period with 15 prompts generated to achieve consistent accuracy for one study-specific format, a Phase one trial with a summary cover page. Gemini 2.5 Pro AI model generated a markdown summary table in three minutes for 20 reports with 100 percent accuracy. Previously the Gemini 2.5 Flash AI model was able to generate a markdown summary table in the same amount of time but required additional Researcher time for training of the model and prompt specificity to achieve the same level of accuracy. Further testing of CIOMS safety reports without summary cover pages utilizing the same prompt in the Gemini 2.5 Pro AI model demonstrated potential generalizability to multiple clinical trials. Depending on the model utilized, system limitations were

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identified at >40 report batch uploads, with the AI model producing either an error message or taking longer to produce results with 80 reports. Cross-platform validation across Gemini, ChatGPT, and Claude AI models is ongoing.

**5. Lessons Learned and Future Directions:**

AI-assisted external safety report processing shows promise for efficiency gains and reducing administrative regulatory burden but requires format-specific prompt engineering. Standardization challenges include external safety report template heterogeneity and platform capacity limitations. Future refinement and experimentation will focus on developing universal prompting frameworks and comparative platform performance analysis.

Disclaimer: During the preparation of this work the authors used Northwell AI Claude Sonnet 4.5 in order to substantiate our hypothesis that the use of AI is more time efficient when used with oversight. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.