CitiusTech

Shaping Healthcare Possibilities

Accelerating Real World Data Protocol Design with Gen AI Assistant

Client is a leading U.S.-based biotechnology company specializing in innovative therapies and cutting-edge research across oncology, immunology, and neuroscience domains. The solution is a Gen AI-powered application designed to automate the creation of the first draft for complex RWD protocols. By utilizing specialized context stores, expert validation, and seamless API integration, PROGEN streamlines study design and the overall protocol generation process

CASE STUDY

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Problem Statement

Protocol development for Real-World Data (RWD) studies is often time-consuming, complex, and prone to methodological inconsistencies. There is a growing need for an AI-powered assistant that can streamline and enhance this process by providing intelligent support across key areas—study design, cohort selection, and literature review. The lack of integrated tools to ensure statistical rigor, reduce selection bias, and ground protocols in current evidence leads to inefficiencies and potential risks in study validity. Addressing this gap is critical to accelerating protocol creation while maintaining scientific integrity.

Solution Description and Architecture

Manual clinical research design is prone to bias, inefficiencies, and outdated evidence. Three AI assistants address this by ensuring methodological rigor, optimizing patient selection, and integrating current literature. They enhance study validity, reduce bias, and streamline protocol development through real-time guidance, statistical support, and AI-powered evidence synthesis.

Need of AI Assistant to enhance protocol development. It has following AI assistance

Design & Methods Assistant –

- Ensures methodological rigor and statistical validity from the earliest stages of protocol development
- Recommends optimal study design based on research questions.
- Proposes statistical methods tailored to your objectives.
- Provides R code snippets for statistical analysis.
- Answers methodology questions in real time

CohortBuilder Assistant –

- Strengthens patient selection strategy to ensure appropriate population targeting and reduce selection bias.
- Analyses your initial inclusion/exclusion criteria against best practices
- Identifies potential gaps in patient eligibility criteria.
- Suggests additional criteria to reduce bias and enhance study validity
- Recommends precise operational definitions for each criterion
- Literature Search Assistant: Ensures your protocol is grounded in the most current evidence, strengthening scientific justification and identifying research gaps.
- Conducts AI-powered semantic search across scientific publications
- Performs gap analysis comparing your draft to existing literature.
- Creates enhanced background text incorporating relevant research findings.
- Summarizes latest research relevant to your study

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Outcomes

The successful deployment of the protocol generator has significantly enhanced the workflow for the customer's RWD (Real-World Data) Scientists, streamlining the creation of standardized protocols and reducing manual effort.

Key success metrics include improved turnaround time for protocol generation, increased accuracy and consistency in documentation, and positive user feedback from the scientific team.

The customer's satisfaction highlights the tool's value in accelerating research processes and enabling more efficient data-driven decision-making.

Lessons Learnt

Throughout this learning experience, we gained valuable insights into various AI models, particularly Large Language Models (LLMs), and their capabilities. We learned how to craft effective prompts to interact with these models and explored how different AI models can be integrated into various programming languages. These lessons have strengthened our understanding of AI-driven development and enhanced our ability to apply these tools in practical, technical scenarios.

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