



Protocol Module

Simplify Protocol Development with Saama's AI-Powered Document Generator

The Protocol Module, a key component of Saama's AI-Powered Document Generator, simplifies and accelerates clinical protocol creation. Leveraging a "Decision by Jury" approach powered by multiple LLMs, including Saama's proprietary clinical LLM, it generates more accurate outputs. Combined with GenAI, customizable templates, and guided workflows, it boosts efficiency, minimizes errors, and ensures consistent, high-quality protocol drafting across therapeutic areas.

Benefits

Streamline Protocol Design

Reduces manual effort with AI-driven content generation and reusable templates, accelerating protocol creation by up to 40% (early customer results) and lowering resourcing costs.

Automated Quality Checks

Ensures consistency within sections and across submission documents, reducing errors and enhancing compliance.

Cross-Team Collaboration

Enables real-time authoring and review across study teams on a unified platform, reducing handoffs and delays.

Minimize Protocol Amendments

Decreases errors per draft by 20–40% (early customer results), improving accuracy with fewer revisions and smoother approvals.

Compliance with ICH M11

Supports adherence to ICH M11 standards, helping ensure protocol content meets global regulatory expectations.

Features



Protocol Authoring

Automates generation of key protocol sections, including eligibility criteria, study objectives, and schedule of events, applying a Decision by Jury approach across multiple LLMs for higher-confidence outputs.



Guided Workflows & Human in the Loop

Guides users step-by-step through protocol development with real-time prompts and progress tracking, plus built-in review checkpoints that keep subject matter experts in control.



Template Management

Upload and customize protocol templates aligned to ICH M11 and organizational standards, with flexibility across different therapeutic areas and sponsors.



Role-Based Access Control

Enables secure collaboration with defined permissions for editing specific sections, and automatically tracks all changes with version history for transparency and accuracy.



Prompt Library

A centralized library of reusable, customizable prompts for Inclusion/Exclusion criteria, Schedule of Activities, study objectives, and other protocol sections.



Knowledgebase & Medical Lens

A self-improving, sponsor-specific repository of study data and reference documents, plus natural-language search across literature and internal documents, with full source traceability.

The Saama Difference

Saama's AI-Powered Document Generator Protocol Module combines advanced AI, customizable templates, and guided workflows to transform protocol creation. It enhances accuracy, reduces errors, and accelerates timelines, empowering clinical teams to meet the demands of modern clinical trials.

Contact info@saama.com to schedule a personalized demonstration.