Agentic AI for Clinical Document Authoring

From User Input to Regulatory Submission

Your Co-pilot in Clinical Document Authoring

Author: Swetha Balaji

Contact: Swethab@zyliq.com

# Executive Summary

This white paper presents an Agentic AI framework designed to revolutionize the process of clinical trial document authoring. By leveraging automation, regulatory compliance checks, and real-time progress tracking, this framework significantly accelerates submission timelines while maintaining accuracy and trust. The system supports all phases of clinical authoring and enables medical writers to focus on insights and quality rather than repetitive tasks.

# Problem Statement

Clinical trial document authoring is a time-intensive and resource-heavy process. Manual preparation introduces inefficiencies, risks of non-compliance with evolving guidelines, and limited transparency in progress tracking. There is a critical need for tools that streamline workflows, enhance compliance, and reduce cycle times while keeping human expertise central to decision-making.

# Proposed Solution

The Agentic AI framework acts as a supportive co-author for clinical documents. It automates repetitive authoring tasks, validates terminology with the latest regulatory standards, and provides visibility into document progress. By integrating Retrieval-Augmented Generation (RAG) and AI agents, the framework ensures accuracy, compliance, and scalability across multiple studies.

**Workflow**

**A diagram of a system

AI-generated content may be incorrect.**

**Workflow Components and Roles**

**User Input Module**: This component gathers study objectives and contextual details directly from clinical teams, ensuring the AI has accurate information to begin drafting.

**AI Authoring Agent**: It automatically generates structured sections of clinical documents, reducing manual effort and speeding up the authoring process.

**RAG-powered Validator**: This module checks all terminology and content against the latest regulatory guidelines, guaranteeing compliance at every stage.

**Human Reviewer**: A subject matter expert reviews and refines the AI-generated content, adding trust, accountability, and domain expertise.

**Progress Tracker**: This feature provides real-time visibility into document status and timelines, ensuring transparency across all stakeholders.

# Process Flow

# Clinical team provides instructions on what they want to do—whether to draft a section, validate content, or check the progress of document development.

# The AI drafts sections of the clinical document, automating repetitive tasks and ensuring consistency across content.

# The draft is validated against regulatory guidelines and internal standards using RAG, ensuring up-to-date compliance and reducing revision cycles.

# Subject matter experts refine the AI-generated draft, by providing their inputs and comments, making the system trustable and users expert assistant.

# The system consolidates outputs, monitors timelines, and provides stakeholders with real-time visibility into document status, resulting in a submission-ready, regulatory-compliant document.

# Key Benefits

* **Accelerated Authoring:** The framework reduces authoring timelines by up to 70%, enabling faster preparation of high-quality clinical trial documents and quicker regulatory submissions.
* **Regulatory Compliance:** By integrating a RAG-powered validator, the system continuously aligns content with the latest regulatory guidelines, minimizing the risk of non-compliance.
* **Transparency in Progress:** The built-in progress tracker provides real-time visibility into document status, version history, and timelines, fostering trust and collaboration across stakeholders.
* **Scalability Across Studies:** The framework can be applied across multiple therapeutic areas and studies, ensuring consistency while reducing redundant efforts.
* **Support for All Phases:** From protocol development to regulatory submission, the system supports the full spectrum of clinical document authoring, making it adaptable to diverse requirements.
* **Human-AI Collaboration:** The model balances automation with human expertise, ensuring accountability, scientific accuracy, and trust in the final deliverables.
* **Improved Resource Efficiency:** By automating repetitive tasks, medical writers and regulatory teams can focus on higher-value insights, improving overall productivity.
* **Enhanced Quality and Consistency:** Standardized outputs reduce variability and errors, ensuring that documents are not only faster to produce but also more reliable in quality.

# Who Uses It?

This framework is designed for medical writers, clinical operations teams, regulatory affairs professionals, and research organizations seeking to accelerate documentation workflows while maintaining compliance and accuracy.

# Conclusion

Agentic AI for Clinical Document Authoring represents a transformative step toward efficient, compliant, and scalable document workflows. By combining automation with human oversight, the framework reduces authoring time, ensures adherence to regulatory guidelines, and empowers teams to focus on strategic insights. This approach accelerates submission timelines while fostering accountability and trust in clinical documentation.