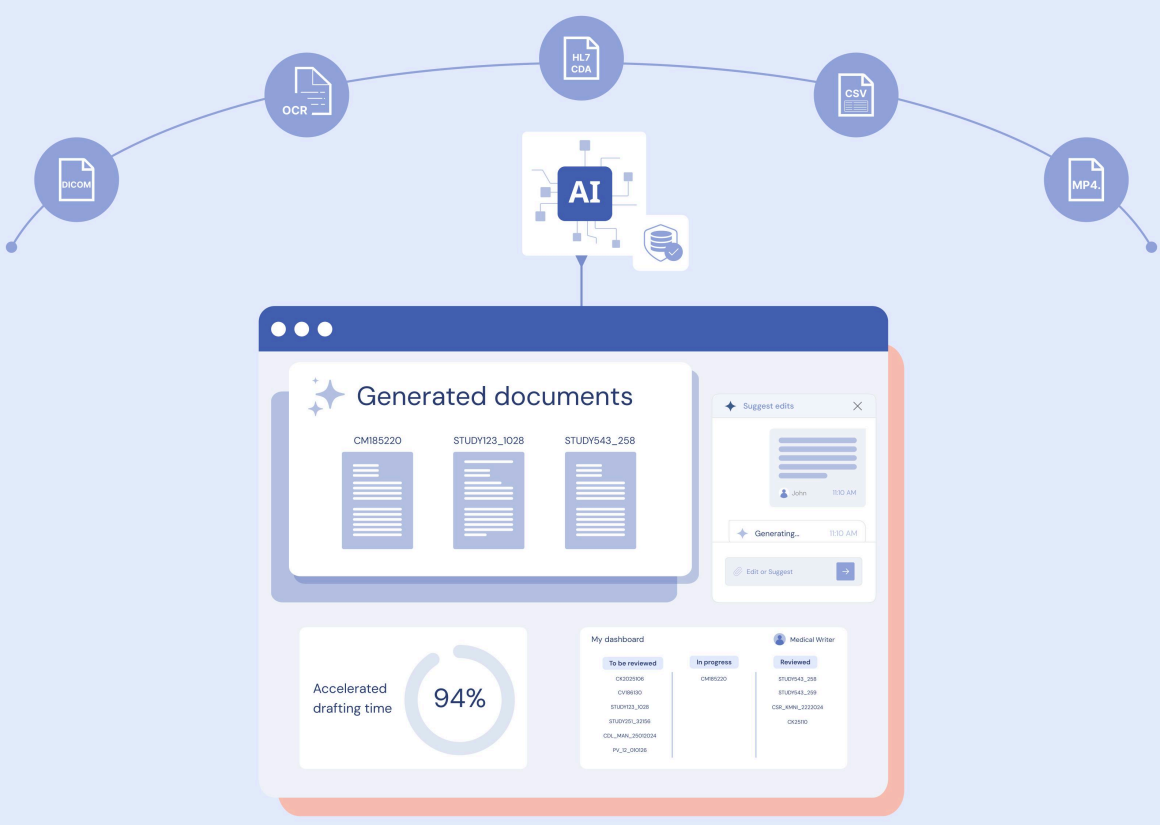
CASE STUDY

Accelerating Regulatory Submissions with Gen AI–Powered Medical Writing



Zemoso

Introduction

In the world of drug development, time is measured not just in months but in millions of dollars.

A single 12-month clinical trial can generate over 3 million data points, while a Biologics License Application (BLA) may span 10 million pages of documentation. Every page must meet strict ICH and FDA regulatory guidelines, and the bottleneck has long been the availability of specialized medical writers. Their expertise is irreplaceable, but the process is slow, manual, and costly.

A leading innovator in generative AI set out to transform this paradigm by re-engineering how regulatory documents are created—bringing automation, security, and human oversight into a single multimodal platform.

Industry challenge

The healthcare and life sciences sector faces a dual pressure: scale and compliance. The sheer data footprint of modern trials, coupled with the complexity of regulatory audits, makes document preparation a mission-critical risk area. Industry benchmarks suggest that delays in document readiness can stall approvals, extend trial timelines, and drive up costs significantly—sometimes adding $600K to $8M per day in opportunity costs for late drug launches. Without new approaches, the pace of medical writing cannot keep up with the data explosion.

Zemoso's partnership challenge

The client struggled with:

- Fragmented data hand-offs: Biostatisticians provided offline datasets, leaving writers to reconcile discrepancies manually.
- Rigid templates: Each CRO or pharma sponsor imposed unique formats tied to ICH guidelines, demanding heavy rework.
- Human bottlenecks: Even expert writers spent weeks collating, structuring, and validating sections before submission.

The challenge was not just building an AI that could "write," but engineering a system that could integrate multimodal data, enforce regulatory compliance, maintain traceability, and remain secure in a highly regulated industry.

Impact created

The Gen AI–powered writing platform cut document authoring time by 70%, turning weeks of drafting into days. It enabled parallel creation of PNs and CSRs, improved traceability, and removed hand-off bottlenecks, amplifying medical writers' capacity to focus on higher-order validation and scientific judgment.

How did we do this?

The platform was built as a multi-agent, human-assisted Gen AI solution that combined security, modular workflows, and regulatory intelligence:

- **Architecture for compliance and security:**
  - Deployed on an Azure OpenAI private instance, ensuring HIPAA-grade compliance.
  - Data stored in encrypted form, with PGVector extensions enabling in-cloud retrieval without leaving the customer's environment.
- **Dynamic workflow orchestration:**
  - Multi-agent workflows orchestrated the full authoring cycle—from data ingestion and OCR-based extraction, to template-driven generation, to human validation.
  - A Kanban-style progress board tracked section-level status ("Pending," "Authored," "Completed") for full audit visibility.
- **Regulatory intelligence baked in:**
  - Templates were pre-configured against ICH guidelines, with prompts aligned to document structure (CSR, PN).
  - Discrepancies in datasets triggered dependency checks and automatic re-runs once reconciled.
- **Human-in-the-loop editing:**
  - Writers could regenerate sections, fine-tune prompts, or roll back to source-verified content.
  - Every section was traceable back to the originating dataset, reinforcing regulatory defensibility.

How did Zemoso deliver excellence

This engagement demonstrates how multimodal Gen AI platforms can redefine regulated workflows without compromising on compliance or accuracy. By embedding security at the architectural layer, automating regulatory adherence, and keeping humans in the loop, the solution not only accelerates today's submissions but also lays the groundwork for future capabilities—such as AI-augmented clinical trial monitoring, predictive quality assurance, and ESG-aligned reporting of trial outcomes.

For healthcare innovators, it's a step toward a future where medical writing is no longer a bottleneck, but a strategic advantage in bringing therapies to market faster and safer.

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