CAYLENT

Clinical Document Writer

AI-Powered Regulatory Documentation for HCLS

aws PARTNER Premier Tier Services

Manual Documentation Processes are Draining Clinical Resources

Companies face extensive regulatory documentation requirements that drain resources and delay submissions. Manual document writing involves fragmented data systems, siloed teams, and limited quality controls. With *documentation consuming up to 40% of clinical development timelines*, companies struggle with inconsistencies across submissions, review rounds, and high costs for specialized writers. Without a simplified approach for better documentation, organizations risk extended timelines, rising costs, and diminished competitive advantage in today's fast-paced therapeutic landscape.

Cut Documentation Time by 40% with AI that Works with You

Our solution uses Amazon Bedrock and Amazon SageMaker AI to create compliant documentation. It integrates fragmented data sources through agentic intelligence to automatically generate comprehensive regulatory documents (from protocols to patient safety narratives) with built-in quality checks that identify inconsistencies in real-time. By incorporating real-world evidence and automating routine document elements, this approach significantly reduces document creation while cutting documentation costs in half, allowing clinical teams to focus on strategic priorities rather than administrative tasks.

Source: McKinsey Research

Impact & Benefits

Cost Efficiency

50% reduction in documentation costs through automation and reduced manual labor for regulatory document preparation

Time-to-Submission

40% faster document creation, reducing time from data lock to submission-ready documentation

Quality Improvement

2x fewer quality control issues, reducing rework and easing review workloads

Learn More

Driving Business Value

Ensuring growth, efficiency, and success through strategic alignment

Areas of Focus

Document Generation	Creation of protocols, clinical study reports, safety narratives, and other critical submission documents
Quality Control Automation	Built-in systems to identify errors, inconsistencies, and compliance issues before they impact submissions
Evidence Integration	Seamless incorporation of relevant data and insights into safety and health economics documentation
Compliance Management	Continuous updates to reflect evolving submission guidelines across global regulatory authorities

Taking Action

Delivering work that ensures successful execution and maximum impact

Deliverables

Discovery Workshop	Assessment of documentation challenges and opportunities for automation and improvement
Proof of Value	Targeted implementation demonstrating measurable improvements in document creation speed and quality
Implementation Roadmap	Detailed plan for full solution deployment with integration requirements and change management considerations