WHITE PAPER

CERTARA®

A Tailored Generative AI Solution for Regulatory Writing

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Introduction: The Need to Increase the Efficiency of Regulatory Writing

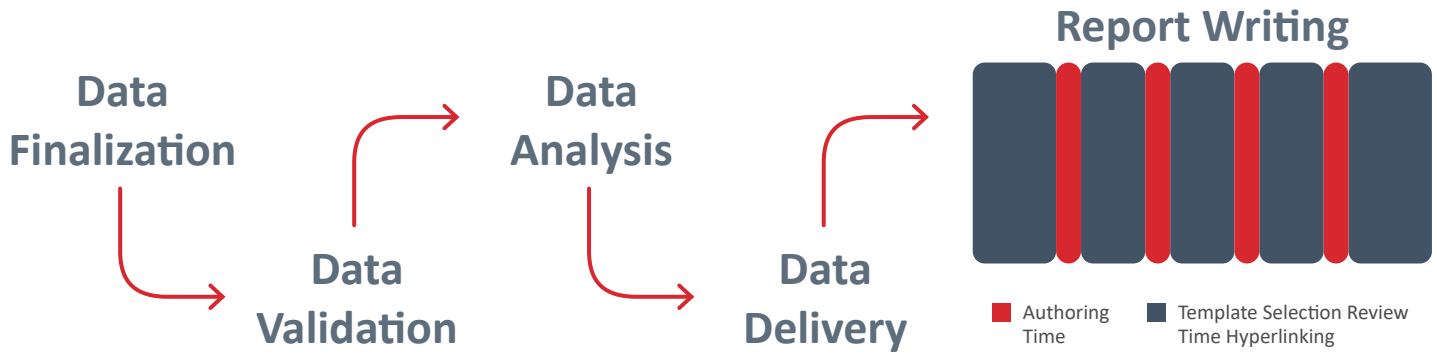
Stacks of clinical trial data, patient narratives, and regulatory guidelines cover your desk. Medical writers must review each document to ensure the drug program's final submission is accurate, consistent, and compliant.

The sheer volume of work is daunting. The importance of avoiding mistakes adds to the pressure.

Formatting documents drains your time and mental energy. A single error can cause costly delays and increased scrutiny from regulatory bodies. This can delay the approval of a new treatment for waiting patients.

Regulatory writing has traditionally been a labor-intensive process from start to finish, requiring manual compilation and precise formatting of extensive documentation. For example, a Clinical Study Report (CSR) usually requires a regulatory writing team about 120 hours of work over four weeks. And that's just the start! A fully reviewed and approved CSR can take an average of 83 days from database lock to completion.

The Process for Writing a CSR



The emergence of artificial intelligence (AI) has brought new opportunities to streamline writing processes. However, implementing AI into regulatory writing requires an industry-specific approach that goes beyond the basics of everyday AI applications. The complexity and high stakes of regulatory documentation demand tailored AI solutions that ensure accuracy while enabling efficiency.

Certara is leading the way in delivering these solutions. They are also educating regulatory writing teams on how to best use AI for reliable results.

Understanding AI's Capabilities

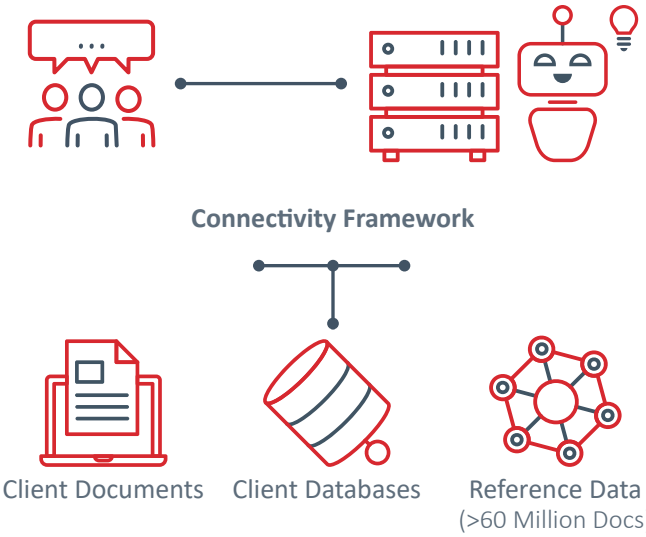
To successfully integrate AI into regulatory writing, it's important to understand its strengths and weaknesses. Generative Pre-trained Transformers (GPTs) are particularly adept at generating human-like text, summarizing complex information, and identifying patterns within large datasets. These capabilities can significantly reduce the time and effort needed to draft critical regulatory documents, including CSRs, investigational new drug applications (INDs), patient narratives, and submission dossiers.

GPTs possess broader capabilities than both classical machine learning and natural language processing models. Their deep learning architecture allows for the generation of human-like language, not just manipulating existing text. This adaptability has arisen from increases in model size and advances in deep learning architecture.

However standard GPTs don't always capture the specific nuances of language without proper guidance. In turn, they can sometimes generate errors, or "hallucinate," creating plausible but incorrect information.

Certara's AI regulatory writing software, CoAuthor™, recognizes these challenges and their potential impact on regulatory approvals. That's why the software uses retrieval augmented generation (RAG) to refer to specific information sources (Figure 1). This design strengthens the accuracy and reliability of AI-generated content.

Figure 1: Certara.AI's Retrieval Augmented Generation Architecture



Verifying AI-Generated Text

At their core, GPTs are language models, not knowledge models. It's RAG that provides the information needed to transform a GPT into the latter. CoAuthor doesn't rely solely on pre-trained data. RAG allows the software to pull in relevant data from documents in real-time to generate precise and contextually appropriate content.

For instance, when generating a report on adverse events occurring in a clinical study, RAG ensures that the model uses relevant documents. More importantly, medical writers are always "in the loop" when using this technology. The medical writer decides what prompt (query/command) is directed to the GPT. In addition, the writer defines what document sources the prompt is run against.

By directing the GPT to refer to specific items, QC professionals can trace AI-generated content to corresponding source documents. The ability to validate the origin of each sentence in a document creates trust. Without verifiability and trust, the efficiency gains of AI could be negated by time-consuming reviews. CoAuthor helps maintain the balance between speed and precision in regulatory writing.

Streamlining an AI-Enhanced Workflow

Enterprise AI needs to seamlessly blend with existing document management systems and workflows. Microsoft Word is the most used workspace for drafting and editing regulatory documents. By embedding CoAuthor within Microsoft Word, Certara is meeting regulatory writers where they spend most of their time. Writers don't need to click out to another interface or copy and paste from an app back into Word. They can write fluidly and efficiently with reliable assistance from AI.

This technology fits into existing workflows rather than creating new ones. Thus, CoAuthor makes AI more approachable for organizations that are interested in adopting AI but hesitant to disrupt established processes.

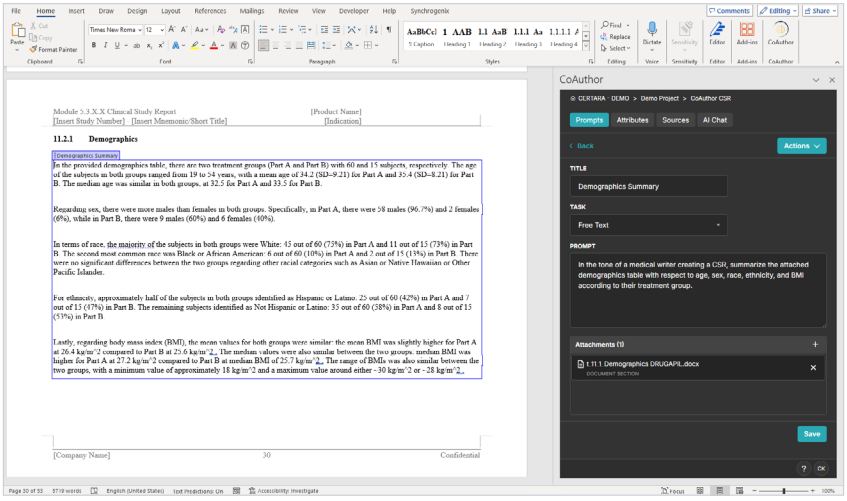
> **When you think about the regulatory process from a patient's perspective, the faster we can get a submission prepared and submitted, the faster that submission gets approved, and the faster patients have access to that medicine or whatever the health care solution is.**
>
> *- Heather Graham, Vice President, Regulatory Writing & Scientific Publications, Certara*

CoAuthor is delivered via a Microsoft Word Add-In, providing a secure, program specific generative AI toolbelt for regulatory writers.

CoAuthor Add-In provides writers with:

- Content blocks provide transparency into AI generated content with references to source data for accelerated QC
- Generative AI prompt library
- Pre-extracted study attributes for auto-populating documents
- Direct access to all source documents
- AI Chatbot for free-form content generation and summarization
- Document templates streamline formatting and structured content authoring

Schematic Showing How Writers Use CoAuthor to Help Them Create Documents



Ensuring Data Privacy and Security

Organizations across virtually every industry rightfully have a major concern in common with introducing AI into their workflows: enterprise security. Regulatory documents, especially, contain highly sensitive information, including patient and clinical trial staff details and intellectual property.

Meanwhile, mainstream AI platforms can pose significant risks relating to data processing on third-party servers. Shared servers increase the risk of data breaches, where unauthorized entities might gain access to confidential information. The use of large-scale applications can also result in inadvertent data leakage, where AI processing exposes sensitive information.

CoAuthor provides enterprise security in the simplest, most reliable way possible. Each customer receives their own GPT. An organization's AI model is not shared or used in any other setting. The data never leaves the company's firewall, offering end-to-end control over the entire AI process.

Certara has also designed CoAuthor with strict data isolation. Model retraining and active learning processes are disabled by default to prevent data leakage from one project to another, even internally, and ensure that customers have total control over how their GPT uses their data.

CoAuthor's security measures are not just features but fundamental aspects of the software's design and architecture. It all ties back to trust. Organizations need to be able to trust that using AI will help, not hinder their goals of bringing safe and efficacious drugs to market.

Supporting the Nuances of Medical Writing

CoAuthor is more than a standard GPT repurposed for regulatory writing. This purpose-built platform was designed with a custom GPT and enhanced with RAG to address medical writers' specific challenges. By streamlining routine tasks and generating reliable drafts, writers can focus on refining and reviewing key messaging.

Certara's CoAuthor developers collaborated with hundreds of internal medical writers to create an accurate and verifiable tool that helps drive efficiency.

How does CoAuthor compare to other software?

Feature	CoAuthor	Microsoft Copilot®	Other Regulatory Tools
Regulatory Document Template Suite	X		
Structured Content Authoring	X		X
Regulatory-specific Generative AI	X		X
Auto Styling & Hyperlinking	X		
Traceability & Version Control	X		X
Real Time Preview	X	X	
Collaborative Authoring & Review	X		X
Meta-Data & Document Repository	X		
Automated De-identification	X		
MS Word Integration	X	X	
Regulatory Document Repository	X		
Tech-Enabled Medical Writing Services	X		

Quick Tips When Using AI in Regulatory Writing

Tip #1 Get to Know Your AI
Learn the features and capabilities of your AI tool to make the most out of its writing functionalities.

Tip #2 Leverage AI for Drafting
Reduce time spent on drafting and repurpose it toward data analysis and message development.

Tip #3 Maximize Structured Content Authoring (SCA)
SCA is the practice of creating, managing, and publishing content in predefined structures or templates. Pair SCA with AI to quickly reference and reuse content.

Tip #4 Automate Routine Tasks
Program your AI to handle repetitive tasks such as data extraction and formatting.

Tip #5 Customize Your AI
Train a GPT on your data so that it understands your unique use cases and terminology.

Tip #6 Always Verify
Ensure that medical writers review and validate all AI-generated content for accuracy.

Tip #7 Collaborate with AI as a Writing Assistant
Use AI as a tool to accelerate the writing process. It's not a replacement for the critical thinking and expertise of human writers.

Explore Certara.AI

Certara.AI is a secure, flexible platform for deploying life science-specific GPTs across your organizational data. Certara.AI offers a secure solution for the pharmaceutical industry. It can save time and money while enhancing drug development efficiency from discovery to clinical research and regulatory writing.

Learn more about Certara.AI and schedule a live demo of CoAuthor.

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About Certara

Certara accelerates medicines using biosimulation software, technology, and services to transform traditional drug discovery and development. Its clients include more than 2,400 biopharmaceutical companies, academic institutions, and regulatory agencies across 66 countries. Learn more at certara.com.