



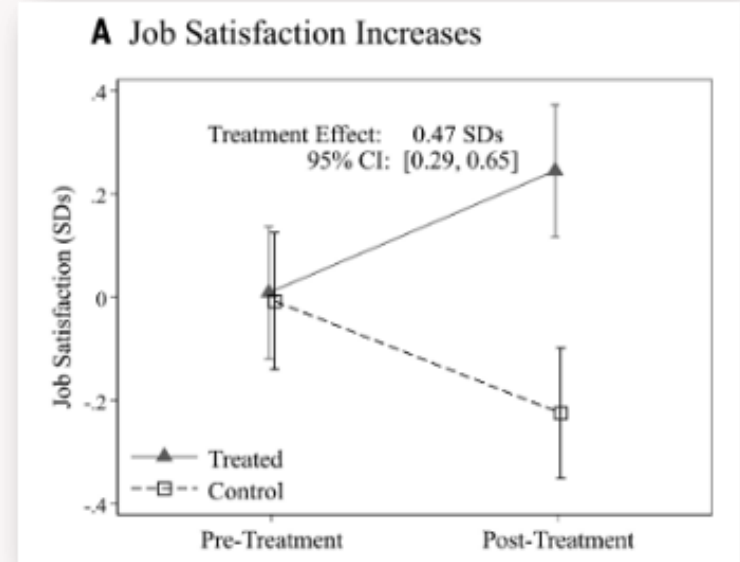
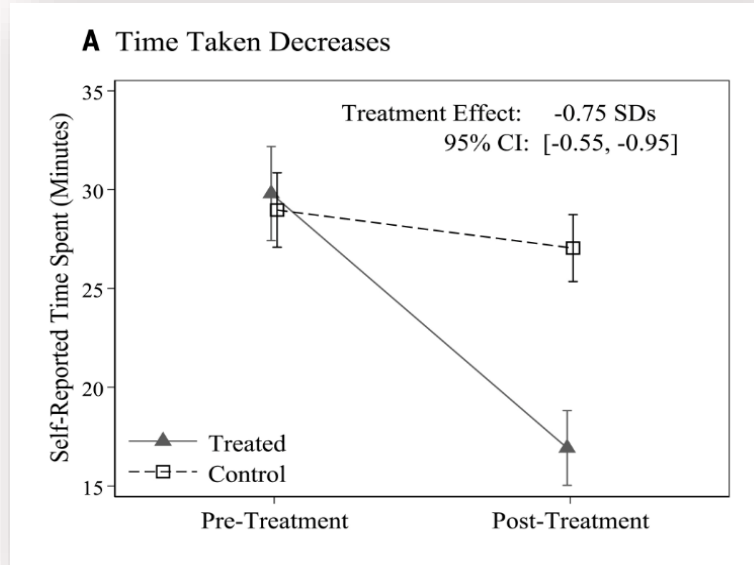
CoAuthor

GenAI-Powered Authoring

Overview

Name, Title, Certara.AI | Date

Improving Writing Productivity & Job Satisfaction



Randomized experiment shows leveraging GPTs for professional writing tasks present a 40% productivity increase while improving output quality by 18%.

Writers exposed to GPTs reported higher job satisfaction.

CoAuthor Overview

CoAuthor is a purpose-built writing software designed to streamline and accelerate the creation of regulatory documents by empowering writers.

The software can generate patient clinical study reports, protocols, patient narratives, CMC and other clinical documents.

Writers have various tools at their disposal such as Digital Data Flows, Structured Content Authoring, Data Integration, and Artificial Intelligence to maximize automation.



Empowers teams to focus on key decision points

Focus on data interpretation and key message development.



Ensures consistency and quality through standardization

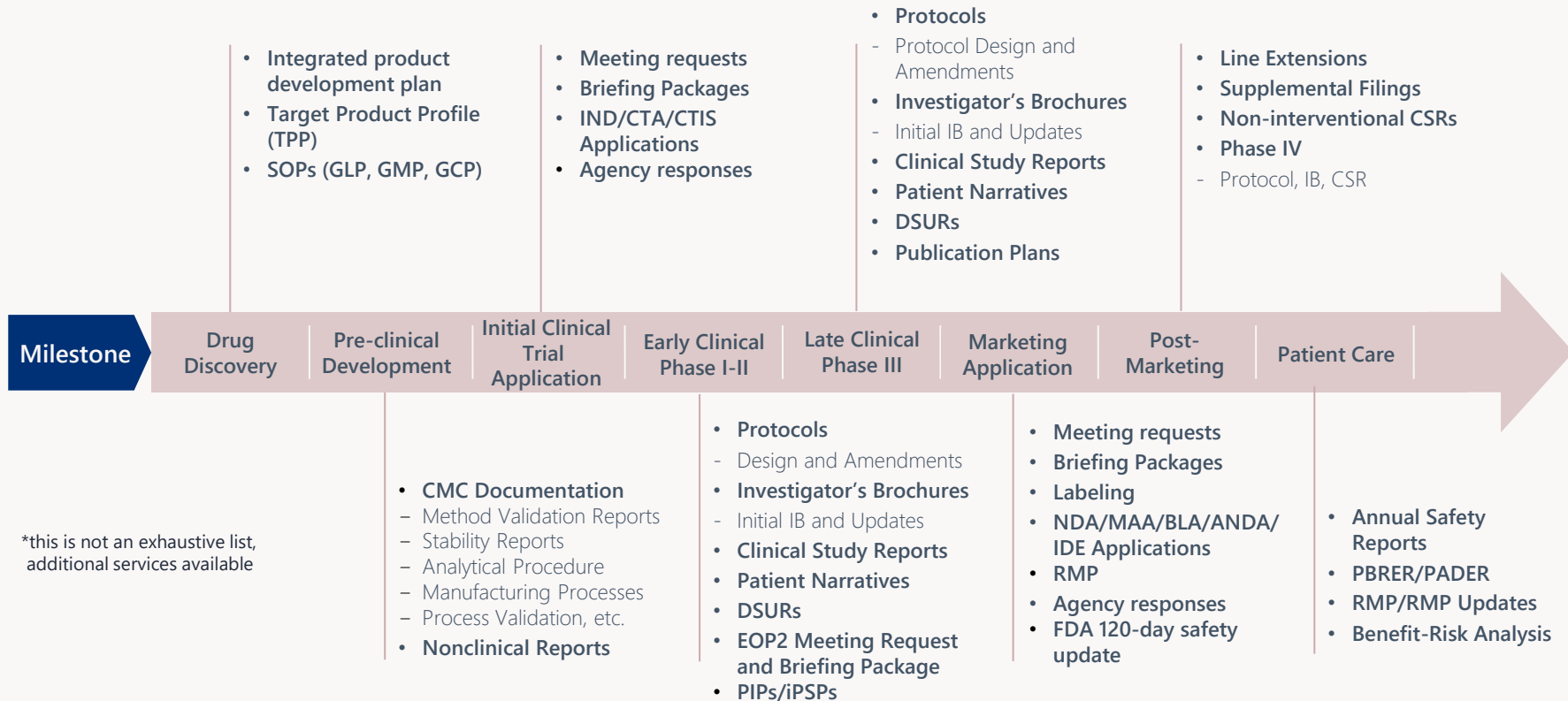
Say the same thing, in the same way, each time and in each place across many documents.



Increased output with reduced time and costs

Streamline your authoring and review processes to meet expedited timelines.

CoAuthor[®] Support Throughout the Development Lifecycle



CoAuthor's Comprehensive Authoring Capabilities

Ingests a range of sources & formats

Supports a wide variety of templates, sources, & formats (.docx, .rtf, .sas7, .bdat, .xpt, .csv, .xlsx, .zip)

Supports various document types

Regulatory documents (eCTD Modules 1-5) Protocols, PSURs, CERS

Any Microsoft Word-based documents that could benefit from automation (e.g. design history files, device master records, device history records, quality system records)

Update & Adjust TLFs

Easily update of pre- & post-DBL data, allowing teams to begin drafting earlier.
Users can modify columns/rows of tables



Streamlined Formatting

Manage organization-specific or Certara-provided document templates and macros to reduce formatting tasks

Collaboration & review

Monitor progress across all documents in your submission

Maintain audit trails

All saved versions & drafts logged for reference
Log can be exported to provide audit trail.

CoAuthor's Specialized GPT Approach

- **Secure, Client-Specific GPT:**

- CoAuthor features a secure, client-specific GPT. Active learning is turned off from the GPT to eliminate risk of data leakage.
- GPT operates exclusively on data provided by the user, with no access to the public internet.

- **Retrieval Augmented Generation (RAG)**

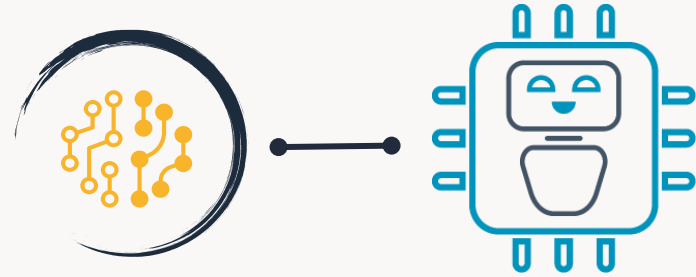
- Reduces chance of hallucinations by limiting the amount of data the GPT model is operating against.
- Enables referencing of GPT outputs, allowing for transparency to source material and accelerating QC by writers.

- **Prompt Library**

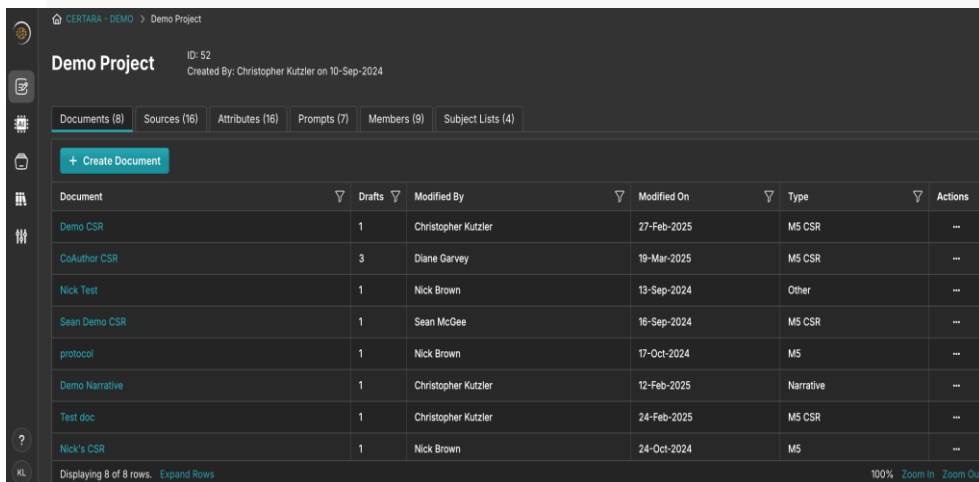
- CoAuthor provides a growing library of 250+ GPT prompts pre-validated by Certara regulatory writers to accelerate your draft automation process.
- Users can refine Certara provided prompts or create and manage their own prompts for use across teams.

- **Microsoft Word Integration**

- All document generation occurs within CoAuthor's Microsoft Word add-in, providing the complete Word experience.



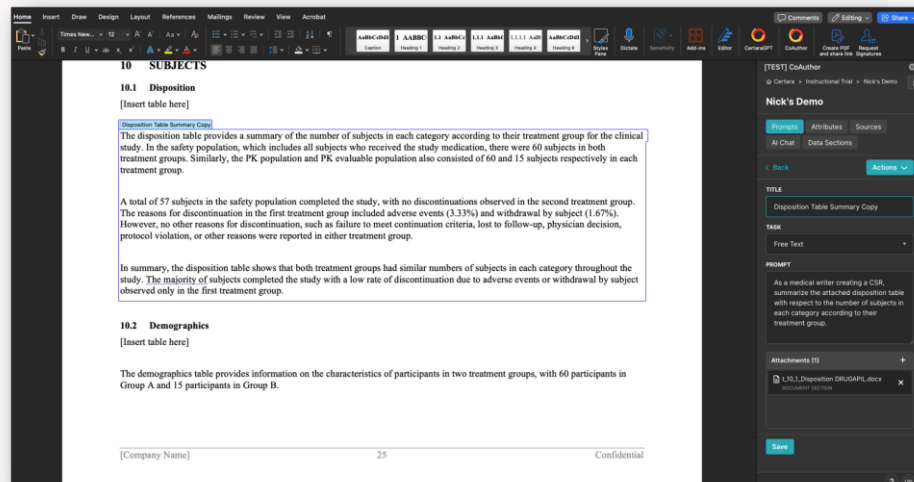
CoAuthor's Program Management & Authoring Interfaces



The screenshot shows the CoAuthor Admin Portal for a 'Demo Project'. At the top, it displays 'ID: 52' and 'Created By: Christopher Kutzler on 10-Sep-2024'. Below this is a navigation bar with tabs for Documents (8), Sources (16), Attributes (16), Prompts (7), Members (9), and Subject Lists (4). A '+ Create Document' button is visible. The main area contains a table with columns for Document, Drafts, Modified By, Modified On, Type, and Actions. The table lists several documents, including 'Demo CSR', 'CoAuthor CSR', 'Nick Test', 'Sean Demo CSR', 'protocol', 'Demo Narrative', 'Test doc', and 'Nick's CSR', each with associated draft counts, modification details, and document types.

Document	Drafts	Modified By	Modified On	Type	Actions
Demo CSR	1	Christopher Kutzler	27-Feb-2025	MS CSR	...
CoAuthor CSR	3	Diane Garvey	19-Mar-2025	MS CSR	...
Nick Test	1	Nick Brown	13-Sep-2024	Other	...
Sean Demo CSR	1	Sean McGee	16-Sep-2024	MS CSR	...
protocol	1	Nick Brown	17-Oct-2024	MS	...
Demo Narrative	1	Christopher Kutzler	12-Feb-2025	Narrative	...
Test doc	1	Christopher Kutzler	24-Feb-2025	MS CSR	...
Nick's CSR	1	Nick Brown	24-Oct-2024	MS	...

Displaying 8 of 8 rows. Expand Rows 100% Zoom In Zoom Out



The screenshot shows the CoAuthor Authoring Interface, which integrates with MS Word. The document is titled '10 SUBJECTS' and contains sections for '10.1 Disposition' and '10.2 Demographics'. The 'Disposition' section includes a table summary copy and a detailed description of the study population. The 'Demographics' section provides information on participant characteristics. The interface includes a sidebar with navigation options like 'From', 'Attributes', 'Sources', 'AI Chat', and 'Data Sections'. A 'Save' button is visible at the bottom right.

Admin portal supports project management including:

- Documents & Drafts
- Source data
- AI prompt library
- Attributes
- User permissions

Authoring takes place within MS Word with direct access to source data, study attributes, GPT prompts, and chatbot.

CoAuthor Benchmarks



40% Productivity Increase: Document sections that once took hours to complete are now drafted and QC'd in minutes. Ex: CSR sections are complete and edited in 12 minutes.



22.5 Minutes: Time spent generating sections 1-9 of your CSR



2.25x Boost: Individual writers report a 2.25x efficiency gain when drafting content.



>90% TLF Accuracy: Automate the analysis and summarization of tables, listings and figures (ex: demographics, safety, exposure tables) with accuracy and quality.

CoAuthor Success & Integration Strategy

Training & Education



Training & Education: Upon deployment of CoAuthor, our team of experts rolls out a comprehensive training and education schedule, customized to your priority use cases. Learn how to best leverage generative AI – from understanding how AI models operate and how to navigate generative AI across different source data.

Hands-On Phase 0 Schedule: We leverage a step-by-step onboarding schedule allowing you to take a crawl – walk – leap approach to leveraging generative AI in your writing workflows.

Change Management



Dedicated Support: Our Customer Success team is committed to helping users maximize the value of CoAuthor, from onboarding through ongoing usage. It includes both data scientists, engineers, and medical and regulatory writing support.

Prompt Generation: We actively assist users in creating prompts that fully leverage CoAuthor's AI capabilities, enabling smoother workflows and greater accuracy, across multiple use cases.

Scale



Robust API Infrastructure: Certara CoAuthor's powerful APIs enable seamless integration with clients' core applications, such as document management systems, regulatory submission tools, and data repositories.

Customizable Connections: Tailor the integration to meet your organization's specific needs, ensuring a flexible and scalable solution that grows with you.

Enhanced Workflow Efficiency: By integrating with your existing software stack, CoAuthor becomes part of your established workflow, minimizing disruption and maximizing efficiency.

CoAuthor Resources

[CoAuthor Website](#)

[Fact Sheet - CoAuthor Overview](#)

[Blog - GenAI Tools for Regulatory Writing](#)

[Video - Certara CoAuthor 5-min Tour](#)

[Webinar - CoAuthor: The Gen-AI Enabled Solution for Regulatory Writers](#)

[Webinar - CoAuthor: Summarize This! GPTs for Regulatory Writers](#)

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CoAuthor 

Supplemental Slides

Agenda

Topic	Duration	Time	Who



Please add your questions to the chat so we can compile and review them during the Q&A session.

The Evolution of CoAuthor



CoAuthor Press Release

CoAuthor Advantages

Utilizing CoAuthor in the document creation process enables medical and regulatory writers to boost efficiency, minimize errors, and maintain regulatory compliance. This allows authors to spend less time on mundane, manual tasks and more time on higher-level activities such as data analysis and interpretation.

- **Automating Content Creation:** Using templates and pre-defined content to ensure consistency and compliance.
- **Extracting Key Information:** AI can extract essential information from source documents like clinical study reports, protocols, and safety narratives. This ensures consistency and accuracy in the presented data
- **Summarizing Data:** Generative AI can summarize complex data from tables, figures, and listings (TFLs), making it easier to understand and ensuring consistency with the original data
- **Reusing Content:** AI can reuse content from previously created documents, promoting consistency and reducing redundancy. This is particularly useful for recurring information in regulatory submissions
- **Collaborative Authoring:** Allowing multiple stakeholders to contribute and review documents in real-time.
- **Version Control:** Manage audit trail, document revisions, and ensure the latest version is always accessible through Microsoft Word
- **Regulatory Compliance:** Ensuring documents meet the specific requirements of regulatory bodies like the FDA and ISO standards

CoAuthor Roadmap

Q3 '24

Q4 '24

Q1 '25

Q2 '25

Q3 '25

Q4 '25

Narrative Expansion

DMS Integration with Veeva

Redaction & Anonymization Modules

Single document coauthoring

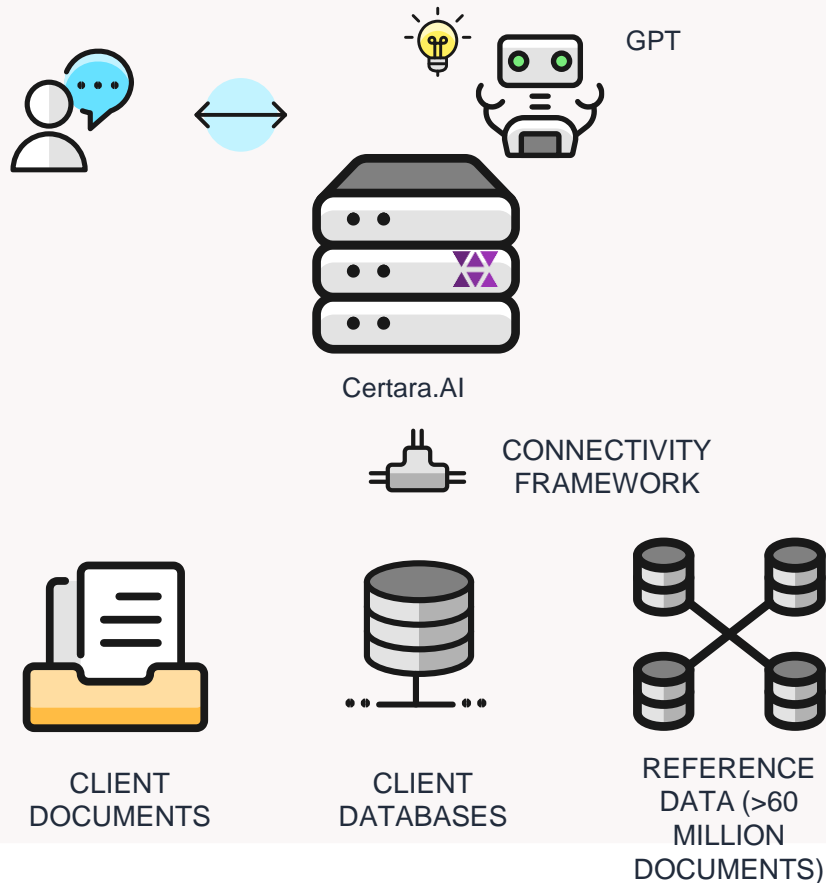
Many to One Structured Content Authoring

Guided Prompts

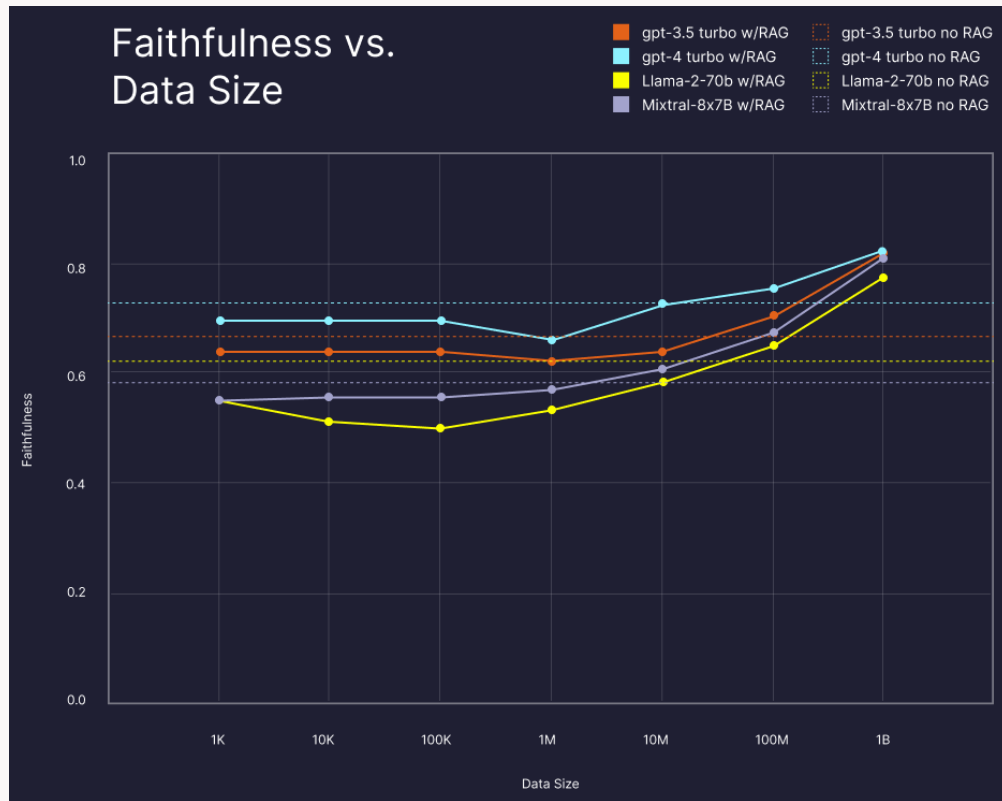
Template
Management

Certara.AI Retrieval Augmented Generation Architecture

- We can deploy Laya + GPTs behind a client's firewall or on a secure hosted server such that the client's data stays within their firewall
- By giving a GPT access to life sciences reference data and client data we can solve for these weaknesses
- The GPT is able to respond with up to date information and to provide references for what it responds with
- There are important IP considerations to using internal versus third party GPTs



RAG Evens The Playfield For Smaller GPT Models



“Our study not only underscores the scalability of RAG in enhancing LLMs but also demonstrates that with the application of RAG—LLMs of varied power and sizes can achieve almost equal high levels of accuracy and reliability—democratizing access to state-of-the-art capabilities of generative AI across different LLMs.”

- RAG with more data significantly improves the results of GenAI applications.
- The more data you can search over, the more "faithful" (factually correct) the results. As tested with a 1B dataset, which scales logarithmically.
- RAG with massive data on-demand is better than GPT 4 (without RAG), even with the data it was trained on.
- RAG, with a lot of data, provides SOTA performance no matter what LLM you choose. This insight unlocks using different LLMs (e.g., open-source or private LLMs).

Designed for Writers, By Writers

- CoAuthor is built in collaboration with its Certara.AI and Certara's writing team to ensure a secure, collaborative way to leverage generative AI to accelerate the document creation process.

Document Agnostic

- We support Modules 1-5
- CoAuthor is delivered via Microsoft Word, allowing it to be document agnostic and flexible with your preferred document templates.

Prompt Library

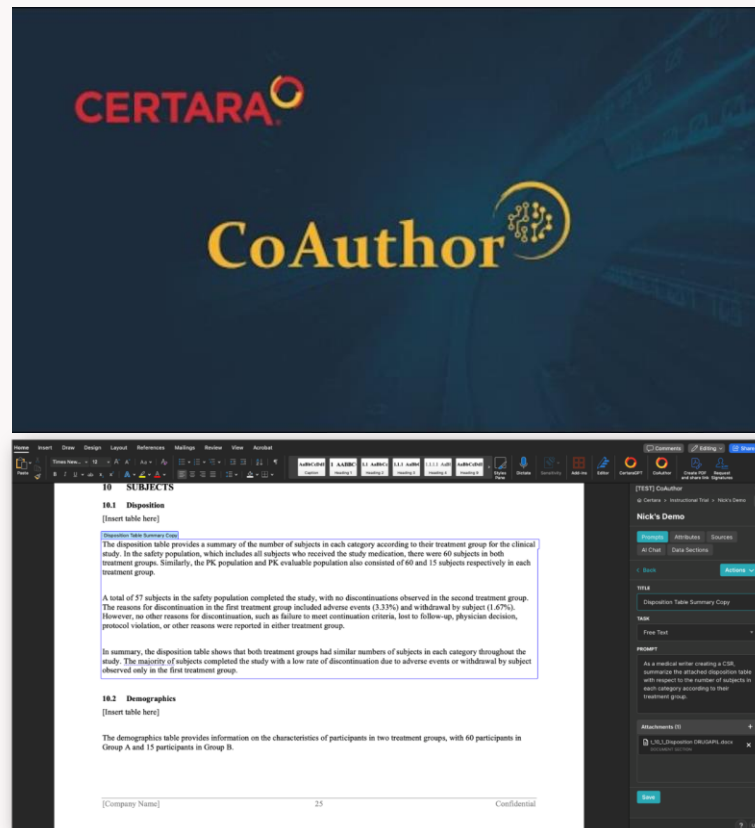
- CoAuthor features a library of GPT prompts developed by Certara's data science and medical writing teams. Prompts are built and reusable across multiple document types.

Structured Content Authoring

- CoAuthor combines generative AI with structured content authoring features to improve document formatting and content reuse.

> 40% Efficiency

- Early benchmarks of CoAuthor represent greater than 40% efficiency for each individual writer leveraging CoAuthor.



LLM versus Rules-Based Systems

Criteria	LLM	Rules-Based System
Flexibility and Adaptability	Can understand and generate text across a wide range of topics without needing predefined rules.	Requires extensive manual updates to handle new scenarios.
Contextual Understanding	Leverages vast amounts of data to understand context, nuances, and complex language structures.	Limited by predefined rules, often struggling with complex language and context.
Efficiency and Productivity	Automates content creation, reducing the time and effort required for drafting and reviewing documents.	Time-consuming to set up and maintain, with manual intervention needed for updates and corrections.
Consistency and Quality	Ensures consistent language and tone across documents, maintaining high-quality standards.	Prone to inconsistencies due to rigid rules and potential human error.
Scalability	Easily scales to handle diverse writing tasks without needing extensive reprogramming.	Scalability is limited by the complexity and number of rules required.
Innovation & Continuous Learning	Continuously learns from new data, staying up-to-date with the latest medical research and regulatory changes.	Static in nature, requiring manual updates to incorporate new information.

CoAuthor



Use Cases

CSR Case Study: Understanding the Impact of CoAuthor

What could your team achieve with this type of cost & time savings?

Situation	Solution	Result
<ul style="list-style-type: none">On average, it takes 83 days to complete the CSR development process <i>(from date of DBL to finalization)</i>Submission teams are under more pressure than ever to accelerate timelines	<ul style="list-style-type: none">By using CoAuthor for CSR development, users reduce timelines by 20% or more on average 	<ul style="list-style-type: none">Average of 16.6 days saved during CSR development with use of CoAuthor<ul style="list-style-type: none">Enabling accelerated submission timelinesGetting treatments to patients soonerEquates to savings of approx. \$20,000 per CSR (+/-) of writing costs for one CSR

CoAuthor users also save an average of 40%+ during CSR development

Narratives Case Study: Increased Productivity & Quality

How can your team accelerate timelines, without sacrificing quality & consistency?



CoAuthor users also save an average of 60%+ during Patient Narrative development

Narratives Case Study: Urgent Health Authority Request

Can your team quickly accommodate this type of unexpected requests?

Situation

- American biopharma company received an unexpected request for safety narratives
- Needed to report requested lab parameters in both tabular & running text format for 100's of patients
- No timeline flexibility given by the health authority

Solution

- Upon receipt of data, team quickly mapped & generated narrative template, meeting new criteria



Result

- Team was able to achieve 100% automation
- Eliminated need for manual edit from writing or QC team
- Successfully finalized narratives within 3 business days for submission to health authority

CoAuthor 

GenAI-Powered Authoring