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Transforming Medical Writing with Generative Artificial Intelligence (GenAI)

Placing No Regret Bets on Medical Writing

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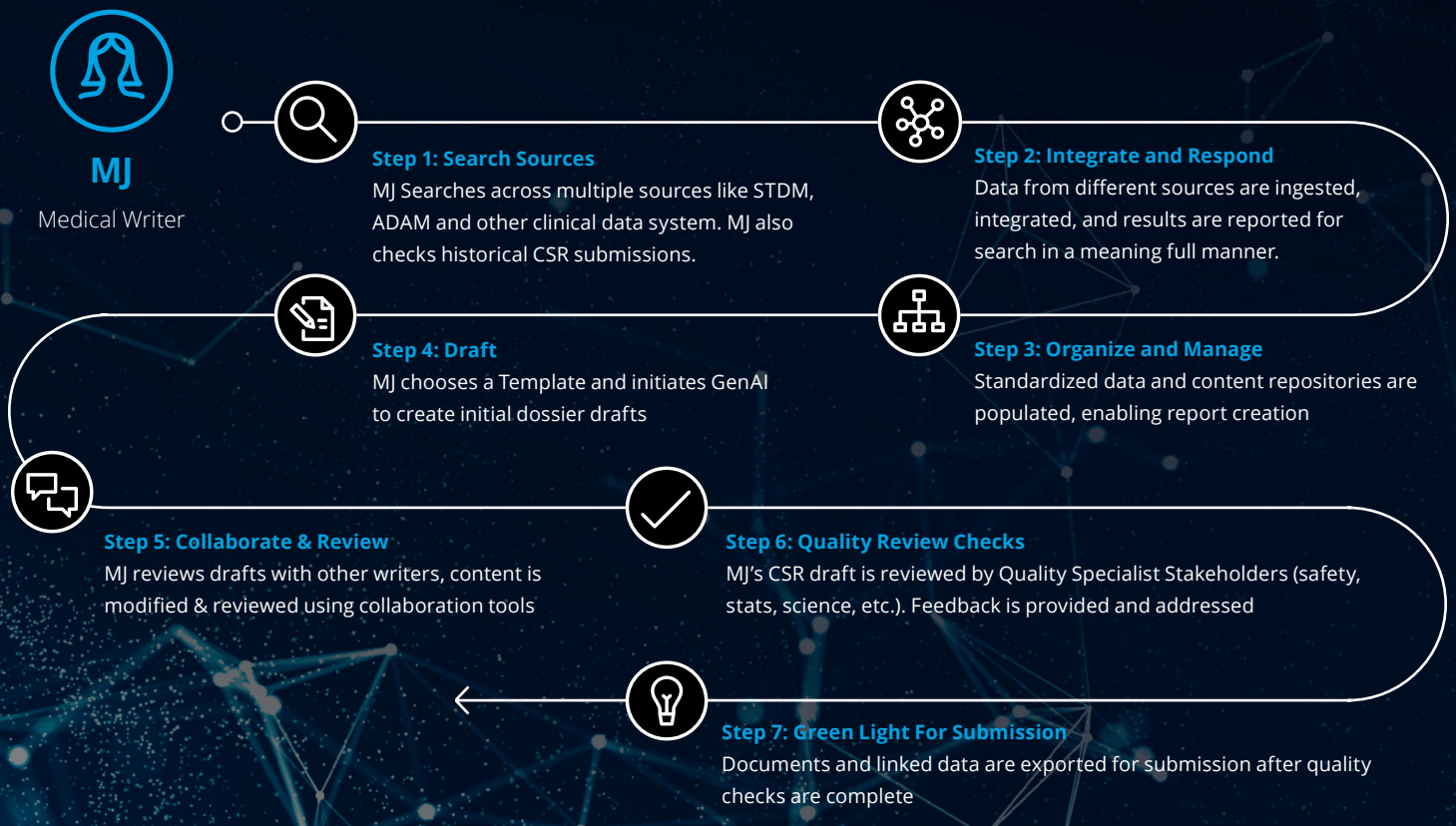
Placing a 'no regret bet' on Medical Writing

Our recent article, Realizing Transformative Value from AI & Gen AI in Life Sciences, estimated that Life Sciences companies have an opportunity to unlock $**5-7 billion (Bn) in value** from the use of artificial intelligence (AI), with **30-40%** of the value opportunity coming from R&D alone. Across R&D, one of the greatest opportunities for value realization from AI & Gen AI is in regulatory document authoring.

The drug development lifecycle currently involves significant time spent on regulatory authoring, submission, and review processes. While incremental technology advancements have been made since the days of physical paper submissions, the regulatory process remains largely manual, and document based. Our experience suggests that AI-driven automation in regulatory authoring, and medical writing in particular, is a 'no-regret bet' that can deliver high value to the enterprise in a relatively short timeframe. We estimate these solutions can reduce medical writer effort by **20-30% across multiple document artifacts and workflows**, yielding an annual cost savings of **$30 million** on average for a top 10 biopharma company (assuming a 50-candidate pipeline).

The data-driven nature of medical writing means that many of the tasks performed during authoring can undergo some form of automation, such as the drafting of clinical summaries and the repetitive pasting, formatting, and referencing of data tables. Improved automation allows focus to shift from writing into activities that create additional value for the enterprise, such as scientific research, engagement with external research communities, and benefit/risk assessments. In addition to process efficiencies, GenAI-enabled automation also drives repeatability, minimizing opportunities for errors or inconsistencies and can streamline the translating and localizing of content.

Vision for accelerated clinical document authoring



Transforming Medical Writing requires a holistic approach

The medical writing domain covers a wide range of documents and authoring scenarios. Across study documents, such as Protocols, Statistical Analysis Plans, and Clinical Summaries, an author may need to write narrative text, create plain language versions of content, localize content for a specific region, develop figures and tables, and ensure consistent references and citations. On top of this, the data and content for a particular program or study must be consistent across multiple documents. The complexity of medical writing therefore makes it inherently challenging for a single technology to address the variety of scenarios that can be faced in assembling documents.

While we are optimistic about the capabilities of GenAI in medical writing, our experience indicates that greatest value realization comes when GenAI is integrated with existing enterprise data ecosystems and platform solutions, including Content Management Solutions and Structured Content Authoring platforms. Choosing the 'right tool for the job' has been the core underpinning of our approach in holistically solving for medical writing automation.

We demonstrate below our approach to introducing GenAI into the medical writing process through a case study with the Clinical Study Report (CSR).

Case study: Automating Authoring of the Clinical Study Report (CSR)

Let's take the Clinical Study Report (CSR) as an example. The CSR is a combination of content including narratives, summaries based on insights, tables, figures, and lists. To solve for CSR authoring automation, we take a holistic view of the solution components as "pearls on a string", an end-to-end view that breaks down the art of possible in embedding technology across the value stream.

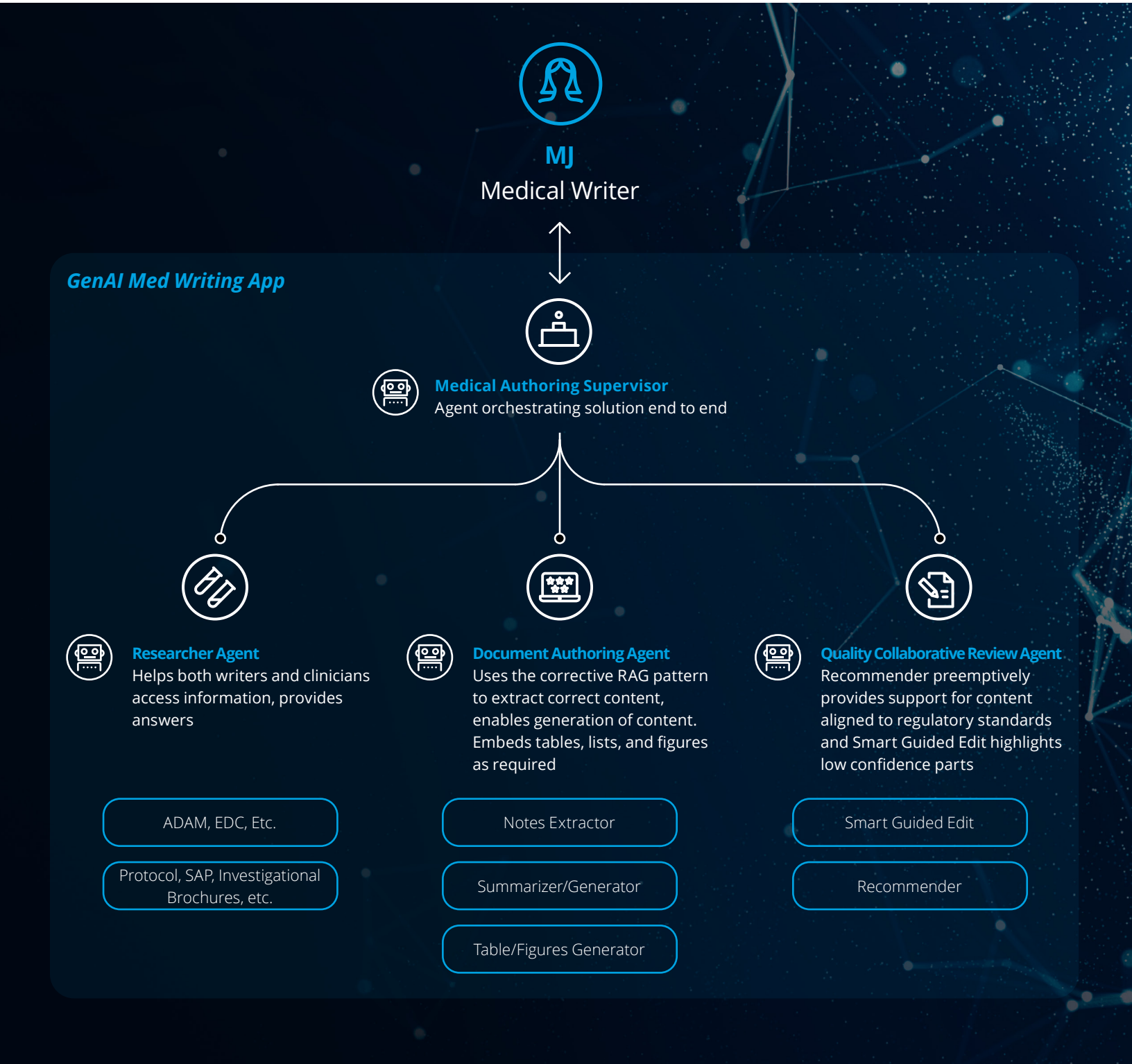
Automating authoring of the Clinical Study Report means breaking down the document into specific scenarios and choosing the right tool for each task.

OBJECTIVES	USE CASES	GENERATIVE AI	MACHINE LEARNING	ENGINEERING	DATA	ECOSYSTEMS & INTEGRATIONS
01. Obtain relevant information from Study and Protocol Documents	Information Gathering	RAG based Q&A on Studies and Protocols		Ingest, Aggregate and Build Analytical Datasets	Protocol Documents	
02. Preparation of analytical data sets	Build Analytical Data Sets	Summarize Analysis into Insights or Story Highlights			STDM: Lab, Demographics, Adverse Events, Dosing	
03. Summary based on context and summary of tables	CSR Summary Generation	Generate Summary of Content	Source to Target Mapping	Generate Lists & Figures	STDM other Domains: Disease Disposition, Response, etc.	Veeva , SharePoint, Document Repos
04. Generate the tables, narratives and summaries as required	CSR Document Generation	Document Drafting and Table Generation		List and Figures	ADAM Datasets – Subject Level, Lab, Dosing, AE, etc.	Cloud Hyper Scalers
05. Measure the Generated Content Quality & Provide Feedback	CSR Quality Checks	Providing Smart Guided Edits	Confidence Score Prediction		Clinicaltrials.gov	SCA Solution Partners
06. Build and Submission of the eCTD to Health Authorities	Submission of Dossier	To be Explored		Dossier Generation		Integration to Health Authorities

The CSR is constructed in a componentized fashion, with automation or author augmentation of each document section being performed by the right tools for the job across GenAI, traditional AI, engineering, data, or enterprise system integrations.

To generate domain specific content, the solution leverages Large Language Models and employs three specific prompting techniques based on the recent paper from Microsoft on MedPrompt. The first technique we use is Context Learning with Few Shot Prompting, where a clustering-based approach (KNN) is used to identify and choose content examples for specific authoring scenarios. We additionally use a technique for insightful deduction through Chain of Thought prompting which is accomplished using Question & Answer Pairs. The third prompting technique we use allows us to generate a comprehensive narrative by capturing a large breadth of perspectives. For this, we ensemble the outputs from separate question and answer responses. A vote function then allows the LLM to select and aggregate the best outputs.

A TOP 10 BIOPHARMA AVERAGING 50 ANNUAL SUBMISSIONS ESTIMATED A 25% EFFICIENCY GAIN AND ~$13M USD IN RECURRING VALUE BY USING GENAI FOR AUTHORING CSRs



Integrated AI Agents in Complex Task Management

For complex tasks, the solution leverages 'agents' that combine an LLM with a role-specific persona and skills

Research Assistant Agent
Tells the science story by connecting clinical data including demographics, drug efficacy, lab results, adverse events, and more.

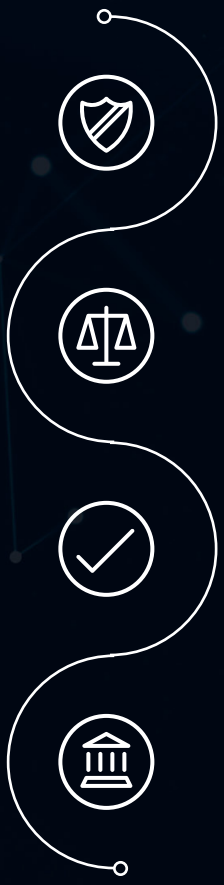
Drafting Agent
Writes summaries from Input Sources like protocol documents, statistical analysis plans, and investigational brochures. Embeds factual tables, figures, and lists to compliment the data narratives and stories. The agent also leverages Past Submissions as One-shot Examples with variations created using a few inputs from medical writers.

Quality Collaborative Review Agent
Enables smart guided edits for highlighting portions of generation where there is low confidence. Low confidence insight is provided by comparisons to past submission documents.

Quality Collaborative Review Agent
Provides inputs on additional reinforcements that ensure the document content is solid per compliance standards.

Considerations

While GenAI is positioned to dramatically change the medical writing process, it comes with new considerations and precautions to ensure it is used responsibly and ethically, maximizing its potential to enhance medical communication without compromising accuracy, trust, or human expertise. Some considerations when introducing GenAI into the authoring process include:



Data Privacy and Security
Design and implement controls for data privacy and security to ensure protection of patient data and sensitive company information.

Ethical Considerations
Plan, design, and monitor for bias and misinformation in generated content. Ensure that content is transparent and traceable, with proper attribution to source material via citations.

Quality Assurance
Embed human oversight and review into the submission development processes leveraging qualitative and quantitative techniques, such as BLEU, Cosine Similarities as well as using large language models (LLMs) themselves as champion-challengers for self-evaluation of performance.

Regulatory Compliance
Ensure solutions adhere to emerging regulatory requirements on the use of AI in generating submission content.

Looking ahead

As GenAI capabilities continue to evolve and become more engrained in document-based business processes, GenAI will evolve from **simple drafting of content** to **providing content intelligence**. Integrating GenAI with Structured Content Authoring solutions, for example, will allow the LLM to learn document structures and writing styles, putting less reliance on rigid, challenging to manage SCA content and templates. Writers will also be provided intelligent regulatory review agents trained on regulations and past health authority inquiries, that can ensure documents comply with relevant regulations and standards. Authoring assistant agents will also contain embedded knowledge of regional regulatory requirements, terminology, and translations allowing for simplified authoring of regional document variants.

Conclusion

There are often high expectations put on emerging digital technologies, with many failing to live up to the initial hype. However, with GenAI we believe that the technology is here to stay, and the promise is real. Medical writing is a complex process, requiring specific domain expertise and multiple technologies, and GenAI cannot solve every piece of the authoring challenge on its own. We have a clear vision of integrating GenAI with existing technologies and tools to streamline the authoring workflow, ensure regulatory compliance and global reach, and enhance collaboration and knowledge sharing.

Given that a reduction in regulatory authoring and review timelines means lifesaving drugs can get to patients faster, it is a worthwhile endeavor to determine how GenAI can fit into the overall authoring automation process especially for writing Protocols, SAP, and other documents. The technology should be viewed as a tool to be used with the appropriate controls to solve specific problems. We feel that with the right framing, GenAI is going to make a longstanding impact on the Life Sciences industry with benefits stretching across medical writers, life sciences organizations, and ultimately patients.

Stay tuned for our upcoming deep dives on GenAI Augmented Medical Writing, where we continue to dive deep into our ‘No Regrets Bets’ for implementing Generative AI across the Life Sciences organization.

For more information and to see a live demo reach out to George Pushchinsky and Nirav Mehta.

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