P6 - Enhancing Clinical and Regulatory Documentation with Structured Content Authoring and AI Integration

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INTRODUCTION

The pharmaceutical industry is transitioning from manual, unstructured document development to a content-based approach using structured content management (SCM) tools. This shift aims to streamline workflows, improve consistency, and enhance efficiency in clinical and regulatory documentation. As the industry explores generative artificial intelligence (GenAI), structured content authoring (SCA) emerges as a key enabler for integrating AI-based solutions into regulatory and medical writing processes.

METHODS

Parexel Medical Writing Services implemented SCA for various clinical study documents and periodic safety reports in 2022. Recently, we have been augmenting SCA with GenAI functionality, allowing pre-configured AI prompts and user-derived GenAI content incorporation. We have collated qualitative lessons learned from the implementation of SCA and GenAI augmentation of our SCM system.

RESULTS

SCA implementation demonstrated decreased document production time, enhanced first-time quality, and improved content strategy implementation through metadata-driven standardized content incorporation and configurable templates. GenAI augmentation further enhanced efficiency by reducing adoption barriers through programmable prompts, allowing targeted control of prompt usage, and offering users enhanced flexibility in content generation and modification.

CONCLUSIONS

The integration of SCA with GenAI enhances efficiency, consistency, and quality in the development of clinical and regulatory documents. This combination streamlines workflows, improves information summarization, and enhances quality control. As these technologies evolve, they promise to transform traditional content creation processes, potentially accelerating time-to-market for new products while maintaining compliance with industry standards, marking a significant advancement in regulatory and medical writing.