Adoption and Case Studies of Generative AI Tools in Medical Writing

Generative AI (GenAI) tools are revolutionizing medical writing in the pharmaceutical and medical device industries. These tools enhance efficiency, improve accuracy, and reduce costs by automating repetitive processes, ensuring compliance, and accelerating timelines for document creation. Below is an integrated report highlighting adoption trends, ROI, and case studies associated with these tools.

Adoption of GenAI Tools

Several companies have adopted GenAI solutions to streamline medical writing processes and improve regulatory compliance. These tools enable faster creation of clinical, regulatory, and pharmacovigilance documents while enhancing document quality and consistency. Key players in the industry have implemented these solutions, reporting measurable returns on investment (ROI) through time and cost savings.

Examples of GenAI Tool Adoption

1. Cognizant and Yseop Partnership: Cognizant partnered with Yseop to scale medical writing operations. Yseop's GenAI platform automates repetitive tasks, enabling medical writers to focus on high-value activities. The partnership has resulted in significant productivity gains, reducing medical writing time for Clinical Study Reports (CSRs) and Patient Narratives by up to 50%.

2. Novo Nordisk's AI Initiatives: Novo Nordisk has integrated AI solutions into document quality assurance and summarization workflows, reducing document review times from 40 hours to just 40 minutes. This initiative highlights the potential for AI to enhance efficiency and accuracy in regulatory and clinical documentation.

3. Certara's CoAuthor™ Platform: Certara's CoAuthor™ combines generative AI with document templates to streamline the creation of regulatory submissions, including INDs, NDAs, and BLAs. This tool reduces medical writing time by 20-30%, improving compliance and ensuring timely submissions.

4. TrialAssure LINK® AI: TrialAssure's LINK® AI facilitates the development of clinical and technical documents, including Clinical Study Protocols and Plain Language Summaries. By automating document drafting, the tool reduces time spent on repetitive tasks by up to 40%, delivering significant ROI in terms of faster regulatory approvals.

ROI of GenAI Tools in Medical Writing

1. Time Savings: Up to 50% reduction in document drafting and review times.

2. Cost Efficiency: Reduced reliance on external contractors and manual processes.

3. Improved Compliance: Enhanced document consistency and adherence to regulatory standards.

4. Faster Market Entry: Accelerated regulatory submissions lead to earlier approvals.

Case Studies of GenAI in Medical Writing

1. Deloitte's Integration of GenAI in CSRs: Deloitte applied GenAI to automate Clinical Study Reports (CSRs), reducing medical writing effort by 20-30%. The integration with enterprise data systems ensured consistency and compliance, resulting in significant cost savings and improved submission timelines.

2. Novo Nordisk's Document Quality Assurance: Novo Nordisk collaborated with AI start-ups to enhance document summarization and quality assurance processes. By leveraging AI, they reduced document review times from 40 hours to 40 minutes, showcasing the tool's ability to increase efficiency while maintaining high standards of quality.

3. TrialAssure's LINK® AI for Regulatory Compliance: TrialAssure's LINK® AI enabled pharmaceutical companies to meet growing demands for transparency and compliance. The tool automated the creation of Clinical Study Protocols, Plain Language Summaries, and clinical trial disclosure documents, reducing time spent on repetitive tasks and ensuring regulatory adherence.

4. IBM Watson Discovery for Literature Reviews: IBM Watson Discovery was used to streamline literature reviews for regulatory and clinical documentation. Its advanced AI capabilities accelerated the identification of relevant references, significantly reducing the time required for literature searches and improving the quality of manuscripts and regulatory submissions.

5. Generative AI in Clinical Documentation: A study demonstrated the use of GenAI to generate clinical notes, such as SOAP (Subjective, Objective, Assessment, Plan) and BIRP (Behavior, Intervention, Response, Plan) notes. By employing natural language processing (NLP) and automatic speech recognition (ASR), healthcare providers saved time and improved documentation quality, enabling more focus on patient care.

Applications and Types of Documents Supported by GenAI Tools

- Regulatory Documents: INDs, NDAs, BLAs, sNDAs, Annual Reports.

- Clinical Trial Documentation: CSRs, Investigator Brochures, Patient Narratives.

- Pharmacovigilance Reports: Risk Management Plans, Periodic Safety Update Reports (PSURs), Adverse Event Narratives.

- Transparency and Disclosure Documents: Plain Language Summaries, Clinical Trial Registrations.

Conclusion

The adoption of Generative AI tools in medical writing is transforming the pharmaceutical and medical device industries. With measurable ROI in terms of time savings, cost efficiency, and improved compliance, these tools are enabling companies to optimize their

documentation processes and accelerate product development timelines. Case studies from Deloitte, Novo Nordisk, Certara, and others highlight the tangible benefits of integrating AI-driven solutions into medical writing workflows, demonstrating their critical role in the future of life sciences.