How Generative AI and Digital Transformation are Reshaping Regulatory Report Authoring

PROBLEM STATEMENT

For approved pharmaceutical products marketed in the US and globally, Aggregate Safety Reports are submitted periodically to regulatory authorities. Currently, these reports are manually assembled, with all key information compiled, collated, and transformed by members of pharmacovigilance, regulatory, and labeling teams. This manual process is labor-intensive, often consuming the bulk of researchers' time in compilation, assembly, and coordination rather than review and summary. Additionally, there is a lack of clear ownership of components and an audit trail when assembling even a draft version of the report.

SOLUTION

The primary problem areas in the current aggregate report generation are precisely where digitization and generative AI can significantly enhance workflows and reduce human involvement. By implementing innovative technologies and optimizing workflow strategies, the industry can mitigate risks, improve regulatory compliance, and ultimately safeguard public health. Navikenz has developed a sophisticated generic software platform designed to digitize and accelerate the labor-intensive process involved in creating aggregate safety reports. This platform empowers Subject Matter Experts (SMEs) responsible for authoring report sections by providing efficient content creation tools while ensuring robust traceability and data integrity measures are maintained throughout the workflow. Most importantly, Navikenz's solution incorporates advanced Generative-AI capabilities to offer intelligent assistance to section-content authors wherever feasible.

RESULTS

- **Streamlined collaboration**

Navikenz's unified portal provides a single platform for all stakeholders to access and contribute to the report generation workflow, promoting efficient collaboration and communication. Additionally, there are dashboards at role levels to provide a quick overview of ongoing activities.

- **Enhanced productivity**

The platform's generative AI-based content authoring tools accelerate the authoring process, making it faster and more efficient.

- **Quick access to historical information and generation of response**

Navikenz enables the rapid retrieval of historical data and facilitates swift response generation, empowering users to make informed decisions and meet regulatory requirements promptly.

- **Positive user experience**

Navikenz prioritizes a user-centric design, offering an intuitive interface and customizable features, resulting in a seamless and enjoyable user experience that ultimately enhances satisfaction and adoption rates.

CONCLUSION

Navikenz addresses critical challenges faced by pharmaceutical companies in manual report generation. Through the implementation of advanced automation and notification mechanisms, we empower stakeholders to efficiently navigate the report generation workflow, resulting in improved efficiency, compliance, and overall effectiveness in drug safety reporting. Navikenz's commitment to innovation and user-centric design positions it as a valuable partner in advancing pharmaceutical safety and regulatory compliance initiatives.