Smarter Reviews: Trusted Evidence

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Stryker Improves Literature Evidence Management Efficiency by 70% with DistillerSR

DistillerSR integrated fully into Stryker's T&E Clinical Affairs technology ecosystem and enabled more accurate insights and expedited decision-making processes.

Significant Efficiency Gains

The implementation of DistillerSR significantly enhanced Stryker's T&E efficiency in literature review and evidence management. The platform standardized forms and templates, minimized manual tasks, and streamlined processes from initial screening to data extraction, and creation of clinical evaluation documents to support regulatory submissions.

Enhanced Compliance and Data Management

The introduction of the European Union medical device regulation (EU MDR) required stricter compliance and comprehensive documentation throughout the device lifecycle. DistillerSR's scalable platform facilitated compliance, enhanced data quality, streamlined regulatory submissions, and improved audit readiness.

Improved Cross-Functional Collaboration

DistillerSR effectively dismantled data silos within Stryker, promoting cross-functional data reuse and collaboration. This holistic approach to evidence management led to greater efficiency, consistency, and a collaborative culture, ultimately boosting productivity while enabling data-driven decision-making.

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"The introduction of the new medical device regulation (MDR) motivated us to reevaluate our processes and improve operational efficiencies. As we navigated MDR, we encountered significant data growth and increased complexity, alongside a rapidly expanding team. This steep learning curve prompted us to replace our Microsoft Access database with a more reliable and robust system. Consequently, DistillerSR emerged as a foundational step in our strategy to enhance efficiency and compliance."

– SEPANTA FAZAELI, CLINICAL SYSTEMS AND MEDICAL DATA LEAD AT STRYKER

When Sepanta Fazaeli, Clinical Data and Medical Systems Lead, joined Stryker's Trauma Business Unit in the Trauma and Extremities division three years ago, team members were relying on Microsoft Access, a database management software, to conduct literature reviews and manage the extracted data. While highly configurable, the database was not designed to handle the complexities and requirements of systematic literature reviews at large scale. As the number of users and projects grew, the system became inefficient. The need to manually synchronize references from the Microsoft Access database with the company's library was another major pain point. This resulted in a significant bottleneck for fast procurement of full text publications, delaying the literature reviews. Finally, the user experience was cumbersome, further complicating data management and leading to errors.

Sepanta explained: "Microsoft Access followed a tabular dataset framework, which, at the time, was quite advanced," he said. "However, as we expanded our team to manage the increasing number of reviews, we spent a lot more time creating forms, labels, dropdown menus, and other elements. This time-consuming process not only put a huge strain on the system but also led to data inconsistencies. Additionally, we had to manually connect the references stored in the company library database. When we assessed the time spent on these manual tasks and the risk of errors, we quickly realized that Microsoft Access was not a viable long-term option."

Inefficient Data Management Amidst New EU MDR Compliance Challenges

The introduction of the European Union Medical Device Regulation (EU MDR) required stricter compliance and comprehensive documentation throughout the device lifecycle. In response to these growing complexities, Stryker's Trauma & Extremities division recognized the need to adopt a more robust, efficient, and scalable platform. DistillerSR proved to be an ideal solution to meet these heightened demands.

According to Sepanta: "The introduction of the new medical device regulation (MDR) motivated us to reevaluate our processes and improve operational efficiencies. As we navigated MDR, we encountered significant data growth and increased complexity, alongside a rapidly expanding team. This steep learning curve prompted us to replace our Microsoft Access database with a more reliable and robust system. Consequently, DistillerSR emerged as a foundational step in our strategy to enhance efficiency and compliance."

In this new regulatory landscape, the volume and complexity of data required for EU MDR–compliant clinical evaluation reports (CERs) grew exponentially. This increase equalled the extensive documentation needed for each medical device throughout its lifecycle, from pre-market approval to post-market surveillance. As our portfolios expanded, the need for a centralized and efficient management of literature review processes and extracted data became paramount.

DistillerSR equipped Sepanta and his team with a robust and reliable solution tailored for comprehensive medical device lifecycle traceability, from product development to post-market analysis. This audit-ready system streamlined submissions and enabled rapid, accurate responses to inquiries from notified bodies. The overall confidence in regulatory submissions was significantly enhanced, and the use of standardized protocols, templates, and forms boosted efficiency and productivity. Sepanta noted: "By standardizing our forms and templates in DistillerSR, we have significantly streamlined the literature review processes, from initial screening to data extraction and the creation of clinical evaluation documents for regulatory submissions. Sepanta continues: "We have identified specific families of devices with similarities in labeling and indications, and overlapping search results. This allowed us to reuse extracted data across these similar products. As a result, we have achieved an estimated 70% improvement in efficiency since adopting DistillerSR."

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Breaking Silos to Facilitate Cross-Functional Data Reuse

Data reuse in the medical device industry is challenging due to technical, regulatory, and organizational factors. Evidence is sourced from clinical trials, scientific literature, real-world evidence, and post-market surveillance data, each adhering to different formats and standards. This variability complicates efficient data integration and reuse. Ensuring data quality and integrity is critical, as incomplete or inaccurate data can adversely affect regulatory submission timelines and delay market entry.

In large organizations like Stryker, data is often managed in silos by different functional teams, such as clinical, regulatory, HEOR, and marketing. This compartmentalization leads to redundant efforts, inefficiencies, increased costs, and inconsistent findings across departments. Implementing DistillerSR enabled Sepanta and his team to adopt a holistic approach to evidence data collection, management, analysis, and sharing. They engaged cross-functional stakeholders to leverage previously extracted literature review data and collaborated with other business units to share standardized workflows and improve overall efficiency. In the context of CERs, the reuse of templated forms and dropdown menus for reference inclusion and exclusion facilitated efficiency gains across multiple groups and business units.

"In our Trauma and Extremities division, we successfully created standardized forms and templates in DistillerSR, enabling data reuse and enhancing efficiency," Sepanta explains. "Over the past few months, we have also started to share our best practices and methodologies with other divisions using DistillerSR."
This collaboration has been highly productive and represents a step towards harmonized practices across the organization. We are moving beyond a save-and-store data mindset and establishing a dynamic, sharing culture that leverages accessible data lakes. Ultimately, I envision a future of collaboration and shared practices across all business units and groups.

Data Harmonization Driving Optimized Evidence Management

Accessibility is a crucial aspect of developing a consistent and reliable data repository across the enterprise, and the first step towards fostering a sustainable sharing culture is data harmonization. Standardized ontologies establish a common vocabulary for specific domains, such as adverse event reporting. This approach reduces variability and ambiguity in how adverse events are recorded, ensuring that all stakeholders interpret the data uniformly and minimizing data entry errors. Consequently, this leads to higher data quality and reliability. In the context of global compliance, standardized ontologies enable the creation of a unified repository for adverse event data, applicable across various markets, thereby expediting the regulatory submission process.

According to Sepanta, DistillerSR seamlessly integrated into Stryker's technology ecosystem, facilitating efficient data reuse and analysis. This integration has significantly enhanced their team's ability to derive insights and make evidence-based decisions.

The People Factor: Emphasizing Employee Engagement for Successful Technology Adoption

Introducing new technology in a heavily regulated environment can be challenging. Employees are often under pressure to meet tight deadlines and may be hesitant to learn new software without clear benefits. DistillerSR's customer success team worked closely with Stryker to provide ongoing support. While there were some initial adjustments, this support helped staff become proficient relatively quickly. Responsive customer service was crucial in addressing questions and enhancing the user experience: "We expected the team to become more efficient, and we were pleased with how smoothly the transition went and how quickly we started seeing positive results," Sepanta remarked on the implementation journey.

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Transforming Evidence Management: A New Era of Efficiency and Collaboration

DistillerSR has been pivotal in advancing Stryker's enterprise evidence management strategy by addressing critical inefficiencies and compliance challenges. By internally building advanced automation and centralized data management on top of DistillerSR, the team minimized redundancy and reduced costs. The adoption of standardized protocols and templates, along with a comprehensive approach to data collection, sharing, and management has accelerated regulatory compliance. Furthermore, it has fostered a culture of cross-functional collaboration and efficient data reuse.

Sepanta concluded, "I see new opportunities for leveraging DistillerSR across various functions and areas beyond systematic literature reviews. As a domain-agnostic evidence management platform, DistillerSR can be utilized for a wide range of data management purposes, consolidating diverse data types. This capability supports marketing, downstream, and commercial teams by centralizing evidence management and facilitating data reuse. By integrating clinical data with sales and marketing databases, we can accelerate the generation of insights and promote data-driven decision making." ⌘

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