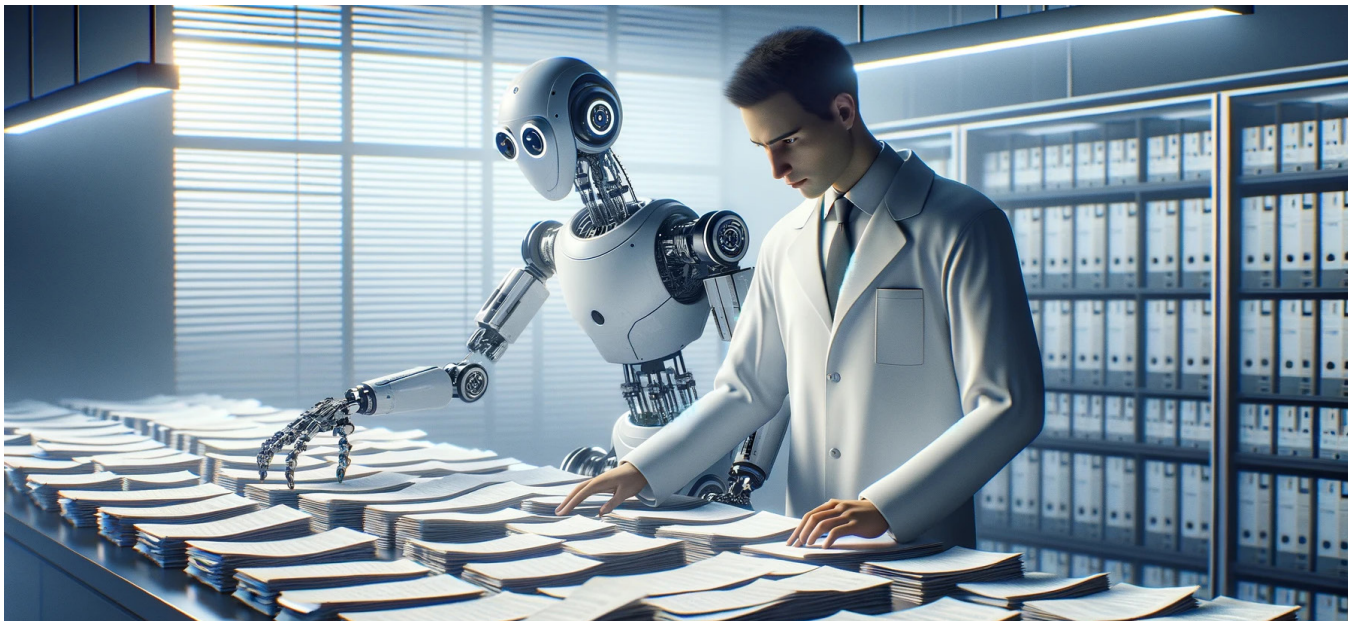
Effortless CRO Data Transfers into Veeva Vault eTMF with CROAssist™



CROAssist™ from fme in partnership with Just in Time GCP (JiT) encapsulates a revolutionary approach to Trial Master File (TMF) management in clinical trials. In the pharmaceutical industry, your TMF is a critical piece of your asset and managing the intricate flow of records from Contract Research Organizations (CROs) to the Trial Master File (TMF) housed in systems like Veeva Vault eTMF is a critical task. By automating data transfer from CRO systems to Sponsor systems and ensuring seamless integration, CROAssist eliminates the typical complexities and manual errors associated with TMF management. Its advanced capabilities ensure that records from various CROs are accurately and efficiently integrated into the Veeva Vault eTMF system, thereby ensuring standardization and enhancing the overall integrity and accessibility of trial data.

The seamless integration facilitated by CROAssist optimizes data flow and enables the sponsor to ensure compliance with regulatory standards, a paramount concern in clinical trials. CROAssist's ability to validate and align data with the specific requirements of Veeva Vault eTMF significantly reduces the time and effort traditionally required for data management. This efficiency gain is crucial for pharmaceutical companies looking to expedite the trial process while maintaining the highest data quality and compliance standards. CROAssist, therefore, stands as a pivotal solution in modern clinical trial management, redefining how companies handle the critical task of TMF management, making it more efficient, reliable, and effortless.

CHALLENGE

Sponsor organizations face a complex array of challenges in TMF management, which significantly impact their clinical trial operations. One of the primary challenges is managing the vast and diverse records that clinical trials generate. These records are not only extensive but varied in nature, encompassing clinical study reports, regulatory documents, and a multitude of other critical records. Managing this data manually is not only time-consuming but fraught with risks of inaccuracies, which can compromise the integrity of the trial.

Efficiency in trial management is also a key concern. Inefficient TMF processes can lead to significant delays in the trial timeline, impacting the time-to-market for new drugs. This inefficiency often stems from outdated manual processes that are slow and prone to errors.

These challenges underscore the need for an advanced TMF management solution like CROAssist, which comprehensively addresses each aspect.

SOLUTION

CROAssist provides a holistic solution to the TMF management challenges, offering efficiency, compliance, and security in one integrated package. CROAssist is engineered to tackle the multifaceted challenges faced by Sponsor organizations in TMF management.

CROAssist is a comprehensive solution tailored to provide:

Comprehensive TMF Strategy: CROAssist defines a comprehensive TMF strategy that accounts for the variability and complexity of operating models and outlines the solution to risk-based oversight in real-time. This strategy leverages a robust governance structure between sponsors and CROs that allows for TMF Management as agile as your product pipeline.

Advanced Data Management: CROAssist employs sophisticated algorithms and AI to manage large volumes of diverse clinical trial records. This technology automates the categorization and organization of records, transforming the laborious process of manual processing into a streamlined, error-free operation. It ensures that data integrity is maintained, enhancing the reliability of the trial data.

Streamlined Trial Management: CROAssist optimizes trial management efficiency by automating various TMF tasks accelerating record processing and management. This leads to faster trial completion and a quicker path to market for new drugs. By minimizing manual intervention, CROAssist also reduces the potential for human error, further enhancing trial efficiency.

Scalability and Integration: CROAssist's scalable architecture accommodates growing data volumes and the increasing complexity of clinical trials. Its compatibility with existing systems, like Veeva Vault Clinical, enables seamless integration and a smooth transition to this advanced TMF management system.

OUR OFFERING

Just in Time, GCP and fme are collaborating to provide a holistic solution that leverages fme's deep system and migration knowledge with JiT's experience creating risk-based approaches to TMF management to ensure inspection readiness for sponsor organizations. CROAssist enables sponsors to provide oversight to the authoritative source of their TMFs while allowing CROs to maintain business continuity.

CROAssist begins with developing and implementing a comprehensive strategy that includes TMF Management, TMF Governance, and Organizational Change Management. It then utilizes advanced technologies, such as Artificial Intelligence and Natural Language Processing, to categorize diverse record types efficiently, ensuring accurate, standardized organization and retrieval within the TMF management system. Following the classification, fme's **migration-center** tool expertly facilitates data migration into the TMF. This process is meticulously managed to maintain data integrity and compliance.

Post-migration, CROAssist performs a thorough verification of the migrated data. This crucial step includes providing a detailed validation summary, which encapsulates the work done, ensuring transparency and accountability. Finally, the successfully imported and validated data is turned over to the sponsor to execute oversight activities as outlined in the TMF Strategy. This end-to-end process, from classification to data handover, exemplifies CROAssist's commitment to delivering a seamless, efficient, and reliable TMF management experience.

CROAssist's offering is not just a tool but a strategic asset for pharmaceutical companies, aligning TMF management with the industry's move toward more sophisticated digital solutions and empowering long-term strategic partnerships that build efficiency and optimize performance. It provides a seamless, efficient, and compliant TMF management experience, making it an indispensable tool for pharmaceutical companies.

BENEFITS

- **Inspection Ready TMF:** Streamlined TMF Strategy that ensures standardization across portfolios and the agility to respond to changes in the regulatory landscape.
- **Strengthened Partnerships:** Clear governance structure and engagement model that empowers long-term strategic partnerships.
- **Business Impact Reduction:** CROAssist significantly reduces the operational burden on businesses by managing complex TMF processes.
- **Efficient Data Flow Management:** Seamlessly manages data flow between sponsors and their CROs, ensuring smooth communication and coordination.
- **Validated Data Integration:** Provides validated data importation into Veeva Vault eTMF solutions, enhancing data integrity and reliability.
- **Streamlined Operations:** Simplifies TMF management, allowing businesses to focus on core activities.

FOR MORE INFORMATION

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