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Improve Quality and Consistency by leveraging AI for Trial Master File classification.

The Trial Master File (TMF) allows an effective way to collect and manage study-specific documents during a clinical trial. The TMF serves as a complete and accurate record of the trial's conduct, including the protocol, informed consent forms, study reports, and other important documents. With the increasing volume of documents generated during clinical trials, managing them manually is inefficient, time-consuming, and often overwhelming.

Artificial Intelligence (AI) with automated classification schemas can be configured to auto-classify and manage the documents generated during clinical trials, driving efficiency, and ensuring greater consistency and quality.

This paper outlines how ProPharma works with study sponsors to drive TMF efficiency through automation. ProPharma's R&D Technology Solutions team specializes in digital transformation, including the implementation and configuration of a wide array of clinical and research systems. This use-case explores optimizing Veeva Vault eTMF to enable an AI-powered solution, the TMF Bot, to automate the classification of documents.

AI and automated classification schemas can revolutionize document management during clinical trials.

Veeva Vault's TMF Bot Overview.

Veeva Vault's TMF Bot is an AI-powered solution that uses natural language processing (NLP) and machine learning (ML) algorithms to automate the classification of documents in an electronic Trial Master File (eTMF). The TMF Bot analyzes the content of each document uploaded via the Document Inbox and identifies its classification. It then auto-classifies each document based on its learnings from trained models.

Maximizing Study Sponsor Success: The Benefits of Implementing the TMF Bot.

1. Improved Accuracy and Consistency

One of the main advantages of leveraging Veeva Vault's TMF Bot for eTMF classifications is improved accuracy and consistency. Manual classification of documents is slow and often results in misclassified documents. Utilization of the TMF Bot ensures documents are classified with precision and in a consistent manner, which helps streamline eTMF management and improve eTMF quality.

2. Increased Efficiency

Leveraging Veeva Vault's TMF Bot for eTMF classifications also increases efficiency by enabling faster document processing. With the TMF Bot, documents are classified automatically, reducing the need for manual intervention. This frees up valuable resources, allowing study teams to focus on more critical tasks. Trial performance improves and products can get to market faster as a result.

ProPharma's Holistic Approach to TMF Bot Implementation: A Comprehensive Guide for Study Sponsors.

Here are the steps ProPharma's R&D Technology Solutions team takes to help study sponsors get their TMF Bot up and running. ProPharma provides tailored support during every step of the process to maximize the value of the sponsor's trained model Implementation.

1. TMF Health Check

Every study sponsor has unique document management needs. That is why it is necessary to perform a thorough quality assessment of the documents in your Vault and evaluate the overall health of TMF documents before implementing the TMF Bot. This assessment captures the baseline data needed to configure the trained model and identify the best strategy to implement the TMF Bot for the sponsor's specific needs.

2. Create a Trained Model

ProPharma partners with study sponsors to create a trained model, a record capturing details about an ML model that has been created or will be created for a sponsor's Vault. There are several parameters that must be defined when creating a trained model such as the Prediction Confidence Threshold and Minimum Documents per Document Type. Since different companies have varying levels of risk aversion, the trained model's parameters can be customized to align with each company's corporate objectives.

3. Select Documents for Training

Accurate document classifications are extremely important for the success of a clinical trial. After analyzing the overall health and composition of a study sponsor's documents, ProPharma's experts provide a recommendation for the most effective method of selecting documents to train the TMF Bot, whether it be a Training Window Start Date or an attached Computer System Validation (CSV) of Document IDs, to ensure the highest level of accuracy when it comes time for the TMF Bot to begin auto-classifying documents.

To deploy the most optimal trained model for their TMF Bot, here are some key factors study sponsors should keep in mind when looking to leverage the TMF Bot:

- Recommend using a minimum of 1,000-3,000 accurately classified steady-state documents in the Vault (Approved/Final) to increase the prediction quality (maximum of 200,000 documents)
- A minimum of 10 documents within each document type (e.g., Trial Management, Central Trial Documents, Site Management, Investigational Product and Trial Supplies, Data Management, etc.) if loading between 1,000-10,000 documents (minimum increases if loading 10,000+ documents)
- Exclude non-English, video, audio, ZIP, statistical, and database files
- Exclude Document Types mapped to TMF Document, Final CRF, and Sites Evaluated but not selected

The more accurately classified document classifications are, the more accurately trained the TMF Bot will be when deployed.

4. Evaluate and Deploy

After training the trained model, ProPharma collaborates with study sponsors to review and analyze the Training Summary Results, Model Performance Metrics, Extraction Coverage Percentage, and Individual Predictions. Our trained experts work closely with study sponsors to ensure that all summary results meet expectations before assisting in the deployment of the trained model. Once deployed, the TMF Bot begins auto-classifying documents in the sponsor's Vault, enabling study teams to automate business processes.

5. Post TMF Bot Deployment Surveillance

ProPharma's R&D Technology Solutions team understands that deploying the TMF Bot is only the beginning of the journey towards successful implementation. To ensure study sponsor satisfaction, support can be customized to determine the optimal cadence for spot-checking documents auto-classified by the TMF Bot, monitoring the prediction data, and deploying additional trained models as needed.

From Implementation to Optimization: ProPharma's Support Services for Realizing the Full Potential of TMF Bot.

Once sponsors have launched the TMF Bot, ProPharma helps unlock the full potential of their Vault's TMF Environment.

1. Prediction Data Review

Once the trained model is deployed, ProPharma realizes the importance of ensuring TMF Bot adequacy for the content uploaded to the Document Inbox. A few weeks after deployment, ProPharma collaborates with study sponsors to review the Predictions Report to confirm the trained model is performing as expected.

ProPharma provides ongoing monthly or quarterly quality/verification checks of sponsor's Predictions Report, depending on the agreed-upon cadence. These reviews confirm that the trained model remains adequate for the content being uploaded and identify content in need of reclassification. Through this iterative process, ProPharma enables study sponsors to get the most out of the TMF Bot and ensure its ongoing success.

2. General Release Gap Analysis

Keeping abreast of the latest innovations and functionalities of the Veeva Vault Platform is a key priority for ProPharma. That is why in addition to our impact analysis service for every General Release, for study sponsors who are leveraging the TMF Bot, ProPharma provides a thorough gap analysis and risk assessment to ensure they are taking full advantage of any new TMF Bot-related enhancements in upcoming releases. By continuously evaluating and updating their TMF Bot, sponsors can be confident that their eTMF is optimized for maximum efficiency and accuracy.

Want to Implement AI for Your Trial Master File?

If you are looking for a trusted partner to implement Veeva's TMF Bot and enhance the quality and consistency of your TMF documentation, ProPharma's R&D Technology Solutions team is here to help. Our team of experts has the knowledge and experience to seamlessly integrate Veeva's TMF Bot with your existing systems and provide ongoing support to ensure your success.

Contact us today to learn more about how we can help you streamline your TMF documentation process and achieve your regulatory compliance goals..

https://www.propharmagroup.com/

info@propharmagroup.com