

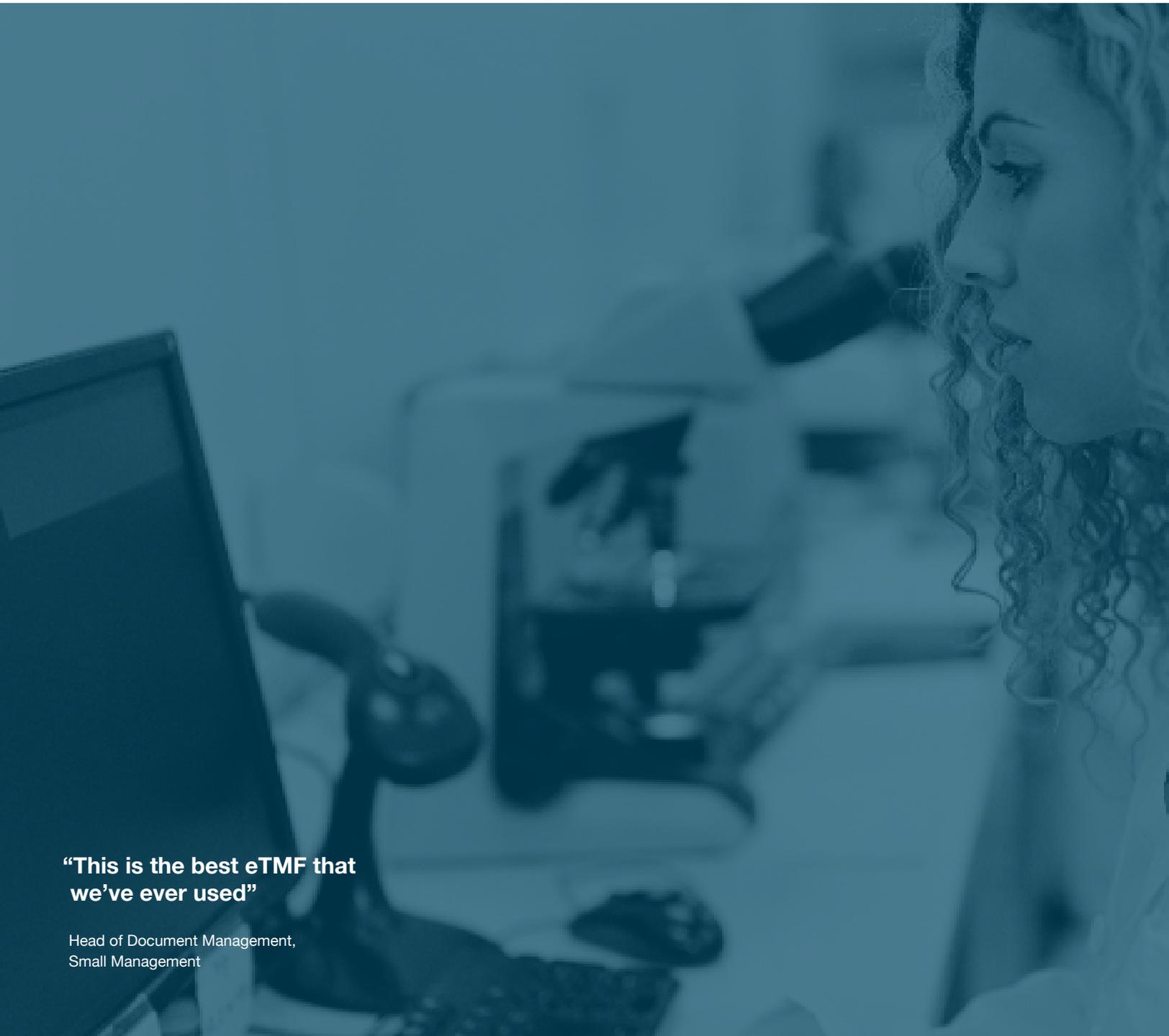
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# eTMF Document Management System



RISE  
ABOVE

eTMF not only provides a paperless and automated system for collecting essential documents but helps identify gaps and manage workflow processes across multiple team members and functional groups in real-time



**“This is the best eTMF that we’ve ever used”**

Head of Document Management,  
Small Management

## 5 Reasons To Choose Prevail eTMF

1. Automated, configurable, paperless system for collecting documents with site launch logistics
2. Dynamic progress tracking across CRAs, CROs, and sites in accordance with ICH and 21 CFR 11
3. Leverage automation and integration to create an efficient and effective workflow
4. Customizable user roles and alert messaging to drive process and manage critical deadlines
5. Real-time dashboards for leadership oversight

# Improve TMF Compliance With Less Effort

## Compliance & Quality Control

Quality control and yearly reviews are improved by allowing auditors and managers to review documents from anywhere in the world.

## Real-Time Document Tracker

Throw out excel trackers and ensure that sponsor / CRO project managers and consultants see the progress of collecting essential documents in real time.

## Configurable Categories & ECTD

Easily group regulatory documents to sponsor and FDA specifications for an unprecedented level of NDA submission preparedness

## Secure Remote Monitoring

Easy remote access at the touch of a button, even if your sites are spread across three continents.

## Improve Site Launch

Proactively manage the steps to getting sites up and enrolling by assigning and tracking responsibilities, with alerts triggered by non-performance. Track percentage by site, monitor, country, or region.

# How it Works

## System Configuration

- Default configuration is based on TMF Reference Model V3.1
- Fully configurable artifact subfolder identifiers and indexing structure
- Bulk configuration of document metadata

## Document Submission

- Tailored submission process for all study end user roles (Site users, external vendor users, TMF specialists, and beyond)
- Expedited document submission with robust bulk upload capabilities
- Flexible document submission from anywhere and everywhere with email-into-TMF submission features

## Processing

- Customizable document flags for improved workflow oversight (e.g. flagging of SIV-Required documents and documents requiring translation, etc)
- System-generated reporting tools to monitor TMF submission status
- Custom reporting tools to suit every project

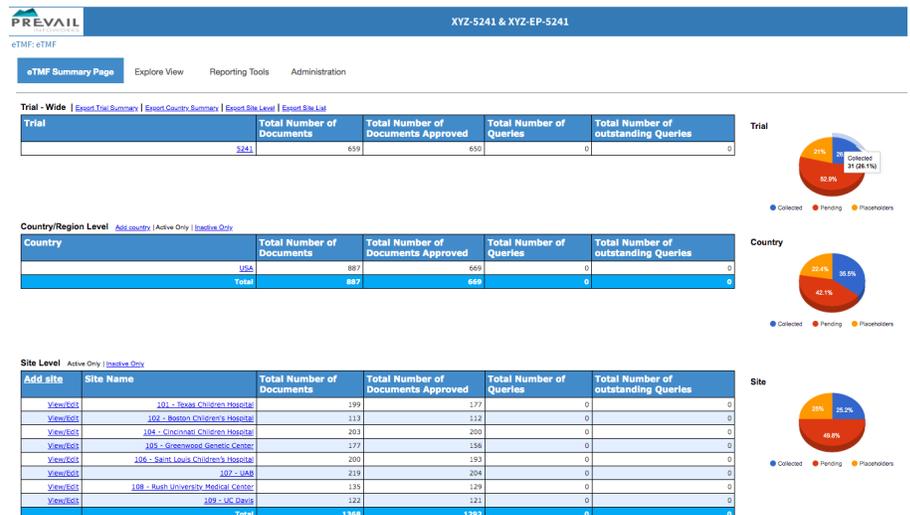
## Quality Check

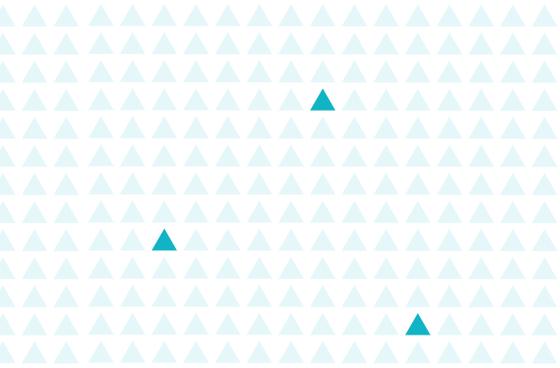
- Review documents for compliance and flag those that are inspection ready
- System-generated reports document quality review activities in real time

## Archive/Availability

- Exportable TMF indexing structure for easy document downloads at any time throughout the project
- Ease of access to archival TMF for compliance with regulatory requirements

The Prevail eTMF user can determine immediately the status of the TMF at any time.





### Key Features & Benefits of Prevail eTMF

The Prevail eTMF provides strategic insights regarding what your study will require for final submission, when those documents will be generated during the conduct of the trial, and the party that will be responsible for generating them before the study has even started.

The Prevail eTMF user can determine immediately what documents may be outstanding, where they can/will be sourced, where they would be filed, and contains applicable performance metrics to monitor status for all functions. Users have the option of configuring their TMF based upon industry-tailored template structures, or configure the platform to make it their own.

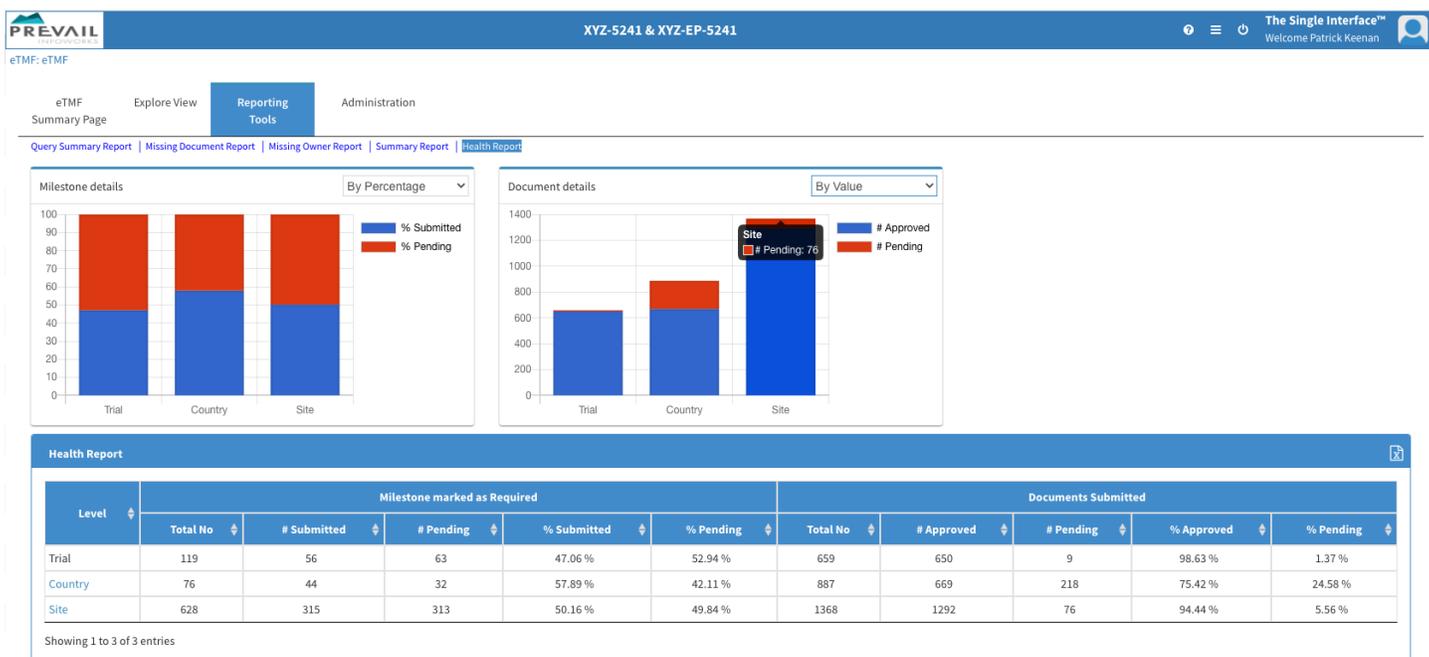
Expedite document configuration through automated, bulk metadata configuration, eliminating the need to apply metadata one document at a time. Expedite study start up by aggregating multiple eTMFs from multiple studies/ systems or use previous folder structures for easy cross-trial reconciliation.

Unparalleled oversight tools are immediately available, providing users access to Query Summary Reports, Missing Document Reports, and Quality Compliance reports, supporting quick and effective oversight on what is required, who is responsible, and what needs to be replaced.

Users have access to a full suite of processing tools tailored that support their individual workflow preferences. Love or hate placeholders, for example? The end user decides whether you use them.

Detailed reporting tools allows users to easily assess TMF status.

Tailored alert management systems ensure study teams receive email notifications for the milestone triggers most important to Sponsors.





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### About Prevail InfoWorks

Prevail is a pioneering life sciences software company with a unique combination of clinical expertise and engineering prowess, delivered through a best-in-class, modular eClinical ecosystem with sophisticated analytics and visualizations and supported by Prevail domain experts.

Our innovative and patented technology quickly and easily integrates, normalizes, reconciles, and presents aggregated data, analysis, trends, and metrics encompassing all study-related data sources through a single interface - making clinical development faster and easier, while reducing trial risk. With Prevail, trial sponsors can obtain unmatched, real-time answers to virtually any clinical, operational, and financial question regarding a study or program.