

Your Leap with BASE AI eTMF Suite

The current state: costly and tedious

Even in a digital age, Trial Master File management remains heavily manual and fragmented. A typical Phase III study can demand over 1,700 FTE hours for scanning, classification, and quality control alone - driving up operational costs and diverting resources from other valuable trial-critical activities.

Inspection readiness is equally challenging. Misaligned data and asynchronous processes caused by complex stakeholder environments and high volumes of data and content lead to incomplete and nonsynchronous Trial Master Files. The typical solution: continuous labour-intensive quality management and EDL updates that increase the risk of non-compliance.

The AI advantage

AI agents deliver innovation where traditional digitalization falls short by introducing intelligent automation and data generation across foundational TMF processes. This spans content classification, quality control, TMF completeness, and inspection readiness. AI agents can:

1. Reduce manual effort
2. Improve accuracy
3. Free TMF teams to focus on strategic, trial-critical activities

AI agents make all of this possible while enabling accurate and timely oversight that drives faster, smarter decision-making.

Putting AI to work in Clinical Trials

BASE life science delivers end-to-end, agentic AI embedded across critical TMF management processes and transforms how TMF operations are executed, monitored, and governed.

Our approach blends business, technology, and scientific expertise to tailor AI to your processes, data, and therapeutic areas ensuring it works in practice and deliver real business value.

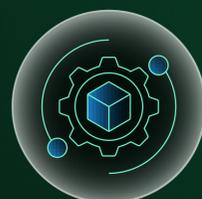
BASE life science AI design principles ensures that each use case is:



Anchored to real
business challenges



Fully embedded
into Vault workflows



Designed across
the R&D value chain



BASE life science AI Offerings for eTMF management



Autoclassification

Simplify TMF document management with eTMF auto-classification. Upon upload, our AI autoclassification tools automatically identify documents, extract critical metadata and instantly populate into the TMF. This reduces manual input, improves accuracy, and ensures every file is correctly classified from the start.



ALCOA + Document QC

Ensure every document in your TMF meets ALCOA+ standards with intelligent, automated quality control. BASE's ALCOA + Document QC assistant identifies critical document quality issues and automates the QI creation to streamline compliance and reducing manual review. Your team gains confidence in TMF integrity while saving time on routine checks.



TMF Risk Management

Adaptive TMF risk management enables users to define document-type risk profiles, apply intelligent randomization mechanisms, and embed risk signals into periodic TMF health reporting. This structured approach delivers actionable insight and oversight, supporting continuous risk calibration and proactive quality management throughout the trial lifecycle.



Automated TMF Health Reporting

Automate periodic TMF health reporting with intelligent summarization and trend insights across completeness, timeliness, and quality. This module dynamically generates and tracks periodic health check issues, enabling users to initiate corrective actions while ensuring full traceability, stronger oversight, and continuous inspection readiness throughout the trial lifecycle.



Dynamic EDL Management

Ensure your clinical trial stays audit-ready with automated updates to expected EDL items - no manual intervention required. Our Dynamic EDL Management tool allows you to manage your expected number of EDL items continuously throughout your clinical and maintaining a gold standard for TMF completeness without the manual burden and risk of misalignment.



TMF Inspection Readiness

Our TMF Inspection Readiness Management Tool enhances trial oversight by identifying misalignments across study parameters and TMF content. It allows for automatic non-compliance detection across study conduct with focus on our most business-critical processes and documents.