

IQVIA eTMF

Leverage industry leading technology and first-to-market innovations to optimize eTMF health

ADVANCED AND INTUITIVE INTERFACE

The IQVIA eTMF delivers the most advanced and sophisticated features and functionality available today. Its progressive UI and UX provide instant insights into eTMF health and include countless automated features to reduce manual efforts, minimize the need for user input, increase efficiency and reduce risk.



Study Setup Wizards

Clients can custom configure their eTMF upfront to meet the specific demands of their study. Wizards prompt a series of questions tailored to study, site, and country. Responses automatically generate placeholders for where artifacts, specific to the study, are uploaded to the eTMF. Clients can identify anything that they would like to adjust, adapt, or expand to align with the needs of each trial.

eTMF as a Factory

Our platform showcases automated processes that make the document workflow more fluid by identifying languishing activities to maintain productivity and avoid backlogs. To support this concept, we automate as many steps as possible to eliminate the need for manual input and reduce the chance for errors in planning and execution, with a partial list including the following:

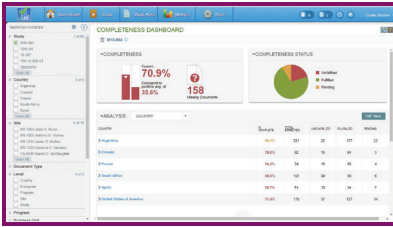
- Automatic Generation of Placeholders for New Investigators
- Automatic Generation of Placeholders for Monitoring Visits
- Automatic Generation of Placeholders for Protocol Amendments
- Automatic Trial Management Timeline Planning
- Auto Creation and Deletion of Sites
- Automatic Language Detection
- Auto-Naming of Documents
- Auto-Population of Metadata

Risk-Based Approach

The clinical landscape requires less people to do more. Since there are thousands of documents in a typical eTMF, it is not practical to evaluate 100%, so risk level is automatically assigned to every document on a scale of 1-10 when placeholders are initially set up. This way clients can prioritize scrutinizing the documents with highest rating for potential failure in the event of an inspection.

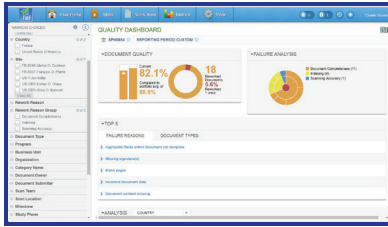
Quality by Design

Our KPI metrics of Completeness, Quality, and Timeliness help clients proactively identify and correct problems and measure results to improve productivity and expedite timelines. Our engineered approach drives a constant vetting of the work being done (whether internally or by CRO partners) to deliver real-time inspection readiness. The IQVIA eTMF provides an instant view of TMF health immediately upon login, without running reports, with one-click drilldown to learn more about TMF health issues.



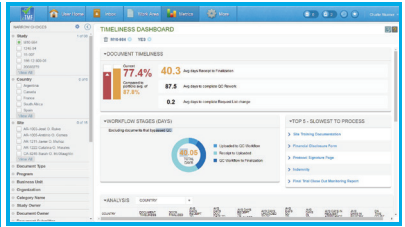
COMPLETENESS

Quickly identify missing and overdue documents based on what should be in your TMF at this point in the trial and take action.



QUALITY

Understand why documents are failing QC and how often they must be resubmitted and corrected.



TIMELINESS

Measure whether documents are being promptly filed and finalized in eTMF once received.

Advanced UI and UX

The IQVIA eTMF platform provides an intuitive web interface, giving users simple, easy to use, dashboards that deliver at-a-glance status overviews. Our system is designed to provide transparency and insight without a lot of drill down. It also offers a consumer-grade user experience with instinctual navigation features that minimize training and maximize efficiency, improving end-to-end productivity while promoting real-time eTMF compliance.

Quick & Lean Implementation

Our accelerator package includes SOP's, Training Modules, a Validation Package, and our Risk Assessment Tool, and is available free of charge, providing a shortcut to victory and allowing full integration with client systems and processes.

Validation Support

IQVIA provides a set of UAT materials at no cost, including a User Requirements Specification, Risk Assessment tool, test plan, test scripts for all User Requirements, and a test summary report designed to be easily adapted by clients to fulfill testing needs and documentation. Full traceability of requirements into test scripts is included, and implementation is accelerated by providing existing templates. Unlike competitors, this service is offered free of charge.

We're in it Together

We share in your vision as true partners, performing as an extension of your workforce and applying new technologies to help ensure ongoing client success. We have successfully migrated customers from every major competitor with no one ever failing to renew. Discover for yourself why we have never lost an eTMF client.

Top 10 Reasons to Choose IQVIA eTMF

1. Industry leading features and functionality
2. State of the art metrics, reports, and dashboards
3. Transparency & insight without drilldown
4. No cost for upgrades & accelerator packages
5. Expert services to assist in managing eTMFs
6. Track record of successful client partnerships
7. World-class support well beyond the sale
8. Clean inspections - no eTMF related findings
9. Industry expertise & thought leadership
10. Lower total cost of ownership