

eTMF Essentials

Take eTMF ownership with a leading regulatory-compliant system on any budget

The challenge

Clinical operations teams recognize that the eTMF (electronic Trial Master File) is one of the most important technologies employed in clinical trials, because it tells the story of how the clinical trial was conducted. Small to mid-sized pharmaceuticals and biotech companies often rely on their CRO to prepare the eTMF. Typically, the CRO bears little to no responsibility in the eyes of the regulatory authority, with full responsibility and accountability placed on the sponsor.

The primary barrier keeping small and mid-sized life science organizations from having their own eTMF is cost. Beyond the cost to license the application, there are also all the expenses associated with implementation, validation and the human capital required to maintain and manage an eTMF. Smaller sponsors need an affordable eTMF option enabling them to conduct and manage their clinical trial more effectively and efficiently.

The solution

IQVIA addresses this challenge with eTMF Essentials, an offering that leverages the industry leading IQVIA eTMF (formerly known as Wingspan). With its ease of use and functional dashboards, this solution guarantees inspection readiness at an affordable total cost of ownership.

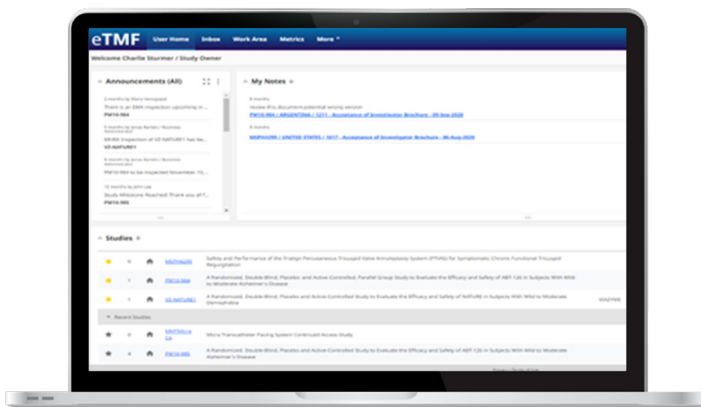
What it includes:

IQVIA eTMF Application

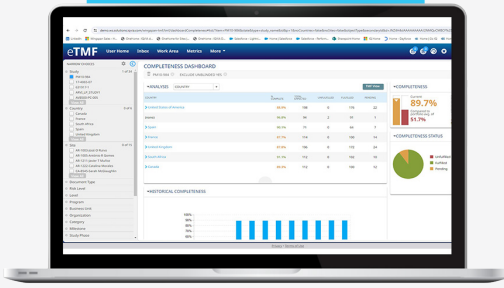
Through an intuitive web interface, IQVIA eTMF gives users simple, easy-to-use dashboards that deliver at-a-glance status overviews. Our system is designed to provide transparency and insight without layers of drilldown. It also offers a consumer-grade user experience with instinctual navigation features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

Easy implementation

Our accelerator package includes SOPs, 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. Due in large part to the accelerator package and our streamlined process the implementation for eTMF Essentials can require as little as two weeks.

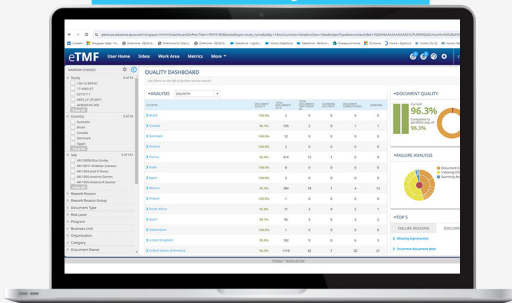


Completeness



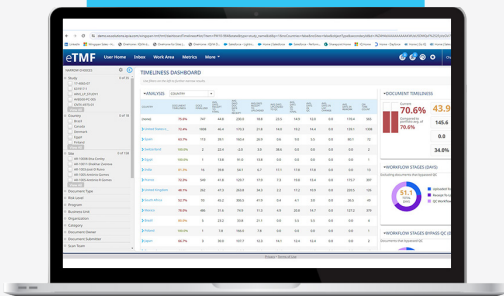
Quickly identify missing and overdue documents based on what should be in your TMF at this point in the trial and take action.

Quality



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

Timeliness



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

Dashboards and more

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 quality-by-design engineered approach drives a constant vetting of the work being done (whether internally or by CRO partners) to deliver real-time inspection readiness.

IQVIA eTMF provides an instant view of TMF health immediately upon login, without need to run reports, offering one-click drilldown for details on TMF health issues out of the box. eTMF Essentials allows you to track documents from clinical trial startup to closeout. We even have a built-in workflow that allows you to move a study from active to archive where it can be held for up to 25 years.

Support and services

IQVIA shares in your vision as true partners, performing as an extension of your workforce and applying new technologies to help ensure ongoing client success. We can lighten your load by providing on-demand TMF services. Having successfully migrated customers from every major competitor, we help with scanning, document upload, QC, TMF management, inspection preparation, and much more. Discover for yourself why IQVIA has never lost an eTMF client.

Reduced total cost of ownership

When you choose eTMF Essentials, you get an industry-leading solution where you can expect low total cost of ownership. Implementation costs are minimal, software subscription is very competitive and administration, maintenance and day-to-day operations are covered by IQVIA's eTMF expert services and customer support teams at minimal yearly costs.

Contact

Schedule a consultation about IQVIA's eTMF solutions and a calculation of the total cost of ownership for you.



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