eTMF Master | Trial Master File

eTMF Master FAQs

What is eTMF Master?

eTMF Master is a powerful, regulated clinical content management solution from Anju that lets you easily maintain and manage your Trial Master Files, which are collections of all documents, images, and other content that are mandated by regulatory authorities to be collected during the conduct of all clinical trials.

Who can use eTMF Master?

Clinical trial sponsors, CROs, and Investigator Sites that are participating in clinical trials can use eTMF Master for their Trial Master File content management needs.

How is eTMF Master accessed?

eTMF Master is a cloud-based application that can be hosted on various cloud platforms. This provides a high level of flexibility and scalability for customer implementations. Users can log on to eTMF Master via any standard supported internet browser.

Does eTMF Master support industry standards for clinical trials?

eTMF Master supports the TMF Reference Model, which provides an industry-standard taxonomy and metadata for Trial Master Files and outlines a reference definition of TMF content. As per this model, the system sets up a folder hierarchy of zones, sections, and artifacts. By default, the application currently supports the TMF Reference Model version 3.1 but it can be configured as necessary when setting up the TMF for each clinical trial.

Does eTMF Master meet regulatory compliance standards?

eTMF Master is a fully validated system that is compliant with all applicable regulatory standards and guidelines, including GxP and 21 CFR Part 11.

Is eTMF Master based on a content management platform?

eTMF Master is based on AnjuSafe, a powerful enterprise content management platform for life sciences that provides all standard content management functionalities, including document upload/classification/approval, workflow management, version control, metadata management, role-based access, folder and document level security, and powerful content administration.

Can eTMF Master be used by different organizations involved in a clinical trial?

eTMF Master can support users from study sponsors, CROs, and Investigator Sites. Each user or group has permissions to perform specific actions on a particular clinical trial TMF and each can perform their actions on designated folders or documents in the TMF structure.

Is eTMF Master inspection-ready?

All finalized documents in eTMF Master are inspection-ready and can be audited and inspected by sponsors or regulatory authorities at any time. Auditors can be provided with access to view only the approved versions of documents in the TMF.

How can I determine the overall health of my TMF?

eTMF Master provides actionable dashboards for common TMF health metrics such as Completeness and Timeliness. Using these dashboards, you can easily gauge the overall status and performance of your study TMF, or drill down to get insights per country, site, or study milestone.

How does eTMF Master support study milestones?

For each study, eTMF Master maintains a list of standard study milestones (as defined in the TMF Reference Model) and provide metrics on TMF document status by milestone. Milestone dates can be updated, if necessary, depending upon the progress of the study.

How does eTMF Master manage different types of metadata for trial documents?

eTMF Master manages metadata at the study level (e.g., protocol and other study details) as well as at the individual document and folder levels. Standard study, document, and folder attributes are system-defined at the time of study set-up and represent relevant attributes that you need to maintain for each study's TMF.

How do I know what documents are missing from my TMF?

When a study structure is initially set up via an easy-to-use interactive process, eTMF Master can create a placeholder for each expected document in the TMF. Documents can be uploaded into the system to replace the appropriate placeholders. At any given time, placeholders represent missing but expected documents in the TMF. An intuitive dashboard provides real-time visibility into missing documents.

How do I find a particular document within my TMF?

eTMF Master provides a powerful search functionality that you can use to quickly find the relevant documents. Search results can be exported in standard formats such as PDF or Excel.

How do I ensure that my documents are properly classified and filed in the TMF?

eTMF Master provides intuitive workflows for the classification, review, and approval of a document. Workflow tasks can be assigned to users or groups who receive notifications/alerts for pending workflow tasks. Documents can also be moved or re-classified to a different country, site, zone, section, or artifact in the TMF structure if they have been incorrectly classified.

How are actions on documents tracked?

eTMF Master contains a comprehensive audit trail that tracks all activity on documents and workflows, and records the username, date and time, and details of the activity. The audit trail logs can be viewed by TMF administrators and they cannot be modified.

Does the system support electronic signatures?

eTMF Master supports electronic signatures for the approval of all documents. Electronic signatures are associated with a specific document version and they are also attached to printed, approved documents.

How do I manage multiple versions of a document?

eTMF Master supports strict document versioning. Minor and major versions are defined and maintained based on the completion of workflow tasks on a document. For example, uploading or editing a document can create a minor version, and final approval of the filing of a document can create a major version.

How can I edit documents within eTMF Master?

eTMF Master provides in-app Office 365 compatibility, so you can easily edit and view Word documents. The integrity of document changes is maintained by locking a document while it is being edited by a user so that no concurrent changes can be made by other users.

Does eTMF Master allow mapping of content and data from other clinical applications?

eTMF Master is part of Anju's adaptive eClinical suite of products, and provides APIs that can support bringing together information from other Anju applications as well as other sources to be mapped into your TMF.

eTMF Master is a product of Anju

Anju provides adaptive technologies for clinical trials, medical affairs, and data with world-class customer support. Leveraging AI and data-driven analytics, our leading suite of solutions with data and application integration capabilities serves the worldwide pharmaceutical, biotech and contract research Life Sciences markets.

Learn more about Anju's eClinical solutions. Scan the QR code

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