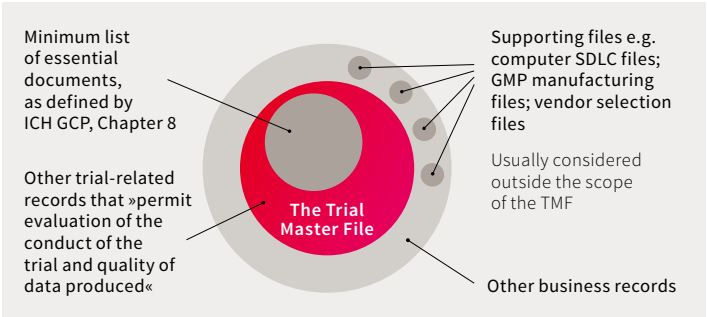
OpenText Documentum For Life Sciences – Electronic Trial Master File (eTMF)

fme's Offering

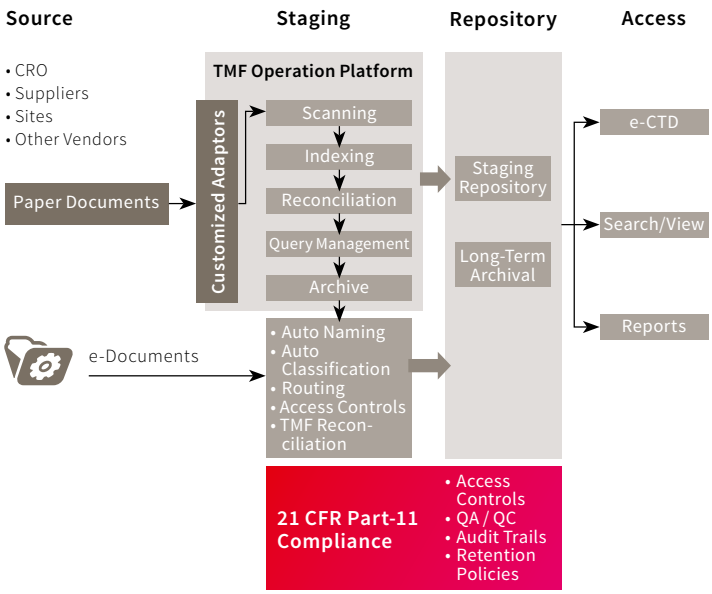
Trial Master Files (TMF) documents are Good Clinical Practice (GCP) pharmaceutical records that contain essential documents, established at the beginning of the clinical trial life cycle, which are subject to regulatory agency oversight. The DIA has given recommendations on how to organize the TMF with respect to artifacts, meta-data, document naming, versioning, creation methods and folder structures, etc. However, there are still many areas which have not been defined in any sufficient depth – e.g., maintenance of essential documents, exchange procedures, and electronic signature standards.

fme has gained substantial experience over the years especially in consulting with pharmaceutical companies to implement new systems supporting the management of Trial Master Files.

1. Assessing which content is to be migrated, archived and/ or destroyed
2. Proper indexing of TMFs to help integrate with corporate taxonomies and data standards designed for streamlining records management, current retention policies, and potential legal hold requirements
3. Developing business use cases for content migrations and data governance work streams
4. Verify ETL and test data migrations (with support from our Information Analytics and Remediation solution and its accelerators)
5. Discovery and re-engineering of inadequate functional TMF processes
6. Reconciling and remediating paper records and electronic copies (on average 40.9 % of companies)
7. Transforming information to the industry-driven Drug Information Association (DIA) TMF Reference Model



TMF core and supporting elements



A CTMF migration adhering to the TMF Reference Model

With fme's TMF solutions we assist our client's ability to effectively plan, collect and maintain essential clinical trial documentation. TMF Management is challenging and, at times, risky especially as Life Sciences companies continue to offset costs by relying on clinical research organizations (CRO) for the majority of clinical trials. fme partnered OpenText Documentum Electronic Trial Master File (eTMF) solution, as part of the OpenText Documentum for Life Sciences solutions, enables Life Sciences organizations to easily and effectively control and synchronize study artifacts, track progress in clinical trial documentation, and ensure fast, secure access to documentation both during and after the trial.

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