
Delivering inspection-ready Trial Master Files with a centralized service model



Trusted partner for your Digital Journey

Atos | **Syntel**






Achieving an inspection-ready Trial Master File (TMF) with complete insight into quality, completeness and timeliness is a top-priority for sponsor organizations. However, meeting these requirements can be a difficult and time consuming task.

To ensure you can deliver inspection and submission-ready TMFs, your eTMF operations must be designed to ensure the following needs are met:

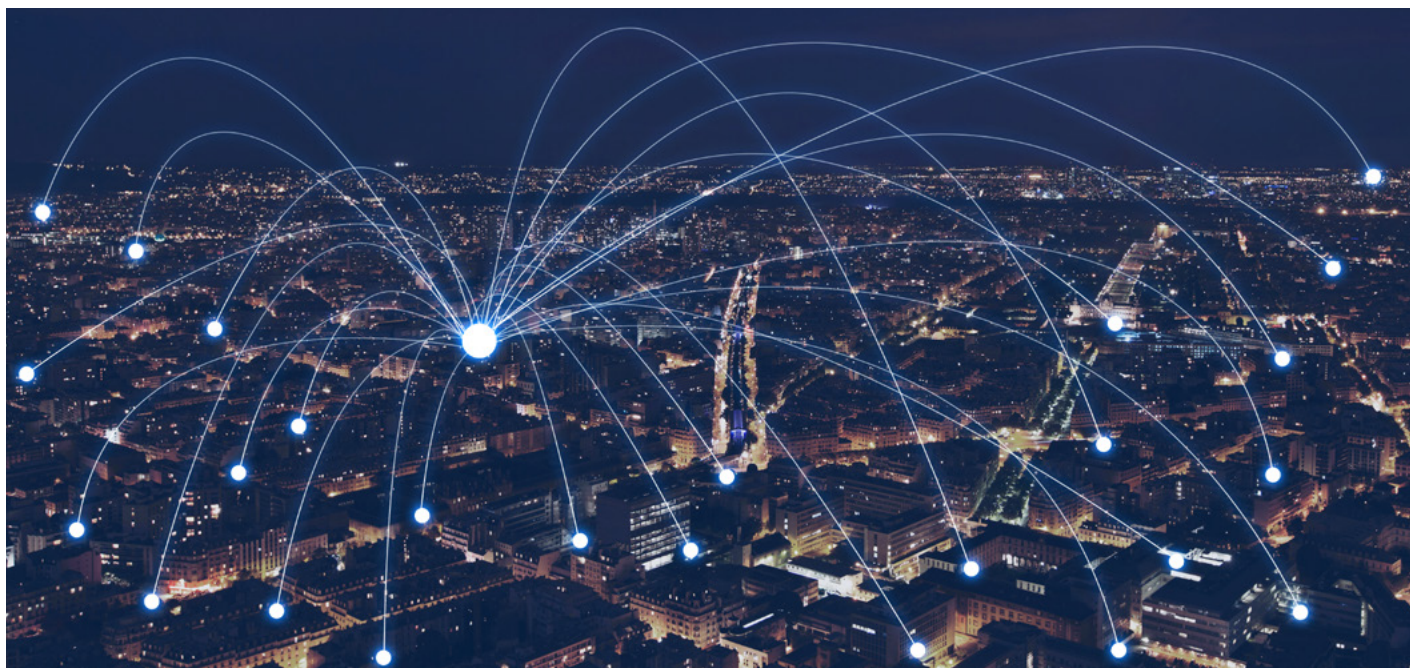
- They are **compliant** with existing and new regulations
- They deliver the highest document metadata **quality and accuracy**
- Internal and external stakeholders have **full oversight**
- Your records management process is **lean and sustainable**
- You can **effectively manage collaboration** and Contract Research Organization (CRO) relations

AtosSyntel solution

AtosSyntel has designed a trial master file (TMF) management solution that leverages a **centralized managed services model** with a clear governance plan and metrics to ensure the correctness, completeness and timeliness of TMF documents. Our end-to-end suite of TMF services includes:

TMF Consulting 	TMF Operations (Paper & Electronic) 	TMF Governance 	Digital Services 	Transformation Services 
Change management	Paper TMF digitization	TMF oversight	eTMF tool implementation & maintenance	AI, ML, NLP, big data enabled process automation
Regulatory consulting	Archival/retrieval requests	Quality management	Integration & migration support	Automated eTMF metadata extraction
Technical redesign	M&A support	Audit and inspection support	Cloud enablement	Independent quality control (closed & ongoing studies)
Digital transformation	eTMF operations	Pharma regulation compliance	M&A support	RPA-based document upload
	Submission support			

Our services are delivered in a highly efficient, centralized managed services model, with nearly 700 experts working with CROs in 50+ countries. Our TMF management team consists of physicians, pharmacists, clinical researchers and associates who have a deep understanding of CRO operations.



AtosSyntel managed services model



We follow every individual TMF plan and maintain a full traceability matrix with powerful dashboards to provide sponsors with full TMF health insights.

Business benefits

- Consistent, inspection and submission-ready TMFs
- Improved quality, with 98+% quality accuracy
- 30+% cost reduction with industry-best processes and automated workflows
- Faster turnaround time, with documents processed/finalized within 48 hours
- Improved compliance through a dedicated global team trained on standard operating procedures and work instructions

Why AtosSyntel?

- Strong remote support capabilities for distributed workforces
- Mature TMF capabilities with in-depth knowledge of eTMF systems, reference models and ICH GCP E6 guidelines
- 12+ years of strong clinical domain experience with life sciences clients
- Highly scalable and flexible eTMF model
- Powerful automation-driven TMF processes that ensure high data quality by reducing manual effort and manual errors
- Independent quality control: achieving uncompromised and unbiased data quality and integrity with robust QC and QA processes

AtosSyntel in action

Automated metadata extraction for eTMF migration support

AtosSyntel collaborated with a top 5 life sciences organization to migrate its TMF documents to a new platform. We implemented a human-guided, AI-enabled metadata extraction process to optimize the workflow and improve accuracy. Our innovative process enabled a massive repository with 1,000+ document types to be migrated 40% faster, meeting the client's tight timeline.

Cloud-based eTMF platform implementation and support

We executed a data migration, helping the client transition to an industry-leading cloud-based eTMF platform that acts as a centralized document management system for TMF and clinical documents. The productivity of the migration process was boosted by our detailed cause code and effort analysis. In addition, AtosSyntel deployed an analysis team to execute a post-migration data verification to ensure the accuracy of the migration.

End-to-end TMF management operations

AtosSyntel currently provides 24/7 global TMF operational support for a top 10 global pharmaceutical company. The client had experienced delays in document retrieval that were impacting audits and inspection. We stepped in to prioritize the documents according to criticality, then implemented quality check gates across the process, ensuring the highest quality deliverables. Our solution increased productivity by 23% by reducing manual efforts and implementing centralized quality controls, and provided an optimal balance between quality, speed and cost

About Atos|Syntel

Atos|Syntel is a leading provider of integrated digital and knowledge process services and a member of the Atos Group, a global leader in digital transformation with 110,000 employees in 73 countries and annual revenue of €12 billion. We help enterprises accelerate their digital journeys, increase agility and business performance, evolve to “Digital native” standards, and deliver scale and flexibility for the Digital Age.

Atos|Syntel unites Atos's scale and world-class technology capabilities with Syntel's industry focus, global delivery model, and services powered by intelligent automation.

Learn more at: www.atos-syntel.net

Let's start a discussion together

