Implementing a Scalable eTMF Model for Faster Clinical Trials and Drug Launches

Clinical records need to be produced in a timely manner for inspections and audits, but for many life sciences, medical devices, and research organizations, meeting such requirements is a difficult and time consuming task.
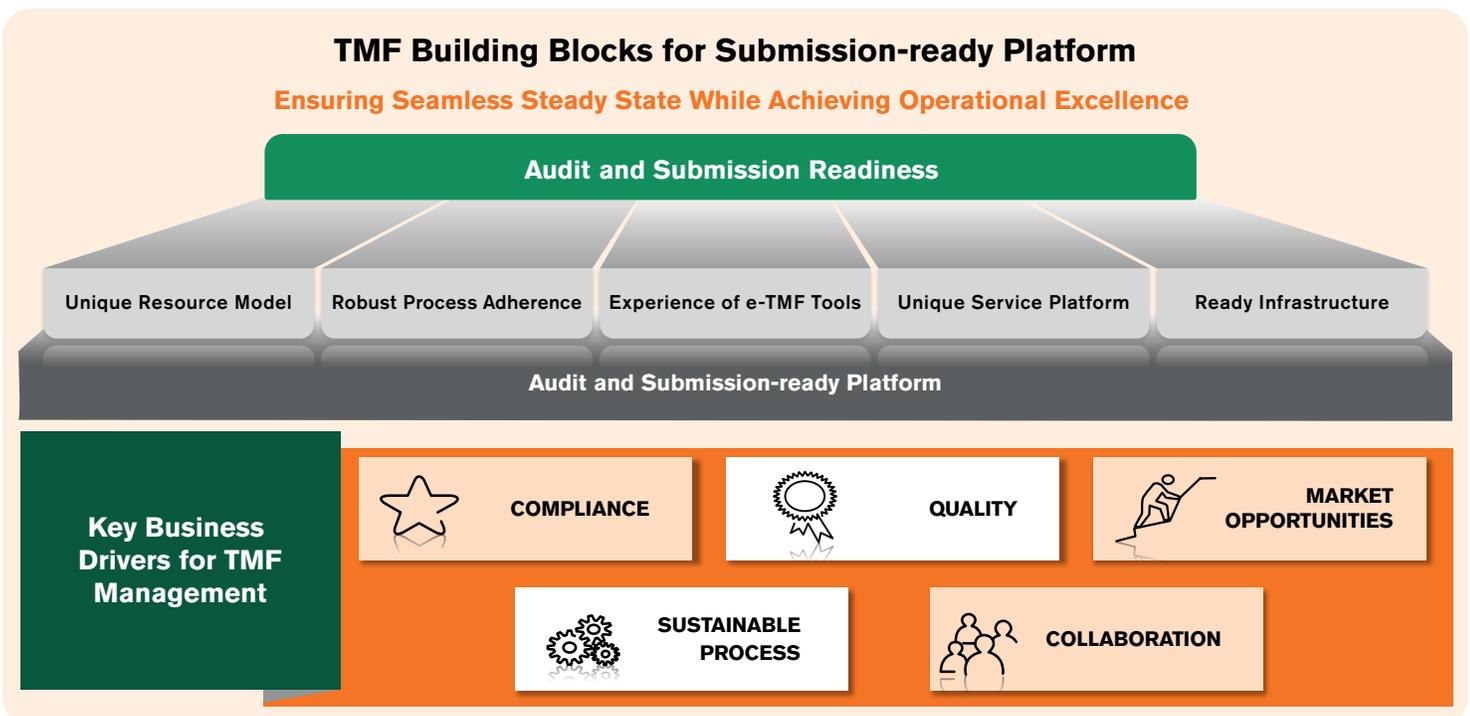
Due to the collaborative nature of producing requirement documents, organizations need an end-to-end operational model that leverages an efficient document management system and a centralized team to coordinate with internal and external stakeholders.

Syntel's Solution

Syntel has designed a trial master file (TMF) management solution that leverages a **centralized managed services model** to overcome the data, process and innovation-related issues of conducting clinical trials in an evolving digital world.

Syntel's TMF management team consists of physicians, pharmacists, clinical research associates and allied science graduates who have a deep understanding of CRO operations. Syntel employs industry-standard processes, teams of domain experts, and the latest technology to provide our clients with services like:

- TMF consulting
- Digitization
- Business operations
- Document migration
- Inspection and audit support
- Digital modernization
- Service desk and IT support

TMF Building Blocks for Submission-ready Platform

Ensuring Seamless Steady State While Achieving Operational Excellence

Audit and Submission Readiness

Unique Resource Model	Robust Process Adherence	Experience of e-TMF Tools	Unique Service Platform	Ready Infrastructure

Audit and Submission-ready Platform

Key Business Drivers for TMF Management

- COMPLIANCE
- QUALITY
- MARKET OPPORTUNITIES
- SUSTAINABLE PROCESS
- COLLABORATION

BUSINESS BENEFITS

- **Launch drugs faster** by accelerating the processing of clinical trial documentation

- Leverage the SyntBots® automation platform to **achieve a 20%+ increase in productivity**

- **Ensure data quality** by reducing manual effort and manual errors

- **Reduce operations costs by 25%** with industry-best processes and workflows

- **Better data quality control and compliance** in a centralized document repository

Syntel has a wealth of experience managing both electronic and paper TMF to ensure data quality, regulatory compliance and inspection readiness. In our work with leading life sciences companies, we have collaborated with Contract Research Organizations (CROs) across the globe to meet FDA and MHRA audit requirements.

Another key step that life sciences companies must take is to proactively identify emerging technologies and TMF models that may disrupt the industry. With Syntel's transformational approach, your operations are shifted to a centralized managed service model with **standardized processes, greater transparency**, and **improved quality control** — all of which enable **better agility and responsiveness** to evolving requirements and market drivers.

Solution Highlights

- **Strong clinical domain experience:** 10+ years of experience with life sciences clients
- **Mature TMF capabilities:** In-depth knowledge of eTMF systems, TMF models, ICH GCP E6 guidelines, TMF Reference and OASIS Models
- **SyntBots automation:** IT tools and accelerators, robotic process automation and cognitive computing to automate repetitive manual processes
- Independent quality control: Achieve uncompromised and unbiased data quality and integrity with robust QC and QA processes
- LEAN methodologies: Higher productivity and efficiency with emphasis on continuous improvement

Why Syntel?

- **Size, Scale and History** - 23,000+ associates at 30+ offices on four continents; Stable and profitable since 1980 (NASDAQ: SYNT)
- **Solutions for the Digital Age** - Evolve the core to drive efficiency, agility and value; Go digital to engage customers, discover new insights and create a more connected enterprise.
- **"Customer for Life" Philosophy** - Focus on world-class customer service with the agility to meet changing client needs
- **Investing in Excellence** - Sustained investments in world-class facilities, domain expertise, IP-based solutions, tools and accelerators
- **Integrated IT and KPO** - Tight technology and process alignment; Industry and domain-focused solutions

About Syntel

Syntel (Nasdaq:SYNT) is a leading global provider of integrated information technology and knowledge process services. Syntel helps global enterprises evolve the core by leveraging automation, scaled agile and cloud platforms to build efficient application development and management, testing and infrastructure solutions. Syntel's digital services enable companies to engage customers, discover new insights through analytics, and create a more connected enterprise through the internet of things. Syntel's "Customer for Life" philosophy builds collaborative partnerships and creates long-term client value by investing in IP, solutions and industry-focused delivery teams with deep domain knowledge.

To learn more, visit us at: www.syntelinc.com

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