The EMC Documentum for Life Sciences eTMF Solution enables key clinical trial objectives:

**Risk Management**
- Quickly identify missing documents
- Ensure timely trial start
- Proactively prevent document-related trial delays

**Compliance**
- Align trial documentation to the DIA TMF reference model
- Simplify and accelerate response to regulatory inquiries

Driven by skyrocketing clinical trial costs, which have grown over 70% since 2008, Life Sciences companies now rely on contract research organizations (CROs) for the vast majority of clinical trials. While this reduces costs, it increases the complexity of trial document management. The additional coordination required to collect and maintain trial documents can expose both Sponsor organizations and the CROs themselves to compliance risk.

To help Life Sciences companies manage clinical trial documentation and establish consistent records management practices across the entire virtual research organization, EMC has created the EMC® Documentum® for Life Sciences eTMF Solution, the newest addition to the growing portfolio of solutions in the Documentum Life Sciences Solution Suite.

**EMC DOCUMENTUM FOR LIFE SCIENCES eTMF SOLUTION**

This single source, enterprise-class solution ensures that clinical trial teams can easily and effectively track progress in trial documentation, control and synchronize study artifacts, and ensure fast, secure access both during and after the trial.

**COMPLETE eTMF MANAGEMENT**

- **Comply with Good Clinical Practice (GCP) more easily** with a TMF management system that implements the DIA TMF reference model v2.0
- **Accelerated Trial Start**: Quickly set up trials with reusable templates, and ensure your regulatory package is complete and ready for IRB approval.
- **Improved Visibility Into Trial Activities and Progress**: Plan and manage trials across multiple stages using automated progress tracking, milestone notification, and risk assessment
- **Simplified access and retrieval of trial documents**: Electronic documents and status reports simplify synchronization of site, CRO, and Sponsor TMFs. Rich search features enable immediate location of electronic documents for audits and regulatory reviews.
- **Easily Integrate document sources**: Solution provides bulk ingestion of TMF documents from file system, the ability to export, import, and re-use TMF template configurations, and a services layer for CTMS integration

**UNIFIED PLATFORM FOR DOCUMENT MANAGEMENT**

The eTMF solution includes the Control Configuration for Life Sciences - a platform that provides governance, tools, document control functionality and embedded industry models for consistent document handling across the entire Life Sciences product lifecycle. The platform is designed to support an expanding solution portfolio from EMC and its partners.
The Documentum Life Sciences Document Control platform provides:

- DIA EDM and TMF Reference Model-based Information Architecture, including industry defined data model, dictionaries, and taxonomies.
- Enablers for 21 CFR PART 11 compliance including Electronic Signature capabilities, automated policy enforcement and full audit trail.
- Flexible lifecycles and workflows with four levels of control mapped to DIA EDM and TMF reference model artifacts.
- View, export, and print controls for managing controlled documents.

**EASE OF USE**

Trial Managers, Clinical Document Authors, Trial Librarians, and Clinical Investigators have role-based views of the eTFM portal, with configurable role-based access to documents. Users also have a choice of interfaces including the intuitive D2 Client, SharePoint, or mobile.

Automated checklists and status and risk reporting help ensure documentation is always complete, and simplify eTMF creation, maintenance, and synchronization.

**ENTERPRISE CLASS**

The Documentum Content Management Platform and Documentum D2 technologies that underlie the EMC Documentum Life Sciences Solution Suite have been road-tested and proven at thousands of large enterprises around the globe and applied to the most mission-critical applications. The eTMF is:

- Highly scalable to the requirements of a global enterprise.
- Fully integrated across domains.
- Backed by EMC’s global support organization and global ecosystem of thousands of skilled professionals.

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**THE EXPANDING EMC DOCUMENTUM FOR LIFE SCIENCES SOLUTION SUITE:**

Applications currently available and planned for the suite include:

- eTMF
- Quality and Manufacturing
- R&D
- eSummissions

New solutions are being added based on EMC customer needs.

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EMC Documentum for Life Sciences Solution Suite
FAST TIME TO VALUE WITH EMC SERVICES

The design and delivery of the eTMF solution ensure rapid deployment, eased upgrades aligned with Documentum releases, and ongoing success and value. D2 technology is highly configurable, enabling rapid initial set-up and quick changes to respond to evolving business needs while reducing the cost of validation as the system evolves.

ONDEMAND OFFERS LOWEST TCO, FASTEST TIME TO VALUE

Life Sciences customers have the choice of traditional on-premise or a dedicated cloud OnDemand deployment. With either option, the EMC Consulting organization has created services that ensure your lasting success with the solution.

The OnDemand deployment is implemented and maintained by experts in Enterprise Content Management and EMC technologies, ensuring you always have access to a high-performing, secure system with capabilities from our latest software releases. Combining best-in-class technologies from VMware, RSA®, and EMC, OnDemand increases your business agility, saves time and maintenance costs, and improves IT efficiency.

IMPLEMENTATION

Using best practices-based implementation accelerators and years of Life Sciences experience, the EMC Consulting implementation teams employ an established toolkit to develop specifications, technical designs for integration, and test plans. EMC consultants use a collaborative, iterative implementation process that includes workshops, joint review sessions, prototypes and education classes to configure the solution for your business, and train administrators and users.

MIGRATION

To ensure a low-risk transition, EMC Services brings a certified migration methodology and toolset to convert an existing content repository instead of migrating wherever possible. When migration is required, the DIA Reference Model foundation standardizes metadata mapping thereby enabling accurate Migration Plans, clarified Migration Verification, easily authored Migration Scripts, and Migration reports. Throughout, the EMC consulting team maintains migration logs and an audit trail.

VALIDATION

No system is complete without validation. For both traditional and OnDemand deployments, EMC provides validation documentation packages and services. This includes a validation package with

- A validation plan template
- User Requirement Specification (URS)
- User Acceptance Test (UAT) Plan Template
- UAT test scripts
- User Acceptance Test Report Template
- Trace Matrix (URS to UAT)
- Validation Report Template
- IQ Checklist for LSQM

GETTING IT DONE

- 30-40% faster deployment with Documentum D2
- Simplified future validation
- OnDemand and Traditional deployment options
D2’s native capabilities to generate configuration records, configuration deltas, and serialized installation files dramatically simplify the change control process, enabling innovation and improvements that would be cost-prohibitive with other systems.

INTEGRATION AND PROGRAM MANAGEMENT

EMC Consulting also offers a full portfolio of business services including

- Business case & ROI development
- Process re-engineering
- System harmonization analysis
- Architecture & work stream planning
- Business and user requirements analysis
- Program governance development & control

GETTING STARTED

To find out more about EMC Documentum for Life Sciences eTMF Solution and the Life Sciences Solution Suite, please email EMCLifeSciences@emc.com.

CONTACT US

To learn more about how EMC products, services, and solutions can help solve your business and IT challenges, contact your local representative or authorized reseller—or visit us at www.EMC.com.