FACT SHEET

LifeSphere eTMF™

KEY BENEFITS

- Maintains visibility, status and control of trial documentation
- Improves readiness for audits and inspections
- Enables faster and more efficient site setup and initiation
- Ensures file structure and organization quality with support for the DIA TMF Reference model
- Delivers significant time and labor cost savings compared to paper-based TMF approach
- Streamlines key business processes through integrated workflow
- Enables easy search, retrieval, reporting and status overview of documents
- Fully integrated with agClinical™

A typical clinical trial necessitates the collection, organization, tracking and archiving of thousands of essential trial documents. As such, providing controlled access to essential study documents, known as the Trial Master File (TMF), is no easy task. The time and labor-intensive method of using paper-based or file-share based electronic file cabinets and Excel spreadsheets to store, organize and track the TMF are giving way to electronic, cloud-based electronic Trial Master File (eTMF) solutions that help meet GCP regulatory requirements, all while lowering costs and expediting critical process steps such as setup of sites.

LifeSphere eTMF™

LifeSphere eTMF is an eTMF solution that serves as the centralized, global repository for managing, organizing, storing, accessing and archiving all trial-related documents. It is 21 CFR Part 11 compliant and helps to ensure readiness for audits and inspections. Complete sponsor and investigator files including list of all expected and required documents can be rapidly created for each study.

Easy, Fast TMF Setup

The structure and the content of the TMF may vary from one study to another based on factors such as therapeutic area, type of study (investigator-initiated versus sponsored trial) or sponsor. LifeSphere eTMF allows companies to define multiple TMF templates so the study manager can select the appropriate template and modify it to any study's specific needs. LifeSphere eTMF will then automatically create the folder structure for the TMF as well as a list of all expected documents for each study, country or site. Study managers can easily identify documents required and documents still missing.

Full Document Management Combined with Clinical Trial Logic

LifeSphere eTMF supports the full lifecycle of each document. Authors can upload new documents and start a workflow-driven, review and approval process. Documents are version controlled with specific metadata and attributes. Once approved, they are then rendered as submission-ready PDF documents.

LifeSphere eTMF provides context-sensitive document management capabilities that manage, present and store documents according to their relations to clinical operations contexts, such as projects, processes, products, countries, sites, IRBs/IECs, persons, organizations, investigators

LifeSphere Clinical™ - eClinical Platform
LifeSphere EDC™
LifeSphere CTMS™
LifeSphere Investigator™
LifeSphere Trial Disclosure™
LifeSphere Central Coding™
LifeSphere eTMF™
LifeSphere SUSAR Reporting™
LifeSphere eCOA™
LifeSphere RTSM™
agWorld™ - eCIlnical Portal

or regulatory agencies. This allows sponsors to use LifeSphere eTMF to effectively use the document management function to support trial management processes such as identifying required documents in the green light process

Easy and Rapid Document Retrieval

LifeSphere eTMF retrieves documents rapidly using powerful search criteria that enables rapid access to documents in the system, regardless of the status. Access to documents is tightly controlled based on user roles and study privileges. Documents can be made read-only and specific documents can be made available at any level of the program hierarchy, eliminating potential security concerns and navigation issues.

Fully Validated

LifeSphere eTMF ensures inspection readiness at all times as all documents are kept in a controlled environment. The dashboard and comprehensive reports provide users with a thorough overview and status of complete trial documentation for a given study. Templates and pre-defined workflows are provided to comply with a sponsor's SOPs and ensure a fast and efficient review of each document.

Integration with LifeSphere CTMS and LifeSphere Investigator Portal

LifeSphere eTMF integrates out of the box with LifeSphere CTMS and LifeSphere Investigator Portal, ArisGlobal®'s CTMS and investigator site portal solutions, helping clinical operations teams reduce data entry efforts and ensure the consistency of data in a way that stand-alone applications cannot offer.

Quick Deployment with Hosted Offering

Delivered as a hosted SaaS solution, LifeSphere eTMF is deployed fast and eliminates the investment in new hardware, software and application, as well as infrastructure support staff.

ABOUT ARISGLOBAL®

ArisGlobal is a visionary technology company that's transforming the way today's most successful life sciences companies develop breakthroughs and bring new products to market. The ArisGlobal LifeSphere™ cognitive technology platform integrates machine-learning capabilities to automate the core functions of the product lifecycle. Designed with deep expertise and a long-term perspective that spans more than 30 years, our cognitive platform delivers actionable insights, boosts efficiency, ensures compliance, and lowers total cost of ownership through multi-tenancy.

Headquartered in the United States, ArisGlobal has regional offices in Europe, India and Japan. For more information, visit arisglobal.com or follow ArisGlobal on LinkedIn and Twitter.

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