



LifeSphere® eTMF

Real-time quality and completeness

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ArisGlobal is a leading provider of SaaS solutions for the life sciences industry



30 years of innovation in R&D technology solutions



Building the industry's best end-to-end drug development platform



Global company with strong presence among industry leaders

300+
Customers

40 of the Top 50 Pharma 6
Regulatory Authorities

MIAMI HQ

With offices
in 11 countries

20%

Year to Year
Growth

1200+

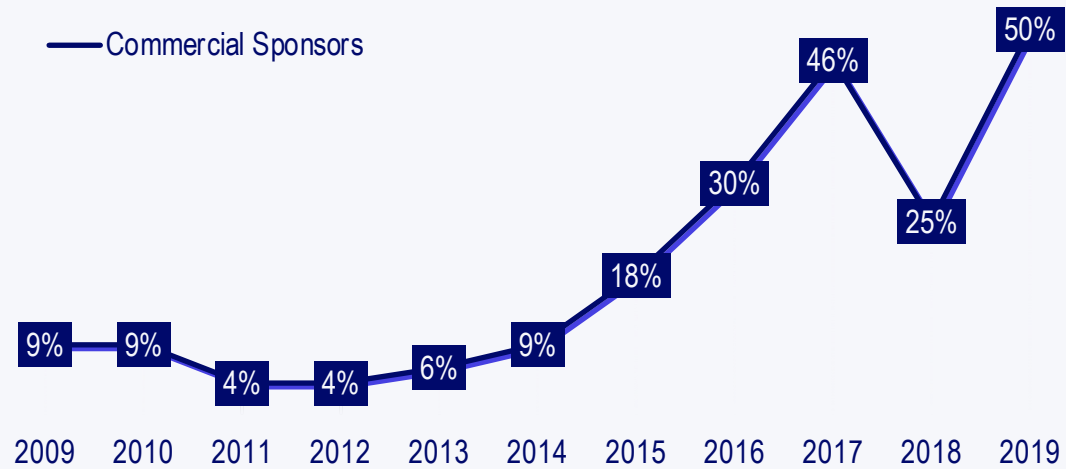
Global
Employees

Placeholder (Customer Priorities)

A hand wearing a blue nitrile glove holds a clear plastic test tube containing a yellow liquid. The test tube has measurement markings. In the background, a person in a white lab coat is blurred, and a rack of other test tubes is visible on the right.

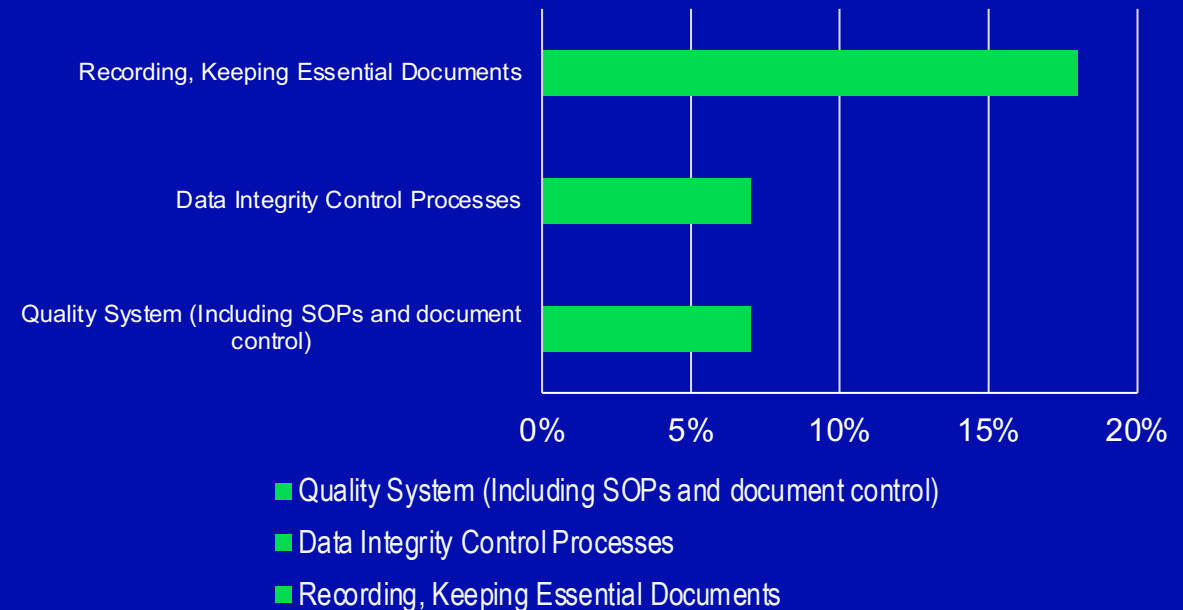
**GCP inspection
failures increasing**

**More pressure on
Clinical Operations**



Percentage of inspections with at least 1 critical finding

Essential Documents are the #1 source of major findings





Current eTMF systems are failing

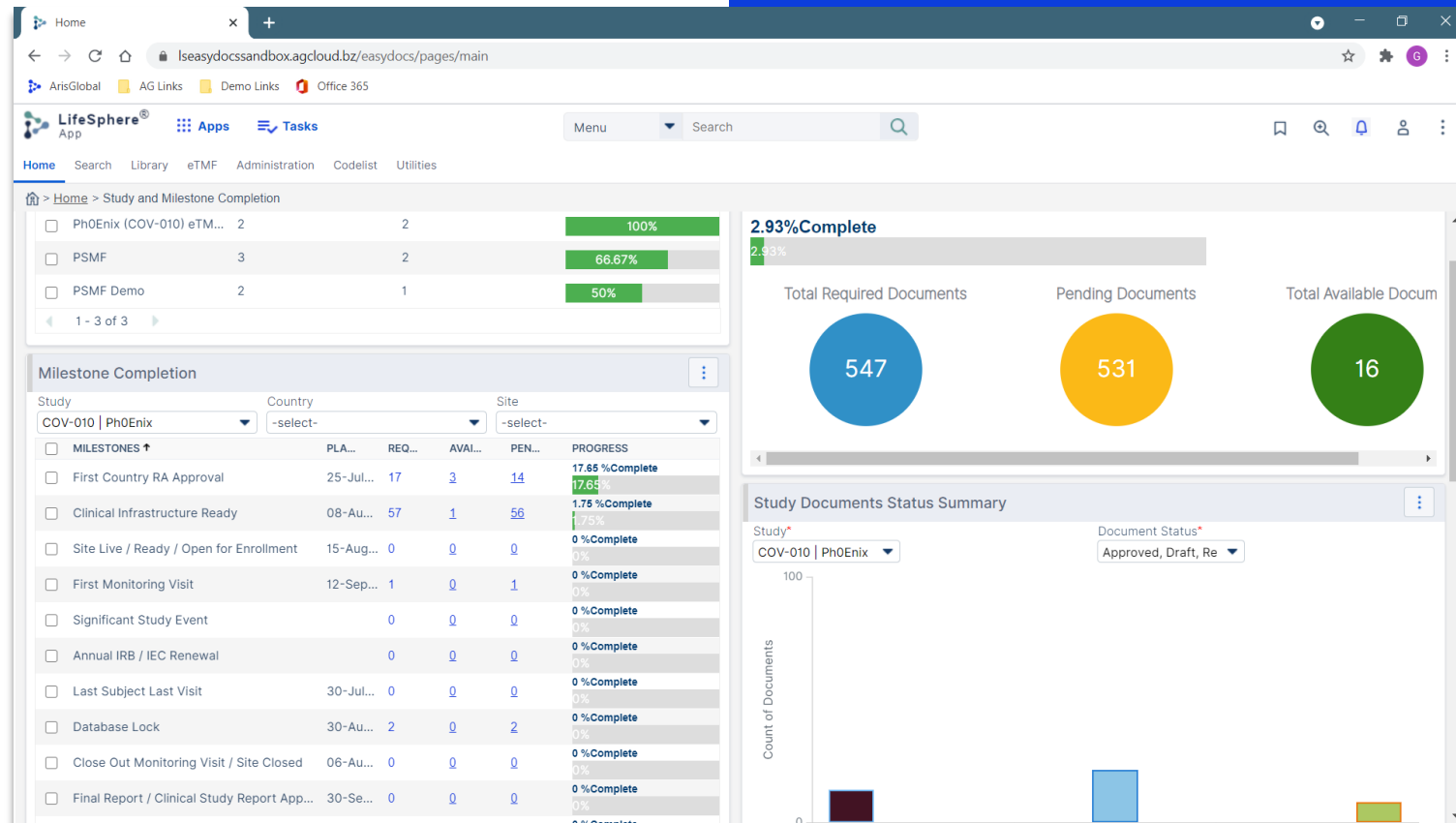
**Their proprietary or archaic
file sharing limits quality,
timeliness, completeness.**



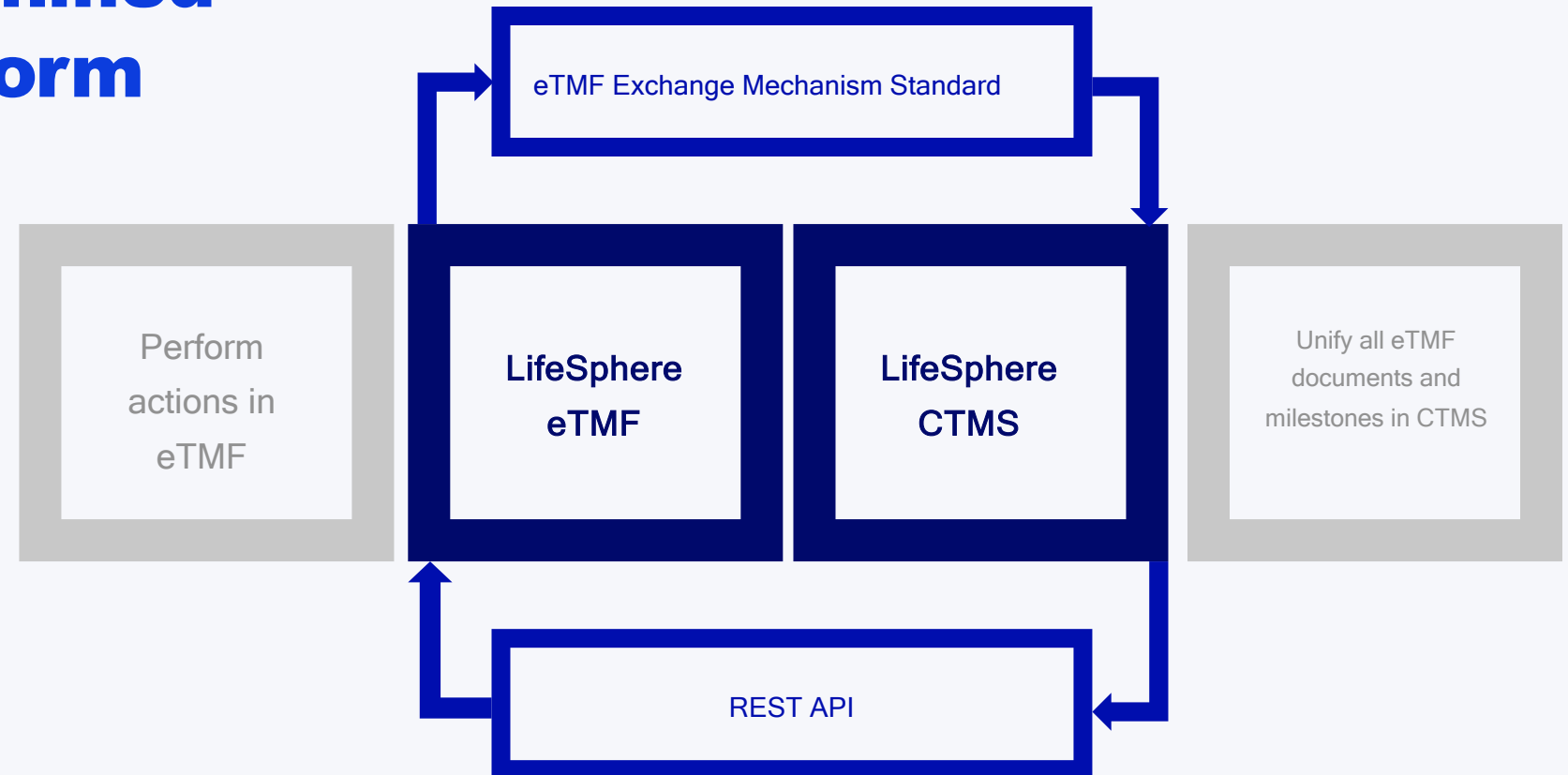
LifeSphere® eTMF

LifeSphere eTMF value

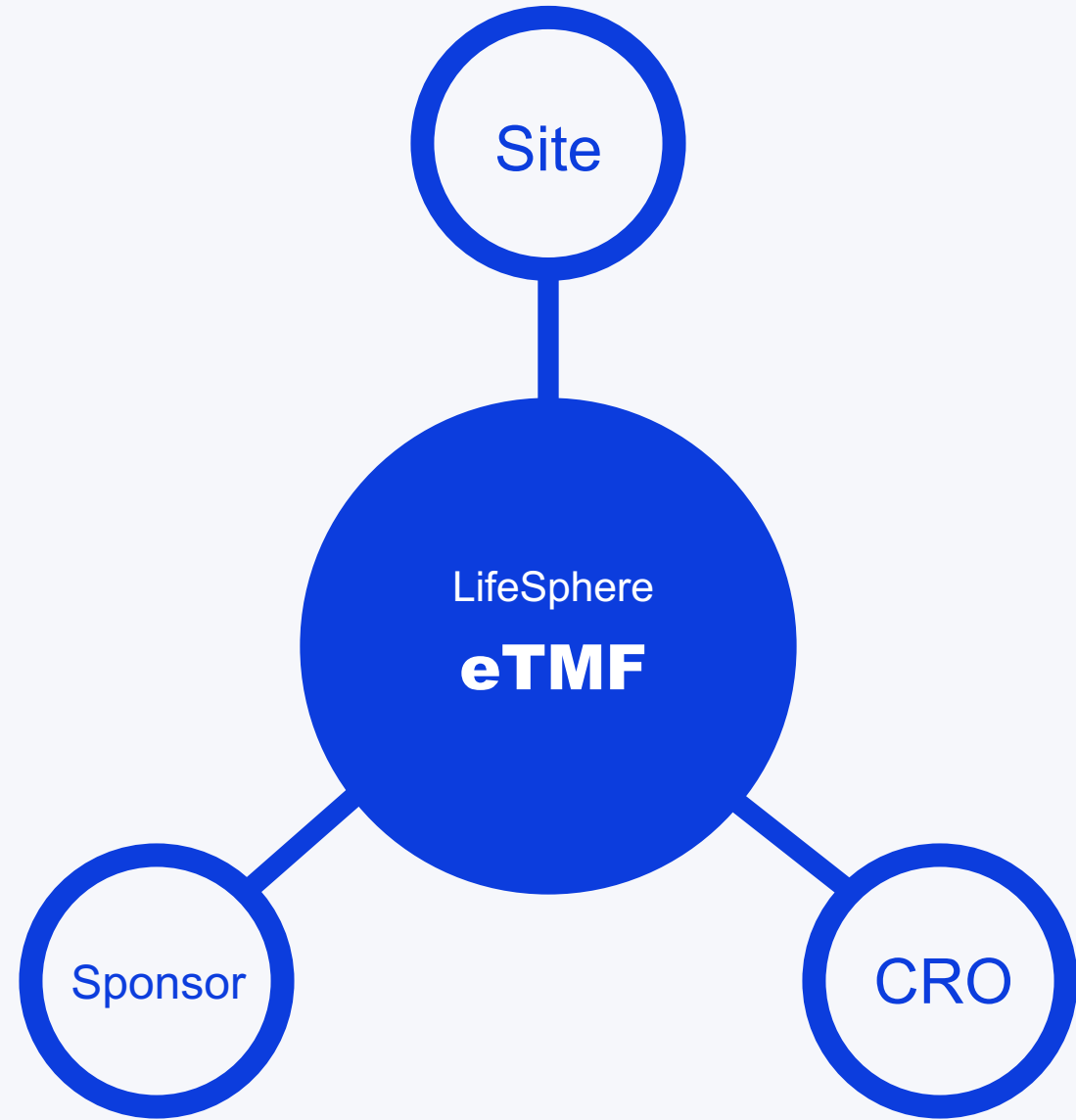
- ✓ Streamline Inspections
- ✓ Future-proof compliance
- ✓ Save time and effort



LifeSphere Unified Clinical Platform

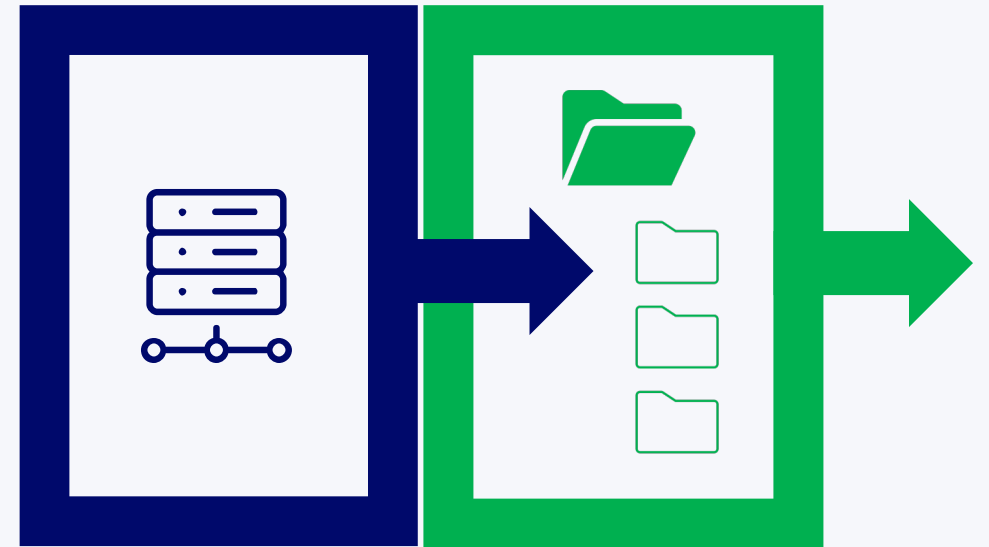


Real-time file sharing



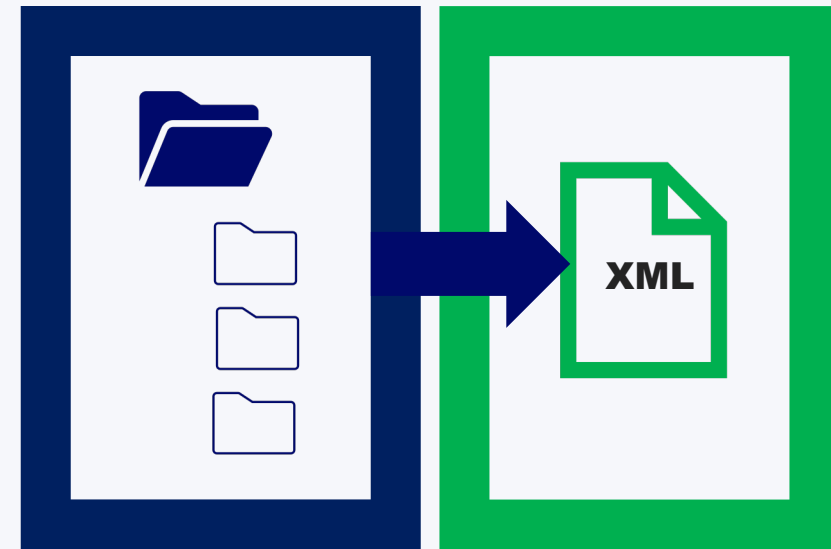
LifeSphere eTMF data exchange

1 Exports eTMF artifacts from folder structure



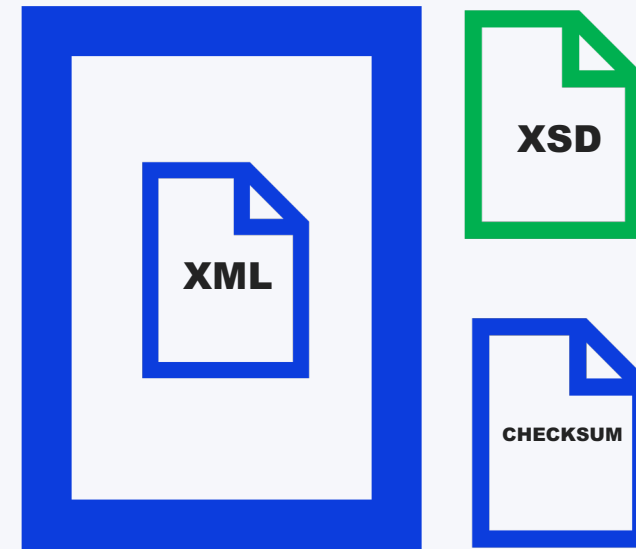
LifeSphere eTMF data exchange

2 Adds XML Exchange File to enable transfer



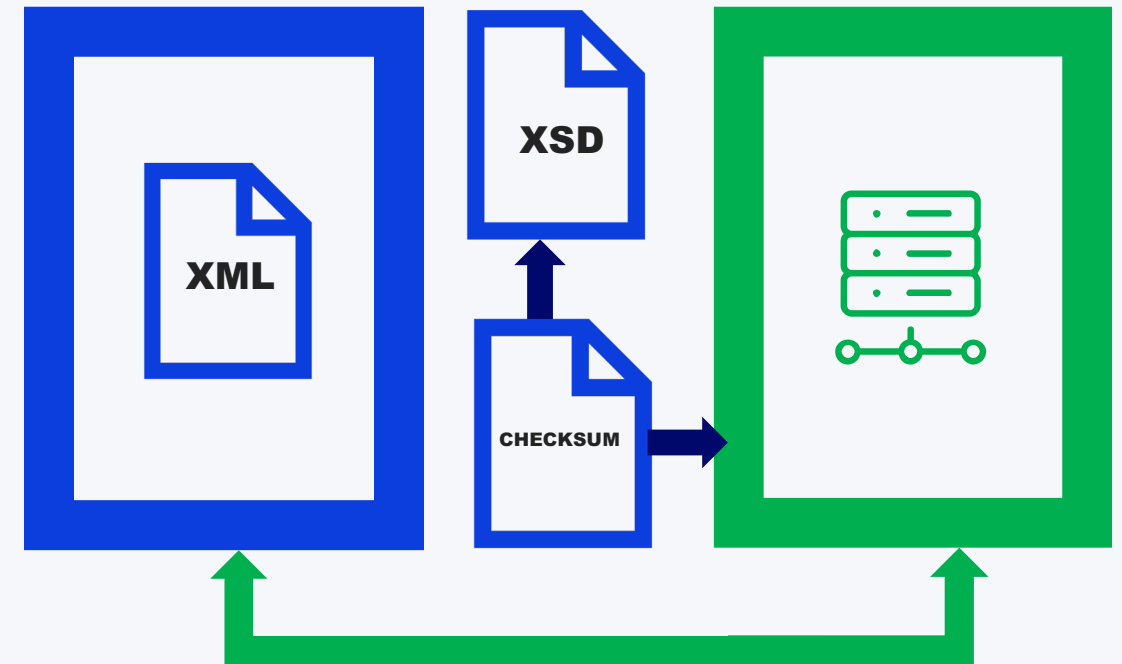
LifeSphere eTMF data exchange

3 **Validates
transfer with
Exchange XSD**



LifeSphere eTMF data exchange

4 eTMF artifacts imported in real time



**How real-time
eTMF improves
collaboration.**



A close-up, over-the-shoulder shot of a female healthcare worker in a surgical setting. She is wearing a light blue surgical mask and a blue and white patterned surgical cap. She is looking back over her right shoulder towards the camera. She is wearing light blue scrubs and a black necklace. In the background, other healthcare workers in blue scrubs are visible, working in an operating room with bright overhead lights.

**No added burden
on sites**

Sponsors with full outsourcing gain oversight and control

- ✓ Be audit-ready as System of Record
- ✓ Invite CROs into eTMF
- ✓ Retain control
- ✓ Get full transparency





Sponsors with outsourced and in-house resources

- ✓ Manage docs in real time
- ✓ Feed insights to data team
- ✓ Ensure systems interoperate



CROs with broad service portfolio

- ✓ Different Sponsors, different doc types
- ✓ Control Sponsor access
- ✓ Easily exchange data with Sponsor

Key LifeSphere eTMF Features

- ✓ Fast, Easy TMF Planning
- ✓ Inspection-Ready TMF Viewer
- ✓ Global Search for Increased Productivity
- ✓ Flexible and Easily Configured
- ✓ Enterprise-Grade Security
- ✓ Streamline Cross-Functional Collaboration
- ✓ Complete Compliance
- ✓ Unified eTMF and CTMS Platform

LifeSphere® App

Apps Tasks

Menu Search

Home Documents Data Library Binders Administration Codelist Utilities

> Binders > eTMF Planner

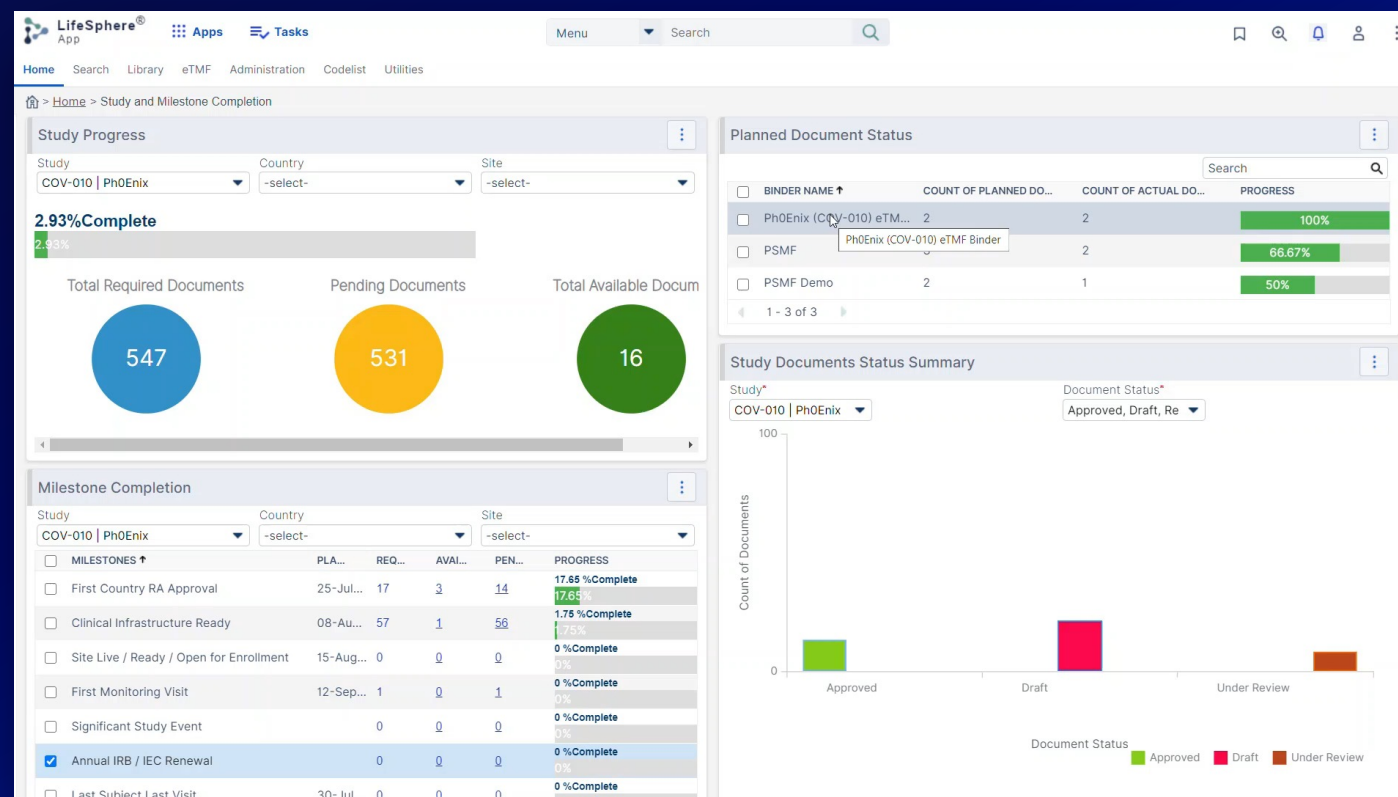
Demo Study 01

Document View Milestone View

Plan Document View Planned Records Save Delete Search 1 - 57 of 57

D...	DOCUMENT NAME*	DOCUMENT TYPE*	CORE/RECOMMEND...	STATUS*	MILESTONE	STUDY	COUNTRY	SITE
<input type="checkbox"/> 1	Monitoring Plan	Monitoring Plan	Q Core	Required	1	Yes 1	No	No
<input type="checkbox"/> 2	Medical Monitoring Plan	Medical Monitoring Plan	Q Core	Required	1	Yes 1	No	No
<input type="checkbox"/> 3	Roles and Responsibility Matrix	Roles and Responsibility Matrix	Q Core	Required	2	Yes 1	No	No
<input type="checkbox"/> 4	Transfer of Regulatory Obligations	Transfer of Regulatory Obligations	Q Core	Required	2	Yes 1	No	No
<input type="checkbox"/> 5	Operational Oversight	Operational Oversight	Q Core	Required	1	Yes 1	No	No
<input type="checkbox"/> 6	Trial Team Details	Trial Team Details	Q Core	Required	2	Yes 1	No	No
<input type="checkbox"/> 7	Trial Team Curriculum Vitae	Trial Team Curriculum Vitae	Q Core	Required	2	Yes 1	No	No
<input type="checkbox"/> 8	Trial Team Training Material	Trial Team Training Material	Q Core	Required	2	Yes 1	No	No
<input type="checkbox"/> 9	Investigators Meeting Material	Investigators Meeting Material	Q Core	Required	2	Yes 1	No	No

Key LifeSphere eTMF Features



More About Us

Empowering R&D teams to deliver breakthroughs **Faster.**

LifeSphere® Platform

Powered by Nava



LifeSphere **Clinical**

- CTMS
- eTMF
- EDC
- eCOA



LifeSphere **Regulatory**

- RIMS
- Publishing
- IDMP



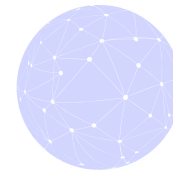
LifeSphere **Safety**

- Intake & Triage
- MultiVigilance
- Signal & Risk Management
- LitPro
- EV Triage



LifeSphere **Medical Affairs**

- Medical Information
- Product Complaints
- Reporter



LifeSphere **Quality**

Innovative functionality across product complaints and quality management. Arriving 2021.

LifeSphere® EasyDocs

Unified document and data management in the cloud.

The LifeSphere Platform Tenets

1

Real-World Automation

Advanced, production-ready automation

2

Built with the Industry

Built with leading life sciences organizations

3

Simple to Use

Intuitive user interface, easy access

4

Easy to Integrate

Easily integrates into existing IT landscapes

5

Unified Platform

Enabling the flow of documents and data

Global Biopharmaceutical

LifeSphere Has Strong
Adoption Across Key
Industry Segments

Johnson & Johnson

astellas

GEDEON RICHTER

Roche

Biogen

Abbott

AstraZeneca

Takeda

VIFOR
PHARMA

Boehringer
Ingelheim

teva

ALK

MERCK

IPSEN
Innovation for patient care

STADA

NOVARTIS

FRESENIUS
KABI

Lundbeck



Health Authority



Statens legemiddelverk
Norwegian Medicines Agency



Contract Research Organizations



The background is a deep blue with a complex, wavy pattern of small, light blue dots. These dots are arranged in a grid that undulates across the frame, creating a sense of depth and movement. The text "Thank You" is centered in the middle of the image.

Thank You

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