Clinical Development Partner Linical

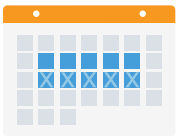
# Linical Americas Delivers TMFs to Sponsors 75% Faster

## Linical is executing compliant trials quicker after unifying their clinical operations with Vault eTMF and Vault CTMS

Linical Americas knew they had to find a digital solution that could unify their globally dispersed teams and create efficiencies at scale. After implementing Veeva Vault Clinical Operations Suite, Linical sped their TMF delivery time to sponsors by 75% and cut study setup time in half. When the pandemic hit, they had the technical foundation in place to quickly adapt to changing regulations and ensure business continuity during uncertain times.

**LINICAL – AT A GLANCE**

- Global Contract Research Organization (CRO) focused on Phase I – IV Oncology, Central Nervous System, and Infectious Disease
- US HQ: Stuart, Florida
- Company Size: 200+ clinical trials across 20+ countries
- Veeva Solutions Used: Vault eTMF, Vault CTMS



**Cut study setup time by 50%**

**75% faster TMF delivery to sponsors**

**Reduced TMF tracking time**

## Capitalizing on Cross-Departmental Efficiencies

As a CRO, Linical knew they needed to modernize their clinical operations systems to remain competitive. Several years ago, the team moved from paper-based TMFs to a cloud file-sharing system. This was an improvement but still did not offer automated reporting, audit trails, or the compliance they needed.

"Our clients were hesitant to use our existing systems, which were not 21 CFR compliant," explained Julie McHugh, chief operating officer at Linical Americas. After a lengthy evaluation process, they chose Veeva Vault eTMF because it met their requirements and was user-friendly.

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>
> *– **Julie McHugh,** Chief Operating Officer at Linical Americas*

A few years after moving to Vault eTMF, Linical implemented Vault CTMS for study planning, site monitoring, and risk management. The ability to customize the system to be client-specific was a huge benefit for Linical, and one of the reasons they selected Vault CTMS.

The team also liked the electronic trip reports, protocol deviation tracking, detailed reporting, and unification with Vault eTMF. "When we moved from two platforms to one, we cut our study setup time in half. We're getting twice the value with Vault Clinical Operations because we are setting up the study once," said McHugh.

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> *– **Julie McHugh,** Chief Operating Officer at Linical Americas*

## More Advanced Site Monitoring

McHugh explained that with Vault eTMF and Vault CTMS they can permanently shift to a hybrid monitoring approach of traditional as well as remote and central monitoring. This will allow them more flexibility in how they work with research sites.

Electronic trip reports have also increased visibility into the visit lifecycle, improving compliance and transforming the way they plan site visits. By including source data verification metrics directly in trip reports, "it's almost like having three different systems integrated into one," said McHugh.

Real-time metrics and reports provide insight and performance monitoring to ensure Linical is compliant with each client's study plan. "The efficiencies from the eTMF Completeness Checklist report were a surprise for us," said Lori McMullin, clinical systems administrator at Linical Americas.

She explained that the team went from doing manual TMF tracking, which can take a month or more, to reviewing the Completeness Checklist daily. "It shows us every document, where it is classified, who uploaded it, and what status it's in. All in about 20 seconds. That transparency is a huge benefit and helps us meet important study milestones for our clients."

> *It used to take months to reconcile and deliver a TMF to a client, but with Vault eTMF, it now takes approximately two weeks.*
>
> *– **Julie McHugh,** Chief Operating Officer at Linical Americas*

## Quicker Validation and Reconciliation

Linical's study teams and sponsors now have access to Vault eTMF and Vault CTMS, which has shortened study timelines. Pre-defined workflows provide increased visibility and ensure compliance across departments. This teamwork has streamlined data validation and reconciliation. "It used to take months to reconcile and deliver a TMF to a client," said McHugh, "but with Vault eTMF, it now takes approximately two weeks."

Required documents seamlessly flow from Vault CTMS into Vault eTMF and are properly classified systematically, reducing manual processes carried out by clinical research associates. This enables Linical to always be inspection-ready.

Vault eTMF utilizes the industry-standard TMF Reference Model with audit trails to demonstrate that the trial workflow was followed. It also helps ensure the studies pass inspections without any regulatory findings. "Our client success rate is remarkably high," said McMullin. "We have minimal to no findings at the end of the study because of the unified system."

## Global Consistency and Expansion

Linical continues to expand globally and strengthen their decentralized clinical trial offerings to provide more cost-effective solutions for clients. “Sponsors are looking for good technology solutions, and the fact that we use Vault Clinical Operations Suite and can demonstrate metrics is a great benefit,” explained McHugh. Linical’s partnership with Veeva has helped secure work and gives sponsors confidence in Linical’s ability to execute trials faster.

Since seeing the benefits of the unified clinical operations platform, Linical is also evaluating adding Vault Study Startup and Vault CDMS to their clinical environment to drive additional cross-team efficiencies. They also plan to partner with research sites using Veeva SiteVault to better facilitate remote monitoring.

To learn more about how unified clinical operations systems and processes can help execute compliant trials quicker, visit our product page.