Achieving a Next-Generation Clinical Environment

Technology Transformation Best Practices from a Top 20 Pharma

Improving trial efficiency, quality, and speed emerged as top priorities for sponsors and contract research organizations while navigating unprecedented challenges presented by the global pandemic. COVID-19 demonstrated the importance of streamlined clinical operations to get drugs to market faster, with technology modernization a key improvement opportunity.

A top 20 pharma embarked on a clinical transformation journey defined by three strategic pillars: transform ways of working, redefine clinical trials, and reimagine healthcare to optimize patient outcomes. Digitization was a key focus area to improve the drug development pathway and value chain.

DIGITAL TRANSFORMATION GOALS

Leverage technology and automation to achieve operational improvements

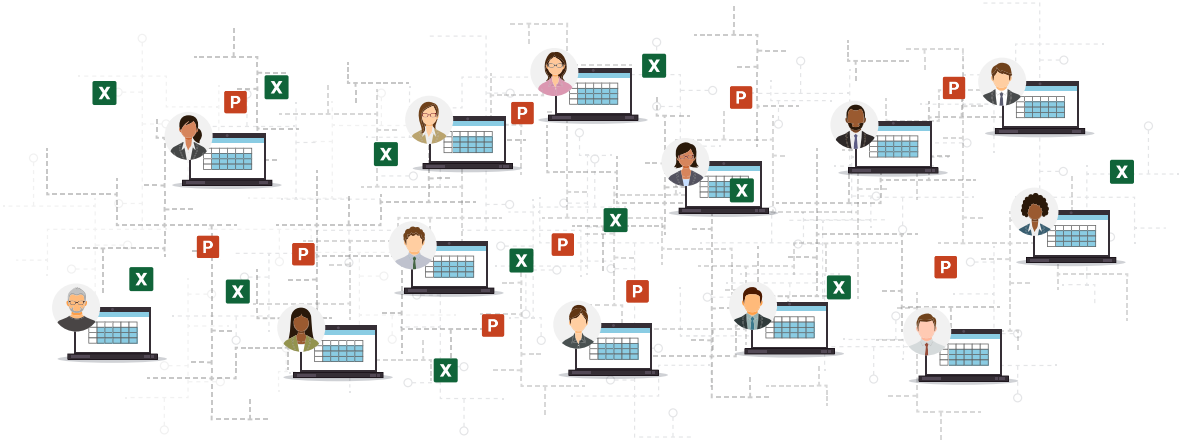
Unify systems to reduce complexity and simplify the end-user experience

Improve cross-functional trial coordination, execution, and transparency

This whitepaper summarizes the top 20 pharma's learnings from deploying Vault Clinical Operations, a unified ecosystem to manage and execute clinical trials.

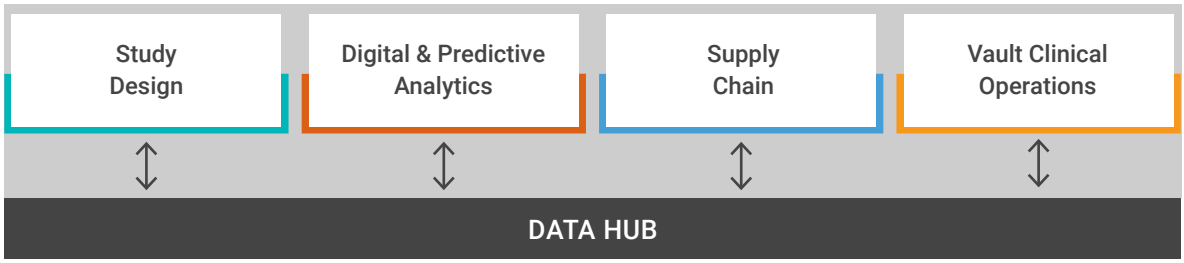
Challenges: Complex and Disconnected

A primary driver to modernize clinical operations was to simplify the technology landscape and address the challenges with data and system silos. Duplicate, inaccurate data, and lags in information transfers between systems resulted in users reverting to local spreadsheets, ultimately causing distrust in the data.



The Vision: Streamlined and Unified

The guiding principle for a sustainable system architecture was a data hub that serves as the single source of truth without duplicate data entry. The top 20 pharma wanted to connect several foundational systems to the data hub to enable data-driven decision-making and real-time study performance monitoring.



WHY VEEVA

- Trial quality and inspection readiness
- Efficient unified ecosystem
  - Consistent user experience
  - No duplicate data entry
  - Seamless data sharing
- Continuous innovation and development
- Meet rapidly changing business needs

Spotlight on CTMS

As the hub of clinical operations, it is common for CTMS to have integrations with other clinical systems and be deeply embedded across the organization. How did the top 20 pharma garner internal support and make the business case to upgrade to modern cloud CTMS? Read on to find out.

WHY REPLACE LEGACY CTMS?

1	2	3	4
Eliminate disparate systems and unify in one platform	Streamline tasks for end-users	Take advantage of regular releases and advancements in CTMS automation	Partner with a company that has a strong vision and roadmap

Learn the decision process for upgrading and selecting a modern CTMS. Watch Now

The CRA Experience

Site monitoring typically accounts for 25%-30% of total clinical trial costs.[1] The top 20 pharma engaged clinical research associates (CRAs) early in the process to understand pain points with legacy CTMS, how long routine tasks take using the system, and opportunities to automate in a new platform to decrease time-consuming activities. This approach shifted the mindset of CTMS replacement from something the company is doing "to them" to a joint, collaborative effort.

Focus groups consisting of global CRAs and local study teams participated in vendor demos with hands-on access to sandbox environments, which helped the key stakeholders feel involved and heard throughout the process. They had the opportunity to provide feedback on the system benefits and challenges that directly impacted their ways of working.

Hear tips to engage CRAs on the path to CTMS modernization. Watch Now

[1] Branch, E. (2016, April 30). Ways to Lower Costs of Clinical Trials and How CROs Help. Retrieved January 21, 2019, from https://www.americanpharmaceuticalreview.com/Featured-Articles/185929-Ways-to-Lower-Costs-of-Clinical-Trials-and-How-CROs-Help/

Justification for Change

Based on these deep dives with global CRAs, the modernization team prepared time and budget estimates that included productivity dollar savings, cycle time reduction, quality, and compliance improvements. In collaboration with Veeva, a complete ROI analysis was presented to the leadership team, including qualitative feedback and satisfaction scores with current processes and systems from end-users.

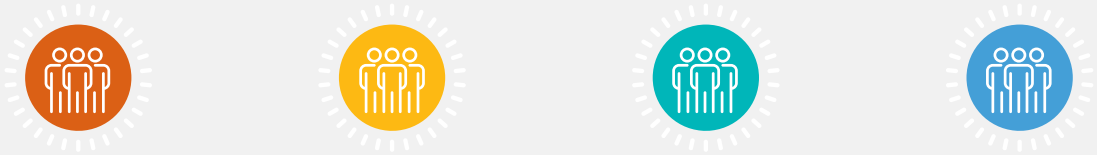
Once Veeva Vault CTMS was selected, the top 20 pharma conducted deep dives to understand what CRAs wanted to be included in a new system.

Implementation Insights

The company took a "big bang" agile implementation approach and standardized on a single environment for 4,000+ global users to avoid the risk and complexity of maintaining two systems and sets of integrations.

The implementation team included representatives from business and IT who could translate project objectives to operational execution, with strong support from Accenture and Veeva.

IMPLEMENTATION RESOURCES



1 Configuration

2 Data Quality and Mapping

3 Testing and Validation

4 Integration

Global workshops were held with user communities to define requirements to ensure user pain points were rectified in the new system. These workshops uncovered internal differences in business process definitions and workflows that needed to be addressed and resolved. The pharma company also discovered several users were requesting data points from outdated practices that didn't support current business goals or contribute to meaningful analysis. Adding in these extra data points would require unnecessary system customization.

Not only did this initial discovery drive internal process alignment, but it also enabled the creation of detailed user stories that assisted the configuration team and IT with technical testing and validation.

PRO TIP: **Invest time up front to map out processes and granular information flows between systems to ensure consistency and clarity.**

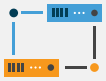
Thinking about implementing modern CTMS?
Listen to top learnings from a Vault CTMS customer.
Watch Now

> People often say that technology should enable the process, but sometimes the process has to change because the technology is available and has evolved.
>
> **Senior Director, Document and Unified Clinical System**

Data Migration Tips

MIGRATION STRATEGY

Migrated all ongoing studies and those with Vault eTMF records



Transferred 8.6 million data points across 1,350 studies

Archived all other studies (accessible in legacy CTMS)

The top 20 pharma invested significant effort to clean operational, reference, and global directory data before migrating to the production environment to ensure data integrity and alleviate downstream issues. They also performed migration dry-runs to identify and resolve any issues before go-live.

PRO TIP: **Allocate enough time for data cleansing activities at the subject level to ensure the best data quality.**

Learn more about effective data migration tips. Watch Now

Preparing the Business for Change

Hear successful tactics to deploy CTMS enterprise-wide. Watch Now

Technology is the enabler, but effective change management activities and leadership buy-in are critical to embed the changes throughout the organization and reap the expected benefits of the technology.

To ensure successful go-live and adoption, the top 20 pharma took a "global coordination, local execution" approach to end-user training and enablement.

Moving to Vault CTMS would impact numerous stakeholders at different levels across the organization, including CRAs, study managers, and other functional users who rely on clinical trial operational data to manage the study portfolio, spend, and more. To ensure effective communication about the upcoming change and impact, stakeholders were classified and received highly targeted messaging based on their group mapping.

The site management and monitoring teams ranked local SMEs as the most helpful resource to adopt, implement, and understand how to use Vault Clinical Operations.

Local subject matter experts (SMEs) and program champions were selected and trained to ensure they could support regional users with the CTMS transition, from conducting workshops in the local language to providing product tips and answering questions. Some countries even had local SMEs per role to facilitate training that demonstrated how daily tasks are performed in Vault CTMS. Country heads were also instrumental in influencing their teams to embrace a better, faster way of working.

The company also launched a mock trial in a sandbox environment to identify if the change and training materials provided resonated with end-users.

This hands-on approach helped users learn the new system and fostered a community spirit.

It's all about people, not just technology!

Post Launch Tactics

The business readiness efforts didn't stop at go-live. A key component to success was planning what would happen immediately post-go-live, and the weeks and months after to sustain momentum. Support teams and program champions were prepared to handle end-user process queries and technical product questions. Office hours were scheduled so team members could ask questions once they had worked in Vault CTMS.

SURVEYS TO THE SITE MONITORING COMMUNITY ARE KEY TO ONGOING SYSTEM OPTIMIZATION

60% global response rate	Collect continuous feedback	Implement enhancements that streamline work processes

EXAMPLE: Changed a Yes/No drop-down to a radio button to save time

Business Results

Vault CTMS has improved the speed and quality of studies through proactive trial management and enhanced productivity.

VALUE FOR CRAS

- » Better interface
- » Fewer clicks
- » Track and assign activities directly in Vault CTMS (not outside of it)
- » Easier navigation
- » One place for data entry
- » Quickly see milestones, drill down to documents, and easily track them

50%
reduction in time to author monitoring visit reports

100,000
person-hours per year savings*

KPI: Numbers of days from monitoring visit to report finalization

220,000
person-hours saved per year with automated reporting*

5%
reduction in time for issue management across all active sites

40
minutes saved per site per month*

KPI: Issue aging and time to closure

*This is an expected benefit. Full savings haven't been achieved yet.

REDUCED CTMS INTEGRATIONS FROM 45 TO 24

Retired separate Japanese platform and implemented Vault CTMS Yuzu functionality to submit compliant clinical trial notifications to Japanese regulatory authorities

Here is a summary of lessons learned moving to modern CTMS. Watch Now

The Value of Unified Clinical Operations

Unifying clinical operations to manage and execute trials has enabled the pharma company to connect operational trial data and documents to speed study execution and inform decision-making with advanced data-driven analytics.

BENEFITS OF A CONNECTED CLINICAL TRIAL ECOSYSTEM

- Lessened the complexity of trial management
- Increased transparency
- Enhanced data quality
- Simplified the technology and data landscape
- Reduced the need for spreadsheets
- Eliminated multiple logins and time spent on password resets

Hear about the impact unified clinical operations has on trial speed and quality. Watch Now

80%
reduction of document scanning and distribution

78,000
paper-based safety letters eliminated per year*

*This is an expected benefit. Full savings haven't been achieved yet.

Using Vault eTMF, Vault CTMS, and Vault Study Startup together, the top 20 pharma can now:

- Create automated dashboards that provide visibility to study setup progress and aid with decision-making
- Effectively capture and review documentation
- Accelerate time to site activation by leveraging pre-built country intelligence workflows

PRO TIP: If you're adding Vault CTMS or Vault Study Startup to an existing Vault eTMF deployment, carefully consider the governance structure and coordinate with the eTMF team to ensure process harmonization.

Future Opportunities to Streamline

> "Our goal is for all CRAs to open Vault CTMS first in the morning, not their email."
>
> **Senior Director, Document and Unified Clinical System**

What's next for the top 20 pharma on their digital transformation journey to optimize clinical studies?

Automation	Access management Technical quality checks
New Feature and Module Adoption	Externally sponsored research Site payments Feasibility
Efficiencies	Leverage cross-Vault connections to accelerate study start-up
Operational Management	Complex study designs Decentralized clinical trials

Vault Clinical Operations provides the scalable foundation to support the top 20 pharma's end-to-end R&D data ecosystem. The company continues to innovate and transform drug development through digital, data, and analytics to improve patient outcomes.