



Advanced Clinical Achieves a Strategic Advantage with Veeva Vault eTMF

Contract research organization leverages cloud solution to run faster, higher-quality trials for study partners

Success Highlights



Increased **speed and quality** of clinical trials



Enhanced **collaboration and visibility** for study partners



Faster document collection from **start-up to trial close**



Actionable insights led to **more proactive** trial decisions



Delivered an **ongoing state of inspection readiness**

The Challenge: Manual Processes Slowed Trial Progress

Advanced Clinical is a full-service, global contract research organization, supporting Phase I-IV clinical trials across all major therapeutic areas. In order to strengthen their position as a trusted partner in clinical trials and research, Advanced Clinical prioritized modernizing their clinical operations environment to increase the speed and quality of their clinical trials.

Advanced Clinical previously used paper to manage trial master file documentation. This time and resource-intensive method impacted internal and external collaboration. It hindered visibility and oversight of the current trial status, making it challenging to draw real-time insights to proactively steer trials. This ultimately impacted their ability to achieve ongoing compliance and inspection readiness.

“Visibility to clinical documents was essentially limited to an office-based archive room,” said JP Miceli, associate director of document management at Advanced Clinical. “While we had trackers on what was in the TMF, we couldn’t easily verify its accuracy.”

ADVANCED CLINICAL – AT A GLANCE

- Corporate HQ: Deerfield, IL
- Global representation in over 50 countries
- 900+ employees

While researching an automated solution to address these challenges, Advanced Clinical discovered many solutions were built on dated infrastructures which would not be able to keep pace with business change and growth.

Advanced Clinical recognized the need to move from paper to a modern, purpose-built eTMF solution to increase speed and quality of trials while driving visibility and oversight for sponsors.

The Solution: Veeva Vault eTMF for Real-time Visibility and Oversight

Advanced Clinical selected Vault eTMF to deliver eTMF services in the cloud. “We wanted a truly innovative system so we could define our business processes and ensure alignment with our configuration. Above all, we wanted to be able to deliver clinical trials faster, better, and more reliably for our sponsors,” said Miceli.

“Vault eTMF allows us to produce meaningful metrics – through easy-to-use, intuitive dashboards and reporting – and consistently offer our clients the control, transparency, and visibility they want.”

Vault eTMF has enabled Advanced Clinical to streamline its processes, improve compliance and collaboration, and deliver higher-quality trials for sponsors.

The Results: Stronger Partnerships and Faster, Higher-quality Trials

Preparation is Key

From outlining document filing processes to implementing best practices for managing document quality, adhering to pre-defined KPIs enables Advanced Clinical to demonstrate improved trial conduct. This discipline ensures the team has early visibility into issues, allowing them to avoid blind spots in document management.

Enhancing Accessibility and Information Sharing

Vault eTMF enables Advanced Clinical to offer the trial visibility stakeholders require. Reports and dashboards provide a view of overall trial progress alongside specific information on key TMF health metrics, like accuracy, completeness, and timeliness. Advanced Clinical retains control of the eTMF, giving sponsors access to the level of information they require. For example, sponsors may want to see final, approved documents and real-time reports, which can be delivered through reliable dashboards.

Improving Document Management and Quality Processes

Vault eTMF offers cross-functional teams access to a shared, authoritative location for documentation. This drives collaboration, ensuring stakeholders use the solution as more than a static repository.

It also enables Advanced Clinical to streamline existing document management processes. For example, data managers can now upload safety data listings into Vault and route to medical monitors for feedback, through a pre-defined authoring workflow. They can respond within the system, alerting data managers to act and send the eTMF record for quality control (QC) review in real-time.

When it comes to QC, Vault eTMF functionality is helping to reduce the number of rejected documents.

“We’re excited to use quality issue objects. To have object life cycles on it, that’s a seismic change. Otherwise, we lack the visibility into why documents were rejected, and it is hard to go and fix, or to reduce the number of rejected documents. It’s a major improvement,” added Miceli.

Streamlining Document Exchange

Using Vault eTMF enabled Advanced Clinical to dramatically reduce costs around document exchange. Uploading documents directly to Vault reduced TMF submission time by eliminating transmittal forms and courier shipments.

“Previously, there was a risk and cost to transport documents from the field to the TMF. Choosing to upload documents directly took away that concern and made it easier to identify any document issues,” said Miceli.

Driving a Continuous State of Inspection Readiness

Since implementing Vault eTMF, Advanced Clinical has supported and facilitated successful client, mock, and internal audits in Vault as well as agency inspections by MHRA and the FDA.

“We have close visibility to auditors’ actions taken in the system and leverage the system logs to generate daily summaries of all records that are viewed or downloaded,” added Miceli.

“Our filing oversight procedures measure quality and performance to compel continuous inspection readiness which eases pre-inspection stress and eliminates the chaotic filing we’ve all seen in the past.”

The Bottom Line: Optimizing Clinical Trials for Study Partners

Moving to a purpose-built eTMF has enabled Advanced Clinical to deliver faster, higher-quality trials for study sponsors. It has replaced time and resource-intensive manual processes, streamlined collaboration, and boosted visibility and oversight for study partners.

“Vault eTMF gives us and our partners a strategic advantage. We can speed document collection, from startup through trial close, while enabling anytime-anywhere access and visibility for study partners throughout the entire study,” said Miceli.

“It has enabled us to conduct faster, higher-quality trials and ultimately enabled us to drive an engaged culture of ongoing inspection readiness.”

About Veeva Systems

Veeva Systems Inc. is the leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 800 customers, ranging from the world’s largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices throughout North America, Europe, Asia, and Latin America. For more information, visit veeva.com.