Ora, Inc. Speeds Study Execution with Vault Clinical Operations

CRO unifies clinical systems and processes to improve efficiency and visibility across global trials

Success Highlights

Increased speed and quality of clinical trials

Reduced study closeout from weeks to days

Improved decision-making and proactive trial management

Faster global site selection and activation

Enhanced sponsor collaboration

The Challenge: Managing a Growing Number of Global Studies and Sponsors

Ora, Inc. is a fast-growing contract research organization (CRO) specializing in ophthalmology. As their business expanded, the increasing complexity of managing more global studies for sponsors prompted the need to modernize their clinical environment.

ORA, INC. – AT A GLANCE

- Corporate HQ: Andover, MA
- Global locations in Japan and the UK
- 250 full-time employees
- Area: Ophthalmology

Ora collected and managed trial documentation manually using paper, email, and scanners, which impacted collaboration and transparency for internal and external stakeholders. The lack of automated version control and tracking for TMF documents affected inspection readiness, while the inability to collaborate on documents in real-time reduced productivity.

The value of Vault Clinical Operations is the immediate impact on users. With streamlined processes and complete visibility, our teams work more efficiently and effectively.

— Ed Leftin, Director, Clinical Systems

"Our current systems and processes couldn't scale with our growth," said Edward Leftin, director, clinical systems at Ora. "We needed to increase operational efficiency and visibility across global studies."

To address these challenges, Ora recognized the need to modernize their clinical systems and processes to better manage end-to-end trial processes and gain insight to make more informed decisions.

The Solution: Vault Clinical Operations for Improved Efficiency and Visibility

Ora chose Vault Clinical Operations to bring together CTMS, eTMF, and study start-up on one platform to unify clinical information and processes. Now Ora can leverage the same source of information throughout the trial lifecycle, enhancing productivity and speeding workflows. For example, teams can create site monitoring reports or CVs in Veeva Vault CTMS or Veeva Vault Study Startup and they automatically become part of the TMF. This eliminates manual steps and enables cross-functional teams, including sponsors, to leverage information in real-time.

With Vault Clinical Operations, internal stakeholders and sponsors have complete visibility into how the trial is progressing, from study start-up to closeout. Study teams are working from the most current information and can provide updates in real-time, improving collaboration and enabling proactive decision-making. With role-based security, Ora is confident that only authorized staff can access information relevant to their jobs.

"Data collection is streamlined and we're able to see what everyone is doing," added Leftin.

"Interactive dashboards make it easy for our teams to know the status and take immediate action to complete next steps."

Unifying Clinical Systems and Processes

Ora's transition to a unified clinical environment started with Veeva Vault eTMF to help clinical teams move paper-based processes to a purpose-built eTMF application. Vault eTMF manages documents and processes in real-time as the TMF is generated, making it easier for Ora to maintain the TMF in a constant state of inspection readiness.

Implemented in eight weeks, Vault eTMF delivered immediate tangible benefits, including increased staff productivity and process efficiency, and improved inspection readiness. "With all TMFs updated in real-time, teams no longer have to waste time configuring a paper TMF, reducing study close out time from weeks to days," said Leftin.

In the next phase, Ora added Vault Study Startup to speed global site selection and activation. Vault Study Startup includes built-in country intelligence that automatically generates a list of essential documents and activities required to activate a site. This helps Ora get sites up and running faster. "With start-up documents and activities shared across applications, we don't have to manually enter this information in two places," said Leftin.

With Veeva, we accelerated clinical trial execution while providing the highest level of quality for sponsors.

— Ed Leftin, Director, Clinical Systems

Veeva enables Ora to track multiple study start-up documents, such as protocols, CTAs, and in a single application. "With Veeva Vault Study Startup, we can quickly spot delays, such as why the clinical trial agreement isn't complete, and know what the holdup is," said Leftin.

The need for improved visibility and proactive study management prompted Ora to adopt Veeva Vault CTMS, empowering clinical teams with greater insights across the trial lifecycle. "With Veeva Vault CTMS, we are performing true project management without spreadsheets," said Leftin. Instead of manually compiling information in multiple spreadsheets, project managers have real-time access to study data so they can make better decisions.

Ora's global expansion and growing number of sites prompted the need to manage a higher volume of clinical research site payments in multiple currencies. The company chose Vault Payments to eliminate manual and paper-based processes and streamline its payments workflow.

With Vault Clinical, Ora's clinical operations teams can manage information and end-to-end trial processes, from site activation to study closeout, all on one platform.

The Bottom Line: Improving Study Execution and Quality for Sponsors

Moving to a unified clinical environment enabled Ora to execute studies in less time and with fewer errors. "The value of Vault Clinical is the immediate impact on users," said Leftin. "With streamlined processes and complete visibility, our teams work more efficiently and effectively."

With Veeva, Ora also improved collaboration with sponsors by providing real-time access to trial status. Now Ora can build a more strategic partnership with sponsors to help bring new products to market faster.

Vault Clinical helped us bring together eTMF, study start-up, and CTMS on a single, modern cloud platform," added Leftin. "With Veeva, we accelerated clinical trial execution while providing the highest level of quality for sponsors."

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 1,100 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.
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