Atlantic Research Group Optimizes Clinical Studies with Veeva Vault eTMF and Veeva Vault CTMS

Contract research organization streamlines clinical operations and trial efficiency with cloud technology

Success Highlights

Increased TMF quality

Reduced complexities of integrating Vault CTMS, EDC, and ARISg

Shortened study setup time by three days

Maintaining a Competitive Edge with Technology

Atlantic Research Group (ARG) is a contract research organization (CRO) that provides clinical program development services focused on oncology, immunology, rare, and neurodegenerative diseases. As the operational arm for sponsors' clinical studies, ARG aims to make every engagement highly individualized. Key to their delivery model is leveraging modern technologies to drive efficiencies and differentiate their services.

ATLANTIC RESEARCH GROUP – AT A GLANCE

- CRO focused on oncology, immunology, rare, and neurodegenerative diseases
- Corporate HQ: Charlottesville, VA
- Founded in 2004

Improving Trial Execution and Visibility with Veeva Vault eTMF and Veeva Vault CTMS

With a focus on innovation and speed, ARG sought to eliminate manual processes to better serve sponsors and study partners. Hunter Walker, chief technology officer, says "our goal with automation is to free our resources to tackle challenging tasks and solve bigger problems, not reduce headcount."

As part of its strategy to modernize its technology landscape, ARG selected Vault eTMF to drive TMF quality, speed, and improve collaboration. Vault eTMF fully supports the industry's TMF Reference Model, enabling ARG and its partners to easily and quickly locate documents. "Now, when sponsors ask us to add different types of documentation at the end of studies, we can easily accommodate the requests with minimal effort," says David Tyson, clinical operations manager.

Due to the success with Vault eTMF, ARG felt they could drive even greater efficiencies and service levels by modernizing their CTMS. Rather than integrate their proprietary system TrialVista with Vault eTMF, they chose to replace it with Vault CTMS. "While it's possible to integrate disparate systems so that data flows between them, we knew continuing to invest in TrialVista was not optimal," explains Walker. "We wanted to keep our IT team small, nimble, and focused on clinical research processes, not server architectures, operational systems, and security."

IMPLEMENTATION BEST PRACTICES

1. **Decide on process changes before implementation.** Evaluate current processes and decide if template updates are needed (e.g., amend trip report templates before study go-live to eliminate change controls later).
2. **Align with the clinical operations team.** Collaborate early and often to assist with change management. Provide proper training before the first study launches in Vault to ensure a successful rollout.
3. **Account for validation timelines.** Build adequate time into the project plan for validation script creation, execution, and summary reports.
4. **Institute a site naming convention.** Follow a site naming convention for all studies to assist with reporting and programmatically control the naming of documents via the metadata fields within the document.

Why Veeva Vault?

Unified Clinical Platform	Vault eTMF and Vault CTMS are complementary applications built on the Vault platform, so all studies and workflows are unified in one database. ARG can easily track study progress, pull reports and dashboards on-the-fly, and always be inspection-ready.
Ease of Use	Vault's simple user interface is key to end-user training and adoption, as people don't have to learn multiple interfaces.
Configurable	Vault is flexible and adapts with business change. ARG can update their applications without the hassle of rigid, complex customizations.
Continuous Innovation	With three Veeva releases per year, ARG can take advantage of Vault eTMF and Vault CTMS enhancements, so they stay current with the newest features.
Open API	Veeva's API architecture facilitates data exchange between systems, simplifying trial management and reporting.

The Benefits of Vault eTMF and Vault CTMS for ARG

Achieving Inspection Readiness

Vault eTMF helps ARG achieve a continuous state of inspection readiness. "We use Vault reports to perform pre-inspection quality control (QC). The ability to generate a report showing all unblinded study documents enables us to quickly review content and minimize stress," says Jen Stanislawski, quality assurance manager. Vault's robust audit capabilities and documentation management provide oversight so that ARG's processes and systems pass qualification audits as well.

As relevant documents from Vault CTMS are finalized, they are automatically filed in Vault eTMF, increasing TMF quality, timeliness, and completeness. ARG has saved many hours of QC, eliminated misfiled and missing trip reports, and enabled active TMF operations. ARG achieves a constant state of inspection readiness by managing all TMF documents, related information, and processes in the same system as they're executed.

Driving Efficiency and Productivity

With Vault CTMS and Vault eTMF, ARG has unified its clinical systems and processes, enhancing productivity and speeding workflows. Their previous CTMS TrialVista was not unified, so setting up new sponsors and studies required IT resources to manually add new components and perform QC. Moving to the Vault platform eliminated three days of study setup time, as new studies and sponsors can be quickly added and leveraged across applications. Vault Clinical Operations also provides a repository for investigator and site information, so all studies leverage the global directory that can be reused across studies.

Moving to a unified platform enabled ARG to execute studies in less time with fewer errors. For example, study teams can create trip reports in Vault CTMS and they automatically become part of the TMF. Clinical research associates (CRAs) previously spent 10 minutes on every trip report, and with 10 CRAs and 100 reports over the life of a study, this became a significant cost. Adding in QC hours to review work done by the CRAs exacerbated costs. Now that the entire trip report and confirmation letter process is automated in Vault CTMS and auto-filed in Vault eTMF, these inefficiencies have been eliminated. Trip reports are now much easier for CRAs to perform and they can focus on more important activities during monitoring visits.

Gaining Real-Time Study Views

The Vault platform easily integrates with ARG's other clinical systems using comprehensive REST APIs. For example, they integrated their EDC and ARISg safety database with the unified Vault clinical platform, so when a serious adverse event (SAE) is entered in EDC, the relevant data flows to Vault in real-time. "We integrated these applications quickly and easily. Now, we have the visibility we need to monitor trial progress and course correct when necessary," says Walker.

Optimizing for Tomorrow's Trials

As ARG continues to evolve end expand into new therapeutic areas, functional units, and geographies, executing smart, feasible studies at reduced costs is critical to sustaining their strategic advantage. Leveraging technology to provide high-value differentiated services and adapt to complex trials is key to ARG's strategy and vision. Vault eTMF and Vault CTMS enable them to improve the speed and quality of clinical studies through proactive trial management and visibility that drives informed decision-making. "We look forward to serving our sponsors better and partnering with Veeva to disrupt the industry with highly specialized trials and technology," says Walker.

Hunter Walker discusses the complexity of clinical trials and the value of being nimble with technology.

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