

NAMSA®

NAMSA Improves Pharmacovigilance Efficiency for Sponsors

HIGHLIGHTS

85%

Faster changes to application configuration

>50%

Reduction in training time

Real-time

Data visibility and collaboration

NAMSA, a global CRO offering end-to-end development services, implemented a modern, cloud-based safety application to provide clients the ability to rapidly set up studies, modify processes, and enable direct data access cross-functionally. With easier software upgrades, they can help clients leverage new application capabilities or stay up-to-date with regulations. Now NAMSA is delivering a broader range and higher level of service while reducing overhead and passing savings on to clients.

NAMSA

Global contract research organization (CRO) offering end-to-end development services

Corporate HQ: Toledo, Ohio, United States

Founded in 1967

Global associates: 1,600

600+ studies across 3,500+ clinical sites

Scaling, Collaborating, and Expanding Client Service Offerings

NAMSA provides a wide range of clinical trial support to clients, including safety services, developing and managing safety databases, intake, case processing, coding, narratives, and regulatory reporting. The move to digital trials has sponsors asking for more from their CROs, such as real-time data access. To meet these needs head-on, NAMSA has scaled its clinical service offerings to support growing client demands.

In the past, it was time-consuming and costly to set up studies, modify user fields or system processes, and upgrade software releases. System changes often required help from the IT team or other safety team members with specialized technical skills. NAMSA needed a modern, cloud-based safety solution that was easier to modify and maintain while enabling them to expand their offerings.

Implementing a Modern Safety Solution

Implementing **Veeva Vault Safety** allowed NAMSA to reduce IT overhead and provide customers of all sizes with a higher level and broader range of safety services. Sponsors now have direct access to their safety data, enabling real-time visibility and seamless collaboration with NAMSA on case intake, processing, and submissions.



Veeva Vault Safety provides a great way for small companies to maintain compliance and study oversight easily. And as they grow from pre-clinical to commercial, the application will automatically scale to meet business and regulatory requirements.

— Jennifer Kratz, Senior Product Development Strategist for Pharmacovigilance, NAMSA

Improving Alignment with Clients for a Higher Level of Service

Now, NAMSA can set up new studies or modify user fields and safety processes to align with client workflows in less than one day. Using Vault Safety's built-in reporting and dashboards, the CRO also shortened turnaround times for client reporting requests and gained greater operational visibility. Sponsors and NAMSA can better manage workloads, track case status, and monitor client-oriented service metrics. "Database customization used to take a week to complete," said Jennifer Kratz, senior product development strategist for pharmacovigilance at NAMSA. "Now, our customers see the effectiveness and efficiency of the system. And, we're providing a better user experience because we're aligning with their processes."

Boosting Productivity and Speeding Training with a User-Friendly Interface

NAMSA reports that its end-users and system administrators are now happier, take less time to train, and are more productive with an easy-to-use solution. Vault Safety's modern user interface also allows the CRO to rapidly customize user fields and processes to align with client workflows.

Vault Safety enabled NAMSA to cut the training time for novice case processors by approximately 50% and administrators by about 80% compared to the previous system. "An intuitive solution reduces errors and improves productivity," explained Kratz. "Vault Safety is easy to use, so we can train and complete tasks faster, saving time for our clients."

Lowering IT Overhead with a Simplified Pharmacovigilance Solution

A scalable, cloud-based solution with built-in submission gateways, dashboards, and reports, Vault Safety also reduced the number of software applications and integrations needed to support pharmacovigilance at NAMSA.

NAMSA easily built data analytics to oversee operations, regulatory compliance, and vigilance, as well as to provide vendor oversight for sponsors. In addition, eliminating the need for a separate gateway application enabled seamless electronic submissions to regulatory authorities. "We can now support regulatory submissions for our clients much more cost-effectively with Vault Safety," said Kratz.



With Veeva Vault Safety, we no longer need to invest in multiple software applications and integrations to run reports or submit data to regulatory authorities.

— Jennifer Kratz, Senior Product Development Strategist for Pharmacovigilance, NAMSA

Simplifying Upgrade Releases for New Capabilities

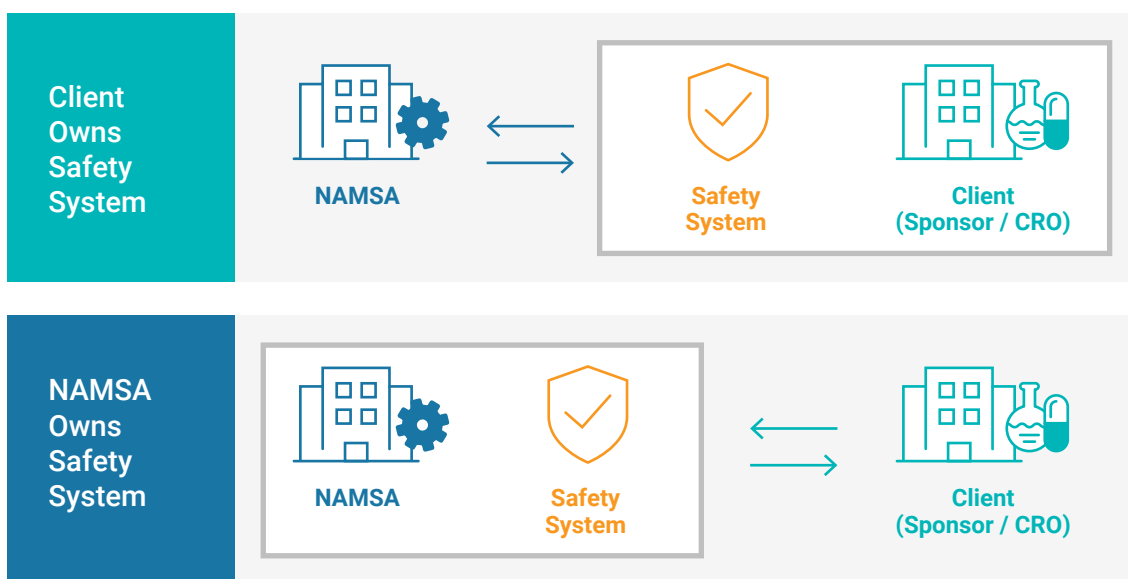
Vault Safety’s automatic updates three times a year enable NAMSA to deliver new capabilities or support new regulatory requirements, such as new data formats or additional data fields. Instead of spending time and resources to manage and maintain systems, NAMSA can focus on providing better services for clients.

“The upgrade process has been such a welcome relief,” said Kratz. “Each release has automatically enabled and optional features, allowing new capabilities to be delivered when it is most convenient.”

Supporting Flexible Outsourcing Models

Sponsors can own Vault Safety and have NAMSA set up, maintain, and perform assigned safety tasks. Alternatively, NAMSA can own Vault Safety and manage a range of pharmacovigilance activities from intake to submissions while providing sponsors with direct application access for real-time data visibility. With granular security permissions, internal and external users can view specific data or perform individual tasks.

“Veeva Vault Safety allows us to be very flexible,” said Kratz. “We can control who can access the application and how it is used to easily support a broad range of services.”



Strengthening CRO and Sponsor Relationships

Because both CRO and sponsor have direct access to the safety application, business relationships are strengthened with greater transparency and efficiency.

“With Veeva Vault Safety, we can better collaborate with our clients,” said Kratz. “They can view case data and run reports or queries. Or even create reports that are only viewable by them and their team.”

Reducing time to set up, customize, or complete client requests allows NAMSA to pass cost savings on to clients. With greater efficiency, NAMSA can provide more comprehensive services to meet the needs of large and small clients while delivering a higher quality service.

To hear how NAMSA collaborates with sponsors, [watch these short videos](#).