saama

CASE STUDY

Saama Solutions Help This Pharmaceutical Company Discover Added Value from Data.

CUSTOMER PROFILE

Primary Business	Pharmaceutical
Headquarters	Tarrytown, NY
Employees	6500
Annual Revenue	$5.9B
Trial Portfolio	• 24+ Studies, • 4 CROs • 12+ Data Feeds

The Challenge

Data Confusion Was Creating Chaos

By relying on multiple CROs, IVRs, and many different internal data sources for information, study teams at one pharmaceutical company had no way of overseeing clinical activities with consistency or comprehensiveness.

Studies run by CROs were lacking information as well as transparency, and studies conducted internally were even worse. Critical milestones were being missed, simply because the right information was not in the right place at the right time.

To improve the way it delivers life-transforming medicines for serious diseases, the sponsor began a quest to get a better handle on its clinical operations data.

The goal was to create a clinical data repository to help meet study timelines more effectively, ensure compliance, and track and assess protocol deviations at the product, site, and study levels more quickly.

Key Solution Components

> Data Ingestion
> Centralized Monitoring
> Real-Time Reporting
> CRO Collaboration
> Customized Dashboards

Why Saama?

> Scalability to 200+ sites
> Elimination of manual workflows, such as emails and trackers
> Data output standardization
> Role-based dashboards
> Responsive support

Key Results

> Active monitoring, with the ability to determine where holdups are taking place (internal, CRO, site, IRB, etc.)
> Ability to locate and determine the status of required documents
> Ability to view baseline, forecasted, and actual enrollment data for a study and drill down to countries and sites

> "We're really excited about some of the new ways we can apply analytics. Even non-technical people can use the dashboards and view the metrics they need."
>
> *Director of Clinical Data Standards and Analysis*

The Solution

Wide Visibility Opens People's Eyes to the Power of Data

The sponsor chose Saama to create a single source of truth that would allow key stakeholders to access vital study data for much-needed oversight.

The first order of business was to ingest all the data from an initial group of 15 studies. The Saama team collaborated with the sponsor and CROs to collect the data, determine ownership, and establish connectors for feeding automatic updates into the centralized data repository from disparate systems.

Once everything was running smoothly and meaningful data started coming in from some of the studies, previously hidden issues bubbled to the surface for fast action. Queries were being closed out faster. It became easier to allocate limited resources for more productive site visits. And study managers felt greater peace of mind around documentation and compliance.

It soon became clear that Saama's suite of applications could be used to gather insights beyond the study conduct phase. So the executive team requested dashboards for analyzing study-startup data, enrollment data, and changes in patient status.

In the startup phase, study managers are using data to make sure that countries are activated on time, and that approvals involving protocols, ICFs, contracts, and IRBs occur within the expected time frame. Specific KPIs were configured related to regulatory documentation, site onboarding, and monitoring CRA turnover at specific sites.

Enrollments are also being monitored to make sure they proceed according to plan. A single dashboard enables senior management to view real-time enrollment on all active trials. Timely updates allow the operations group to remove or add countries and sites, to meet specified target dates for First Person First Visit (FPFV) and other milestones.

Saama Products

Operations Insights

Provides a faster, more efficient way to identify and act on study, site, and staff performance issues, before they become major problems. The solution also facilitates collaboration between sponsors and CROs, ensuring that regulations are met and that any site or staff performance issues are identified and acted upon as quickly as possible.

Risk Based Monitoring

Enables smarter resource allocation and risk reduction through full visibility into KRIs across an entire study portfolio. WIth the ability to view and analyze data in a central location, the need for traditional site visits is greatly reduced, saving both time and travel expenses.

Next Steps

The Start of Something Big

Having access to a unified study data model, and raw study data to measure relevant performance metrics, has created a great deal of enthusiasm among study teams.

The sponsor already has several super-users who are touting the benefits of the centralized data repository throughout the company. More study teams are wrapping their heads around the data and what it can do for them, and the sponsor's ultimate goal is to get all its studies, even the old ones, into the system.

Access to historical data enables the sponsor to answer a multitude of questions, including which CROs are performing at higher levels and which principal investigators and sites are the most productive.

Get Started with Saama Today

Learn more about how Saama can help you improve clinical trial performance and reduce risk.
Visit saama.com or call us at 888-205-3500.

www.saama.com Request a Demo

About Saama Technologies, Inc.

Saama Technologies is the advanced clinical data and analytics company, unleashing wisdom from data to deliver actionable business outcomes for the life sciences industry. Saama's unified, AI-driven clinical data analytics cloud platform seamlessly integrates, curates, and animates unlimited sources of structured, unstructured, and real-world data to deliver actionable insights.