



To Improve Clinical Trial Performance and Reduce Risk, One Medical Device Company's Executive Team Keeps an Eye on Data.

CUSTOMER PROFILE

Primary Business	Medical Devices
Headquarters	Irvine, California
Employees	12,000
Annual Revenue	\$3.44B
Trial Portfolio	<ul style="list-style-type: none">• 23 Studies• 8+ Data Systems

The Challenge



Unknown Data Issues Were Raising Red Flags

For one medical device company, a lack of visibility into data was causing unnecessary delays and cost overruns across a portfolio of dozens of clinical trials. The company needed better data access to proactively monitor performance indicators, generate custom reports, and mitigate risk.

The first step was to ingest and aggregate data from multiple systems, including Medidata RAVE, Medidata CTMS, Veeva Vault eTMF, Merge Adjudication, ECLM, Sharepoint, Excel, and Argus Safety. The company also wanted to create a more robust data governance program, so different business units could collect clinical data in a uniform and consistent manner.



Key Solution Components

- > Data Ingestion
- > Data Aggregation
- > Data Cleanup
- > Data Dashboards
- > Real-Time Reporting

Why Saama?

- > Reduced reliance on spreadsheets and other stand-alone BI reporting tools
- > Harmonized aggregation and reporting of clinical trial information for senior executives
- > Instant visibility into query status
- > Standardized dashboards and reports
- > Uniform study metrics
- > Cultural shift towards individual accountability for study conduct

Key Results

- > Uncovered serious data holes and inconsistencies, especially around site activations and queries
- > Enables sub-study analytics for a broader view of specialized metrics and adverse events (AEs)
- > Reduced manual processes and human error

The Solution



Saama Wins the Trust of Company Executives

The company hired Saama to aggregate and unify its data. Data management was much easier, but the solution revealed serious data holes that needed to be filled quickly to keep the company's clinical trials on track.

The success of the data management project got the attention of the sponsor's VP of Global Clinical Affairs. She was so impressed that she inquired about creating an Executive Dashboard to provide data visibility to business leaders at the director level and above. Saama was up against an internal team at the company, which was trying to build a solution using a horizontal business intelligence tool.

Leveraging the power of pre-built KPIs, the Saama team built a proof of concept that won out. "It blew our socks off," said the VP. "The reporting capabilities were comprehensive, and the color-coded dashboards made it easy to identify issues that needed a quick response."

Directors across several business units use the Executive Dashboard primarily for planning purposes. For example, if the dashboard shows that a particular CRA isn't as productive as expected, decisions can be made about providing training or lessening the individual's workload if they're on more than one study. Directors can also monitor sites for performance outliers, and make sure data is as clean as possible in preparation for analysis.

With greater visibility, executives at the VP level are more proactive about raising issues to study teams. They can also make sure that milestones across the study portfolio are met on time. "The dashboard is really easy to navigate," says one ClinOps VP. "The red-yellow-green colors tell you where to go."

In the C-Suite, top officials are using data from the Executive Dashboard to make sure that the company maintains its focus on improving patient outcomes and enhancing lives.

“It blew our socks off.”

VP of Global Clinical Affairs

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.



Clinical Insights

Brings all safety- and subject-level data into a unified structure for consistent and proactive medical review and safety signal analysis.

Get Started with Saama Today

Learn more about how Saama can help you create data transparency from the top down.

Visit saama.com or call us at 888-205-3500.

www.saama.com Request a Demo

Results



Previously Hidden Problems Finally Got Solved

When the new Executive Dashboard was first activated, a strange thing happened: all site activation indicators showed up as red. It was soon discovered that people weren't entering site activation dates in the same place across data systems. The error was corrected and data quality risk was minimized going forward.

The metrics regarding queries were also raising concerns, revealing that thousands of queries had been open for more than 28 days. A programming issue in the EDC system was partly to blame, but the issue also highlighted a systemic problem in the corporate culture that queries don't really matter.

Queries were never given much attention until a study milestone was put in jeopardy. Then it was all hands on deck to manage the crisis. Now, with the Executive Dashboard in place, senior managers can see the status of queries on a daily basis and make sure they're answered in a timely manner.

Next Steps



The Beginnings of a Larger Go-To-Market Strategy

With the Executive Dashboard supported by Operations Insights and Clinical Insights from Saama, the medical device company envisions a day when Saama's Life Science Analytics Cloud (LSAC) can feed a single set of dashboards across every business unit in the enterprise.

In conjunction with the data governance program, everyone at the company will one day align on the same nomenclature across the entire clinical trial portfolio for greater consistency in data analytics, so new devices and treatments can get to market faster.



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.