saama

CASE STUDY

To Stop Delays and Unnecessary Costs, One Global Biopharma Company Changed the Way it Manages Multiple CROs.

CUSTOMER PROFILE

Primary Business	Biopharmaceuticals
Headquarters	Dublin, Ireland
Employees	1,000+
Annual Revenue	$1.6B
Trial Portfolio	• 4 Studies, • 3 CROs • 9 Data Systems

The Challenge

Poor Data Visibility Created an Untenable Situation

Outsourcing work to multiple CROs slowed the progression of important clinical studies for an international biopharmaceutical company, whose main focus was on unmet medical needs. Data visibility was severely lacking, as information was siloed in nine disparate systems across three different CROs.

When data was received it was typically up to a month old, which made it difficult for the sponsor to mitigate risks and address operational issues such as late enrollments and site startup delays.

The sponsor also struggled to confirm whether or not its CROs were meeting agreed-upon terms and quality plans. The lack of comprehensive oversight regularly extended milestones and added unnecessary costs.

Copyright © 2020 Saama Technologies

Key Solution Components

- Data Ingestion
- Real-Time Reporting
- CRO Collaboration
- Customization

Why Saama?

- Data unification and transparency
- Purpose-built KPIs, which eliminated hours of analytic coding
- Real-time, threshold-based alerts
- Workflow productivity and data-driven collaboration

Key Results

- Reduced study delays through proactive monitoring of site performance and risk indicators
- Minimized costs due to study delays and uninformed resource allocation
- Increased effective decision-making across studies, with insights based on real-time data
- Weeded out an uncooperative CRO and improved collaboration with other CROs

> "With the insights required to manage risk thresholds, ensure compliance, and meet timely study milestones, we're now in a much better position to collaborate with our CROs."
>
> *VP of Clinical Operations*

The Solution

Saama Saved the Day with Limited IT Involvement

Knowing that it was at the mercy of its CROs, the sponsor wanted a single system that could provide real-time access to its operational data. To create such a system internally, however, would have required resources the sponsor just didn't have. "We wanted to get up and running pretty quickly," said the VP of Clinical Operations. "We didn't have the people or the time to do it in-house."

Once the do-it-yourself option was ruled out, the sponsor evaluated data analytics solutions and chose Saama for a six-month pilot program.

The pilot focused on the requirements needed to meet study milestones and improve data quality across a set of four clinical trials. With minimal work required from IT, data from nine disparate sources was integrated into a common data model, which could be easily monitored in real time. Using pre-built analytics, issues could be quickly identified and managed before causing any major delays or creating undue risk.

Results

Saama's Solution Provides Value Across the Entire Portfolio

The primary goal of the pilot was to meet the critical business need date of First Patient Dosed for each study. In order to achieve this, engagement from the participating CROs was required.

The initial CRO response was one of resistance, and one CRO was so uncooperative it was ultimately let go. The sponsor reassured the other CROs that the desired data transparency was merely for reporting and oversight purposes, and that the CROs were still in charge of managing the studies.

Copyright © 2020 Saama Technologies

Saama Products

Risk Based Monitoring

Enables proactive study management based on risk thresholds, reduces the need for traditional site visits, and optimizes portfolio oversight, enrollment, subject compliance, and site productivity processes so ClinOps teams can mitigate risk and achieve milestones on time.

Get Started with Saama Today

Learn more about how Saama can help you rethink CRO oversight and collaboration throughout your organization.
Visit saama.com or call us at 888-205-3500.

www.saama.com Request a Demo

Ultimately, the remaining CROs came to realize that it was better for everyone to share data in real time using a single, centralized system. This enabled business owners to benchmark their clinical trial data and helped medical monitors reduce the amount of time required to track and manage adverse events and protocol deviations.

Resources were used more efficiently, and team members could make smarter, more accurate decisions to ensure performance and risk levels consistent with successful clinical trials.

Using forecasts and alerts to proactively identify and escalate priority study issues, safety was markedly improved and data quality risk was significantly lowered. In addition, CRO change orders and cost overruns due to enrollment and data quality related delays were avoided.

Next Steps

Sponsor Improves CRO Oversight and Collaboration for All its Studies

After a successful pilot program, the sponsor decided to continue using the solution for additional studies. According to the VP of Clinical Operations, the company is in a much better place for achieving better results “with the insights required to manage risk thresholds, ensure compliance, and meet timely study milestones.”

Copyright © 2020 Saama Technologies

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.

Copyright © 2020 Saama Technologies