![saama logo](#1 in AI Clinical Analytics)

Operations Insights: Accelerate Clinical Trials with Automated Oversight and Collaboration

Benefits at a Glance

- Proactively manage operational issues
- Better understand subject safety, protocol compliance, and retention

AI-Enabled Insights

Saama's revolutionary Deep Learning Intelligent Assistant (DaLIA) lets you query your data for immediate answers to common questions, without having to waste time tracking down an expert inside your company.
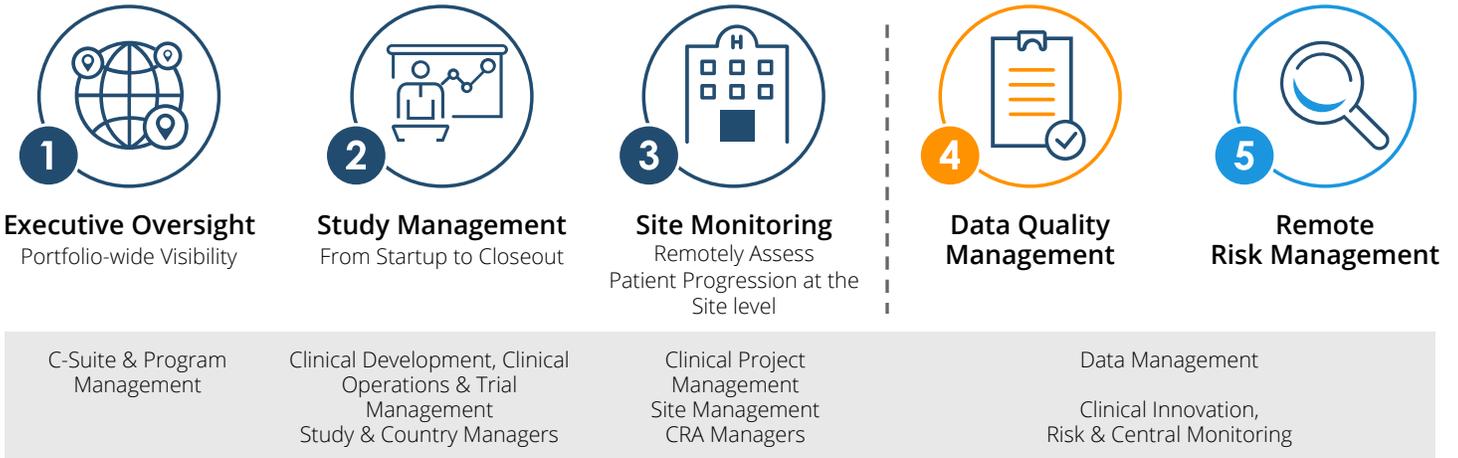
ClinOps VPs, Study and Site Leads, CRA Managers, Data Managers, C-level Executives, and other stakeholders use Operations Insights to monitor the status of studies and sites--and avoid milestone delays.

By optimizing portfolio oversight--using intuitive, drillable dashboards and automated threshold alerts--all your enrollment, compliance, and site productivity issues can be identified and resolved before becoming major problems.

Solution Highlights

- Integrate data from CTMS, EDC, ePRO, IxRS, and other sources into a unified study data model
- Use role-based dashboards to gain insights into common study startup and conduct KPIs (see table)
- Use historical data patterns to predict future outcomes
- Provide oversight consistent with good clinical practice, as outlined in ICH E6(R2) guidelines
- Use a fully auditable task management system to facilitate collaboration and issue investigation
- Easily generate tabular and visual reports for presentations and internal review

Persona-Based Dashboards in Operations Insights

1 Executive Oversight
Portfolio-wide Visibility

2 Study Management
From Startup to Closeout

3 Site Monitoring
Remotely Assess Patient Progression at the Site level

4 Data Quality Management

5 Remote Risk Management

C-Suite & Program Management	Clinical Development, Clinical Operations & Trial Management Study & Country Managers	Clinical Project Management Site Management CRA Managers	Data Management Clinical Innovation, Risk & Central Monitoring	

Gain Control Over Your Data with a Day-to-Day Clinical Operations Portal

Clinical trial workflows are typically bogged down by missing data and error-prone manual processes. Saama solves these problems by automating oversight and collaboration across studies, sites, and systems for sponsors and CROs alike.

Portfolio Analysis

At-a-glance dashboards show real-time status and progress for single studies or your entire portfolio. Predict delays with cross-study comparative forecasts, answer questions about risk areas, and determine resource allocation and investment needs.
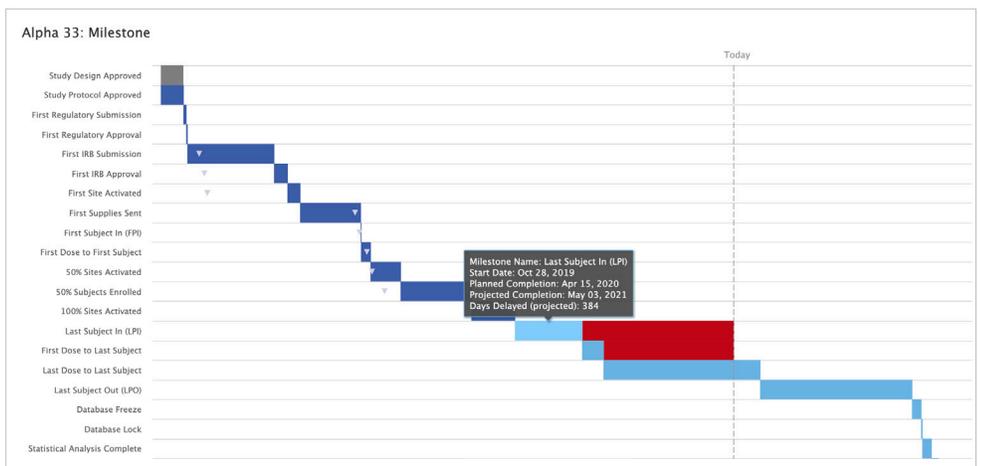
Milestone Achievement
1 studies ahead of target
3 studies on target
0 studies behind plan

Site Activation
1 studies ahead of target
2 studies on target
1 studies behind plan

Enrollment
0 studies ahead of target
2 studies on target
2 studies behind plan

Financial Summary
-- studies forecasted under Budget
-- studies forecasted over Budget

Portfolio Performance Overview

Study	Phase	Current Milestone	Previous Milestone	Site Activation	Subject Enrollment	Screen Failure Rate	AE Rate	PD Rate
Gamma 800	IIa	Last Subject In (LPI)	First Subject In (FPI)	96%	66%	26%	0.01883	0.01301
Gamma 900	II	Last Subject In (LPI)	First Subject In (FPI)	96%	66%	26%	0.01883	0.01301
Race 335	II	Last Subject In (LPI)	First Subject In (FPI)	160%	89%	46%	0.02094	0.00986
Race 337	IIb	First Dose to Last Subject	Last Subject In (LPI)	16%	100%	6%	0.04102	0.02501

Milestone Management

Regional, country, and study leaders can manage sites and studies from a single source of truth. Automated alerts identify issues early, so you can take corrective action that prevents delays and avoids cost overruns.

Alpha 33: Milestone

Today

Study Design Approved
Study Protocol Approved
First Regulatory Submission
First Regulatory Approval
First IRB Submission
First IRB Approval
First Site Activated
First Supplies Sent
First Subject In (FPI)
First Dose to First Subject
50% Sites Activated
50% Subjects Enrolled
100% Sites Activated
Last Subject In (LPI)
First Dose to Last Subject
Last Dose to Last Subject
Last Subject Out (LPO)
Database Freeze
Database Lock
Statistical Analysis Complete

Milestone Name: Last Subject In (LPI)
Start Date: Oct 28, 2019
Planned Completion: Apr 15, 2020
Projected Completion: May 03, 2021
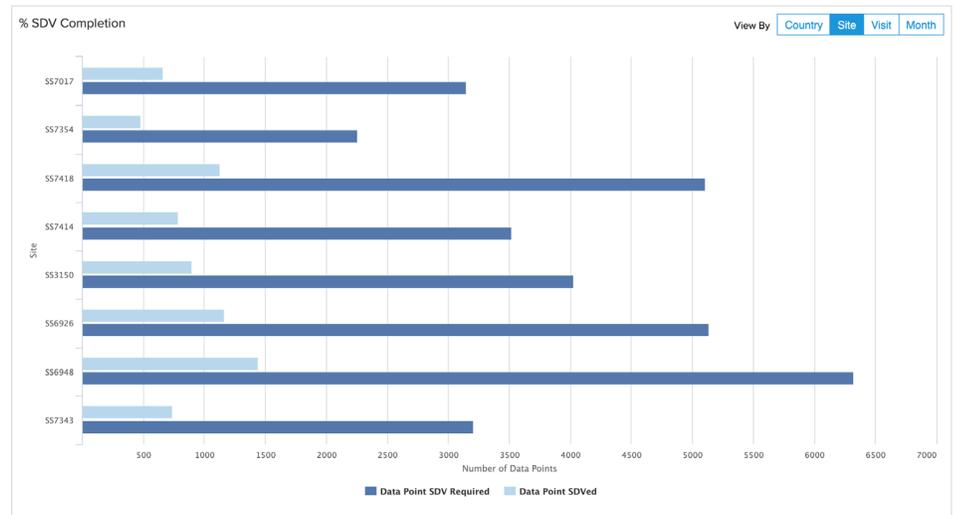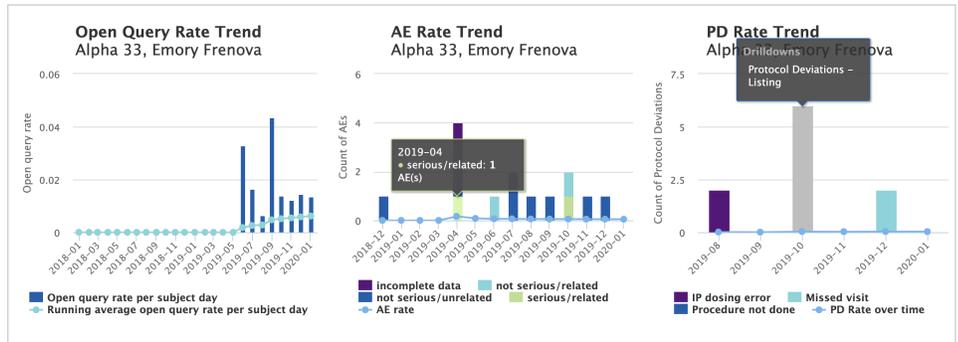Days Delayed (projected): 384

Study and Site Performance Management

End-to-end visibility, pre-built dashboards highlighting KPI's relevant to specific users at the study and site levels, and real-time data aggregation make it easy to identify at-risk sites and resolve issues before they become major problems.

Data Quality and Compliance

Complete data visibility, along with AI-powered predictive capabilities, makes it easier to identify root causes and prevent errors.

Get Started Now

Operations Insights can be up and running in just four weeks from time of data access.
To learn more and arrange a demo, **contact Saama today.**

About Saama Technologies, Inc.

Saama is the #1 AI clinical analytics platform company, enabling the life sciences industry to conduct faster and safer clinical development and regulatory programs. Today, 50 biotech companies—including many of the top 20 pharmaceutical companies—use Saama's award-winning Life Science Analytics Cloud (LSAC) platform to accelerate more than 1,500 studies. LSAC's rich applications facilitate unprecedented and authoritative oversight of comprehensive clinical research data, enabling companies to file New Drug Applications (NDAs) more efficiently and bring drugs to market faster. Discover more at www.saama.com and follow Saama @SaamaTechInc on Twitter.

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