ASPECT CONSULTING, INC.

Clinical Study Monitoring Suite

Dashboard Reporting for Integrated Study Data Monitoring

The Advantage of Clinical Study Data Monitoring

Aspect Consulting's Clinical Study Monitoring Suite is a collection of data integration & dashboard reporting components, placing all the data you need to better monitor clinical study milestones and metrics across your entire platform, improving both operational oversight and risk-based assessment.

Integrate

Centralize and normalize your data. The suite is comprised of a fully scalable data load infrastructure that **combines, validates & standardizes** clinical and operational data sourced both internally and externally across all contract research organizations (CROs).

Know

Know your data. Cross-platform dashboard reporting provides a unified picture of key population, disposition and adverse event metrics across all studies, with drill down to the individual study level, for **improved safety data analysis.**

Take Control

Monitor your risks. Ongoing study dashboard reporting provides clinicians with insight into key milestones, enrollment projections, data accrual, query resolution, deviations, and adverse event data, with drill down by site and subject, for **improved oversight and early detection of potential risks**.

Key Advantages

Integrated Data Across all CROs • Responsive One-Click Analytics • Increased Operational Oversight • Early Detection of Risks

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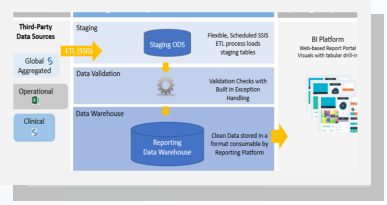
One Unified Data Platform

Clinical Study Monitor is Comprised of ...

Integrated Data Repository

A SQL-server based integration environment stores both internal and externally sourced operational and clinical study data in one centralized repository:

- Ability to load a wide variety of file sources and formats, so that processing is scalable.
- Data is validated and normalized in a format consumable for reporting
- Reduces the manual effort needed to compile and generate cross-study reporting

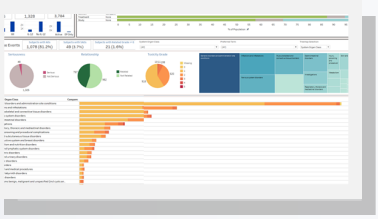


Program Monitor Dashboard

The Program Monitor Dashboard includes metrics that help management-level resources better assess safety data across the entire study platform.

Customizable filters enable users to slice data by program, study, and dosing scenarios applicable to your organization: Users can:

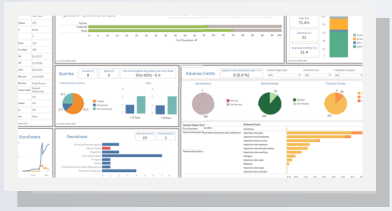
- View key population metrics
- Monitor subject disposition
- Assess adverse event metrics, with drill in to greater detail. Apply additional filters for advanced safety analysis.



Study Monitor Dashboard

The Study Monitor Dashboard includes metrics that help clinicians better assess progress toward study milestones and monitor metrics that provide at a glance insight into possible risks, with drill in by site and subject. Clinicians can:

- View study-specific milestones and monitor enrollment projections
- Track subject status and deviations
- Measure data accrual metrics and monitor query response
- Assess adverse events by seriousness, relationship and toxicity grade, and sort by system organ class and preferred term.



Features

FLEXIBLE AND FULLY SUPPORTED DATA ENVIRONMENT

Cloud-based or In-house Repository

Components can be hosted by a secure third party hosting company, or reside in-house within your infrastructure.

Scalable Data Load Platform

Processing is scalable and can accommodate future growth and additional data vendors.

Complete Data Support

Our experts will support your data and reporting environment on an ongoing basis, working with you and your CRO vendors to continually ensure the integrity of source data.

DASHBOARD REPORTING WITH DATA RICH VISUALS

Customizable Filtering

Slice and dice your data by customizable filters designed to meet your specific dosing scenarios.

In-Depth Safety Analysis

View summarized adverse event data or drill through and filter the complete adverse event data set for expanded safety data analysis.

Risk-Based Monitoring

View progress toward key data accrual, query response, deviation, and adverse event metrics at the study level for early detection of factors that have the potential to impact submission milestones.

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