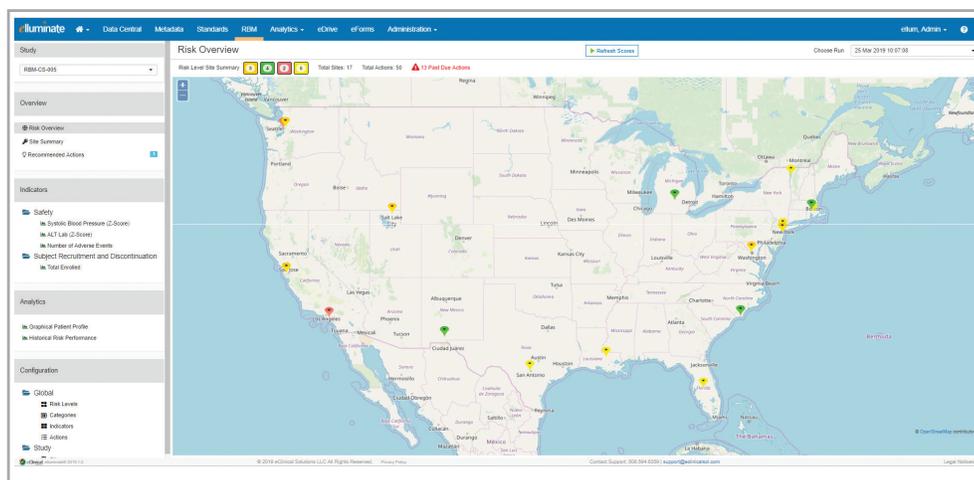# elluminate®

RISK BASED MONITORING

KRIs and Analytics in Real-Time Across Any Data Source

Map-Based Risk Overview by Site

elluminate® Risk Based Monitoring provides clinical teams with a single platform that transforms numerous study data streams into actionable analytics. The result is a more focused and data driven monitoring effort that enables sponsor oversight and improves the quality and compliance of a clinical trial or program. Users work with data visualizations that highlight key risk indicators pre-defined using the TransCelerate RACT methodology and then review recommended actions that help document risk owners and the steps taken to mitigate risk.

KEY BENEFITS

Comprehensive Risk Profiles

elluminate provides one platform for all the data sources used in a trial and provides comprehensive data to feed key risk indicators (KRIs) at the site level. Numerous visualizations and data scoring algorithms highlight risk levels according to configurable parameters. These complete risk profiles allow monitors to focus time and resources on sites that need the most attention.

Rapid Implementation

The elluminate platform provides real-time integration and interoperability with numerous data sources and enables mapping to standard formats and publishing data to different datamarts, for actionable analytics. This platform approach allows RBM to rapidly incorporate numerous data sources that feed the KRIs.

Effective Study Oversight

The holistic view of risks driven by KRIs across data sources provides better visibility into the status of the study for all stakeholders. Recommended actions with due dates keep monitors focused on taking actions to keep trials on track and ensure appropriate quality oversight and patient safety, with transparency across the organization.
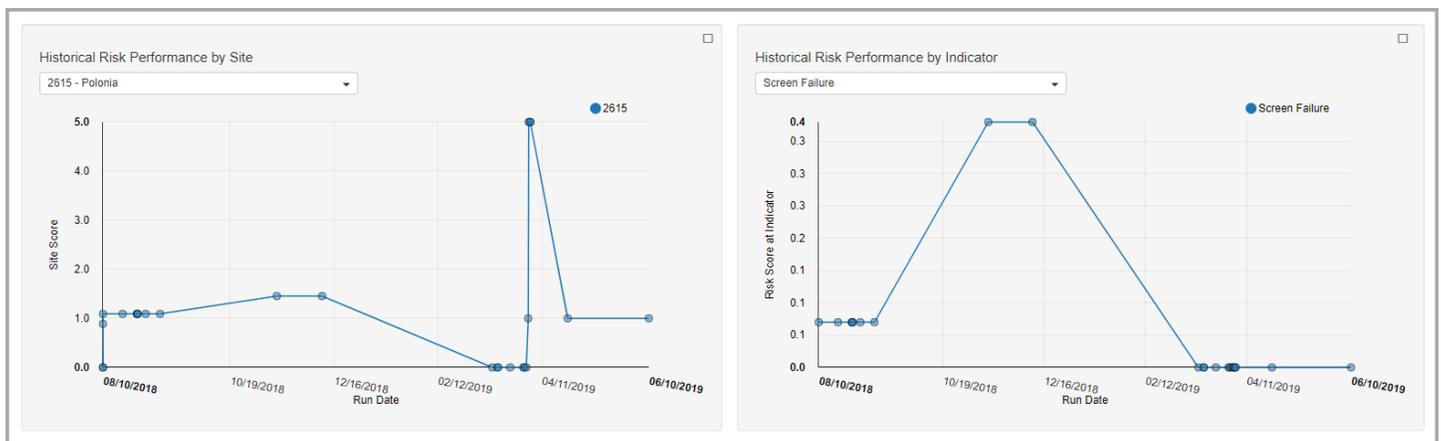
KEY FEATURES

KRIs & Recommended Actions

KRIs are associated with recommended actions specific to the risk, then assigned to an owner and tracked with completion dates to ensure risks are addressed in a timely manner. End users log in and see the actions that are assigned to them, guiding them to focus on the highest risk activities that need resolution.

Numerous Data Sources to Develop

Access the numerous data sources in elluminate to develop the most relevant KRIs using data from any system including EDC, Labs, eCOA, SAEs and others, supporting users to focus time spent monitoring and tracking data-driven risks.

Patient Profiles and Visualizations

elluminate has a powerful analytics engine that provides rich visualizations with drill-down capabilities for review of both aggregate and detailed KRIs at the site level. Recommended actions are automatically generated based on risk level and can be assigned to users for follow-up and tracked over time.

Risk performance by site overall and by selected indictor

LEARN MORE

The elluminate® Clinical Data Hub is a cloud based enterprise software platform that makes clinical data acquisition, mapping and analysis easy and intelligent for clinical teams. More than 100 life sciences companies have used the elluminate platform and software enabled services from eClinical Solutions to regain control of their clinical trial data. For more information or to request a demonstration, visit us at **www.eclinicalsol.com** or email us at **info@eclinicalsol.com**.

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