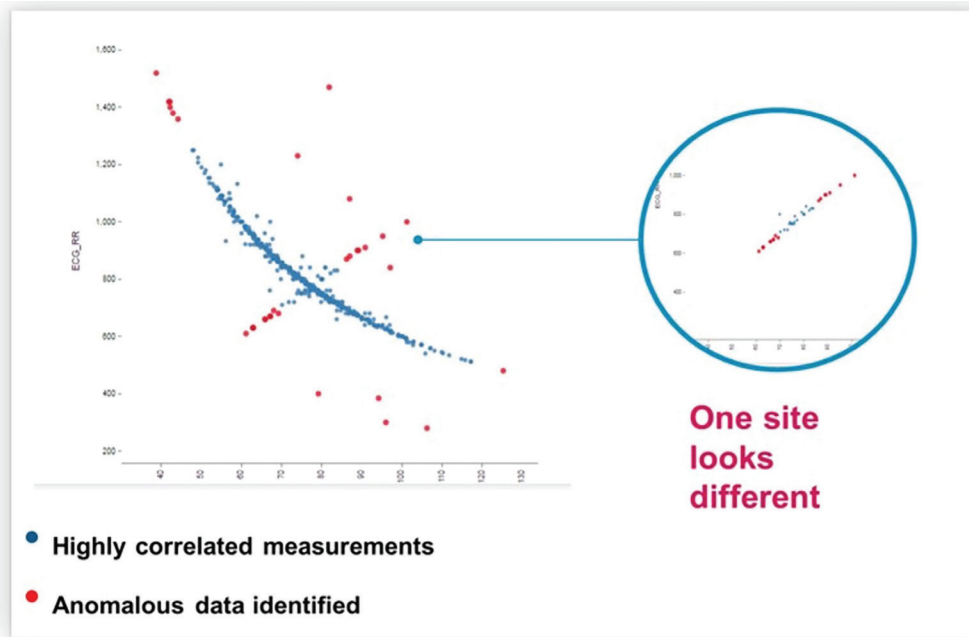


Rave Trial Assurance - Protect Your Trial from Avoidable Risk



The increasing complexity of clinical trials has made monitoring and reviewing clinical trial data ever more challenging. Current practices to evaluate protocol adherence and data entry are often insufficient for identifying critical data quality issues that may impact the study results. This can lead to missed adverse events, data anomalies, and procedural deviations which could negatively affect timelines and lead to costly study delays.

Powerful data analytics are required to identify errors which may slip through normal data management processes and edit checks. Rave Trial Assurance is a **service** that evaluates the integrity and quality of all clinical data within a clinical trial. Powered by Medidata Detect, our real-time anomaly detection tool, you gain immediately actionable insights to improve your clinical trial performance and data quality.

Product Benefits

Protect data integrity

- A data-driven approach to maintain accurate and consistent data over the life of a clinical trial

Become inspection-ready

- Prevent avoidable study failure and prepare the study database before regulatory submission

Gain actionable insight

- Improve clinical trial performance and data quality, which may impact study results and future regulatory reviews

Know the unknown

- Unified lab and clinical data reviews allow study teams to discover unreported adverse events

Features

Comprehensive analysis of data powered by Medidata Detect, with emphasis on data quality and study integrity

Summary report and presentation of results

Analyses led by former FDA statistical reviewers

Statistical analytics including data anomalies, probable data errors, and site-level procedural differences

The Medidata Advantage

Trial Assurance is a unique service both in the analysis and the holistic view it provides by contextually comparing lab and clinical data. Medidata Detect is the analytics engine at the center of the Trial Assurance service.

Using machine learning, Medidata Detect continuously scans and learns proper and acceptable ranges for all data fields across your trial. It surveys millions of data points, comparing every variable in the data set to every other variable, searching for and identifying statistical relationships between them. It visually unifies all relevant data for each individual patient, making it easier to identify inconsistencies within a patient history. This analysis of the study database often turns up data quality issues not previously identified.