Rave CSA Critical (Centralized Statistical Analytics)
Mitigating Risk with Patients, Sites and Studies

All clinical research stakeholders are navigating a "new normal," due to the COVID-19 pandemic that requires agile adaptation of technology, processes, and resources for current and future research efforts. This paradigm shift necessitates patients, sites, CROs and sponsors to rapidly come up with novel, creative solutions to minimize adverse impacts to patient safety and clinical trial integrity.

Medidata is here to help during this time by providing centralized data ingestion, integration and analysis with Rave CSA Critical - a solution that mitigates your limited resources by delivering:

- Timely data availability for proactive early data oversight

- Focused Key Risk Indicators (KRI) on areas of greatest risk

- Early detection of data patterns and anomalies

- Automated insights into subject safety, data integrity, and site performance

- Mitigation of risk due to disruptions in site monitoring and patient visits

Central monitoring can be used to rapidly assess which studies have been impacted by COVID-19 and to what extent. This Rave CSA Critical package should be used alongside study-specific risk assessment and mitigation strategies.

- Proactive oversight by enabling Sponsor and CRO access to real time data

- Performance of 18 focused KRIs associated with reduced patient visits, reduced site monitoring, and associated impact to patient safety and data integrity

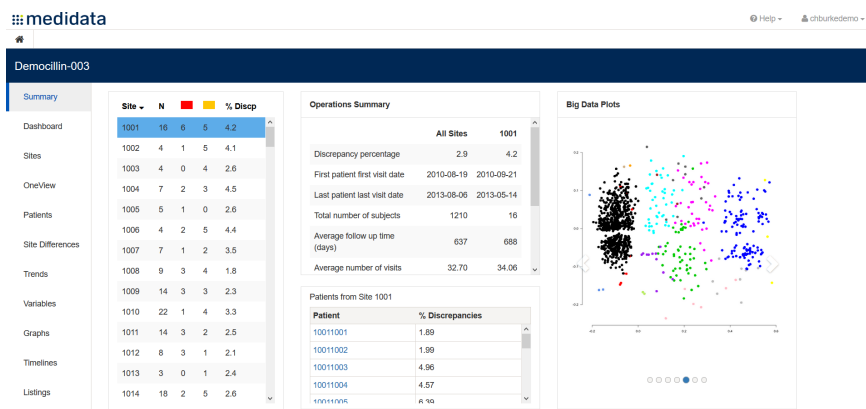- Automated insights into site data anomalies and patterns

QUICK, FOCUSED SET-UP:

- Delivery of Rave CSA within 2 weeks

- Medidata-built, standardized study setup 1-2 weeks after receipt of all startup requirements

- Accommodating up to 3 external (non-Rave) data sources

- Query data included in the first refresh

- Up to 10 "Key Data Points"

- Select Key Risk Indicators

- Access to Patient Profiles

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Automated Detection of Data Anomalies

Clients are faced with two real risks: the inability of subjects to participate in in-clinic activities and the inability of monitors to travel to perform on-site monitoring activities. In an effort to help, Medidata designed Rave CSA Critical to enable you to rapidly visualize the impact of reduced patient visits and onsite monitoring visits. An example of the Summary Dashboard is highlighted in Exhibit 1.
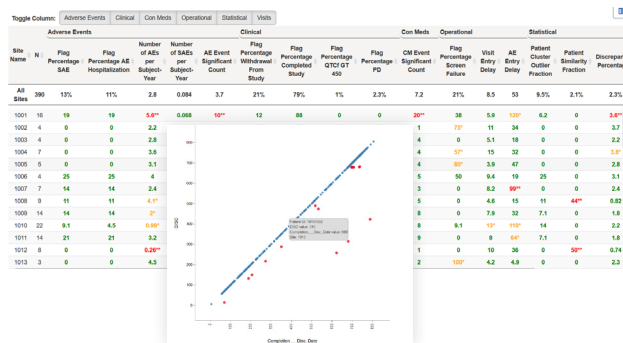
Exhibit 1: Summary Dashboard

Rave CSA Critical leverages Rave CSA to identify anomalies and risks in the data of a specific study. Rave CSA is a unique solution that applies sophisticated statistical algorithms to interrogate the clinical data in your trial for outliers, data anomalies and trends. The algorithms are "smart" in that are generated programmatically by the system, so there is zero statistical programming required by you. Rave CSA Critical relies on 18 Key Risk Indicators - a focused subset of Rave CSA KRIs fundamental to patient safety, site performance and data quality oversight highlighted in Exhibit 2.

Exhibit 2: KRI Table and Trending Graph

ONGOING ANALYTICS:

- Access for 6 months
- Up to 5 monthly refreshes

VIRTUAL TRAINING:

- WebEx Overview provided to client personnel
- Reviewing Rave CSA Critical Output
- Introduction to CSA Navigation eLearning

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Rapid Enablement

Medidata does the heavy lifting for you by taking in your data, integrating it, and delivering query results to ensure data quality.

- Get automated insights and analytics, such as:

  - Subject safety

  - Data integrity

  - Site performance

- Enable remote management to mitigate risk associated with site monitoring and patient visit disruption

- Identify data inconsistencies and transcription/data entry errors via machine learning

- Ensure timely and accurate reporting of Adverse Events and Serious Adverse Events

Rave CSA Critical can be implemented within 2 weeks. You can easily identify problems with patient safety or data quality by performing centralized data review for 6 months, inclusive of 5 data refreshes performed by Medidata.

Early identification of issues allows for remediation so that the final study database properly reflects the study design and objectives, inclusive of any COVID-19 related amendments. This CSA package is used alongside study-specific risk assessment and mitigation strategies.

Contact us to learn how Medidata can help you with technology to empower sites, patients, CROs and sponsors to deliver robust clinical trials in a changing environment.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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Reduced costs | Improved time to market | Faster decisions | Minimized risk

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