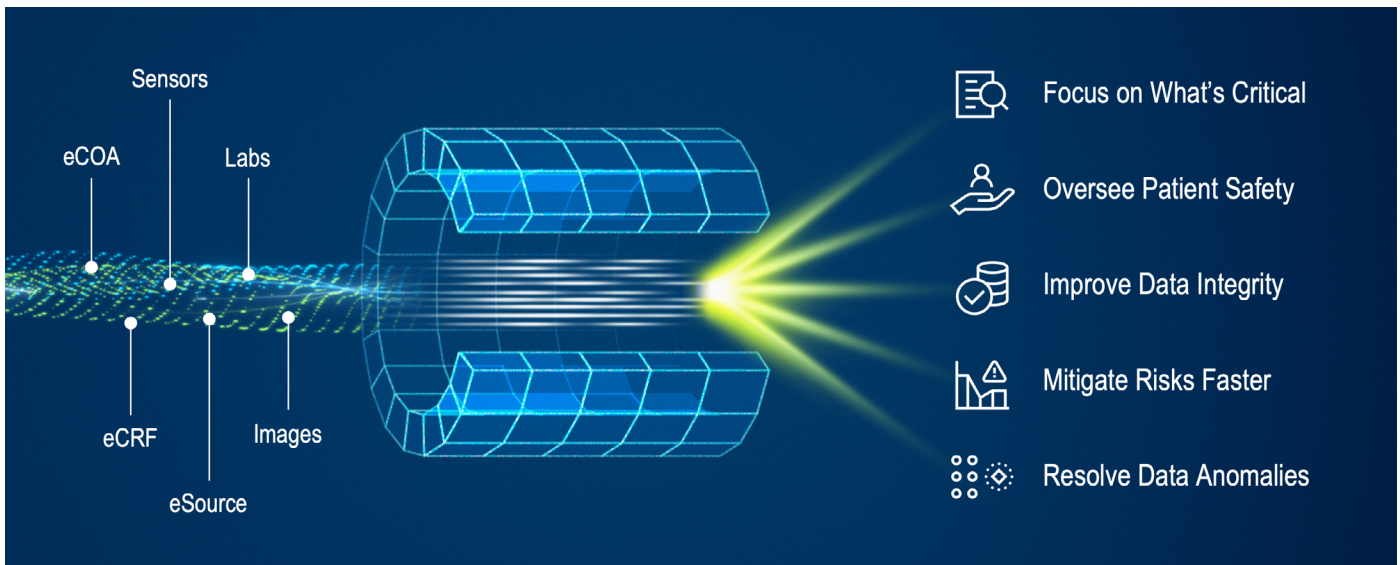


Medidata Detect

Ensure Quality With Comprehensive Data Surveillance and Risk Monitoring



Oversight of data quality and patient safety during a clinical trial is a team effort. The explosion of novel ways to collect and monitor on-site and remote data provides opportunities to uncover valuable insights during clinical research. However, it also increases the complexity and pressure on operational teams to support and scale these new approaches. Too often, siloed working groups and systems prevent timely identification and correction of quality issues, negatively impacting trial timelines and operational costs.

Medidata Detect is a robust data and risk surveillance technology that solves these challenges by harmonizing data from many sources in a single location, breaking down operational and data source silos. Detect provides data managers, medical monitors, and clinical operations teams with role-based capabilities powered by advanced analytics that improve patient safety, data quality oversight, and risk management.

Medidata Detect Benefits

Manage Quality in One Place

Aggregated data from almost any source all in one solution. Data review, safety monitoring, risk management, site performance oversight, advanced analytics, and study level insights increases your confidence in data integrity and trial quality.

Optimize Resource Utilization

Central monitoring insights support shifting from prescriptive on-site monitoring to a less expensive targeted approach and creating more efficient monitoring strategies.

Generate Fast Data Insights

Near real-time data refreshes allow for ongoing signal detection and course correction, eliminating database lock delays saving time and cost.

Accelerate Decentralized Trial Execution

Remote and decentralized activities provide flexibility and generate actionable insights from anywhere.

Modular and Scalable

Modular solution with a fit-for-purpose role-based user experience that scales as needed..

Improve Data Quality with AI

Complex data reconciliation and anomaly detection powered by AI improves efficiency and detects potential issues earlier.

Medidata Detect Features

Medidata Detect includes modular capabilities that aid planned risk monitoring, such as Key Risks Indicators (KRIs) and Quality Tolerance Limits (QTLs), machine learning capabilities to identify data anomalies and trends, targeted analyses to determine site performance issues, fraud, and misconduct, as well as features to support full data review, at the individual patient and at the aggregated level. Select the fit-for-purpose activity you need:

Patient Data Surveillance

Patient Profiles for Medical Monitors

- Create complete patient stories with daily data refreshes
- Focus on areas of interest with graphs, side-by-side timeline views, and custom flags
- Interrogate data quickly with direct line into Rave EDC
- Manage workload with patient profile review tracking

Data Reviewer for Data Managers

- View and interrogate aggregated data across multiple sources
- Drag-and-drop to create ad hoc composite variables, and data listings
- Identify anomalies with machine learning
- Automatically post Rave EDC queries
- Explore data insights with visual dashboards

Centralized Statistical Monitoring

- Identify data patterns, site performance issues, and potential misconduct using advanced analytics
- Generate issues without ever leaving the system

Key Risk Indicators

- Track site performance using out-of-the-box and custom key risk indicators (KRIs)
- Surface performance insights across sites and countries, including KRI trending
- Create and save comprehensive reports

Quality Tolerance Limits

- Track systemic errors in endpoint variables using quality tolerance limits (QTLs)
- Enable ongoing monitoring, triggers, trending and CSR reporting
- Ensure compliance with protocol endpoints

Risk Management

- Establish Critical-to-Quality (CtQ) factors upfront during protocol design
- Collaboratively identify risks to CtQ factors in a shared digital solution
- Define cross-functional risk monitoring and mitigation strategies, including targeted SDV, KRIs, and QTLs

The Medidata Advantage

Medidata Detect is unified with [Rave EDC](#), and all our clinical solutions, on the [Medidata Clinical Cloud®](#). Our clinical cloud platform ingests, aggregates, and monitors data from many sources, giving you a complete view of your trial and driving efficient workflows. Now, you can navigate from Detect into Rave EDC with a single click to quickly access data and queries. Integrate Medidata Detect into any stage of your trial and our [Professional Services](#) experts are here to ensure your success. We also offer a fully managed service for Medidata Detect, [Trial Assurance](#). No other company has the depth of capabilities and direct connection to Rave EDC to support real-time aggregated data interrogation and analytics.

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.

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