Medidata Detect

The power to proactively improve data quality and reduce trial risk

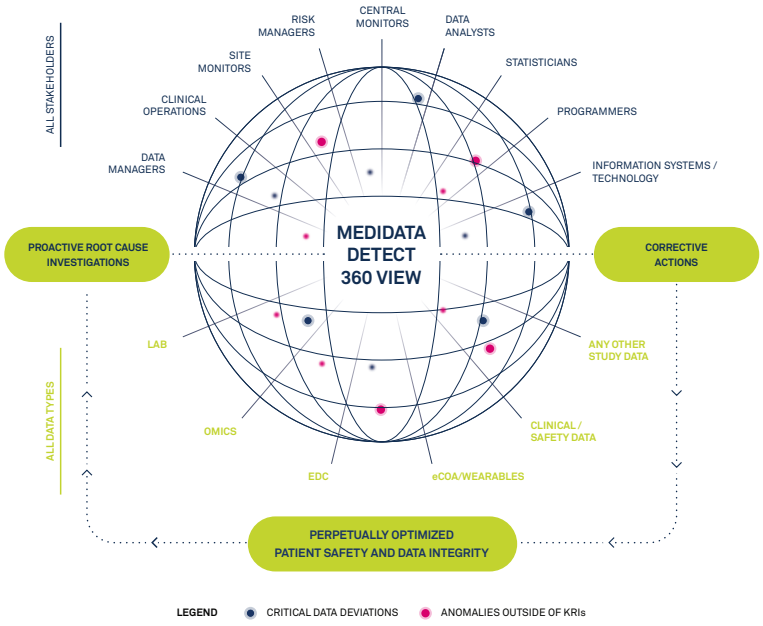
Twenty four percent of study applications require one or more resubmissions before approval. A first unsuccessful submission can delay approval by a median of 435 days.[1] Core to reducing trial risk and adopting a risk-based quality management (RBQM) approach, is the ability to operationalize and oversee data integrity in a risk-based manner.

Sponsors and CROs rely on centralized statistical monitoring to ensure data quality and maintain compliance with ICH and FDA regulations, but challenges can be overwhelming.

Medidata Detect simplifies the detection of errors, trends and anomalies in study data through automated statistical algorithms and tests to improve study data quality and ensure patient safety.

Propel your ability to optimize patient safety and data integrity

Perpetually surveying millions of data points, detect improves data integrity and reduces trial risk by delivering the visibility required to proactively perform root cause investigations and take corrective actions.



Detect is part of Medidata Rave RBQM, the only end-to-end, modular and scalable suite of applications that enable a streamlined process of risk-based quality management designed to meet RBQM requirements.

"Detect enables us to transform data into information that is actionable. We use machine learning to explain the data in meaningful ways. We identify outliers in a patient, site or protocol while finding interdependencies in the data that can not be seen by reviewing smart SAS listings."

Senior Manager
Data Management
Biotech Company

DATA MANAGEMENT AND ANALYTICS

- Reduce number of edit checks
- Increase data quality reducing database unlocks after initial database lock
- Increase efficiency of anomaly identification and data distribution to stakeholders via automation
- Reduce time to extract, consolidate and clean data
- Generate faster reports and analysis
- Cut down LPLV to DBL cycle time for earlier NDA filing

CLINICAL OPERATIONS

- Streamline workflows and data flow for central monitoring
- Quickly identify risks and anomalies to take action, and track resolution
- Visualize data trends to anticipate clinically significant events and insights
- Easily access and understand the data when needed

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The power behind Medidata Detect

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.

Detect screens thousands of patterns in the data to identify inconsistencies or outliers that do not fit the pattern or fall outside the acceptable ranges established. Values related to patients or sites that should be investigated and possibly remediated are flagged in real time.

Against pre-established Key Risk Indicators (KRIs), Detect focuses on areas that are expected to be problematic. It can also identify unusual patterns or values that arise even if they relate to unknown and undefined risks.

The only centralized statistical monitoring system to enable:

- On-demand data refreshes with real-time data
- Automated flow of data for reviewing and tracking issues through remediation
- Unified view of patient profile information
- Minimal set up; no algorithms configuration and purpose-built for all users
- Detection of known and unknown risks
- Advanced statistics and machine learning

Power your data quality management strategy, anytime, at any point of your study

Medidata Detect can be integrated at any stage of your clinical trials. It helps define and manage study risks during trial design and initiation. It uncovers unanticipated data anomalies at any time during your study execution and helps to remediate them to prevent study disruption. Finally, it ensures the required data integrity to close study results and complete reports.

Benefits include:

Oversight

Automate flagging of data anomalies

Reduce risk of undetected anomalies

Compute KRIs and provide early indication of clinically significant trends

Efficiency

50%-55% of data reviews automated

20%-40% reduction in number of edit checks

Data Quality

Identify indications of potential misconduct

Reduce risk of submission delay by submitting cleaner data

Simplification

Reduction from 30 to 5 days to database lock in critical studies

One central system for multiple review outputs (patient profiles, outlier detection, listings, KRIs, etc.)

1. Sacks LV, Shamsuddin HH, Yasinskaya YI, Bouri K , Lanthier ML, Sherman RE, "Scientific and Regulatory Reasons for Delay and Denial of FDA Approval of Initial Applications for New Drugs, 2000-2012." JAMA.2014;311(4):378–384. doi:10.1001/jama.2013.282542

Medidata Rave Clinical Cloud®
Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk

"Medidata Detect delivers cross-functional insight into reviewing the data. Our project managers get in and look at Detect prior to CRA's going out for their visit. They can look at their patients and their sites before the CRA ever arrives to the site. They have identified issues before they even open up that patient's chart."

Director
Central Monitoring
Biotech Company

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 1,500 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at **www.medidata.com** and follow us **@medidata**, The Operating System for Life Sciences™.

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