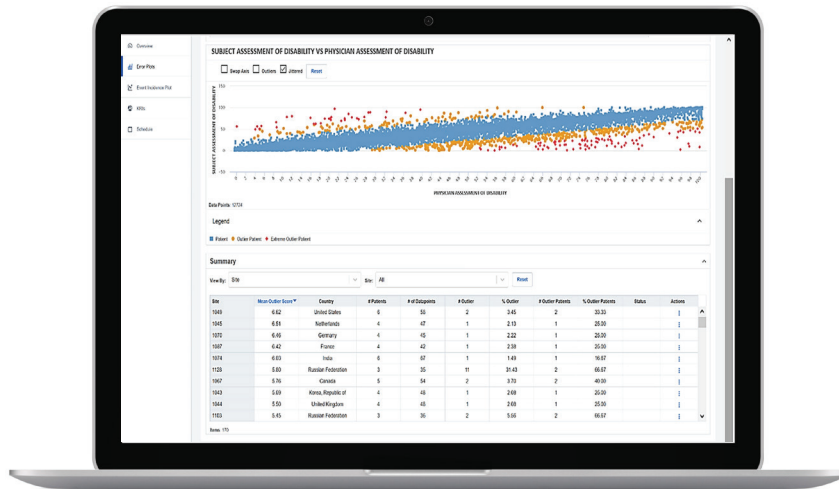


# Medidata Detect – The Power to Proactively Improve Data Quality and Reduce Trial Risk



A key component of reducing trial risk and adopting a risk-based quality management (RBQM) approach is 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, FDA and EMA regulations, but it 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.

## Medidata Detect Benefits

Medidata Detect helps define and manage study risks during trial design and initiation and uncovers unanticipated data anomalies and helps remediate them to prevent study disruption. Medidata Detect can help you with:

### Proactive Monitoring

- Medidata Detect uses automated statistical algorithms and machine learning to detect errors and trends in real time to provide proper oversight

### Increased Efficiencies

- Higher data quality results in a reduced number of edit checks, database unlocks after initial database lock (DBL), and last patient last visit (LPLV) to DBL cycle time to support earlier NDA filing

### Faster Issue Identification

- On-demand data refreshes provide quicker identification of risks and anomalies allowing study teams to take action and track resolution to ensure patient safety

### Reporting

- Study teams can identify key risk indicators (KRIs) and quality tolerance limits (QTLS) prior to the start of a clinical trial to proactively monitor for issues and leverage visualization tools during the trial for easier issue identification and proactive remediation

# Medidata Detect Features

## Built on the Medidata Clinical Cloud™

Allows end-to-end suite of solutions for data capture, data management, trial planning, trial management, and analytics and enables a holistic Risk Based Quality Management implementation.

## Powerful Centralized Monitoring Tool

Scans millions of data points using machine learning to continuously learn proper and acceptable ranges for all data fields and identify statistical relationships between variables.

## Proactive Risk Management

Integrates with Medidata Risk Management to share identified risks, oversight metrics such as KRIs and QTLs, and mitigations strategies to identify and address anomalies proactively.

## Real Time Issue Identification

On-demand data refreshes enable study teams to proactively monitor inconsistencies and outliers so values related to patient safety or site data can be investigated and remediated in real time.

## Increased Efficiencies

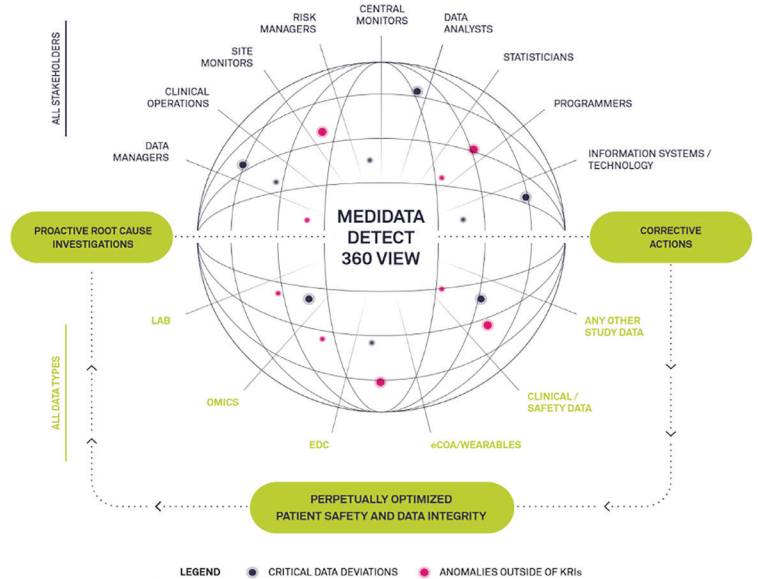
Automated detection of data anomalies reduces the number of edit checks, submission delays and database unlocks to ensure timely NDA filing.

## Comprehensive Reporting

Reduces time to analyze data so users can quickly identify trends and anomalies through visualization tools to evaluate site performance, enrollment trends and risk assessments.

**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 RBQM, the only end-to-end, modular and scalable suite of applications that enable a streamlined process designed to meet RBQM requirements.**



## The Medidata Advantage

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.

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

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