

Medidata Edge Central Monitoring

Enabling more insightful clinical trial reviews

Monitoring and reviewing clinical trial data is a critical step to ensuring the success of any clinical development plan. But today’s manual processes can often result in errors, compromising data quality and incurring costly study delays.

Medidata Edge Central Monitoring (formerly Centralized Statistical Analytics - CSA) provides immediate insight into clinical trial site performance and data quality. An integral part of Medidata Edge Strategic Monitoring (formerly Strategic Monitoring)—our unified solution for risk-based monitoring—Medidata Edge Central Monitoring integrates data from different systems and provides a comprehensive report for each subject, making it easier for teams to detect and track critical data changes throughout trial execution.

Individual reporting at the subject level

Medidata Edge Central Monitoring integrates and analyzes data across multiple domains, generating patient-centric reports to allow for quick and easy clinical trial review. The reports are available via a study portal, which leverages trial data to create and display a customized study dashboard, site dashboards, listing tables and interactive visualizations like adverse events and concomitant medications, along with visit dates and time on study drug. The portal also uses our patent-pending statistical algorithms to mine the database and automatically identify anomalies, outliers, potential fraud and procedural issues—enabling sponsors to work more effectively and attain faster, safer clinical trial data reviews.

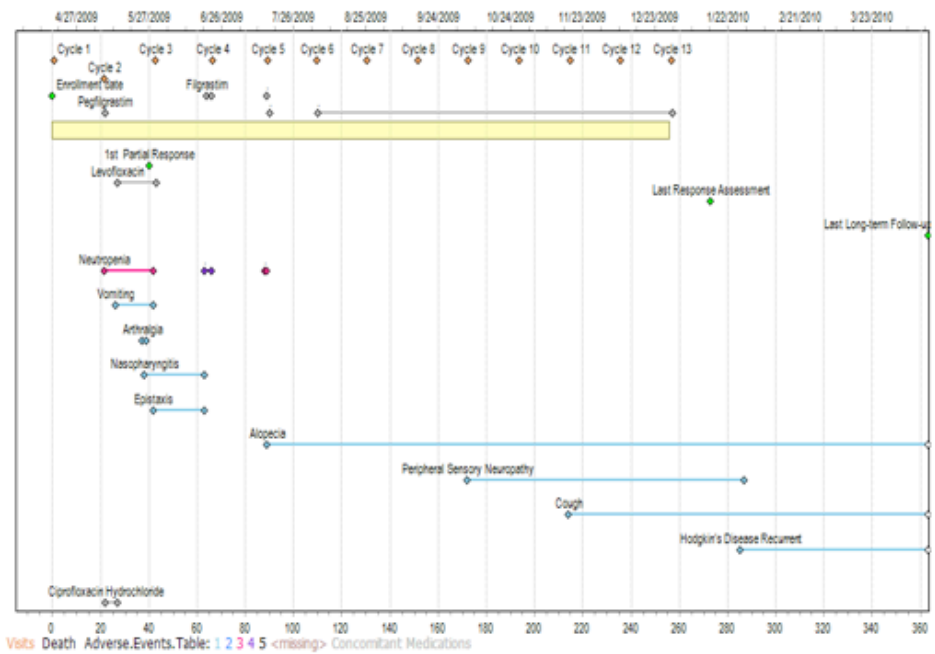
An example of a timeline and lab table from an oncology trial is shown in Figure 1. The time that the patient was on the study drug is highlighted in yellow and the events are color-coded based on user-defined criteria. The data in the table is also color-coded based on normal ranges defined by CDISC’s study data tabulation model (SDTM) variables.

Finding inconsistencies in data can be one of the most frustrating and time-consuming parts of assessing clinical trial data. Medidata Edge Central Monitoring simplifies this process by visually unifying all relevant data for each individual patient. Figure 2 is a representative example of the first page of a patient profile report generated by Medidata Edge Central Monitoring with errors introduced for illustration.

Medidata Edge Central Monitoring processes over 1,000,000 data points and finds over 4,000 patterns in less than one hour. Its advanced statistical analytics turn on in days to provide immediate benefits:

- Automatically extracts and maps data from the Medidata Clinical Cloud® to create individual patient profiles
- Statistically analyzes data and identifies anomalies, outliers, unexpected errors, fraud and procedural issues
- Summarizes and presents overall risks and identifies the sites that need further investigation

Figure 1: Example of a timeline and table from an oncology trial



Medidata Edge Central Monitoring ensures data quality

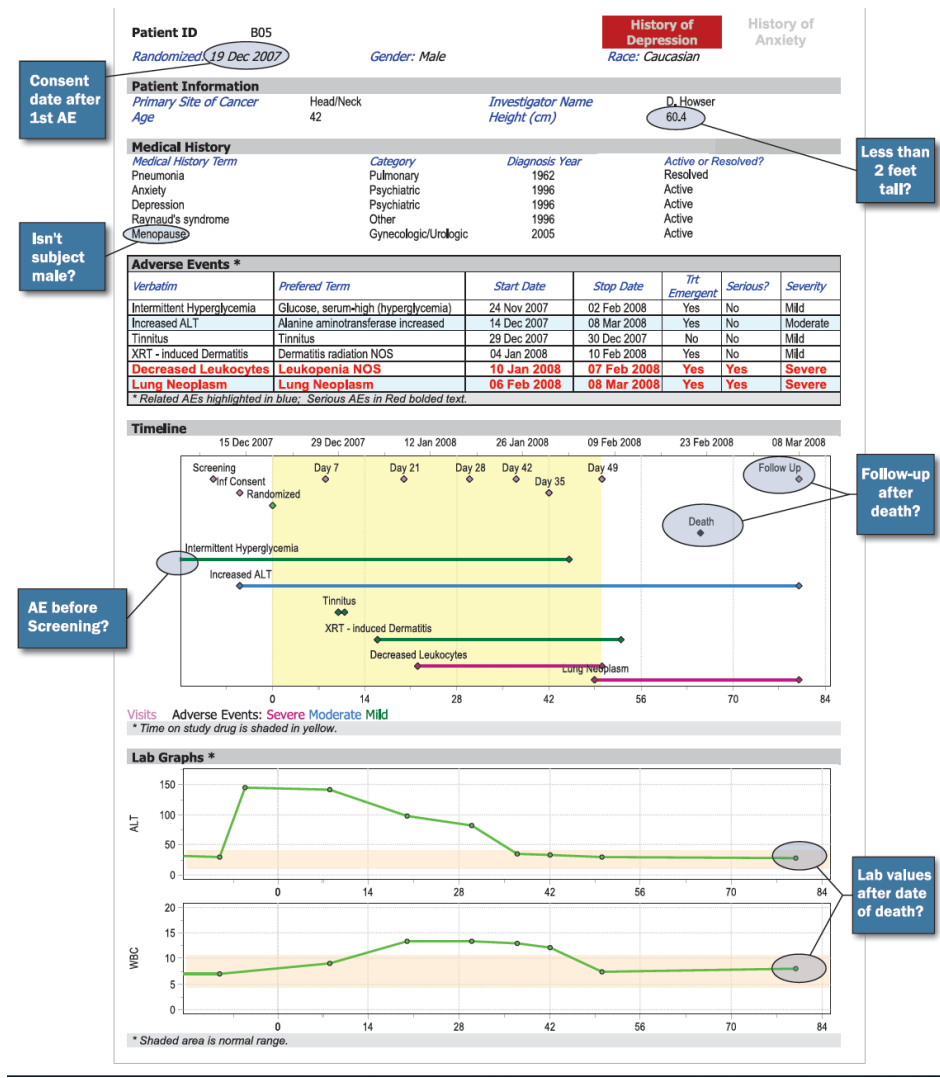
Medidata Edge Central Monitoring helps identify areas of risk much faster and more accurately by providing immediate insight into clinical trial performance and data quality. It is specifically designed for centralized statistical monitoring of data across various functional areas. With its sophisticated statistical algorithms, it interrogates the clinical data in a trial for outliers, data anomalies and trends. These algorithms are generated programmatically by the system, so there is zero statistical programming required on the user's end.

Whether you are a small, mid size or large organization, Medidata has the skills and experience to work hand in hand with your team and ensure success of your RBM vision.

Chemistry & Hematology Labs						
Date	Visit Name	ALT	AST	Hemoglobin	Neutrophils	Leukocytes
4/17/2009	Baseline	15	19	10	3.43	4.77
4/17/2009	Cycle 1 Day 1	16	23	10	3.38	4.59
5/8/2009	Cycle 2 Day 1	43	32	11.7	0.66	1.88
5/29/2009	Cycle 3 Day 1	38	30	10.9	2.58	3.67
6/22/2009	Cycle 4 Day 1	27	24	11.6	8.72	11.19
7/15/2009	Cycle 5 Day 1	50	43	11.1	2.48	3.72
8/4/2009	Cycle 6 Day 1	26		11	2.18	3.73
8/25/2009	Cycle 7 Day 1	21	21	10.5	2.53	3.63
9/15/2009	Cycle 8 Day 1	14	18	10.5	2.52	3.43
10/6/2009	Cycle 9 Day 1	13	16	10.4	1.81	2.59
10/27/2009	Cycle 10 Day 1	10	16	10.6	2.37	3.55
11/17/2009	Cycle 11 Day 1	12	19	9.9	2.42	3.64
12/8/2009	Cycle 12 Day 1	12	19	10.1	2.28	3.59
12/29/2009	Cycle 13 Day 1	10	20	10.4	2	3.56
1/29/2010	End of Treatment	12	16	10.7	4.18	5.55

* Red = High; Blue = Low

Figure 2: Partial sample of a patient profile report



Summary

The advanced and robust statistical algorithms in Medidata Edge Central Monitoring provide a comprehensive scan of a clinical trial database for inconsistencies across data domains, sites and patients. With templates for SDTM data, automated processes can be setup so that every clinical study submitted to the FDA can have a study grade calculated for data quality. The overall study grade can be a measure of overall data consistency, and be compared across sponsors, studies, indications and disease areas. Individual site grades can be used to measure data quality within the site, and identify studies and sites at high-risk for procedural problems and data errors.

Edge Central Monitoring algorithms

A variety of centralized statistical analytics algorithms automate error detection and flag unusual data within a clinical trial. The statistical methodology uses the full set of data collected, including demographics, efficacy parameters, lab values, adverse events and medications to cluster clinical trial patients. The algorithms identify expected values within clusters, and thus can identify patterns (or rules) and flag data that does not fit those patterns. Rules are identified within each patient cluster and across all patients, with typically over 3,000 rules found in the data of a single trial. Figure 3 represents examples of two different rules identified from a clinical data set.

Figure 3: (a) Box plot of BMI (b) Scatterplot pRBC transfusion

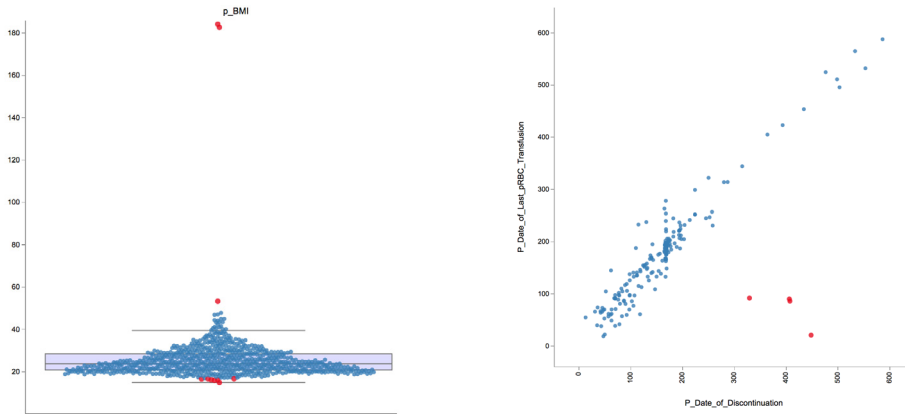


Figure 3 (a) shows a boxplot of body mass index (BMI) in which two patients (from the same site) are flagged as extreme outliers at the top of the graph, as their height was entered in the wrong units. The scatterplot in Figure 3 (b) shows data from the study day of discontinuation vs. the last study day of packed red blood cells (pRBC) transfusion. The four outliers in the graph on the right stand out as unusual because they do not follow the trend of the other data points. These four patients are said to have broken one of the “rules” set by the data. The user does not need to define such rules ahead of time; rather, these rules are identified by the software automatically (not hard-coded in) and alert the user once issues are found.

Individual sites and the overall study are graded for data quality based on the percentage of data points flagged as outliers. As shown in Figure 4, each site has its own dashboard that displays a grade, statistics summary and a list of the patients and variables with the highest percentage of anomalies at that site.

Figure 4: Representative example of a site performance dashboard

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Site Overview		
B <i>Site Grade</i>	A+ <i>Study Grade</i>	High Risk Patients
8 <i>Total Patients</i>	421 <i>Total Patients</i>	Patient
2.62 <i>Percent Discrepancies</i>	2.38 <i>Percent Discrepancies</i>	% Discrepancies
3.48 <i>Average Discrepancy</i>	3.27 <i>Average Discrepancy</i>	4561002
		4561008
		4561007
		4561010

Medidata Clinical Cloud®

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

Edge Trial Planning and Management

Pioneering Analytics Accelerates Clinical Operations

Edge Trial Planning and Management is a product suite that increases patient enrollment, retention, and study execution. Medidata Edge Design Optimization, Site Feasibility, Site Grants, and Payment solutions use historical benchmarks and automation from MEDS to reduce patient burden and site feasibility as well as site grants and payments. This has been proven to increase patient recruitment and retention rates.

Medidata also solves many of the biggest challenges in trial management. Medidata Strategic Monitoring and CTMS holistically address regulatory requirements for RBM by combining anomaly detection with intelligent workflows to enable sponsors, CROs, and sites to confidently move away from 100% SDV. Medidata master data management means that up to 76% of an eTMF's artifacts can be pre-populated from other sources.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 950 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

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Medidata Clinical Cloud®

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