Medidata Edge Trial Assurance: Protect Your Potential Blockbuster from Avoidable Failure

Patient safety and data integrity are critical to the execution of a successful clinical trial. Increasing complexity of clinical trials and globalization have made monitoring and reviewing clinical trial data ever more challenging. Current practices used to evaluate protocol adherence and data entry are insufficient for identifying critical data quality issues that may impact the study results. This often leads to missed adverse events, data anomalies and procedural deviations which could negatively affect timelines and lead to costly study delays.[1] A mechanism employing data analytics in the oversight of clinical trials can easily identify the complex errors which under normal practice can slip through the data management processes and edit checks.

Medidata Edge Trial Assurance (formerly Trial Assurance) is a service that evaluates the integrity and quality of all clinical and lab data within a clinical trial. The offering includes a comprehensive analysis, report and presentation of results. Our customers gain immediate actionable insight to improve clinical trial performance and data quality, which may impact study results and future reviews by regulatory authorities.

How Does Medidata Edge Trial Assurance Work?

Trial Assurance is a blinded analysis of a clinical trial at a snapshot in time. With the aid of automated statistical analyses, a team of clinical analysts, led by two former FDA statistical reviewers, perform a comprehensive 360 degree analysis of the study data, with an emphasis on data quality and study integrity, and provide a summary report and presentation of the results. Medidata Edge Trial Assurance is unique both in the analysis and the holistic view it provides our customers by contextually comparing lab and clinical data. This analysis of the study database often turns up data quality issues that the customer is not aware of.[2] Edge Trial Assurance provides a level of security around the study to prevent an avoidable failure and helps to prepare the study database to be inspection-ready before submission to regulatory agencies.

What Kind of Risk Does Edge Trial Assurance Engagement Mitigate?

Medidata Edge Trial Assurance analyzes the data for a select clinical trial to identify trends that can impact data quality or integrity. Trends include but are not limited to: data anomalies, probable data errors, procedural differences between sites (such as dosing pattern differences), safety signals for specific tests, patients or sites, potential misconduct or fraud, differences in patient- or investigator-reported outcomes. Site-wide trends often affect the study results and future reviews by regulatory authorities.

Unreported adverse events are a red flag to regulatory agencies. Medidata Edge Trial Assurance visually unifies all relevant data for each individual patient, making it easier to identify inconsistencies within a patient history. The following example illustrates how integrating lab and clinical data allows a study team to discover an unreported adverse event.

Figure 1a displays a boxplot of the distribution of blood urea nitrogen (BUN), a lab value that indicates kidney function. Patients with high positive slopes are selected for an in-depth review of the patient's entire clinical profile. The profiles reveal that all three patients appear to have increases in both BUN (Figure 1b) and creatinine (another renal lab test) around day 40 (Figure 2). Hence we would expect to see that all three patients had some kind of renal adverse event logged around Day 40. Visualizing the patient lab data along with the timeline immediately highlights that patients A and C both reported an adverse event related to kidney function as captured on the patient timeline (Figure 2), while patient B is missing an adverse event. Fixing problems like this prior to data lock, and being transparent about problems identified after data lock, are key to a smooth approval process.

Figure 1. 1a (left), Distribution of blood urea concentration of patients over time; 1b (right), Individual BUN values for patients A, B and C respectively over time.

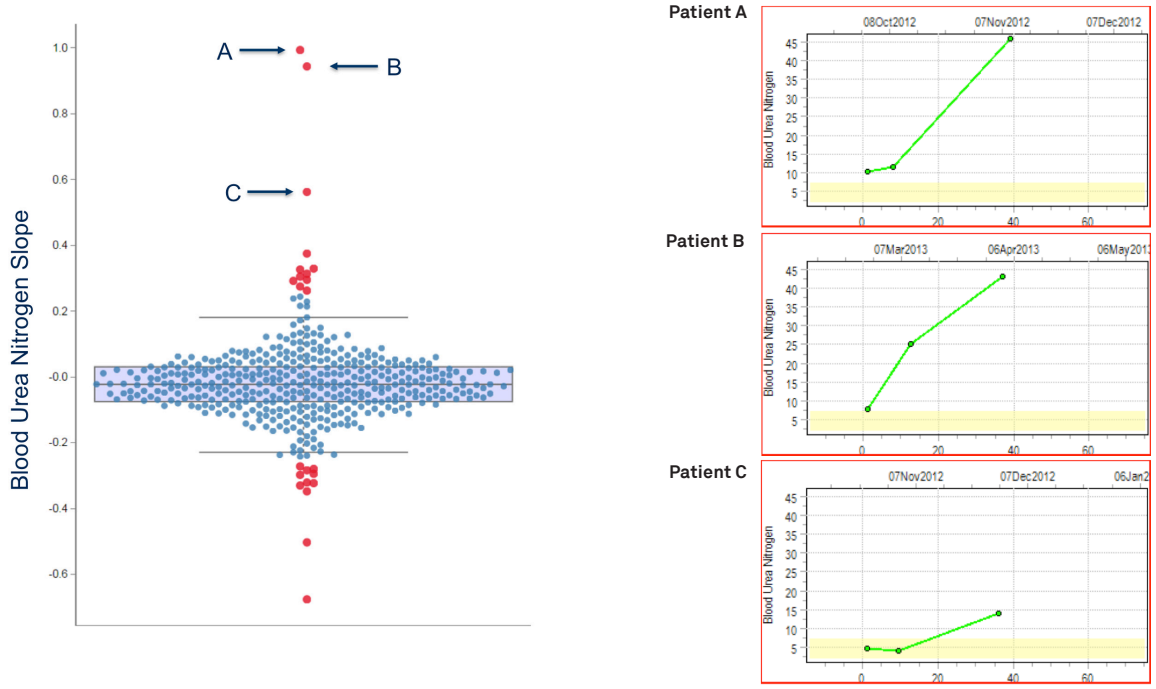
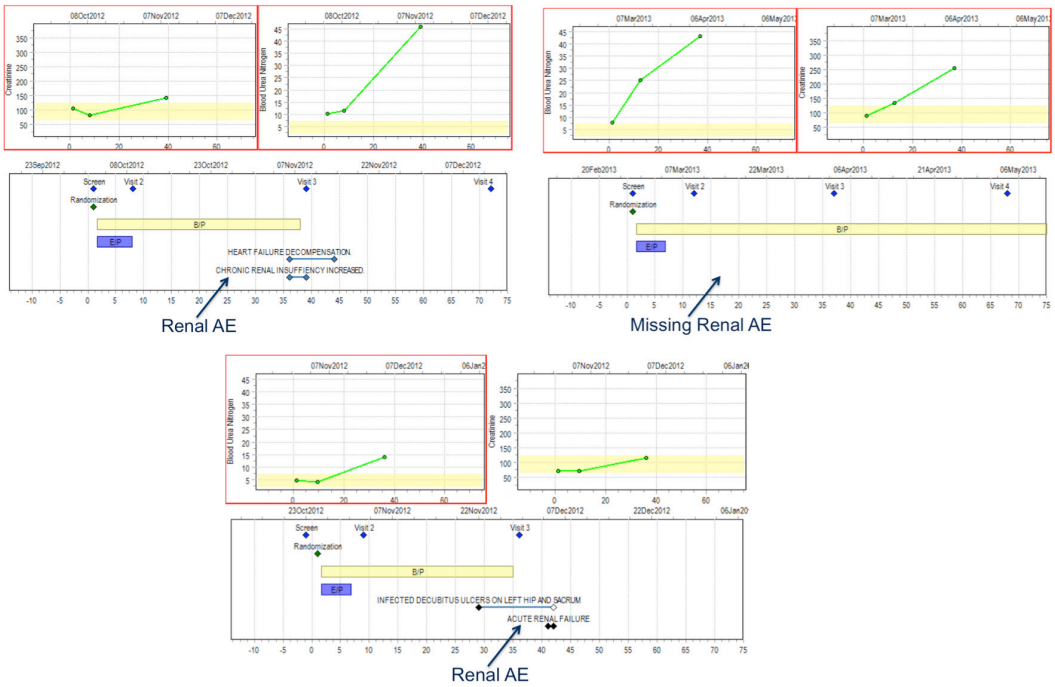


Figure 2. Overlay of the patient BUN values and patient timeline provides a holistic view that adds contextual value to lab and clinical data.



Impact of Data Quality on Clinical Trials

It is reported that up to one in six new molecular entities (NMEs) fail 1st cycle approval due in part to data integrity issues. The difference in approval time between NMEs receiving 1st cycle approval and those requiring multiple cycles is 17.9 months, so any delay can materially impact revenues.[2,3]Medidata Edge Trial Assurance offers a data-driven approach that helps our biopharma customers maintain accurate and consistent data over the life of a clinical trial.

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.

Endnotes

1. Perspect Clin Res. 2011 OctDec; 2(4): 124–128.

2. 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

3. Why NMEs and Therapeutic Biologicals Fail in the First FDA Review Cycle, The RPM Report, Elsevier Business Intelligence, March 2013, with slight modification.

About Us

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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