

# Prevent Data Quality Issues That Derail Drug Approvals

## The Challenge

Nearly 50 percent of new molecular entities (NME) submissions fail their first FDA approval, and 32 percent of these failures are attributed to data quality, data integrity and data inconsistency issues.<sup>1</sup> Avoidable data quality issues have clear scientific and economic implications. NMEs with first-cycle approvals beat others to regulatory approval by a median 17.9 months. The delay to market represents an enormous loss in revenue and keeps drugs from patients who are waiting.

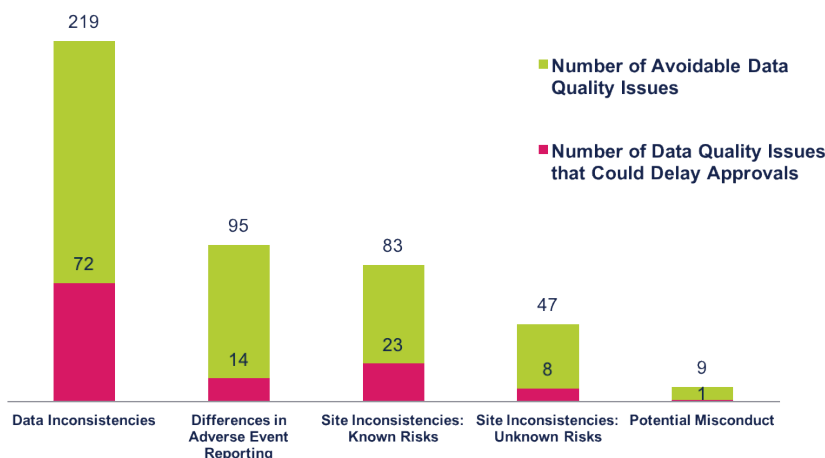
## The Solution

A Top 25 global pharma company used Edge Trial Assurance on 10 of its ongoing trials to identify data quality issues. The results were astounding for the sponsor but were typical findings for Edge Trial Assurance.

# 26%

Of data quality issues found across 10 studies had potential to **delay** drug approval

### Data Quality Issues in 10 Studies



Note: Issues due to misconduct were not all marked as issues with potential approval impact because they were not found on the primary or secondary efficacy variables

<sup>1</sup> 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’s team of data analysts, led by former FDA statistical reviewers, identified **453 avoidable data quality issues across all 10 studies** in five areas commonly examined by regulators:

- **Site inconsistency for unknown risks:** Inconsistencies in site evaluations of endpoints, whether inconsistencies in subjective interpretation (pain levels) or calibration inconsistencies in objective diagnostics. Are sites enrolling participants who violate inclusion/exclusion criteria?
- **Site inconsistency for known risks:** Inconsistencies in how sites follow the protocol—enrolling patients that don’t meet study criteria, fraction of visits that are missing during the study, etc. Are sites conducting activity in ways that may correlate to potential compliance or performance concerns?
- **Differences in adverse event reporting:** Differences in sites’ adverse event reporting (reduce dose or interrupt study drug) for each severity level.
- **Potential Misconduct:** Sites that fabricate data out of neglect or forgetfulness.
- **Data inconsistency:** Anomalous data values due data entry errors (vitals, visit dates, etc.)

These data quality issues aren’t a result of process or an organization’s best practices, they occur in every trial. **Data quality issues may be inevitable, but they are avoidable.**

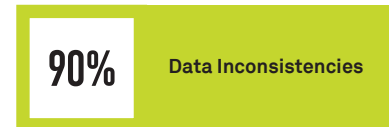
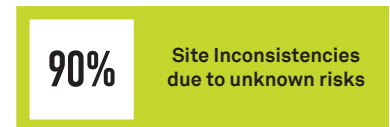
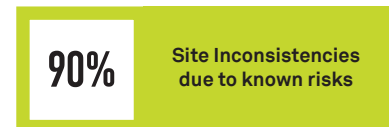
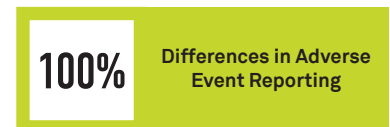
**Minimize exposure to data quality questions from regulators** with the right combination of machine learning anomaly detection and centralized issue management.

**Drastically reduce risk in your NDA submissions** by implementing a plan to tackle these common data inconsistencies.

Prevent avoidable data issues from reaching FDA with machine learning anomaly detection. With Edge Trial Assurance, gain immediate, actionable insights to improve data quality for the benefit of study integrity.

## ANOMALY CATEGORIES DETECTED IN 10 STUDIES

Percent of **studies** with at least one category anomaly



### Trial Assurance By The Numbers

#### Using Machine Learning to De-Risk Your Trials

*Findings For A Top 25 Global Pharma Company*

6

Therapeutic Areas

10

Studies

3,288

Patients

13M+

Data Points

41k

Rules Learned

453

Avoidable Data Quality  
Issues Identified

## About Medidata Solutions

Medidata is leading the digital transformation of life sciences with the world's most-used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by #1 ranked industry experts, the Intelligent Platform for Life Sciences helps pharmaceutical, biotech, medical device companies and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata serves more than 1,000 customers and partners worldwide and empowers more than 100,000 certified users every day to create hope for millions of patients.

Discover the future of life sciences:  
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